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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, 2020

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2020, 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 30, 2020) was $2,347,432,255. As of January 31, 2021, there were 57,625,943 shares of Common Stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2021 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, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Deciphera Pharmaceuticals, Inc.
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Summary of Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision. These risks include, but are not limited to, the following:

- There is no assurance that our commercialization efforts with respect to QINLOCK® (ripretinib), referred to as QINLOCK, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.
- We have limited experience as a commercial company and the marketing and sale of QINLOCK or any future approved drugs may be unsuccessful or less successful than anticipated.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug and drug candidates, including regulatory approval of QINLOCK for second-line GIST, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates or expand our marketing for QINLOCK in additional indications or geographies, and our ability to generate revenue will be materially impaired.
- Our reliance on sole source third-party suppliers could harm our ability to commercialize QINLOCK or any drug candidates that may be approved in the future.
- 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.
- 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.
- 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 for our approved drug.
- QINLOCK or any current or future drug candidates, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to drug candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- If the market opportunities for our approved drug or 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 commercial success of QINLOCK, and of any future approved drugs, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.
- Our failure to obtain additional marketing approvals in foreign jurisdictions, including Europe, would prevent QINLOCK and our drug candidates from being marketed more extensively abroad, and any approval we are granted for QINLOCK or our drug candidates in the United States (U.S.) would not assure approval of QINLOCK or our drug candidates in foreign jurisdictions.
- QINLOCK and 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 QINLOCK or any future approved product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with QINLOCK or any future approved products, when and if any of them are approved. In addition, the terms of the marketing approval of QINLOCK, and any future approved products, 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.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug and drug candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our clinical trials of vimseltinib or rebastinib, our receipt of necessary marketing approvals could be delayed or prevented.
- If serious adverse events or unacceptable side effects are identified during the development of our drug or drug candidates, we may need to abandon or limit such development.

- We may not be able to obtain or, if granted, retain orphan drug exclusivity for our drug or drug candidates.
- The current pandemic of the novel coronavirus (COVID-19) may have a material adverse effect on our business, financial condition, and results of operations.
- We have incurred significant operating losses since our inception and have not generated substantial revenue from product sales. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than QINLOCK, and have not generated substantial revenue from product sales or profits. We may never achieve or sustain profitability.
- 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 commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials and preclinical studies, and those third parties may not perform satisfactorily, or may experience delays in performing these services, including failing to meet deadlines for the completion of such trials or studies, which may harm our ability to obtain regulatory approval for or commercialize our approved drug and drug candidates and our business could be substantially harmed.
- Our reliance on third parties for the manufacture of our drug candidates for preclinical testing and clinical trials, and for the manufacture of QINLOCK for commercialization and clinical trials, increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.
- We may not be able to enforce our intellectual property rights throughout the world.
- If we are unable to obtain and maintain sufficient patent protection for our approved drug or 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 approved drug or drug candidates successfully may be adversely affected.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K (Form 10-K), including our consolidated financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission (SEC). The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

FORWARD-LOOKING STATEMENTS

This 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 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:

- our ability to successfully launch and commercialize QINLOCK for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib, in the U.S., and any other jurisdictions where we may receive marketing approval in the future;
- the success, cost, and timing of our product development activities and clinical trials, including the timing of our ongoing Phase 3 study of QINLOCK for the treatment of patients with second-line GIST and results therefrom;
- our ability to obtain and maintain regulatory approval for QINLOCK or obtain and maintain regulatory approval for any of our current or future drug candidates, and any related restrictions, limitations, and/or warnings in the label of QINLOCK or any of our current or future drug candidates that may receive marketing approval;
- the rate and degree of market acceptance for QINLOCK or any current or future drug candidate for which we may receive marketing approval;
- our ability and plans in continuing to build out our commercial infrastructure and successfully launching, marketing, and selling QINLOCK and any current or future drug candidate for which we may receive marketing approval, including our plans with respect to the focus and activities of our sales force, the nature of our marketing, market access, and patient support activities, and our pricing of QINLOCK;
- the pricing and reimbursement of, and the extent to which patient assistance programs are utilized for, QINLOCK, or any current or future drug candidates for which we may receive marketing approval;
- our expectations regarding the size of target patient populations for QINLOCK, or any of our current or future drug candidates for which we receive marketing approval;
- our ability to obtain funding for our operations;
- our ability to manufacture or obtain sufficient quantities of QINLOCK or our drug candidates, on a timely basis, to support our planned clinical trials and commercialization of QINLOCK or any of our current or future drug candidates for which we receive marketing approval;
- the therapeutic benefit and effectiveness of QINLOCK and our drug candidates;
- the safety profile and related adverse events of QINLOCK and our drug candidates;
- our commercial preparedness efforts and our ability to commercially launch our drug or drug candidates, if and when they are approved, including, without limitation, QINLOCK in Europe;
- our plans to research, develop, and commercialize our drug candidates, including the timing of our ongoing Phase 3 study of QINLOCK for the treatment of patients with second-line GIST, and the timing of investigational new drug (IND) applications, and clearance thereof, for any new product candidates;
- the performance and experience of our licensee, Zai Lab (Shanghai) Co., Ltd. (Zai), to successfully develop and commercialize QINLOCK, if approved, in the People's Republic of China, Hong Kong, Macau, and Taiwan, also referred to as Greater China, under the terms and conditions of our license agreement and the performance of our distributors in other territories;
- our ability to attract additional licensees and/or collaborators or distributors with development, regulatory, and commercialization expertise;
- our expectations regarding our ability to obtain, maintain, enforce, and defend our intellectual property protection for QINLOCK or our drug candidates;
- future agreements with third parties in connection with the commercialization of QINLOCK or any of our current or future drug candidates for which we may receive marketing approval;

- the size and growth potential of the markets for QINLOCK or any of our current or future drug candidates for which we may receive marketing approval and our ability to serve those markets;
- regulatory and legal developments in the U.S. and foreign countries;
- our ability to comply with healthcare laws and regulations in the U.S. and any foreign countries, including, without limitation, those applying to the marketing and sale of commercial drugs;
- 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, medical, commercial, and management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- the impact of global economic and political developments on our business, including economic slowdowns or recessions that may result from the outbreak of COVID-19, which could harm our commercialization efforts for QINLOCK as well as the value of our common stock and our ability to access capital markets;
- natural and manmade disasters, including pandemics such as COVID-19, and other force majeures, which could impact our operations, and those of our partners and other participants in the health care industry, and which could adversely impact our clinical studies, preclinical research activities, and drug supply; and
- our use of the proceeds from 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 Form 10-K and our prior filings with the 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.

NOTE REGARDING TRADEMARKS

The QINLOCK® word mark and logo are registered trademarks, and Deciphera and the Deciphera logo are trademarks, of Deciphera Pharmaceuticals, LLC.

We have, in certain cases, omitted the ®, ©, and ™ designations for these and other trademarks used in this Form 10-K. Nevertheless, all rights to such trademarks are reserved. These and other trademarks referenced in this Form 10-K are the property of their respective owners.

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 biopharmaceutical company focused on discovering, developing, and delivering important new medicines to patients for the treatment of cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to execute our strategy to develop a broad portfolio of innovative medicines. We have one approved drug, QINLOCK, which was developed through our proprietary platform. Beyond QINLOCK, we are developing three clinical-stage drug candidates and advancing our research-stage programs. We wholly own QINLOCK and all of our drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. We are preparing for a potential launch of QINLOCK in Europe and we have entered, and intend in the future to enter, into select distributor arrangements to offer QINLOCK in geographies where we do not intend to distribute QINLOCK on our own, such as Australia and Canada.

QINLOCK - A Broad spectrum KIT and PDGFRA Inhibitor for GIST

On May 15, 2020, QINLOCK was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In May 2020, we launched QINLOCK commercially in the U.S. In June 2020, QINLOCK was authorized for sale in Canada by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In July 2020, the Australian Therapeutic Goods Administration (TGA) approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In November 2020, we announced that we had entered into exclusive distribution agreements for QINLOCK in Canada, Israel, Australia, New Zealand, Singapore, Malaysia, and Brunei.

In July 2020, Zai, our licensee for QINLOCK in Greater China, announced that the China National Medical Products Administration (NMPA) accepted the New Drug Application (NDA) submission for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In June 2019, we entered into a License Agreement (the Zai License Agreement), with Zai pursuant to which we granted Zai exclusive rights to develop and commercialize QINLOCK, including certain follow-on compounds (the Licensed Products), in Greater China.

In October 2020, a marketing authorisation application (EU MAA) for QINLOCK in fourth-line GIST was accepted for review by the European Medicines Agency (EMA). In January 2021, we announced that the Swiss Agency for Therapeutic Products (Swissmedic) accepted the marketing authorisation application (Swiss MAA) in Switzerland for QINLOCK in fourth-line GIST. We also announced plans to file a marketing authorisation application (U.K. MAA) in the United Kingdom (U.K.) for QINLOCK in fourth-line GIST. In preparation for a potential European approval of QINLOCK, we are actively engaged in building a direct commercial presence in key European markets and building a targeted infrastructure to commercialize QINLOCK, if approved. In January 2021, we also announced commencement of planning efforts for a bridging study for QINLOCK in Japan.

In addition, we are studying QINLOCK in our global pivotal Phase 3 study, INTRIGUE, in second-line GIST patients, comparing QINLOCK to sunitinib. The study is being conducted at 122 investigational sites in 22 countries. We successfully completed enrollment of 453 patients in INTRIGUE and expect to announce top-line results from INTRIGUE in the second half of 2021. We are also studying QINLOCK in an ongoing Phase 1 study in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib. We believe QINLOCK has the potential to play an even broader role than in the fourth-line setting in the treatment of GIST, and we are planning further clinical development to explore this potential.

Beyond QINLOCK, we are developing three clinical-stage drug candidates: vimseltinib (DCC-3014), rebastinib, and DCC-3116.

Vimseltinib (DCC-3014) – CSF1R Kinase Inhibition for Tenosynovial Giant Cell Tumor (TGCT)

Vimseltinib is an investigational, orally administered, potent, and highly-selective inhibitor of the colony stimulating factor 1 receptor (CSF1R). We are currently studying vimseltinib in an open-label Phase 1/2 study designed to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of vimseltinib in patients with malignant solid tumors as well as patients with TGCT. The dose escalation portion of the study is designed to determine a Phase 2 dose for the expansion portion of the study. Based on the results of the dose escalation study, in November 2020, we announced the selection of a Phase 2 dose and initiated the expansion portion of the study with vimseltinib in patients with symptomatic TGCT not suitable for surgery. We are continuing to enroll TGCT patients in cohort 9 of the dose escalation portion of the study to complete enrollment in this cohort. In November 2020, we also announced updated preliminary data from the ongoing dose escalation portion of the study of vimseltinib in patients with TGCT. We expect to present updated data for vimseltinib in the second half of 2021.

Rebastinib – TIE2 Kinase Inhibition for Advanced or Metastatic Solid Tumors

Rebastinib is a potential first-in-class investigational, orally administered, potent, and selective inhibitor of the TEK tyrosine kinase (TIE2). TIE2 is the receptor for angiopoietins ANG-1 and ANG-2, an important family of vascular growth factors. TIE2 receptors are expressed on endothelial cells and angiogenic macrophages promoting the survival, maturation, and functional integrity of the vasculature and play a key role in regulating tumor angiogenesis, invasiveness, and metastasis. Rebastinib binds potently into the switch pocket of TIE2, stabilizing the inhibitory switch and displacing the activation switch to block TIE2 signaling. 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, PK, and efficacy in patients with advanced or metastatic solid tumors. 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. Both studies have two parts. Part 1 of each study was designed to select a combination dose of rebastinib with each chemotherapy agent. Part 2 of each study was designed as a Simon 2-stage design; in Stage 1, the combinations are being evaluated in multiple solid tumor cohorts in up to 18 patients each. If there are more than four responses in a cohort, that cohort is expanded to include up to a total of 33 patients. In January 2020, we selected a Phase 2 dose for, and activated, Part 2 of the Phase 1b/2 study of rebastinib in combination with carboplatin. In May 2020, we announced that in Part 2 of the study of rebastinib in combination with paclitaxel, we observed the required number of responses in Part 2, Stage 1 in both the endometrial and platinum-resistant ovarian cancer cohorts, triggering the expansion of enrollment in these cohorts. In addition, based on the clinical activity observed in Part 1, we added a cohort for patients with carcinosarcoma in Part 2 of the study of rebastinib in combination with paclitaxel. We expect to present updated data from the study of rebastinib in combination with paclitaxel for patients with endometrial cancer in the second quarter of 2021 and for patients with platinum-resistant ovarian cancer (PROC) in the second half of 2021.

DCC-3116 – ULK Kinase Inhibition for Mutant RAS/RAF Cancers

DCC-3116 is a potential first-in-class investigational potent and selective ULK kinase inhibitor discovered using our novel switch-control kinase inhibitor platform. DCC-3116 is designed to inhibit autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK 1/2 kinases, which have been shown to be the initiating factors that activate autophagy. In January 2021, we announced plans to initiate a Phase 1 study of DCC-3116 in the second quarter of 2021 under our IND for DCC-3116, submitted in the fourth quarter of 2020 and cleared by the FDA.

Discovery Platform – Switch-Control Kinase Inhibition

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

Kinase inhibitors are 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 switch-control kinase inhibitor platform combines our deep insight into the biology of kinases with our library of drug-like compounds that we designed to interact with specific regions of the kinase regulating switch function. 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. An extension of our platform has been shown to enable the design of switch-control inhibitors for serine/threonine kinases that utilize other kinase domain regions for switch regulation/activation, including the C-helix, P-loop, and catalytic amino acid residues.

Our drug candidates directly target the conformation-controlling switch that kinases rely on for activation and are designed to inhibit the kinase from switching on. 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 is designed to provide broad *in vitro* inhibition of KIT and PDGFRA kinase activity, including wild type and multiple primary and secondary mutations.

We believe the results observed in patients treated with QINLOCK provide strong evidence of our ability to discover and develop novel potential medicines to meet unmet medical needs using our proprietary switch-control kinase inhibitor platform. We designed QINLOCK to inhibit the full spectrum of the known mutant or amplified KIT and PDGFRA kinases that drive cancers such as GIST and believe the positive results from both the Phase 1 study and Phase 3 INVICTUS study demonstrate QINLOCK's differentiated profile. We believe that the rapid clinical development and subsequent FDA approval of QINLOCK, in only four and a half years (from dosing the first patient until receiving FDA approval), highlights our drug development capabilities that we believe will benefit our continued development of QINLOCK 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, if approved, commercialize advanced kinase inhibitors that will have significant benefit for patients with cancer.

Our Strategy

Our objective is to discover, develop and deliver important new medicines to patients for the treatment of cancer. The principal components of our strategy include:

- Successfully commercialize QINLOCK in the U.S., and continue to build our global commercial capability as we actively prepare to bring QINLOCK to eligible patients around the world, including in Europe, if approved.
- Expand the market opportunity for QINLOCK through clinical development in second-line GIST and potentially other areas of GIST treatment.
- Continue to develop vimseltinib as a potential single agent therapy for the treatment of TGCT.
- Continue to develop rebastinib as a combination therapy in solid tumor cancers.
- Develop DCC-3116, our ULK kinase inhibitor, for the potential treatment of RAS or RAF mutant cancers.
- Advance our discovery efforts using our switch-control kinase inhibitor platform.
- Evaluate strategic opportunities to accelerate development timelines and maximize the commercial potential of our drug candidates.
- Foster a values-based culture that embraces diversity and advances our patient-focused mission.

Kinases and their Role in Cellular Function

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. In cancer, 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. Additionally, wildtype kinases (not mutationally activated) in cancer cells or in various cell types in the tumor microenvironment can be co-opted by tumors or malignancies to enable growth, survival, or metastases.

Our Approach: Switch-Control Kinase Inhibitors

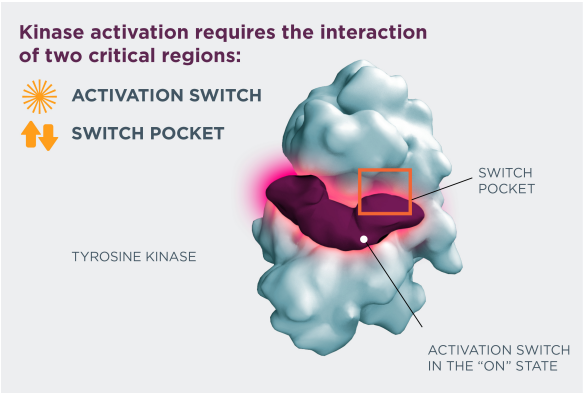
We created our diverse pipeline of drug candidates entirely in-house using our proprietary switch-control kinase inhibitor platform. We developed our platform based on our deep insight into the biology of kinases, which are regulated by control of their shape, or conformation. The transformation of a 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 switch-control kinase 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. An extension of our platform has been shown to enable the design of switch-control inhibitors for serine/threonine kinases that utilize kinase regions other than the activation loop for switch regulation/activation, including the C-helix, P-loop, or catalytic amino acid residues. This expanded platform enables the design of switch-control inhibitors that bind a kinase in either a Type II state (DFG-out) or a Type I state (DFG-in).

Our proprietary switch-control kinase inhibitor platform includes a library of drug-like, switch-control kinase 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.

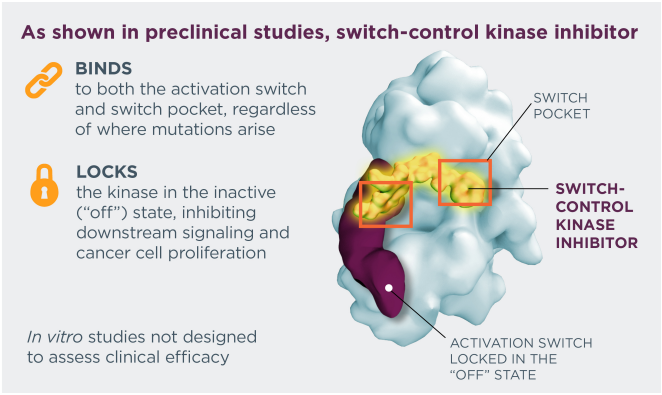
Using our switch-control kinase inhibitor platform, we have developed a diverse pipeline of differentiated, orally administered drug candidates that include three clinical-stage, and ongoing research-stage, programs, in addition to our approved drug, QINLOCK. Our switch-control kinase inhibitors are designed to 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 are designed to bind directly into the switch pocket or other switch-control regions, we believe mutations in these switch regulating regions 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 kinase inhibitors are designed to embed into the switch pocket thereby inhibiting switch activation.

Switched on: Kinase active



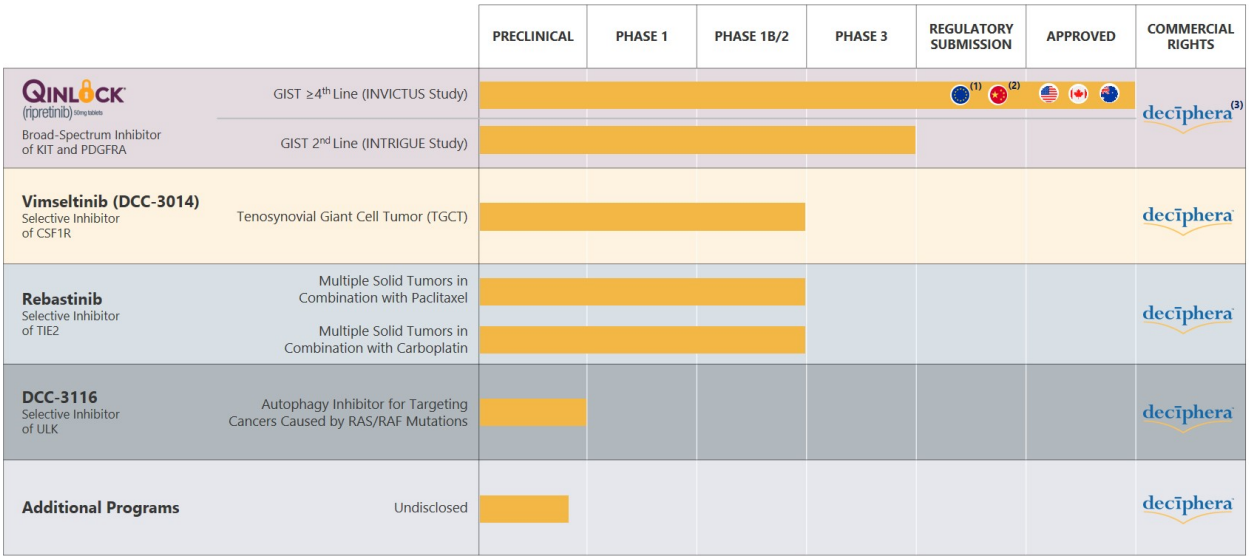
Switched off: Kinase inactive



While we believe that our proprietary switch-control kinase 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 MAP kinase 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 and Drug Candidates

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



QINLOCK: A Broad spectrum KIT and PDGFRA Inhibitor for GIST

QINLOCK is an orally administered switch-control kinase inhibitor developed for the treatment of GIST. While approved kinase inhibitors control certain initiating and drug resistance-causing mutations in KIT and PDGFRA, the kinases that drive disease progression in most GIST patients, these approved drugs fail to inhibit all known mutations. We designed QINLOCK to

improve the treatment of GIST patients by inhibiting the full spectrum of the known mutations in KIT and PDGFRA. QINLOCK is a KIT and PDGFRA switch-control kinase inhibitor that blocks initiating and resistance KIT mutations in exons 9, 11, 13, 14, 17, and 18 known to be present in GIST patients. QINLOCK similarly inhibits the primary initiating PDGFRA mutations occurring in exons 12 and 18 and also inhibits wild-type PDGFRA that is subject to amplification in cancers.

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following FDA approval of QINLOCK, in May 2020, we commenced sales and marketing of QINLOCK in the U.S.

In June 2020, QINLOCK was authorized for sale in Canada by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In July 2020, the Australian TGA approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In November 2020, we announced that we had entered into exclusive distribution agreements for QINLOCK in Canada, Israel, Australia, New Zealand, Singapore, Malaysia, and Brunei.

In July 2020, Zai, our licensee for QINLOCK in Greater China, announced that the NMPA accepted the NDA submission for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In June 2019, we entered into the Zai License Agreement with Zai pursuant to which we granted Zai exclusive rights to develop and commercialize the Licensed Products in Greater China.

In October 2020, an EU MAA for QINLOCK in fourth-line GIST was accepted for review by the EMA. In January 2021, we announced that Swissmedic accepted a Swiss MAA for QINLOCK in fourth-line GIST. We also announced plans to file a U.K. MAA for QINLOCK in fourth-line GIST. In preparation for a potential European approval of QINLOCK, we are actively engaged in building a direct commercial presence in key European markets and building a targeted infrastructure to commercialize QINLOCK, if approved. In January 2021, we also announced commencement of planning efforts for a bridging study for QINLOCK in Japan. We, or our partners, are also pursuing marketing approval of QINLOCK in our other international target markets.

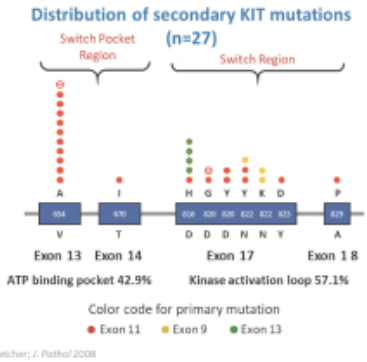
In addition, we are studying QINLOCK in our global pivotal Phase 3 study, INTRIGUE, in second-line GIST patients, comparing QINLOCK to sunitinib. The study is being conducted at 122 investigational sites in 22 countries. We successfully completed enrollment of 453 patients in INTRIGUE. We expect to announce top-line results from INTRIGUE in the second half of 2021 and, if positive, we plan to submit a supplemental NDA to the FDA for approval of QINLOCK for the treatment of second-line GIST patients in the U.S., and similar applications in Europe and other major markets. We are also studying QINLOCK in an ongoing Phase 1 study in patients with different stages of GIST, following treatment with at least one systemic anticancer therapy, such as imatinib. We believe QINLOCK has the potential to play an even broader role than in the fourth-line setting in the treatment of GIST, and we are planning further clinical development to explore this potential.

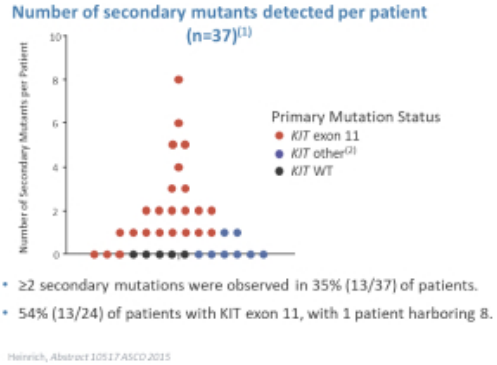
Market Opportunity in GIST

GIST is the most common sarcoma of the gastrointestinal tract and is commonly localized to the stomach and small intestine. GIST can occur at any age, but is more common in individuals aged over 50 years. According to the American Cancer Society, in 2020 approximately 4,000 to 6,000 patients were newly diagnosed with GIST in the U.S. Estimates for 5-year survival range from 52% to 94% depending upon the stage of the disease at diagnosis.

GIST is a disease driven initially by primary mutations in KIT kinase in approximately 80% of cases or in PDGFRA kinase in approximately 5% to 10% of cases. In approximately 10% to 15% of all GIST patients, the disease is not driven by KIT or PDGFRA 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 PDGFRA 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.

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. We believe our design of QINLOCK as a dual switch-control tyrosine kinase inhibitor (TKI) of KIT and PDGFRA 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 PDGFRA 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 Response Evaluation Criteria in Solid Tumors (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 (SD) as neither qualifying for PR nor for 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 PDGFRA-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% had interrupted treatment.

Disease progression in advanced GIST is often due to secondary mutations in KIT or PDGFRA 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 PDGFRA 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.

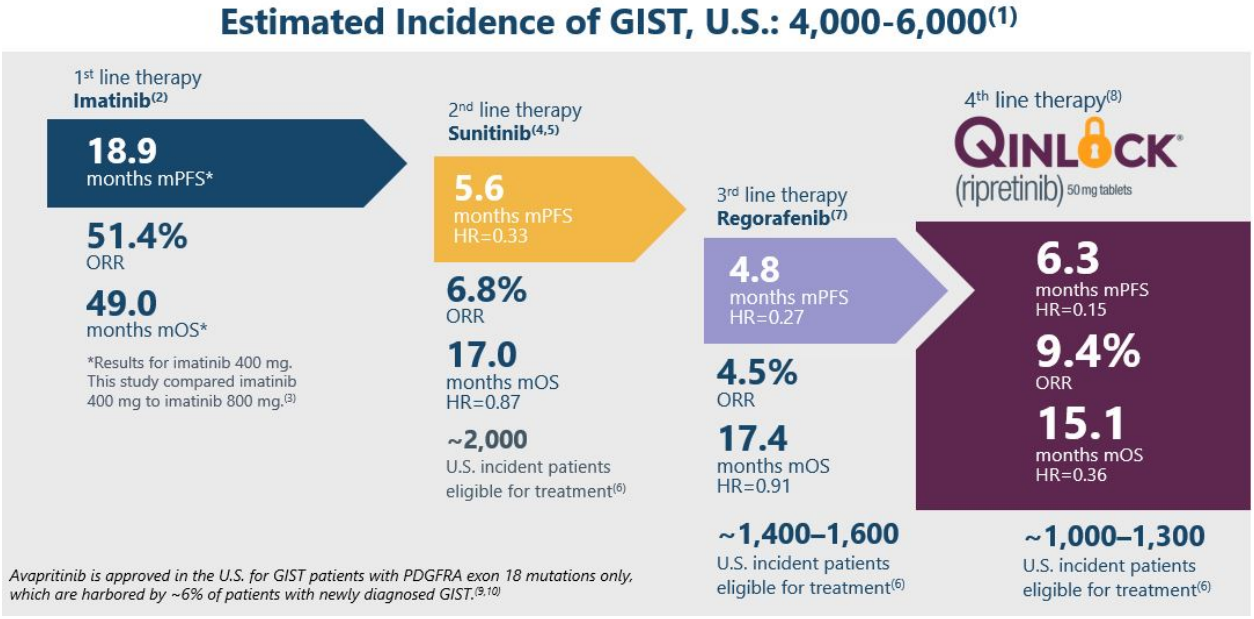
Second- and Third-line Treatments For GIST

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 SD 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), as shown by the 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 was the only approved therapy with activity against a subset of KIT mutations in exon 17, at the time of its approval. 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, ORR, overall survival, all as per RECIST, for imatinib, sunitinib, regorafenib, and QINLOCK in first-line, second-line, third-line, and fourth-line GIST, respectively, based upon the published results of registrational trials that were presented to the FDA for approval of these drugs.



Notes: HR=hazard ratio; mOS=median overall survival; mPFS=median progression free survival. (1) American Cancer Society, Key Statistics for Gastrointestinal Stromal Tumors, Accessed December 18, 2020; (2) Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020; (3) Gastrointestinal Stromal Tumor Meta-Analysis Group (MetaGIST). *J Clin Oncol*. 2010; 28:1247-1253; (4) Sutent [package insert]. New York, NY: Pfizer; 2020, mPFS and mOS converted from weeks to months; (5) Garrett CR, et al. Poster presented at: Connective Tissue Oncology Society: November 13-15, 2008; London, U.K. Abstract 35049; (6) Internal Deciphera estimates of annual new treatment-eligible patients are based on analyses of U.S. claims data; eligible patients for 3rd and 4th lines exclude the estimated proportion of patients across lines that die, discontinue oncology treatment, or enter clinical trial and, therefore, are not eligible for treatment. Estimates are inherently uncertain; (7) Stivarga [package insert]. Germany: Bayer Healthcare; 2020; (8) QINLOCK [package insert]. Waltham, MA: Deciphera Pharmaceuticals; 2020; (9) Ayvakit [package insert]. Cambridge, MA: Blueprint Medicines Corp; 2020; (10) Lopes LF, Bacchi CE. *J Cell Mol Med*. 2010;14:42-50.

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 PDGFRA 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 the annual new treatment-eligible population of second-line GIST patients in the U.S. is approximately 2,000. We estimate that the annual new treatment-eligible population of third-line GIST patients in the U.S. is approximately 1,400 to 1,600 and we estimate that the annual new treatment-eligible population of fourth-line GIST patients in the U.S. is approximately 1,000 to 1,300. These treatment eligible patient estimates 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 4,000 to 6,000 in what is referred to as the EU5, which includes Germany, France, Italy, Spain, and the U.K. 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 specifically for PDGFRA-driven GIST that potently inhibits D842V mutations, which is the most common PDGFRA mutation. We estimate that the annual incidence of new patients with PDGFRA-driven GIST in the U.S. and in Europe and Japan combined is approximately 400 and 700, respectively. In preclinical assays, QINLOCK is potently active against the D842V mutation and other PDGFRA primary mutations. We believe that QINLOCK may offer a potential treatment for these patients in addition to those patients who failed currently approved kinase inhibitors.

Clinical Development of QINLOCK

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

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The FDA's approval of QINLOCK was based on our NDA submission in December 2019, which was reviewed under the FDA's Oncology Center of Excellence (OCE) pilot program, Real-Time Oncology Review (RTOR) and the FDA's Project Orbis initiative, and granted priority review. Our NDA submission was based on positive results from our first Phase 3 study, INVICTUS, in patients with fourth-line and fourth-line plus GIST. Following the FDA approval of QINLOCK, in May 2020, we commenced sales and marketing of QINLOCK in the U.S.

In December 2019, we filed a New Drug Submission (NDS) with Health Canada and a market authorisation application (AUS MAA) with the TGA in Australia for QINLOCK 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. In June 2020, QINLOCK was authorized for sale in Canada by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In July 2020, the TGA approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In November 2020, we announced that we had entered into exclusive distribution agreements for QINLOCK in Canada, Israel, Australia, New Zealand, Singapore, Malaysia, and Brunei.

In July 2020, Zai, our licensee for QINLOCK in Greater China, announced that the NMPA accepted the NDA submission for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

In October 2020, an EU MAA for QINLOCK in fourth-line GIST was accepted for review by the EMA. In January 2021, we announced that Swissmedic accepted a Swiss MAA for QINLOCK in fourth-line GIST. We also announced plans to file a U.K. MAA for QINLOCK in fourth-line GIST. In preparation for a potential European approval of QINLOCK, we are actively engaged in building a direct commercial presence in key European markets and building a targeted infrastructure to commercialize QINLOCK, if approved. In January 2021, we also announced commencement of planning efforts for a bridging study for QINLOCK in Japan. We, or our partners, are also pursuing marketing approval of QINLOCK in our other international target markets.

The INVICTUS Phase 3 study is an international, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The primary efficacy endpoint is PFS based on disease assessment by blinded independent central review (BICR) using modified RECIST 1.1 criteria. The key secondary endpoint is ORR based on BICR. Additional secondary endpoints include overall survival (OS), time to progression, time to best response, PFS by investigator assessment, quality of life, and safety.

In the INVICTUS study, QINLOCK 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% (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.

For the key secondary endpoint of ORR as determined by BICR using modified RECIST, QINLOCK 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 PRs.

QINLOCK also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of OS (median OS 15.1 months with QINLOCK compared to 6.6 months with placebo, HR = 0.36, 95% Confidence Interval (0.21,0.62), 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 QINLOCK treatment.

QINLOCK was generally well tolerated and associated with an acceptable safety profile. The most common adverse reactions (≥20%) in patients treated with QINLOCK were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. Grade 3 or 4 treatment-emergent adverse events (TEAEs) occurred in 42 patients (49%) on the QINLOCK arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the QINLOCK 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 most common grade 3 or 4 laboratory abnormalities (≥4%) were increased lipase and decreased phosphate. Serious adverse events (SAEs) occurred in 31% of patients who received QINLOCK. SAEs that occurred in >2% of patients were abdominal pain (4.7%), anemia (3.5%), nausea (2.4%), and vomiting (2.4%).

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

Phase 3 INTRIGUE Study in Second-Line GIST

In December 2018, we initiated a pivotal Phase 3 study, INTRIGUE, to evaluate the efficacy and tolerability of QINLOCK compared to sunitinib in second-line GIST patients. The study is being conducted at 122 investigational sites in 22 countries. We successfully completed enrollment of 453 patients in INTRIGUE. We expect to announce top-line results for INTRIGUE in the second half of 2021 and, if positive, we plan to submit a supplemental NDA for approval of QINLOCK for the treatment of patients with second-line GIST 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 QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. Patients are randomized 1:1 to either 150 mg of QINLOCK 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 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.

Ongoing Phase 1 Expansion Study of QINLOCK in GIST

We have an ongoing Phase 1 study of QINLOCK in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib. We completed the dose escalation stage of the Phase 1 study, focused on evaluating the safety, tolerability, and maximum tolerated dose (MTD) of QINLOCK, and determined a Phase 2 dose. In the expansion stage, the starting dose for QINLOCK is 150 mg QD. Patients who have disease progression by specified response criteria in the expansion stage may escalate to the higher daily dose (150 mg twice daily (BID)) of QINLOCK after completion of the second cycle. Enrollment in our Phase 1 study is complete and we continue to monitor ongoing patients.

In addition, we believe QINLOCK has the potential to play an even broader role than in the fourth-line setting in the treatment of GIST, and we are planning further clinical development to explore this potential.

We published updated results from our ongoing Phase 1 study of QINLOCK in patients with second-line through fourth-line plus GIST in the Journal of Clinical Oncology in August 2020, 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 QINLOCK as the starting dose, which is the dose being administered in our INVICTUS and INTRIGUE registration-enabling studies, as of an August 31, 2019 data cutoff date. The results were consistent with those previously presented at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. The table below includes local, investigator-assessed ORR by best response as determined by modified RECIST, median duration of response, and mPFS.

Line of Therapy	2nd Line (n=31)	3rd Line (n=28)	≥4th Line (n=83)
ORR (confirmed responses only)	19% (n=6)	14% (n=4)	7% (n=6)
Median Duration of Response	18.4 months	NE[1]	17.5 months
mPFS	10.7 months[4]	8.3 months[5]	5.5 months[6]
Mean Treatment Duration[2][3]	13.2 months	13.4 months	10.5 months

(1) NE = not estimable; n=4; (2) Includes 64 patients who elected for intra-patient dose escalation from 150 mg QD to 150 mg BID; (3) Additional data on file with the Company; (4) Eight patients censored; (5) Six patients censored; (6) 13 patients censored.

QINLOCK 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=10; 7%), hypertension (n=8; 6%), and abdominal pain (n=13; 9%). The most frequent (>30%) TEAEs in patients with GIST receiving QINLOCK 150 mg once daily (n=142) were alopecia (n=88; 62%), fatigue (n=78; 55%), myalgia (n=69; 49%), nausea (n=65; 46%), palmar-plantar erythrodysesthesia (n=62; 44%), constipation (n=56; 39%), decreased appetite (n=48; 34%), and diarrhea (n=47; 33%).

QINLOCK Mechanism of Action

KIT and PDGFRA are kinases that each contain i) an auxiliary inhibitory switch pocket encoded by KIT exon 11 or PDGFRA exon 12 and ii) a main activation switch within the kinase domain encoded by KIT exons 17 and 18 or PDGFRA exons 18 and 19. These mechanisms carefully regulate 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 function and loss of normal, physiologic conformational control. QINLOCK is a novel switch-control TKI specifically designed to broadly inhibit KIT and PDGFRA 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.

QINLOCK precisely and durably binds to both the switch pocket region and the activation switch to lock the kinase in the inactive state, preventing downstream signaling and cell proliferation. For one aspect of its dual mechanism of action, portions of QINLOCK mimic the inhibitory switch and occupy the switch pocket, thereby preventing the activation switch's entry. Additionally, other residues on QINLOCK bind to the activation loop, stabilizing it out of the switch pocket and covering the adenosine triphosphate (ATP) binding site, so phosphorylation cannot occur. This dual mechanism of action secures KIT and PDGFRA kinases in their inactive conformations providing broad inhibition of KIT and PDGFRA kinase activity, including wild type and multiple primary and secondary mutations. QINLOCK also inhibits other kinases *in vitro*, such as PDGFRB, TIE2, VEGFR2, and BRAF.

Vimseltinib: CSF1R Kinase Inhibition for TGCT

Vimseltinib is an investigational, orally administered, potent, and highly-selective switch-control kinase inhibitor of CSF1R. Vimseltinib 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, PDGFRA, PDGFRB, and VEGFR2 and has an even greater selectivity for CSF1R over approximately 300 other human kinases that we tested. Vimseltinib inhibits CSF1R signaling in cellular assays, as well as blocks macrophage-mediated tumor cell migration, osteoclast differentiation, and proliferation of a CSF1R-dependent cell line.

We are currently studying vimseltinib in an open-label Phase 1/2 study designed to evaluate the safety, efficacy, PK, and PD of vimseltinib in patients with malignant solid tumors as well as patients with TGCT. The dose escalation portion of the study is designed to determine a Phase 2 dose for the expansion portion of the study. Based on the results of the dose escalation portion

of the study, in November 2020, we announced the selection of a Phase 2 dose and initiated the expansion portion of the study with vimseltinib in patients with symptomatic TGCT not suitable for surgery. We are continuing to enroll TGCT patients in cohort 9 of the dose escalation portion of the study to complete enrollment of this cohort. In November 2020, we also announced updated preliminary data from the ongoing dose escalation portion of the study of vimseltinib in patients with TGCT. We expect to present updated data for vimseltinib in the second half of 2021.

Market Opportunity in 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. A genetic translocation in certain cells within the tumor causes overproduction of CSF1, the ligand for the CSF1R receptor, triggering migration of inflammatory cells including CSF1R-expressing tumor-associated macrophages to tumor sites. Surgery is the main treatment option; however, these tumors tend to recur in approximately 45% of patients with diffuse-type TGCT and 10% of patients with localized TGCT. 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. TGCT typically occurs in people 30-50 years old and patient burden most commonly includes pain, joint stiffness, restricted mobility, joint damage, and negative impact on quality of life.

TGCTs are divided into types based on where they are and how they grow. Localized TGCT are typically more well-defined and confined to a portion of smaller joints like the fingers, toes, knees, wrists, and ankles. In 2017, annual incidence of new localized TGCT cases in the U.S. is estimated to be approximately 13,000. Diffuse-type TGCT are typically less well-defined and occur most commonly in and around larger joints such as the knee, hips, ankles, elbows, and shoulders. In 2017, annual incidence of new diffuse-type TGCT cases in the U.S. is estimated to be approximately 1,300.

CSF1R inhibition has demonstrated promising clinical benefit in TGCT patients and we believe that despite an approved treatment for TGCT patients in the U.S., there remains an unmet medical need for this population. Pexidartinib is the only approved product for TGCT patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery. In a randomized Phase 3 trial, 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 liver monitoring due to hepatotoxicity risks, thought to be an off-target effect. The EMA adopted the decision of refusal of the pexidartinib EU MAA in November 2020.

Ongoing Phase 1/2 Study of Vimseltinib in Patients with TGCT

The dose escalation portion of our Phase 1/2 study is a single arm study of vimseltinib that is designed to evaluate the safety, PK, and PD of multiple doses of vimseltinib in approximately 60 patients with malignant solid tumors and symptomatic TGCT patients not amenable to surgery. The dose escalation portion of the study was designed to determine the Phase 2 dose and the MTD using a 3+3 dose escalation design with a minimum of three patients enrolled in each dose level cohort; starting at a dose of 10 mg once daily. Loading doses administered in the second cohort and subsequent cohorts were based on PK profiles observed in the first cohort. Based on the results from the dose escalation portion of the study, in November 2020, we announced the selection of a Phase 2 dose for, and initiated, the expansion portion of the study in patients with symptomatic TGCT not amenable to surgery. We are continuing to enroll TGCT patients in cohort 9 of the dose escalation portion of the study to complete enrollment of this cohort. The expansion portion of the study is designed to evaluate the safety, tolerability, preliminary antitumor activity, PK, PD, and patient reported outcomes of vimseltinib in TGCT.

In November 2020, at the Connective Tissue Oncology Society 2020 Virtual Annual Meeting, we announced the presentation of preliminary, updated data from the ongoing dose escalation portion of the Phase 1/2 study of vimseltinib in patients with symptomatic TGCT not amenable to surgery. Safety, PK, and PD data were analyzed as of September 23, 2020, with anti-tumor activity data reported as of October 5, 2020. Tumor reductions from baseline were determined by independent central radiologic review using RECIST. As of the data cut-off date, increasing doses of vimseltinib were assessed in three dose cohorts across 25 patients with TGCT. Each dose cohort received a three to five day loading dose regimen at doses of up to 30 mg followed by a schedule of daily, or twice-weekly maintenance dosing with vimseltinib.

Vimseltinib was generally well-tolerated in patients with TGCT not amenable to surgery. TEAEs occurring in greater than or equal to 15% of patients, regardless of relatedness, were generally grade 1 or 2 and included blood creatine phosphokinase (CPK) increased (52%), aspartate aminotransferase (AST) increased (44%), periorbital edema (44%), fatigue (40%), lipase increased (32%), alanine aminotransferase increased (28%), amylase increased (24%), face edema (24%), headache (24%), pruritis (24%), nausea (20%), rash maculo-papular (20%), arthralgia (16%), diarrhea (16%), myalgia (16%), and peripheral edema (16%). Among the TEAEs that occurred in greater than or equal to 15% of patients, grade 3 or 4 related TEAEs occurred in 9

patients and included grade 3/4 blood CPK increased (20%), grade 3 AST increase (12%), grade 3 lipase increased (12%), grade 3 amylase increased (4%), grade 3 diarrhea (4%) and grade 3 myalgia (4%). No SAEs related to vimseltinib were reported in the TGCT patients. TEAEs led to dose interruption in nine TGCT patients (36%), dose reduction in four TGCT patients (16%), and treatment discontinuation in one TGCT patient (4%) due to an adverse event of asymptomatic grade 3 AST elevation from grade 1 at baseline. Bilirubin levels were within the normal limit and observed transaminase and pancreatic enzyme elevations were asymptomatic and not clinically significant in the TGCT patients.

Similar steady state PK profiles were observed between the 30 mg twice weekly (cohort 5) and 10 mg daily (cohort 8) dosing regimens; lower exposure was observed in the 6 mg daily (cohort 9) dosing regimen. We observed on-target PD inhibition by vimseltinib of CSF1R by causing a dose-related rise in plasma CSF1 and IL-34 and a reduction of CD14dim/CD16+ monocytes in peripheral blood across all TGCT cohorts in this study.

Of the 25 TGCT patients treated as of the data analyses dates, 22 were evaluable for anti-tumor activity by RECIST, 21 by central assessment and one by local assessment. Three of the 25 TGCT patients had not yet reached the first efficacy assessment timepoint. Nine patients, or 41%, across all TGCT cohorts achieved objective response, including one CR (confirmed) and eight PRs (two confirmed and six to be confirmed at future follow up). Seven of the nine responders, or 78%, had a PR at their first restaging scan evaluation. Two of the TGCT patients were on treatment for over 12 months, with responses that deepened over time. At the time of the data cut-off, 22 of 25 patients were receiving treatment with vimseltinib, two patients withdrew from the study and one patient discontinued treatment due to an adverse event.

Based on these results, the Phase 1/2 study of vimseltinib is ongoing and enrolling up to 60 patients in two expansion cohorts, one for TGCT patients with no prior exposure to anti-CSF1/CSF1R agents (n=40) and a second for TGCT patients with prior exposure to anti-CSF1/CSF1R agents (n=20). In addition, enrollment of an additional six patients in cohort 9 of the dose escalation portion of the study is ongoing to complete enrollment in this cohort. The recommended Phase 2 dose for vimseltinib in asymptomatic TGCT patients not amenable to surgery was determined to be 30 mg BID (no loading dose).

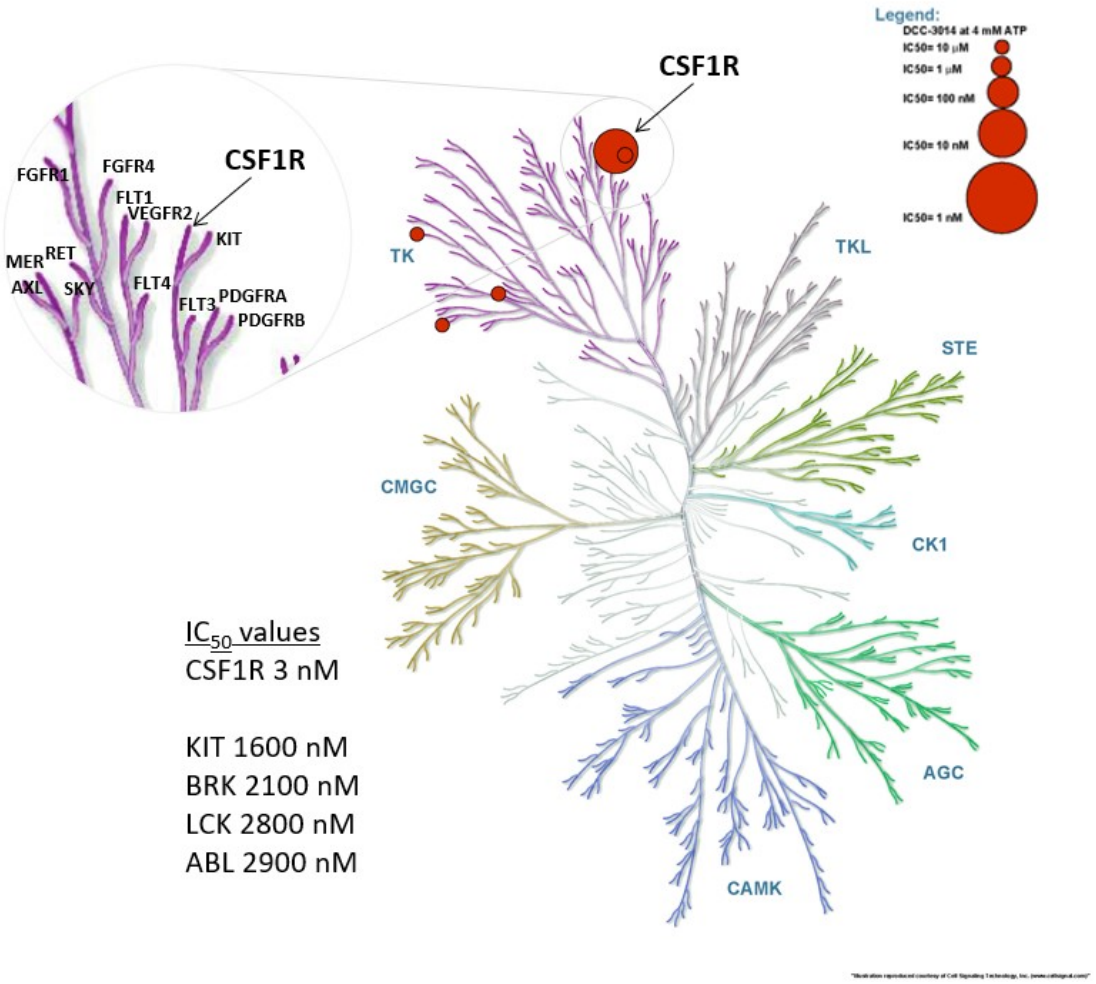
Selectivity and Preclinical Profile of Vimseltinib

We evaluated the selectivity of vimseltinib for CSF1R in a standard biochemical assay, called a kinome screen assay. The kinome screen assay assesses the concentrations of vimseltinib 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 kinome screen assay uses a 10 micromolar concentration of ATP, a standard low concentration typically used in this assay. Kinases inhibited in the kinome screen assay were then assessed in a separate biochemical assay using a 4 millimolar concentration of ATP, equivalent to that present in human cells. The following figure depicts the results of these assays. Each kinase in the assay is depicted as a point at the end of a branch in the figure, and each kinase inhibited by vimseltinib 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. As shown below, vimseltinib inhibits CSF1R at concentrations much lower than the concentrations at which it inhibits other kinases. 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.

Vimseltinib (DCC-3014) Exhibits High Selectivity for CSF1R in Kinase Assays



Rebastinib: TIE2 Kinase Inhibition for Advanced or Metastatic Solid Tumors

Rebastinib is a potential first-in-class investigational, orally administered, potent, and selective inhibitor of the TIE2 kinase. TIE2 is the receptor for angiopoietins ANG-1 and ANG-2, an important family of vascular growth factors. TIE2 receptors are expressed on endothelial cells and angiogenic macrophages promoting the survival, maturation, and functional integrity of the vasculature and play a key role in regulating tumor angiogenesis, invasiveness, and metastasis. Rebastinib binds potently into the switch pocket of TIE2, stabilizing the inhibitory switch and displacing the activation switch to block TIE2 signaling.

Market Opportunity in Endometrial and Platinum-Resistant Ovarian Cancers

Endometrial cancer is a type of cancer that forms in the inner lining of the uterus. Most endometrial cancers are adenocarcinomas. In 2020, annual incidence of new cases of endometrial cancer in women in the U.S. was estimated to be approximately 65,000, with approximately 12,500 women dying from the disease. Overall five-year survival exceeds 80%. However, survival in advanced disease is significantly worse, at approximately 17%. Diagnosed early, surgery with or without radiation may be curative. However, for recurrent or advanced endometrial cancer cases that require systemic therapy, outcomes decline substantially with successive lines of therapy.

Advanced disease is typically treated with platinum-based chemotherapy in the first-line setting with paclitaxel and carboplatin doublet. Subsequent lines of therapy are comprised of a diverse range of therapies, including a combination of pembrolizumab and lenvatinib. The majority of late-stage product candidates in clinical development for the treatment of endometrial cancer is made up of anti-PD1, or programmed cell death protein 1, monoclonal antibodies in combination with chemotherapy, or TKI-based regimens. We believe that, given the significantly reduced success in treating advanced cases of endometrial cancer, and the limited treatment options for patients with advanced disease, there remains an unmet medical need for this population.

Ovarian cancer is a type of cancer that begins in the ovaries. Cancer that responds at first to treatment with drugs that contain the metal platinum, such as cisplatin and carboplatin, but then recurs within a certain period is considered platinum resistant. In 2020, annual incidence of new cases of ovarian cancer in women in the U.S. was estimated to be approximately 22,000, with approximately 14,000 women dying from the disease. The overall five-year survival rate is approximately 47% in the U.S., but only approximately 29% for metastasized disease. The vast majority of patients experience disease recurrence, and eventually develop PROC.

Platinum-free chemotherapy, such as weekly paclitaxel, topotecan, or liposomal doxorubicin, with the option of adding bevacizumab, is typically the first therapy used for platinum-resistant patients. Due to the limited efficacy of current treatment options, there is no widely accepted standard of care for patients who recur. Therapy is selected on an individualized basis and participation in clinical trials is recommended. There are approximately 50 compounds in Phase 1 to Phase 3 development for the treatment of ovarian cancer. More than 75% in Phase 2/3 are combination regimens. Poly(ADP-ribose) polymerase inhibitors and anti-PD-1, or anti-PD-L1, or programmed death-ligand 1, therapies are widely used across lines of therapy and combinations. Somewhat less widely used are product candidates designed to affect tumor vasculature and/or tumor microenvironment. We believe that because outcomes are particularly poor for patients with PROC, there remains a significant unmet medical need for this population.

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. Part 2 of the study was designed as a Simon 2-stage design; in Stage 1, the combination of rebastinib and paclitaxel is being evaluated in multiple solid tumor cohorts in up to 18 patients each. If there are more than four responses in a cohort, that cohort is expanded to include up to a total of 33 patients.

Rebastinib in Combination with Paclitaxel

In Part 1 of the study of rebastinib in combination with paclitaxel, we observed anti-tumor activity across multiple tumor types including a best response of PR in 5 of 24 patients at 50 mg BID and 3 of 19 patients at 100 mg BID. Objective responses were seen in 8 patients, including 3 PRs in PROC. In Part 2 of the study of rebastinib in combination with paclitaxel, the safety, tolerability, and efficacy of the Phase 2 dose of rebastinib in combination with weekly paclitaxel is being assessed across multiple cohorts, including: endometrial cancer, PROC, carcinosarcoma, and breast cancer. This study enrolled 43 evaluable patients in Part 1 and will enroll up to 132 evaluable patients in Part 2. In May 2020, we announced that in Part 2 of the study of rebastinib in combination with paclitaxel, we observed the required number of responses in Part 2, Stage 1 in both the endometrial and platinum-resistant ovarian cancer cohorts, triggering the expansion of enrollment in these cohorts. In addition, based on the clinical activity observed in Part 1, we added a cohort for patients with carcinosarcoma in Part 2 of the study of rebastinib in combination with paclitaxel. Enrollment is ongoing in Part 2, Stage 1 of the carcinosarcoma and inflammatory breast cancer cohorts of the study. The triple negative breast cancer cohort of the study did not advance to Part 2, Stage 2.

Endometrial Cancer Cohort

In May 2020, we presented preliminary data from Part 2 of the endometrial cancer cohort at the 2020 ASCO Virtual Scientific Program. As of the data cutoff date, a total of 21 patients initiated treatment with rebastinib in the Part 2 cohort of endometrial cancer patients. Median duration of treatment was 3.7 months. Sixteen patients were treated at a starting dose of 100 mg of rebastinib BID in combination with weekly paclitaxel 80 mg/m^2 and five patients at a starting dose of 50 mg of rebastinib

BID in combination with weekly paclitaxel 80 mg/m^2. Three of the 21 patients withdrew consent early, resulting in 18 patients in the modified intent-to-treat (mITT) population. Of the 21 patients treated with the combination, all received one or more prior lines of the combination of paclitaxel/carboplatin, and 20 of 21 received two or more prior anti-cancer regimens. Of the 18 patients included in the mITT population, seven PRs were observed (four confirmed) and six patients had SD, for an ORR of 39% (confirmed and unconfirmed) and a clinical benefit rate (CBR), defined as the proportion of patients with best overall response of CR, PR, or SD per RECIST, of 72% at eight weeks. Treatment with rebastinib 50 mg BID in combination with paclitaxel was well-tolerated, with TEAEs consistent with findings from Part 1 of the study and consistent with first-in-human studies of rebastinib, or known to be associated with treatment with paclitaxel. The majority of TEAEs occurring in greater than or equal to 15% of patients, regardless of causality, were grade 2 or less. SAEs at least possibly related to rebastinib occurred only in patients treated with rebastinib 100 mg BID and resolved after dose reductions. Nine patients experienced SAEs at least possibly related to rebastinib including muscular weakness (n=2), acute myocardial infarction (n=1), atrial flutter (n=1), dehydration (n=1), head discomfort (n=1), nausea (n=1), peripheral edema (n=1), and pneumonia (n=1). Enrollment in Part 2, Stage 2 of the endometrial cohort at the rebastinib 50 mg BID dose has been completed and further efficacy and safety evaluation is ongoing.

We expect to present updated data from the study of rebastinib in combination with paclitaxel for patients with endometrial cancer in the second quarter of 2021.

PROC Cohort

At the European Society for Medical Oncology (ESMO 2020) meeting in September 2020, we presented preliminary data from 29 patients from the PROC expansion cohort in Part 2 of the study comprised of 19 patients treated with rebastinib 50 mg oral BID in combination with paclitaxel 80 mg/m^2 IV and 10 patients from the rebastinib 100 mg oral BID with paclitaxel 80 mg/m^2 IV. Preliminary results from 24 of the 29 patients that met the mITT criteria included nine PRs and 12 SDs for an ORR of 38% (confirmed and unconfirmed) and a CBR of 88% at eight weeks. Median treatment duration for the mITT population was 4.2 months. In addition, 59% of patients who were evaluable had a CA-125 response, as defined by the Gynecological Cancer Intergroup CA-125 criteria.

Treatment with rebastinib 50 mg BID in combination with paclitaxel was generally well-tolerated, with TEAEs consistent with findings from Part 1 of the study and consistent with the first-in-human study of rebastinib, or known to be associated with treatment with paclitaxel. TEAEs occurring in greater than or equal to 25% of patients, regardless of causality were fatigue (41%), dry mouth (38%), nausea (34%), diarrhea (31%), stomatitis (31%), abdominal pain (28%), and peripheral sensory neuropathy (28%). 11 patients (38%) had a TEAE of grade 3 or more. Two patients experienced SAEs at least possibly related to rebastinib including muscular weakness/fatigue (starting dose 100 mg BID and resolved with drug interruption), and urinary tract infection (starting dose rebastinib 50 mg BID). Enrollment in Part 2, Stage 2 of the PROC cohort at the rebastinib 50 mg BID dose has been completed and further efficacy and safety evaluation is ongoing.

We expect to present updated data from the study of rebastinib in combination with paclitaxel for patients with PROC in the second half of 2021.

Rebastinib in Combination with Carboplatin

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 is being assessed across multiple solid tumor cohorts. This study was designed 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 50 mg BID of rebastinib and activated Part 2 of the Phase 1b/2 study of rebastinib in combination with carboplatin. Enrollment in Part 2, Stage 1 of the platinum-sensitive ovarian cancer cohort at the rebastinib 50 mg BID dose has been completed and efficacy and safety evaluation is ongoing. The triple negative breast cancer and mesothelioma cohorts of the study did not advance to Part 2, Stage 2.

At ESMO 2020, we presented preliminary data from Part 1 of the study of rebastinib in combination with carboplatin. Rebastinib in combination with carboplatin was generally well-tolerated. The majority of TEAEs were grade 1 and grade 2. One patient (rebastinib 50 mg BID) experienced a rebastinib-related SAE (grade 2 retinal vascular disorder). Based on a higher observed frequency of reversible muscular weakness in preliminary data from the ongoing Part 2 portion of the study phase at rebastinib 100 mg BID, the recommended Phase 2 dose was changed to rebastinib 50 mg BID + carboplatin AUC5 Q3W. The clinical benefit rate, defined as the proportion of patients with best overall response of CR, PR, or SD per RECIST, was 50% at

six weeks and 36% at twelve weeks, and the median duration of treatment was 7.8 weeks. One patient (4.5%) had a PR (unconfirmed) and 10 patients (46%) had SD as best response in this heterogeneous, heavily-treated population where all patients received at least two or more prior anti-cancer regimens and 50% received four or more prior regimens. At the rebastinib 50 mg BID dose level, the exposure of rebastinib was generally comparable to previously published data. Mean circulating Ang-2 levels increased after eight days of treatment for all doses, indicating TIE2 inhibition. The Part 2 portion of the Phase 1b/2 study is ongoing and will evaluate the safety and efficacy of rebastinib at the recommended Phase 2 dose in combination with carboplatin.

Selectivity and Preclinical Profile of Rebastinib

We evaluated the selectivity 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 selectivity 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.

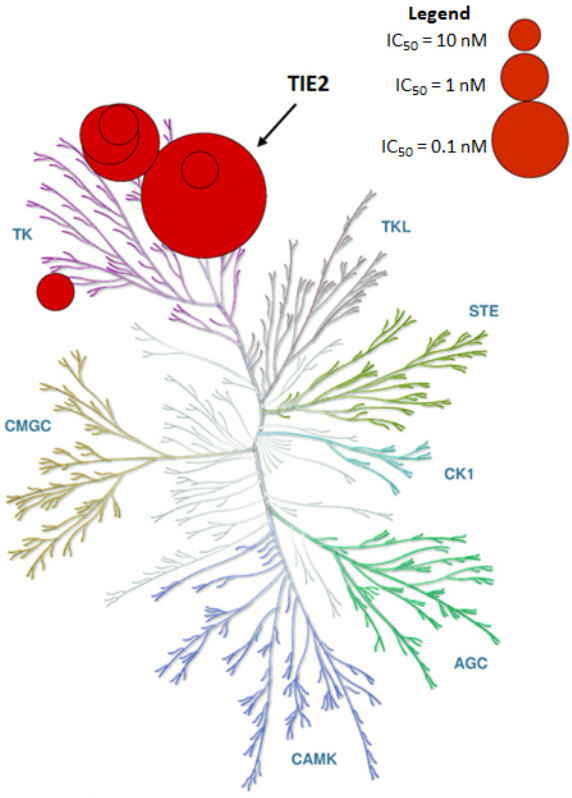


Illustration reproduced courtesy of Cell Signaling Technology, Inc. (www.cellsignal.com)

DCC-3116: ULK Kinase Inhibition for Mutant RAS/RAF Cancers

In January 2021, we announced our plans to initiate a Phase 1 study of DCC-3116 in the second quarter of 2021 under our IND for DCC-3116, submitted in the fourth quarter of 2020 and cleared by the FDA. The Phase 1 multicenter, open-label study will evaluate DCC-3116 as a single agent and in combination with trametinib, an FDA approved MEK inhibitor, in patients with advanced or metastatic tumors with a documented RAS or RAF mutation who have progressed despite standard therapies, or for whom conventional therapy is not considered effective or tolerable, as judged by the investigator. The study will be conducted in two parts, a dose escalation phase and a dose expansion phase. In Part 1, we will start with a standard 3+3 dose escalation design. Once the recommended Phase 2 dose or maximum tolerated dose of single agent DCC-3116 is determined, the first cohort of the combination dose escalation will open for enrollment. The dose expansion phase, Part 2, will be initiated after the recommended Phase 2 dose of the combination is determined, and is expected to include four cohorts of up to 20 patients each. This includes cohorts for patients with pancreatic ductal adenocarcinoma, non-small cell lung cancer, colorectal cancer, and melanoma

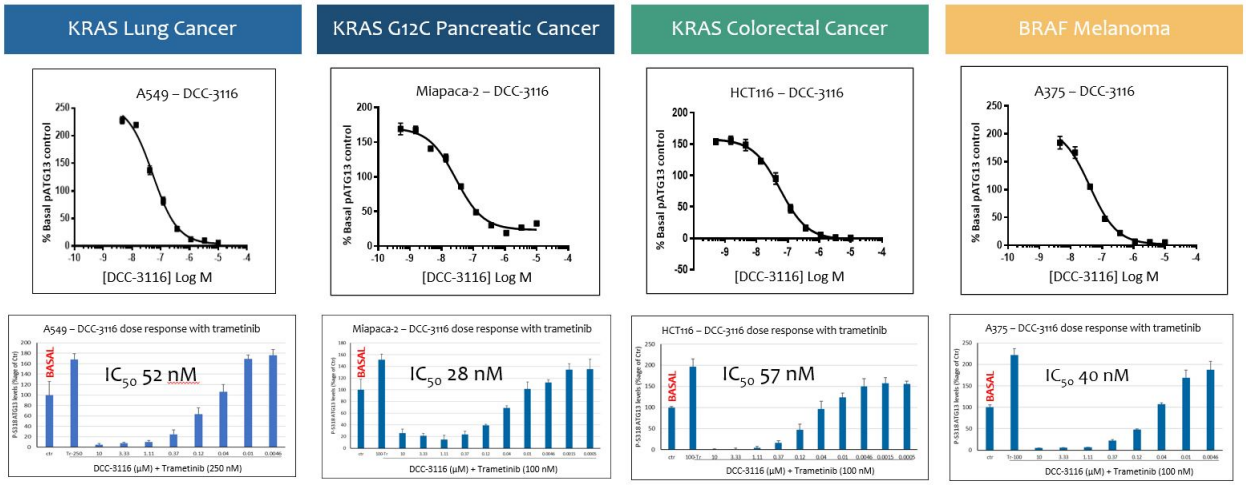
harboring a specified, documented mutation in the RAS or RAF pathway. DCC-3116, discovered using our novel switch-control kinase inhibitor platform, is designed to inhibit autophagy by inhibiting the ULK 1/2 kinases, which have been shown to be the initiating factors that activate autophagy.

Mechanism of Action and Preclinical Profile of DCC-3116

DCC-3116 has been designed to treat cancer patients in combination with RAS/MAP kinase signaling pathway inhibition, particularly in patients with RAS or BRAF mutations. Autophagy is a cellular pathway that has been observed to be upregulated in mutant RAS and mutant RAF cancers and is also known to mediate resistance to inhibitors of the RAS/MAP kinase 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 and RAF cancers are reported to have high basal levels of autophagy, which these cancers use to maintain nutrient supply, and regulate cancer cell metabolism and survival. Cellular studies in mutant RAS and RAF cancers have also demonstrated that treatment with MAP kinase pathway inhibitors, as well as other signaling 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* and *in vivo* models of mutant RAS and RAF cancers, inhibition of autophagy combined with inhibition of RAS/MAP kinase signaling using MEK inhibitors, ERK inhibitors, or KRAS G12C 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 and RAF cancer models.

In our preclinical studies, we have observed DCC-3116 to durably and potently inhibit autophagy in RAS or RAF mutant cancer cell lines through the inhibition of ULK 1/2 kinases. Our *in vitro* studies have also demonstrated that DCC-3116 in combination with inhibitors of the MAP kinase pathway inhibits both basal autophagy (autophagy in the absence of a MAP kinase pathway inhibitor) and also MAP kinase pathway inhibitor-induced increased autophagy in various mutant RAS or RAF 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.

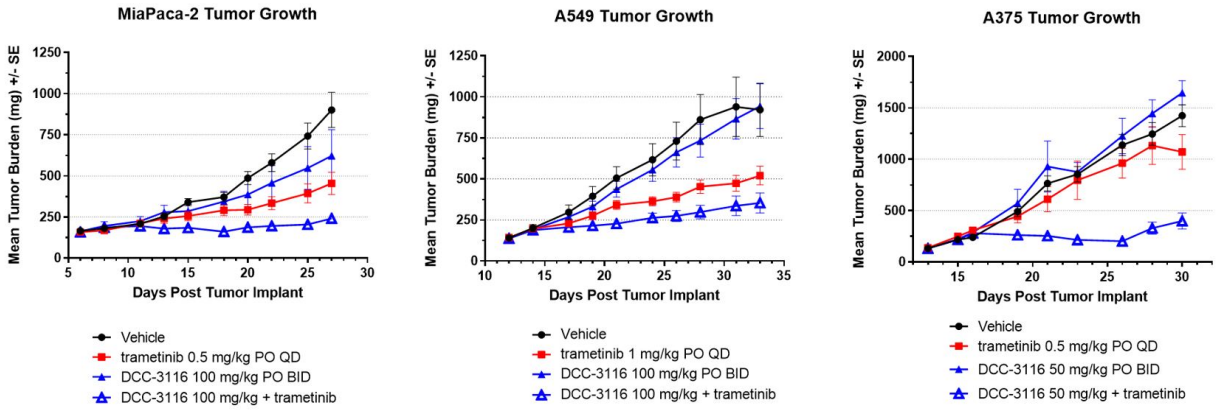
Preclinical Inhibition of ULK 1/2 Kinases by DCC-3116 in Multiple RAS/RAF Cancer Cell Lines



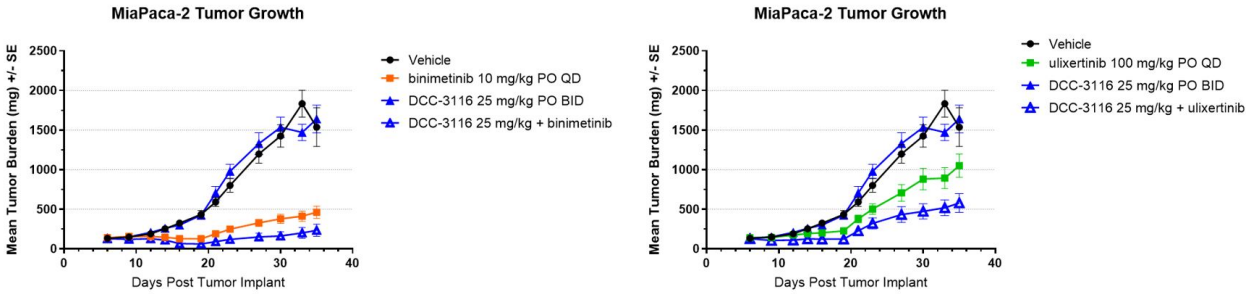
When evaluated in preclinical *in vivo* models, DCC-3116 in combination with inhibitors of the MAP kinase pathway demonstrated synergistic inhibition of mutant RAS or mutant RAF cancer growth as shown below. In KRAS mutant pancreatic, lung, and BRAF mutant melanoma *in vivo* models, DCC-3116 in combination 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 1/2 kinases, DCC-3116 has been designed to address mutant RAS and mutant RAF cancers by inhibiting the basal and compensatory autophagy that mutant RAS and mutant RAF cancer cells use for survival.

Platform Development and Preclinical Pipeline

We intend to leverage our proprietary switch-control kinase inhibitor platform to advance additional drug candidates into clinical development. Our discovery programs are focused on 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 QINLOCK in Greater China

In June 2019, we entered into the Zai License Agreement, pursuant to which we granted Zai exclusive rights to develop and commercialize the Licensed Products in Greater China, also referred to as the Territory. We retain exclusive rights to, among other things, develop, manufacture, and commercialize the Licensed Products outside the Territory. In July 2020, Zai announced that the NMPA accepted the NDA submission for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

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.

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.

In February 2020, we entered into a Supply Agreement (the Zai Supply Agreement) with Zai, as required by terms in the Zai License Agreement, pursuant to which we will supply the Licensed Products to Zai for use in the Territory for clinical trials as well as commercial inventory, if QINLOCK obtains regulatory approval in the Territory. Subject to the Zai Supply Agreement, costs incurred by us for external manufacturing services are reimbursed by Zai.

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 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 QINLOCK, we have established our own commercial and marketing organization in the U.S. and intend to establish a direct commercial presence in key European markets and build a targeted infrastructure to commercialize QINLOCK in Europe, if approved. In addition, we have entered into distributor arrangements in Australia and Canada, and intend in the future to enter into additional select distributor arrangements to offer QINLOCK to geographies where we do not intend to distribute QINLOCK on our own, or to selectively establish partnerships, such as the Zai license for Greater China described above, in other markets outside the U.S. In the U.S., we have built a specialist sales force to target physicians who are high prescribers of treatments for GIST. Our sales force is supported by sales management, internal sales support, an internal marketing group, and distribution support. Additionally, our sales and marketing teams 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 in Europe, we expect to invest financial and management resources, some of which will be committed prior to approval of QINLOCK in Europe, which we may never obtain.

For our drug candidates, we intend to retain commercialization rights in the U.S. and Europe and leverage our commercial and marketing organization for QINLOCK, with appropriate additions or modifications as necessitated by the specific indications pursued, assuming we obtain regulatory approval for such drug candidates in the U.S. and Europe. In addition, 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 in geographies where we do not intend to distribute QINLOCK on our own, 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 produce limited quantities of drug substance for evaluation in our research programs. We currently rely on third parties to manufacture our drug candidates for preclinical and clinical testing, as well as for the commercial manufacture of our current and any future drugs. To date, we have obtained drug substance and drug product from third-party manufacturers for QINLOCK, vimseltinib, rebastinib, and DCC-3116 to support preclinical and clinical testing and commercial supply of QINLOCK. 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 QINLOCK. We acquire many key materials on a purchase-order basis. While we have commercial supply arrangements for our drug substance and finished drug product for QINLOCK, we do not have any long-term supply arrangements in place with respect to our drug candidates and other materials. Furthermore, we do not currently have arrangements in place for redundant supply or a second source of drug substance or drug product. We rely on our sole source suppliers to manufacture all of our drug substance and finished drug product for commercialization of QINLOCK unless and until we add additional sources. We do not currently have a validated manufacturing process in place for any drug candidate, other than our approved drug, QINLOCK, which would be required to support commercialization of any of our drug candidates, if approved.

QINLOCK and 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 QINLOCK, 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, including QINLOCK, 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 and selling 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 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.

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 approved for broader indications or patient populations, are approved for specific sub-populations, are more convenient, or are less expensive than QINLOCK or any other drugs that we or our collaborators may develop. Our competitors also may obtain FDA, EMA, or other marketing 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. 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. We expect that QINLOCK, and any of our drug candidates that achieve marketing approval, will be priced at a significant premium over any competitive generic products.

The key competitive factors affecting the success of QINLOCK and 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.

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

Competition for QINLOCK

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In addition, QINLOCK is currently being investigated in a Phase 3 study for the treatment of patients with second-line GIST.

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 PDGFRA exon 18 mutation only. In addition, there are pharmaceutical and biotechnology companies developing or marketing treatments for cancer that would be competitive with QINLOCK, if such 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 PDGFRA exon 18 mutations only, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRA, and no currently marketed drug provides coverage of all KIT and PDGFRA mutants.

With respect to QINLOCK, there are several large pharmaceutical companies and biotechnology companies marketing small molecule drugs or biologic drugs for the treatment of GIST, including Blueprint Medicines Corporation (Blueprint), Novartis AG (Novartis), Pfizer, Inc. (Pfizer), and Bayer AG (Bayer). We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST including AB Sciences S.A. (ABS), Arog Pharmaceuticals, Inc. (Arog), Chia Tai Tianqing Pharmaceutical Group CO., LTD (CTTPG), Cogent Biosciences, Inc. (formerly known as Unum Therapeutics Inc.) (Cogent), Daiichi Sankyo Company, Limited (Daiichi), Exelixis, Inc. (Exelixis), Immunicum AB (Immunicum), Jiangsu HengRui, Inc. (Jiangsu), Ningbo Tai Kang Medical Technology Co. Ltd. (NTKMT), Novartis, Taiho Pharmaceutical Co. Ltd (Taiho), and Xencor, Inc. (Xencor).

Competition for Vimseltinib

We are initially developing vimseltinib, a potent, and highly selective switch-control kinase inhibitor of CSF1R, for the treatment of patients with TGCT. If vimseltinib receives marketing approval, we may face competition from other companies marketing or developing antibodies and small molecules targeting CSF1R, including Abbisko Therapeutics Co., Ltd. (Abbisko), Daiichi, LifeMax Laboratories, Inc. (LifeMax), and SynOx Therapeutics Ltd (SynOx).

Competition for Rebastinib

We are initially developing rebastinib, a potential first-in-class TIE2 inhibitor, for the treatment of multiple solid tumors in combination with chemotherapy. While rebastinib is a novel molecule, we may face competition from drug candidates in clinical trials that are not TIE2 inhibitors, including small molecule drug candidates in clinical trials from Clovis Oncology, Inc. (Clovis), Eisai Co., Ltd. (Eisai), and Novartis, and from antibody therapeutics from AstraZeneca PLC (AstraZeneca), ImmunoGen, Inc. (ImmunoGen), Roche Holding Ltd. (Roche), Merck & Co., Inc. (Merck), and Tesaro, a GlaxoSmithKline PLC company (Tesaro).

Competition for DCC-3116

We are initially developing DCC-3116, a potential first-in-class ULK kinase inhibitor, for the treatment of cancers caused by RAS or RAF mutations. While DCC-3116 is a novel molecule in early-stage development, we may face competition from drugs or drug candidates in clinical trials that are not ULK inhibitors, but also aim to address cancers caused by RAS or RAF mutations.

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, QINLOCK, vimseltinib, 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 switch-control kinase inhibitor platform.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for our approved drug and 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 our drug or 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 QINLOCK (ripretinib), as of January 31, 2021, 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 2030, 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 six pending U.S. applications, and related pending applications in Europe, Australia, South America, and Asia, as well as three pending Patent Cooperation Treaty (PCT) patent applications directed to methods of using and drug product of QINLOCK (ripretinib) which, if granted, will expire between 2037 and 2040.

With regard to vimseltinib, as of January 31, 2021, 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, will expire in 2039.

With regard to rebastinib, as of January 31, 2021, 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. application and one pending PCT patent application, which, if one or more patents claiming priority to these patent applications is granted, will expire in 2040. We also own one pending U.S. provisional application, which, if one or more patents claiming priority to this provisional application is granted, will expire in 2041.

With regard to DCC-3116, as of January 31, 2021, we own three pending U.S. applications and three pending PCT patent applications, which, if one or more patents claiming priority to these applications is granted, will expire in 2040.

With regard to our early stage programs, as of January 31, 2021, we have 10 pending U.S. provisional applications, which, if one or more patents claiming priority to these provisional applications is granted, will expire in 2041.

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 QINLOCK, vimseltinib, and rebastinib may be entitled to patent term extensions. We have applied for patent term extensions that, if granted, may extend the patent term of one of our granted U.S. patents and the patent terms of our two issued Australian patents for QINLOCK. We have obtained a Certificate of Supplementary Protection for our issued patent in Canada, extending the patent expiry date until 2034. 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 switch-control kinase inhibitor platform and certain aspects of our manufacturing processes. 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.

Moreover, the Right to Try Act, 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.

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 Prescription Drug User Fee Act (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, 2020 through September 30, 2021, the user fee for an application requiring clinical data, such as an original NDA, is $2,875,842. The PDUFA also imposes an annual prescription drug product program fee for human drugs ($336,432). 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 for any of our drug candidates. 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 breakthrough designation, 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. 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. 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 breakthrough therapy designation (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 QINLOCK, 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 promotion), 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, 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 approved drug and drug candidates 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 drug candidates 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 our approved drug or any 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 product; 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 or any 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. We intend to apply for restoration of patent term for one of our currently owned or licensed patents that cover any drug candidate that receives FDA approval 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 European Economic Area (EEA), which includes the 27 member states that comprise the European Union (EU) (the Member States) plus Iceland, Liechtenstein, and Norway (the EEA Member States), 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 orphan 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 a life-threatening or chronically debilitating condition and either (i) the prevalence of the condition is not more than 5 in 10,000 persons in the EEA when the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development. 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 EEA or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

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 EEA, 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 any of the competent authorities in the EEA Member States can accept an application or grant a marketing authorization for 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, it is established that 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. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder consents to such revocation; or (ii) the marketing authorization holder cannot supply enough orphan medicinal product.

Orphan drug exclusivity may be lost if the FDA 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. 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.

Beginning on January 1, 2021, a separate process for orphan drug designation will apply in Great Britain. There will be no pre-marketing authorization orphan designation (as there is in the EEA) and the application for orphan designation will be reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA) the U.K. medicines regulator, at the time of a MAA. The criteria are the same as in the EEA, save that they apply to Great Britain only (e.g. there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain).

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 or 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, 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 or 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 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, as a regulation is directly effective in each Member State, without the need for implementing legislation (which is required for a Directive).

Following the U.K.'s departure from the EU on January 31, 2020, the U.K. (which comprises Great Britain and Northern Ireland) continued to follow the same regulations as the EU during a transition period which ended on December 31, 2020. Now that this transition period has ended, all in vitro medical devices must be registered with the MHRA before being placed on the Great Britain (GB) market. There is a grace period to allow time for compliance with the new registration process, with high risk device (i.e. List A products) requiring registration by May 1, 2021, and low risk devices requiring registration later in 2021 (List B products from September 1, 2021 and general in-vitro diagnostics from January 1, 2022). European CE marks will continue to be recognized in GB until June 30, 2023, following which a U.K.CA mark will be required for an in vitro medical device to be marketing in GB. The new EU Regulation will not automatically apply in GB, so the regulation of medical devices in GB may diverge from EU regulations in future. The EU regulatory framework on medical devices will, however, continue to apply in Northern Ireland under the Northern Irish Protocol and medical devices in Northern Ireland may either carry a European CE mark or a U.K. and Northern Ireland CE (CE U.K.NI) mark (although devices bearing the CE U.K.NI marking will not be accepted on the EU market).

European Drug Development

In Europe, our current or future approved 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) 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). 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) following confirmation of the full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Regulation, through an independent audit. This is currently expected to occur in December 2021. The new Regulation seeks to simplify and streamline the approval of clinical trials in the EU. 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.

The U.K. has implemented Directive 2001/20/EC into national law through the Medicines for Human Use Regulations, so U.K. regulation of clinical trials is currently aligned with EU regulations. Whether the U.K. will amend its legislation to align more closely with the new EU Regulation once that comes into effect is as yet unknown.

European Drug Review and Approval

In the EEA, medicinal products can only be commercialized after obtaining an EU Marketing Authorization. There are two types of marketing authorizations.

The first is the centralized marketing authorization, 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 of the EMA. A centralized marketing authorization is valid throughout the entire territory of the EEA. The CP is mandatory for certain types of drugs, such as biotechnology medicinal drugs, advanced-therapy medicines (gene-therapy, somatic cell-therapy, or tissue-engineered medicines), orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of HIV or AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, 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 marketing authorizations, 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 an EEA Member State, this national authorization can be recognized in other Member States through the Mutual Recognition Procedure. If the drug has not received a national authorization 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 authorization 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 Concerned Member States) 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 marketing authorization in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above described procedures, before granting the marketing authorizations, 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.

Now that the U.K. has left the EU, GB will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized EU authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized authorization were automatically converted to GB marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new GB marketing authorization. A separate application will, however, still be required. The MHRA also has the power to have regard to marketing authorizations approved in EEA Member States through Decentralized or Mutual Recognition Procedures with a view to more quickly granting a marketing authorization in the U.K. or GB.

European Chemical Entity Exclusivity

In the EEA, innovative medicinal products, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. 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. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Brexit and the Regulatory Framework in the 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 remained applicable to the U.K. and ended 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., as the U.K. legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the U.K. in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow now that the transition period is over, which will be updated as the U.K.'s regulatory position on medicinal products and medical devices evolves over time. Brexit has also created uncertainty with regard to data protection regulation in the U.K., and in particular, how data transfers from the EU to the U.K. will be regulated. The EU and the U.K. have agreed a bridging period of up to six months to allow the continued free flow of data from the EU to the U.K., during which time the European Commission will assess whether the U.K. will be granted adequacy status. There is no certainty that an adequacy decision will be granted. If it is not, legal uncertainties regarding the flow of data across borders could increase the complexity and cost of transferring personal data from the EU to 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 QINLOCK and any future approved drugs will depend, in part, on the extent to which such 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 QINLOCK or any future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such drugs. 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 QINLOCK or any of our drug candidates, if approved, are 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 QINLOCK or any future approved drugs 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. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

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 QINLOCK or any of our drug candidates, if approved, or a decision by a third-party payor to not cover QINLOCK or any of 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 (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. 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 QINLOCK or any drug candidates for which we may obtain marketing approval. However, any negotiated prices for QINLOCK or any future 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 (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 Public Health Service's 340B Drug Pricing Program (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 QINLOCK or any of our drug candidates for which we may obtain marketing approval, 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 QINLOCK or any of our drug candidates for which we may obtain marketing approval. If third-party payors do not consider QINLOCK or any future drugs to be cost-effective compared to other available therapies, they may not cover such drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell such 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 (BCA), 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 QINLOCK or any drug candidates for which we may obtain regulatory approval or the frequency with which QINLOCK or any such drug candidate is prescribed or used.

As noted above, the marketability of QINLOCK or any drug candidates 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 QINLOCK or any of our future 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, extended the rebate program to individuals enrolled in Medicaid managed care organizations, and 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 previous President of the U.S. (the previous 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 Tax Cuts and Jobs Act of 2017 (2017 Tax Reform Act) included 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. The current U.S. presidential administration has indicated that enhancing the ACA is a legislative priority. We continue to evaluate legislative efforts regarding the ACA and its possible impact on our business.

The previous U.S. presidential administration 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 previous 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 previous U.S. President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The previous U.S. presidential administration concluded that cost-sharing reduction (CSR) payments to insurance companies required under the ACA had not received necessary appropriations from Congress and discontinued these payments due to the lack of appropriations. 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. In April 2020, the U.S. Supreme Court issued an opinion in *Moda Health Plan, Inc. v. United States* which held that the ACA requires the federal government to compensate insurers for significant losses their health plans incurred during the first three years of the ACA's marketplaces, and that insurers can sue for nonpayment in the Court of Federal Claims. The effects of this decision on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

On January 22, 2018, the previous 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 previous 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, 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 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 BCA, the American Taxpayer Relief Act of 2012 (ATRA), and the Middle Class Tax Relief and Job Creation Act of 2012. In August 2011, the BCA, 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 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the BCA were suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. 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 our products that obtain marketing approval. 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.

Additionally, 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 drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. 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 previous U.S. presidential administration released a "Blueprint" 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 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 the CMS's policy change that was effective January 1, 2019. The U.S. Congress and the prior U.S. presidential administration have each indicated that they would 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.

In the U.S., the MMA contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and

until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, the CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, the CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code for an 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 market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing 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.

Other Healthcare Laws

For our drug and any drug candidates that obtain regulatory approval and are marketed in the U.S., our arrangements with third-party payors, customers, and other third parties 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 QINLOCK or 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 (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, that is intended 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 federal healthcare programs such as the Medicare and Medicaid programs. Violations of this law are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, administrative civil monetary penalties, and exclusion from participation in government healthcare programs. In addition, 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. 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 False Claims Act (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. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.
- 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 marketing and activities relating to the reporting of wholesaler or estimated retail prices for QINLOCK or any future products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for QINLOCK or any future products, and the sale and marketing of QINLOCK 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.
- The federal 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, 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), willfully obstructing a criminal investigation of a healthcare offense, and knowingly or willfully falsifying, concealing or covering up by any trick or device 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 relating to healthcare matters. 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 impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their 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, 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 directly 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 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 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 (Sunshine Act), enacted as part of the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologics, 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 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. 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.
- Analogous state and foreign laws and regulations, such as state anti-kickback, false claims laws, 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 payor, including commercial insurers. 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources, require drug manufacturers to report information related to pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to physicians and other

healthcare providers and entities, require the registration of pharmaceutical sales representatives, 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.

In California, the California Consumer Privacy Act (CCPA) was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, and creates new individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires 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. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "Business" regulated by the scope of the CCPA.

In addition to the CCPA, new privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate depending on the new U.S. presidential administration. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

In the U.S., to help patients afford QINLOCK and any other products, if approved, we 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 November 2013, the 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 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 Office of Inspector General (OIG) of the 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 Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons.

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.

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. In November 2020, the OIG issued a Fraud Alert highlighting its view that pharmaceutical promotional speaker programs can pose a high risk of fraud and abuse. 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, individual imprisonment, disgorgement, exclusion of drugs 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 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. 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 may also adversely affect our business. 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.

European Data Collection

In the EU, we may also face particular privacy, data security, and data protection risks in connection with requirements of the General Data Protection Regulation (EU) 2016/679 (GDPR), and other data protection regulations. 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 has enhanced data protection obligations for 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, restrictions on transfers outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and has created onerous new obligations and liabilities on services providers or data processors. 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. Moreover, data subjects can claim damages resulting from infringement of the GPDR. The GDPR further grants non-profit organizations the right to bring claims on behalf of data subjects. 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. In addition, further to the U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. As of January 1, 2021, the GDPR has been brought into U.K. law as the 'U.K. GDPR', but there may be further developments about the regulation of particular issues such as U.K.-EU data transfers. We may be required to take steps to ensure the lawfulness of our data transfers, particularly if by the end of the transition period there will not be an adequacy decision by the European Commission regarding the U.K.

Human Capital Resources

Our employees are a key factor in our ability to achieve our mission of discovering, developing, and delivering important new medicines to patients for the treatment of cancer. As of January 31, 2021, we had approximately 350 employees located in approximately 30 states across the United States. More than 200 employees are located at our headquarters in Waltham, Massachusetts and approximately 50 employees are located at our research facility in Lawrence, Kansas.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We emphasize a number of measures and objectives in managing our human capital assets, including, among others, employee engagement, development, and training, talent acquisition and retention, employee safety and wellness, diversity and inclusion, and compensation and pay equity. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. In addition, we regularly conduct employee surveys to gauge employee engagement and identify areas of focus.

We believe that developing a diverse, equitable and inclusive culture is critical to continuing to attract and retain the top talent necessary to deliver on our growth strategy and key to our long-term success. As such, we are investing in the creation of a work environment where our employees can feel inspired to deliver their workplace best every day. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce, from working with managers to develop strategies for building diverse teams to promoting the advancement of leaders from different backgrounds. Our guiding principles of patient-focus, accountability, transparency, honesty and integrity, and stewardship, serve as our cultural pillars. Grounded in these guiding principles, we focus our company-wide efforts on creating a collaborative environment where our colleagues feel respected, valued, and can contribute to their fullest potential.

Corporate Information

Deciphera Pharmaceuticals, Inc. is a Delaware corporation that was formed in August 2017. Deciphera Pharmaceuticals, LLC, one of our wholly owned subsidiaries, is a Delaware limited liability company that was formed in 2003 as our initial company entity. Our principal executive offices are located at 200 Smith Street, Waltham, MA 02451, and our telephone number is (781) 209-6400.

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 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 material and other risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this 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 Business and Commercialization

Risks Related to Business Development and Commercialization

Our business depends heavily on our ability to successfully commercialize QINLOCK in the U.S. and in other jurisdictions where we may obtain marketing approval, including Europe. There is no assurance that our commercialization efforts with respect to QINLOCK will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.

To date, we have not generated substantial revenues from the sale of products. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Our business currently depends heavily on our ability to successfully commercialize QINLOCK as a treatment for GIST in the U.S. and in other jurisdictions where we may obtain marketing approval, including Europe. We may never be able to successfully commercialize our product or meet our expectations with respect to revenues. We have never marketed, sold, or distributed for commercial use any pharmaceutical product other than QINLOCK, with respect to which we only recently began commercial sales. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the launch and commercialization of QINLOCK in the U.S. in GIST, or that we may build in Europe, will be sufficient for us to achieve success at the levels we expect.

We may encounter issues and challenges in commercializing QINLOCK and generating substantial revenues. We may also encounter challenges related to reimbursement of QINLOCK, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering QINLOCK. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. We may face other limitations or issues related to the price of QINLOCK. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Other factors that may hinder our ability to successfully commercialize QINLOCK, or any of our future approved drugs, and generate substantial revenues, include:

- the acceptance of QINLOCK by patients and the medical community;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of QINLOCK at acceptable costs, to remain in good standing with regulatory agencies, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;

- FDA-mandated package insert requirements and successful completion of any related FDA post-marketing requirements;
- the actual market size for QINLOCK, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- our ability to obtain marketing approval for QINLOCK in Europe;
- our ability to successfully complete our Phase 3 study of QINLOCK for second-line GIST and obtain marketing approval in such indication and potentially other areas of GIST treatment;
- the sufficiency of our drug supply to meet commercial and clinical demands which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;
- our ability to effectively compete with other therapies; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to QINLOCK.

Any of these issues could impair our ability to successfully commercialize our product or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to QINLOCK. We may also experience significant fluctuations in sales of QINLOCK from period to period and, ultimately, we may never generate sufficient revenues from QINLOCK to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize QINLOCK in the U.S., and any other international markets where it may subsequently be approved, including Europe, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

We have limited experience as a commercial company and the marketing and sale of QINLOCK or any future approved drugs may be unsuccessful or less successful than anticipated.

While we have initiated the commercial launch of QINLOCK in the U.S., and are preparing for the launch of QINLOCK in Europe, if approved, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling QINLOCK, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drug and any future drugs;
- obtain adequate pricing and reimbursement for QINLOCK and any future drugs;
- obtain regulatory authorization for the development and commercialization of the drug candidates in our pipeline;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop drug candidates, commercialize QINLOCK or any future drugs, raise capital, expand our business, or continue our operations.

Our reliance on sole source third-party suppliers could harm our ability to commercialize QINLOCK or any drug candidates that may be approved in the future.

We have scaled up our manufacturing process for QINLOCK in anticipation of greater drug requirements for commercialization. We do not currently own or operate manufacturing facilities for the production of QINLOCK or any drug candidates that may be approved in the future. We rely on sole source third-party suppliers to manufacture and supply QINLOCK which may not be able to produce sufficient inventory to meet commercial demand in a cost-efficient, timely manner, or at all. Our third-party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drug. As a result, there can be no assurances that we will be able to obtain sufficient

quantities of QINLOCK or any drug candidates that may be approved in the future, which could have a material adverse effect on our business as a whole.

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 QINLOCK and any drug candidates for which we obtain marketing approval. Our arrangements with third-party payors, customers, and other third parties 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 QINLOCK and any other 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. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances;
- 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;
- 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 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 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 payor, 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.

In the U.S., to help patients afford our approved product, we may utilize 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 the 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 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.

On November 30, 2020, the OIG published a final rule effective January 1, 2022 amending the existing safe harbor protecting certain discounts to eliminate safe harbor protection for certain rebates provided by a manufacturer of prescription pharmaceutical products to a plan sponsors under Part D or pharmacy benefit managers (PBMs) under contract with them. The final rule also creates new safe harbors effective January 29, 2021 for point-of-sale reductions in price on prescription pharmaceutical products and certain PBM service fees. The impact of these changes on our business are unclear at this time.

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 our drug is uncertain. QINLOCK and 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, including certain European countries, 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 QINLOCK or one or more of our drug candidates, even if such drug candidates obtain marketing approval.

Our ability to successfully commercialize our drug and 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 and 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 or 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, including those in Europe, 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 or drug

candidates. Accordingly, in markets outside the U.S., including in Europe, 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 or requiring companies to pay additional rebates in order to receive reimbursement from the state Medicaid programs, 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 the CMS, an agency within HHS. The CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow the 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. 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 the 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 the 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 our approved drug or any drug candidate for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our drug and 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 from 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 or drug candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, our approved drug or 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 approved drug and any of our drug candidates for which we obtain marketing approval, 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 our approved drug and any of our drug candidates for which we obtain marketing approval, 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 340B program (described below), to include additional types of covered entities. We will participate in the 340B program for QINLOCK and any of our drug candidates for which we receive approval. 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 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 or 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 and 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 or 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, 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 for our approved drug.

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 our approved drug and any drug candidates for which we obtain marketing approval.

In the U.S., the 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 our 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 approved drug and 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 non-compliance;
- 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 by the previous U.S. 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 ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it 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. The current U.S. presidential administration has indicated that enhancing the ACA is a legislative priority. We will continue to evaluate legislative efforts regarding the ACA and its possible impact on our business.

The previous U.S. presidential administration 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 previous 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 previous U.S. President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The previous U.S. presidential administration concluded that CSR payments to insurance companies required under the ACA had not received necessary appropriations from Congress and discontinued these payments due to the lack of appropriations. 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 previous U.S. presidential 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. In April 2020, the U.S. Supreme Court issued an opinion in *Moda Health Plan, Inc. v. United States* which held that the ACA requires the federal government to compensate insurers for significant losses their health plans incurred during the first three years of the ACA's marketplaces, and that insurers can sue for nonpayment in the Court of Federal Claims. The effects of this decision on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

On January 22, 2018, the previous 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 previous U.S. President signed into law H.R. 1865, which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. 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, 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 the CMS uses to determine this risk adjustment. In addition, the 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 BCA, ATRA, and the Middle Class Tax Relief and Job Creation Act of 2012. In August 2011, the BCA, 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 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the BCA will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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 our products that obtain marketing approval. 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 previous U.S. presidential administration's budget for fiscal year 2020 contained further drug price control measures that could be enacted in other future legislation, including, for example, measures to permit Part D plans to negotiate the price of certain drugs under 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 previous U.S. 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 the CMS's policy change that was effective January 1, 2019. The U.S. Congress and the prior U.S. presidential administration have each indicated that they would 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 Drug 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.

On July 24, 2020 and September 13, 2020, the previous U.S. President signed several Executive Orders aimed at lowering drug prices. On July 24, 2020, previous U.S. President signed Executive Orders directing the Secretary of the HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Part D plans or PBMs that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center (FQHC) as part of the 340B drug pricing program to purchase those drugs at the discounted price paid by the FQHC. On September 13, 2020, previous U.S. President signed an Executive Order directing the HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug or biologic manufacturer sells in a member country of the Organization for Economic Cooperation and Development (OECD) that has a comparable per-capita gross domestic product.

In response, the HHS on (i) November 20, 2020 issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in OECD countries with a similar gross domestic product per capita. The MFN Model

regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge; and (ii) November 20, 2020, finalized a regulation removing the safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through PBMs, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. The FDA also on October 1, 2020, published a final rule that allows for the importation of certain prescription drugs from Canada as discussed above. On September 25, 2020, the CMS stated drugs imported by individual states in the U.S. under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, the CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. It is unclear if, when, and to what extent the Executive Orders may be further implemented. The regulatory and market implications of the Executive Orders are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs may decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability.

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 or 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 products. Such reforms could have an adverse effect on anticipated revenue from our drug or 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 future 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 and 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 our approved products. 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 and drug candidates, if approved. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results.

QINLOCK or any current or future drug candidates, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to drug candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.

Undesirable side effects caused by QINLOCK or any future approved drugs could limit the commercial profile of such drug or result in significant negative consequences such as a more restrictive label or other limitations or restrictions.

Undesirable side effects caused by our drug candidates or our existing drug being developed for new indications could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, or other regulatory authorities.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of QINLOCK or of our current or future drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug, and those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by QINLOCK or any future approved drug (or any other similar drugs), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;
- regulatory authorities may refuse to approve label expansion for additional indications for QINLOCK or any future approved drugs;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drugs;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drugs from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking such drugs; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected drug, and could substantially increase the costs of commercializing such drugs and significantly impact our ability to successfully commercialize such drugs and generate revenues.

We may incur significant liability if enforcement authorities allege or determine that we are engaging in commercial activities or promoting QINLOCK in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, we may not promote QINLOCK in the U.S. for use in any indications other than the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

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.

To the extent we expand our operations outside of the U.S., including in Europe, 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 U.K. 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. To the extent we expand our presence outside of the U.S., including in Europe, 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.

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 Europe, 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. During the Brexit transition period, which ended on December 31, 2020, the U.K. continued to follow all of the EU's rules and maintained its current trading relationship with the EU. The U.K. and EU have signed a EU-U.K. Trade and Cooperation Agreement (the TCA), which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the U.K. and the EU. The TCA sets out the arrangements between the U.K. and EU on trade in certain areas (e.g. goods and some services, energy, fisheries, social security coordination), however there is still uncertainty over how its terms will play out in practice and there are still key aspects of the U.K.’s relationship with the EU which are not covered by the TCA, such as in respect of financial services. We expect that uncertainty over the terms of the TCA and other future 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 will, 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 there is greater understanding on how the terms of the TCA will play out in practice, and until the terms of other potential agreements that the U.K. may eventually enter into with the EU are known, it is not possible to determine the extent of 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, since the regulatory framework in the U.K. covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorizations, commercial sales and distribution of medicinal products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our current or future product candidates in the U.K.. For instance, the U.K. will now no longer be covered by the centralized procedure for obtaining

EEA-wide marketing authorizations for medicinal products, and a separate process for authorization of drug products will be required in the U.K., resulting in an authorization covering the U.K. or GB only. 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 U.S. federal and state and foreign privacy and data protection laws, which could adversely affect our business, results of operations and financial condition.

In California, the CCPA was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, gives California residents expanded individual privacy rights and protections and provides for civil penalties for violations and a private right of action for data breaches. Further, a new California privacy law, the California Privacy Rights Act (CPRA) was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA and CPRA may impact our business activities if we become a "Business" regulated by the scope of the CCPA or are subject to CPRA.

In addition to the CCPA, new privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate as a result of the outcome of the 2020 U.S. presidential election. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

In the EU, we may also face particular privacy, data security, and data protection risks in connection with requirements of the GDPR, and other data protection regulations. 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 has enhanced data protection obligations for 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, restrictions on transfers outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and has created onerous new obligations and liabilities on services providers or data processors. 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. Moreover, data subjects can claim damages resulting from infringement of the GPDR. The GDPR further grants non-profit organizations the right to bring claims on behalf of data subjects. 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. In addition, further to the U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain U.K. specific amendments) into U.K. law (referred to as the U.K. GDPR). The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In addition, the U.K. is now regarded as a third country under the EU's GDPR which means that transfers of personal data from the EEA to the U.K. will be restricted unless an appropriate safeguard, as recognized by the EU's GDPR, has been put in place. Under the TCA, however, it is lawful to transfer personal data between the U.K. and the EEA for a six-month period following the end of the transition period, with a view to achieving an adequacy decision from the European Commission during that period. Like the EU GDPR, the U.K. GDPR restricts personal data transfers outside the U.K. to countries not regarded by the U.K. as providing adequate protection (this means that personal data transfers from the U.K. to the EEA remain free flowing).

We currently conduct clinical trials in the EEA and the U.K. and intend to engage in regulatory and commercial operations there in the future. As a result, we are subject to additional privacy laws, including the GDPR and U.K. GDPR. 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 or the U.K., 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. 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, the Member States 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 the Member States 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 or the U.K., in particular to the U.S., in compliance with European and U.K. 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 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.

Recent federal legislation and actions by federal, state, and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the U.S. for our approved drug and drug candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the U.S., the MMA contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. On September 25, 2020, the CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, the CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code for an 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 market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

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 switch-control kinase 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.

Risks Related to Sales, Marketing, and Competition

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 approved drug and current clinical-stage drug candidates and will face competition with respect to any drugs and 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 and commercializing our approved drug. 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 QINLOCK and the drug candidates we are developing, if such 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 PDGFRA exon 18 mutations only, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRA, and no currently marketed drug provides coverage of all KIT and PDGFRA mutants. With respect to QINLOCK, there are a number of large pharmaceutical companies and biotechnology companies marketing small molecule drugs or biologic drugs for the treatment of GIST, including Blueprint, Novartis, Pfizer, and Bayer. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST including ABS, Arog, CTTPG, Cogent, Daiichi, Exelixis, Immunicum, Jiangsu, NTKMT, Novartis, Taiho, 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 CSF1R inhibitors that we are seeking to target with our vimseltinib program, including Abbisko, Daiichi, LifeMax, and SynOx. 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, including small molecule drug candidates in clinical trials from Clovis, Eisai, and Novartis, and antibody therapeutics from AstraZeneca, ImmunoGen, Roche, Merck, and Tesaro.

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 QINLOCK or any other products that we

may develop. Our competitors also may obtain FDA, EMA, 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. We expect that QINLOCK, and any of our drug candidates that achieve marketing approval, 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.

The incidence and prevalence for target patient populations of our approved drug and drug candidates have not been established with precision. If the market opportunities for our approved drug or 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, TGCT, and other indications we are exploring, 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 or drug candidates, are based on estimates, which are inherently uncertain.

The total addressable market opportunity for QINLOCK, vimseltinib, 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 our current and future drugs 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 drug, 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.

The commercial success of QINLOCK, and of any future approved drugs, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

The commercial success of QINLOCK, and of any future approved drugs, will depend in part on 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 QINLOCK and any future approved drugs 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 QINLOCK and of any current or future drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the availability, perceived advantages, and relative cost, safety, and efficacy of alternative and competing treatments;
- the prevalence and severity of any side effects, adverse reactions, misuse, or any unfavorable publicity in these areas, in particular compared to alternative treatments;
- our ability (and the ability of our partners) 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 and effectiveness of our marketing, sales, and distribution strategy and efforts, including, without limitation, our own and that of our licensees and distributors, and the degree to which the approved labeling supports promotional initiatives for commercial success;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability and timeliness of third-party payor 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;
- maintaining an acceptable safety profile of our approved drug and drug candidates following approval;
- 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.

Even if a potential drug displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the drug will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our drug may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the therapies marketed by our competitors. Any of these factors may cause QINLOCK, or any future approved drugs, to be unsuccessful or less successful than anticipated.

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

In order to market and sell our products in Europe and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. In October 2020, an EU MAA was accepted for review by the EMA for QINLOCK in fourth-line GIST and we are planning for a potential approval in the second half of 2021. In Greater China, our licensee will be responsible for obtaining marketing approval for QINLOCK and is planning for a potential approval in the first half of 2021. 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 partners, as applicable, may not) obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, or may not be successful in seeking and obtaining favorable local reimbursement and pricing approvals, particularly in light of the impact of COVID-19 on the global economy. 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 outside the U.S., Canada, and Australia.

QINLOCK and 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 QINLOCK or any future approved product from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of QINLOCK, and any future approved products, 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.

QINLOCK and 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 products, 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 FDCA and other statutes, including the 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.

In addition, 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 QINLOCK or any future approved products withdrawn by regulatory authorities and our ability to market QINLOCK or any future approved 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.

If we and/or our partners are unable to maintain and further develop sales and marketing capabilities, we or our partners may not be successful in commercializing QINLOCK, or any of our drug candidates if and when they are approved, and we may not be able to generate substantial revenue.

We have only recently established our sales and marketing infrastructure in the U.S., and are in the early stages of building our commercial capabilities in Europe, and currently have only limited experience in the sale, marketing, or distribution of biopharmaceutical products. To achieve commercial success for QINLOCK or any other product for which we obtain marketing approval, we will need to successfully maintain and expand our sales, marketing, and distribution capabilities, either ourselves or through collaboration, licensing, distribution, or other arrangements with third parties. In addition, our licensee for QINLOCK 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 have built our own focused, specialized sales and marketing organization in the U.S. and are beginning to build commercial capabilities in Europe. In addition to our existing QINLOCK license to Zai for Greater China, we have executed, and intend to seek additional, distribution arrangements in select geographies where we choose not to establish a sales presence to support the commercialization of QINLOCK or our drug candidates for which we obtain marketing approval and that can be commercialized through such arrangements.

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 QINLOCK in Europe 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. We will need to commit significant management and other resources to maintain and grow our commercial organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train, and retain sales and marketing personnel. We cannot be sure that we will be able to recruit, hire, train, and retain a sufficient number of sales representatives or that they will be effective at promoting QINLOCK or any future approved drugs.

Factors that may inhibit our efforts to commercialize QINLOCK or any future approved 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 maintain and grow our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate physicians about the benefits, safety, and effectiveness of QINLOCK or any future approved products, in particular in light of current reduced in-person access to medical institutions and personnel and other significant disruptions to the healthcare system and community due to COVID-19;
- 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 Europe, or if we are unable to successfully establish our own sales and marketing capabilities in the U.S. or Europe 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 QINLOCK or any future approved products 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 QINLOCK or any future approved products effectively. If we do not maintain and expand our sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing QINLOCK or any of our drug candidates for which we receive marketing approval. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of QINLOCK and our drug candidates, if approved, could be delayed which would negatively impact our ability to generate product revenues.

Other Risks Related to Our Business

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

We have expanded and expect to continue 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 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 expanding 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 ransomware or 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, ransomware, 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. Despite our efforts, we may fail to identify these new and complex methods of attack or fail to invest sufficient resources in security measures. In addition, as we increase our commercial activities and our brand becomes more widely known and recognized, we may become a more attractive target for malicious third parties. 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. Any breach of our security measures as a result of third-party action, employee negligence and/or error, malfeasance, defects, or otherwise that compromises the confidentiality, integrity, or availability of our data could result in:

- severe harm to our reputation or brand, or a material and adverse effect on the overall market perception of our technical and organizational measures to protect the confidentiality, integrity, and availability of our information;
- individual and/or class action lawsuits, which could result in financial judgments against us and which would cause us to incur legal fees and costs;
- legal or regulatory enforcement action, which could result in fines and/or penalties and which would cause us to incur legal fees and costs; and/or
- additional costs associated with responding to the interruption or security breach, such as investigative and remediation costs, the costs of providing individuals and/or data owners with notice of the breach, legal fees, the costs of any additional fraud or cyber detection activities, or the costs of prolonged system disruptions or shutdowns.

Any of these events could materially adversely impact our business and results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our drug, clinical development programs, and the diseases our drug and drug candidates are being developed to treat, and we are utilizing what we believe is appropriate social media in connection with our commercialization efforts for QINLOCK and we intend to do the same for our future products, if approved. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event (AE). When such disclosures occur, there is a risk that we fail to monitor and comply with applicable AE reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

The effects of 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 previous U.S. President signed into law the TCJA. The TCJA made 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, 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. Further, on

March 27, 2020, the previous U.S. President signed into law the CARES Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations, and rulings may be enacted, promulgated, or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

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, 2020, 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.

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

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 COVID-19 pandemic, 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 our operations or the operations of our vendors, 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.

Risks Related to Clinical Development, Regulatory Review, and Approval of Our Drug and Drug Candidates

Risks Related to Clinical Development

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 our drug and drug candidates.

We currently have several drug candidates in clinical development, as well as a Phase 3 study to expand the label of our approved drug, QINLOCK, 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, interim or preliminary results of a clinical trial do not necessarily predict final results, and results for one indication may not be predictive of the success in additional indications. 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 study of QINLOCK, the primary objectives were to determine the safety, tolerability, and maximum tolerated dose of QINLOCK and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from the Phase 1 study of QINLOCK were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of QINLOCK, including our ongoing Phase 3 study for QINLOCK in second-line GIST. These factors also apply to the earlier-stage trials for our drug candidates.

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 or 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;
- 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 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, particularly in light of the COVID-19 pandemic;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, due to interruptions to their business, including those impacts caused by the outbreak of COVID-19, or may fail to comply with regulatory requirements;
- we may have to suspend, change, or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks, including potential exposure to COVID-19 in their geography;
- our drug or 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 COVID-19, in or around the countries in which we conduct our clinical trials or where our third-party

contractors operate, could delay the commencement or rate of completion of our clinical trials, or those expected to be conducted in Greater China under our collaboration with Zai;

- the cost of clinical trials for our drug candidates may be greater than we anticipate, particularly in light of the uncertainties associated with the outbreak of COVID-19; and
- the supply or quality of our drug or drug candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials, including those caused by the COVID-19 pandemic.

While we designed QINLOCK to inhibit the full spectrum of the known mutant or amplified KIT and PDGFRA kinases that drive cancers such as GIST, we may find that patients treated with QINLOCK have or develop mutations that confer resistance to treatment. We are aware of a secondary mutation in PDGFRA, in a patient not treated with QINLOCK, where the potency of inhibition determined in *in vitro* assays by QINLOCK suggests that this mutation may confer resistance to QINLOCK in patients. We may identify additional mutations in PDGFRA or mutations in KIT that are resistant to QINLOCK. If patients have or develop resistance to treatment with our approved drug or drug candidates, we may be unable to successfully complete our clinical trials, and may not be able to obtain regulatory approval of additional indications for our approved drug or for 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 continue to generate additional data that may be requested by the FDA or other regulatory agencies. 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 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. 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.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our clinical trials of vimseltinib or rebastinib, 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 or 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., or our clinical trials may be delayed if enrollment is slowed or paused due to health considerations or access restrictions resulting from COVID-19 or other factors. In addition, some of our competitors have ongoing, or planned, clinical trials for drug candidates that treat the same indications as our drug or 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 drugs or 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, in particular in light of considerations surrounding COVID-19;
- diversion of healthcare resources as a result of COVID-19, and the availability of qualified investigators to conduct clinical trials during the COVID-19 pandemic;

- the ability to monitor patients adequately during and after treatment, in particular in light of travel restrictions, access restrictions to medical institutions, and the impact of social distancing and quarantine guidelines as a result of COVID-19; and
- the proximity and availability of clinical trial sites for prospective patients, and the ability of patients to travel to study sites during the COVID-19 pandemic.

If we experience higher than expected drop-out rates for an event-driven study, as we previously 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. 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 or drug candidates, we may need to abandon or limit such development.

If our drug or 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 and other diseases 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 drug or drug candidates, if approved.

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

We currently have no products that are approved for sale with the exception of QINLOCK. We are early in our development efforts for all of our drug candidates. Three of our drug candidates are only in Phase 1 or Phase 1/2 studies.

Our drug and drug candidates target key interactions with kinase switch regions to inhibit kinase activity. 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 continued product revenues will depend heavily on the successful development and commercialization of our approved drug and drug candidates, if approved. Our success in the development of our approved drug and drug candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including our ongoing Phase 3 study of QINLOCK for second-line GIST;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize any current or future drug candidates for which we obtain marketing approval;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug and 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 and drug candidates;

- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- protecting and enforcing our rights in our intellectual property portfolio.

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 QINLOCK or any current or future drug candidates for which we receive approval, which would materially harm our business. For example, our business could be harmed if updated preliminary or final results of our ongoing Phase 3 study of QINLOCK for second-line GIST vary meaningfully from our expectations.

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 study of QINLOCK in fourth-line and fourth-line plus GIST, INVICTUS, and received FDA approval for QINLOCK on May 15, 2020 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, and have an ongoing second Phase 3 clinical study in second-line GIST, INTRIGUE. While we plan to conduct only one pivotal Phase 3 study for second-line GIST, for a single randomized trial to support submission to the FDA of a supplemental 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 study of QINLOCK, there were 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 study, we also plan to have all of the data from our ongoing Phase 3 study of QINLOCK for second-line GIST centrally reviewed. The results from our Phase 3 study of QINLOCK in which all data will be subject to central review may be less favorable than the results of our Phase 1 study of QINLOCK 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, we, or 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 or drug candidates before a local regulatory authority will approve any marketing application. These local studies may involve, among other things, exploration of the effect our drug or 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.

In addition, we may:

- be delayed in obtaining marketing approval for our drug or 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, including QINLOCK, removed from the market after obtaining marketing approval.

Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and review timelines could be extended.

Risks Related to the Industry

With the exception of QINLOCK, we have not received approval or authorization 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, which 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 or expand our marketing for QINLOCK in additional indications or geographies, 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 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. With the exception of QINLOCK in the U.S., Canada, and Australia, we have not received approval or authorization to market QINLOCK or 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 contract research organizations (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 conducted only one pivotal Phase 3 study for our NDA filing in fourth-line and fourth-line plus GIST, and we plan to conduct only one pivotal Phase 3 study for 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 or expanded approval for QINLOCK in additional indications or geographies, the commercial prospects for our drug or drug candidates may be harmed and our ability to generate further revenues will be materially impaired.

We may not be able to obtain or, if granted, retain orphan drug exclusivity for our drug or 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 a marketing application for the same drug, or a product with the same active moiety, 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.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017 (the FDARA). The FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in the FDARA would apply in cases where FDA issued an orphan designation before the enactment of the FDARA but where product approval came after the enactment of the FDARA. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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.

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 approved drug and drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We also make assumptions, estimates, 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. 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.

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.

A fast track designation by the FDA for our drug candidates 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, 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 Breakthrough Therapy Designation (BTD) by the FDA for our drug candidates 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.

We may seek a BTD for some of our 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.

Risks Related to Drug Discovery

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 other 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, distributor, 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 additional 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. 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 COVID-19 Pandemic

The current pandemic of COVID-19, including recurring surges and waves of infection, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition, and results of operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus spread to the majority of countries around the world, including the U.S. To date, the COVID-19 pandemic has caused significant disruptions to the U.S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak continues to evolve as additional cases of the virus are identified, public health officials learn more about the spread of the virus and the efficacy of containment measures, and vaccines against the virus are developed and distributed. Many countries, including certain states and cities in the U.S., have reacted by instituting varying levels of quarantine and social distancing requirements, restrictions on travel, and mandatory closures of and/or occupancy limits for businesses. Although some of these restrictions have been and may from time to time be eased or lifted, in response to local surges and new waves of infection, some countries, states, and local governments have reinstituted, or may reinstitute, these restrictions, and additional, more restrictive orders, proclamations, and/or directives may be issued in the future.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our business, including our commercialization efforts, preclinical studies, and clinical trial operations, will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of such pandemic including future waves of infection, new strains of the virus that causes COVID-19, or the broad availability of effective vaccines, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic, but it could have a material adverse effect on our business, financial condition, and results of operations. The COVID-19 pandemic may also have the effect of heightening many of the risks described herein, including the below:

- Our ability to successfully launch, commercialize, and generate revenue from QINLOCK may be adversely affected by the economic impact of the COVID-19 pandemic. For example, in the U.S. we plan to utilize various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and rising unemployment caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and

reimbursement of newly approved products as well as an increase in the numbers of uninsured patients and patients who may no longer be able to afford their co-insurance or co-pay obligations. These factors may lead to increased utilization of our patient assistance programs, which could reduce revenues.

- The outbreak of COVID-19 may also negatively impact our commercialization strategy for QINLOCK. Some hospitals and other medical institutions continue to have limited hospital access for non-patients, which includes our sales personnel. In addition, social distancing requirements and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. As a result, in many circumstances we have needed to limit our interactions with physicians and payors and adapt our launch strategies and tactics to a virtual model, including developing and deploying various technology-enabled platforms for virtual engagement such as remote detailing, digital and non-personal marketing channels, and social media. These circumstances may adversely affect the ability of our sales professionals to effectively market QINLOCK to physicians and the rate of uptake for QINLOCK, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians in specialties such as oncology have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume.
- We are currently conducting numerous clinical studies. We believe that the COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our ongoing clinical trials. For example, some clinical trial sites have imposed restrictions on site visits by sponsors and CROs, the initiation of new trials, and new patient enrollment to protect both site staff and patients from possible COVID-19 exposure and to focus medical resources on patients suffering from COVID-19. While all our studies remain open, enrollment has slowed at some sites, some sites have, or may in the future, temporarily pause enrollment of new patients, and we have provided guidance to all of our clinical trial sites that new patient enrollment may occur at sites where resources allow these patients to be safely enrolled and closely monitored.
- Other potential impacts of the COVID-19 pandemic on our clinical trials include difficulties associated with patient visits for screening enrollment and study conduct, and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local, or foreign laws, rules, and regulations, including closure of site access to outside monitors, quarantines, social distancing guidelines, or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of clinical trials, heightened exposure of patients, principal investigators, and site staff to COVID-19 if an outbreak occurs in their geography, or other reasons related to the COVID-19 pandemic. We are working closely with our study sites and CROs to allow for utilization of remote and local assessments, such as televisits, in accordance with FDA guidance, as well as to ensure availability of study drug for patients, but we cannot assure you these efforts will be successful or that our clinical trial activities will not be adversely affected, delayed, or interrupted by COVID-19. Despite our efforts to address these risks, some patients and clinical investigators may not be able to comply with clinical trial protocols if quarantines or social distancing guidelines impede movement or interrupt healthcare services or if medical resources are reallocated to focus on patients suffering from complications related to COVID-19. If patients choose to withdraw from our studies or we choose to or are required to pause enrollment and/or patient dosing or other clinical trial related activities in order to preserve healthcare resources, protect trial participants from being exposed to unacceptable health risks or comply with access restrictions resulting from COVID-19, our studies and related timelines may be adversely affected. It is unknown how long these pauses or disruptions could continue. In addition, other aspects of our clinical trials may be adversely affected, delayed, or interrupted while the COVID-19 pandemic continues or if future surges or waves of infection occur, including, for example, site initiation, patient recruitment, availability of clinical trial materials and data analysis.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials and our drug for commercial sales, ship investigational and commercial drug supply for use in clinical trials or by patients, as appropriate, perform quality testing, and supply other goods and services to run our business. If any such third parties in our supply chain for materials are adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, our research and development operations, or for commercial sale of QINLOCK.
- We have implemented precautionary measures to protect the health and safety of our employees, partners, and patients during the COVID-19 pandemic, including encouraging our personnel, other than those engaged in laboratory research activities, to work remotely, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this

could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, IRBs, and ethics committees, manufacturing sites, research or clinical trial sites, and other important agencies and contractors. Our business operations may be further disrupted if any of our employees, officers, or board of directors contract an illness related to COVID-19 and are unable to perform their duties.

- Our employees, and employees of third-party contractors responsible for conducting research activities, may have limited or reduced access to laboratories for an extended period of time as a result of occupancy restrictions or the temporary closure of such workspaces and the possibility that governmental authorities impose or modify current restrictions. As a result, this could delay timely completion of ongoing preclinical activities, including completion of IND-enabling studies, our ability to select future development candidates, and initiation of additional clinical trials for our drug candidates.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and, as a result, review, inspection, and other timelines may be materially delayed. For example, in April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review or inspection resulting from such disruptions could materially affect the development and study of our drug candidates.
- Health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we utilize in response to the COVID-19 pandemic and current regulatory guidance, which could delay, limit, or prevent marketing approval of our drug or drug candidates. For example, the FDA may find our actions, including the use of televisits and local laboratories and physicians to conduct clinical trial activities, fail to comply with evolving regulatory guidance and may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies.
- The trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression, or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business or operations, the continued spread or future waves of COVID-19, measures taken by governments, actions taken to protect employees, and the broad impact of the pandemic on all business activities may materially and adversely affect our preclinical activities, clinical development progress, data and timelines, commercialization efforts including any revenue from sales, supply chain continuity, and general business operations, and our business, prospects, financial condition, and results of operations could be materially harmed as a result.

Risks Related to Litigation

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our approved drug or any of our drug candidates that we may develop.

We face an inherent risk of product liability exposure related to the sale and use of our approved drug and the testing of drug candidates in human clinical trials and use of our drug candidates through compassionate use and expanded access programs, and an even greater risk in connection with our commercialization of our current and future drugs. If we cannot successfully

defend ourselves against any claims that our approved drug or any of our drug candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our approved drug or any of our drug candidates or products that we may develop and commercialize;
- 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 our approved drug or any of our drug candidates that we may develop.

We currently hold $20.0 million in product liability insurance coverage in the aggregate for the U.S. and certain other jurisdictions, with a per incident limit of $20.0 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 anticipate that we may need to further increase our insurance coverage as we expand our clinical trials or if we successfully commercialize additional drugs or 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.

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.

Risks Related to Intellectual Property Litigation

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.

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates, as well as successfully defending these rights against third-party challenges. 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 or 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 or drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

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 and drug candidates, and an unfavorable outcome could harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our drug and 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 or 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 or 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 or 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, drug, 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 drug. 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 or 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 drug or drug candidates, and a finding of infringement could prevent us from commercializing our drug or 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.

Risks Related to Our Financial Position, and Capital Needs, and Ownership of Our Common Stock

Risks Related to Our Financial Position

We have incurred significant operating losses since our inception and have not generated substantial 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 were formed and commenced operations in 2003. Other than QINLOCK, we have no approved products for commercial sale and have not generated substantial revenue from product sales. 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, 2020, 2019, and 2018 we reported a net loss of $266.5 million, $192.3 million, and $99.9 million, respectively. As of December 31, 2020, we had an accumulated deficit of $754.5 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 QINLOCK and our drug candidates and, more recently, establishing a commercial infrastructure. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We are also developing QINLOCK for the treatment of second-line GIST. Except for QINLOCK, all of our drug candidates, including vimseltinib, rebastinib, and DCC-3116, are still in preclinical and clinical development. To date, we have not generated substantial revenue from the product sales of QINLOCK and 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, borrowings under a repaid construction loan, and research and development grants from the Kansas Bioscience Authority. Since our inception, we received an aggregate of $1.2 billion in net proceeds from such transactions. As of December 31, 2020, our cash, cash equivalents, and marketable securities were $561.3 million.

We expect to incur operating losses for the foreseeable future, particularly as we commercialize QINLOCK and advance development of our drug and 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 to incur significant research and development expenses in connection with our ongoing and additional clinical trials for QINLOCK, vimseltinib, rebastinib, and DCC-3116, and development of any other future drug candidates we may choose to pursue. In addition, we will incur significant sales, marketing, and outsourced manufacturing costs and expenses in connection with the commercialization of QINLOCK and

any other approved drugs in the future. We expect to incur costs associated with preparations for commercial activities in Europe in connection with potential marketing approval for QINLOCK in Europe. 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 operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing 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 substantial revenue from sales of QINLOCK, and we do not know when, or if, we will generate profits or positive operating cash flows. We also have not obtained marketing approval for QINLOCK outside of the U.S., Canada, and Australia or for any other indications, and we have not obtained marketing approval for any of our drug candidates. We do not expect to generate significant revenue from our drug candidates unless and until we obtain marketing approval for, and begin to sell, such drug candidates. Our ability to generate further revenue from sales of QINLOCK or revenue from sales of our drug candidates depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our second Phase 3 study of QINLOCK 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 our drug candidates;
- subject to obtaining favorable results from our Phase 3 study for QINLOCK for the treatment of second-line GIST, complete all requirements for the submission of a supplemental NDA, and apply for and obtain marketing approval;
- obtain marketing approval for the EU MAA submitted to the EMA for QINLOCK;
- continue to maintain and expand commercial manufacturing capabilities or make further arrangements with third-party manufacturers for clinical supply and commercial manufacturing of QINLOCK and our drug candidates;
- commercialize QINLOCK by deploying a sales force and marketing QINLOCK in the U.S. and, if approved, in Europe and, either ourselves or through third parties, in other jurisdictions where we receive approval including Canada and Australia, assisting our licensee, Zai, in its efforts to develop and, if approved, commercialize QINLOCK in Greater China, and/or entering into additional license and/or collaboration agreements and/or distribution arrangements with third parties;
- obtain, maintain, protect, and defend our intellectual property portfolio; and
- achieve and maintain market acceptance of QINLOCK, or any current or future drug candidate for which we receive marketing approval, in the medical community and with third-party payors.

To become and remain profitable, we must succeed in developing, and 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 commercial supplies of our drug and drug candidates, obtaining marketing approval for our drug candidates, and manufacturing, marketing, and selling any products for which we obtain marketing approval, including QINLOCK. 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, the development of any of our drug candidates, or as a result of impacts from the COVID-19 pandemic, 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 have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than QINLOCK, and have not generated substantial revenue from product sales or profits. We may never 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, establishing arrangements with third parties for the manufacture of our drug and drug candidates, and establishing a commercial infrastructure. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We are also developing QINLOCK for the treatment of second-line GIST. All of our drug candidates are still in clinical trials or preclinical development.

We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials other than for QINLOCK in fourth- and fourth-line plus GIST and we have not generated substantial 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 are in the early stages of transitioning from a company with a research and development focus to a company supporting commercial activities and we have limited experience with activities designed to conduct large-scale sales, marketing, and distribution activities necessary for successful product commercialization. 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.

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.

We have broad discretion in the use of working capital and may not use it effectively.

Our management has broad discretion in the application of working capital, and stockholders do not have the opportunity to assess whether working capital is being used appropriately. Because of the number and variability of factors that will determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Management might not apply working capital in ways that ultimately increase stockholder value. Failure by us to apply working capital effectively could harm our business. Pending its use, we may invest our working capital in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. In addition, the fair value of such investments is subject

to change as a result of potential market fluctuations, including resulting from the impact of the COVID-19 pandemic. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Risks Related to Our Capital Needs

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 commercialization efforts.

We expect to incur significant expenses in connection with our ongoing activities, particularly as we commercialize QINLOCK and advance additional indications for QINLOCK, and our drug candidates, vimseltinib, 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 supplies of and seek marketing approval for our drug candidates. In addition, we expect to incur significant commercialization costs and expenses related to product manufacturing, marketing, sales, and distribution of QINLOCK, including preparations for a commercial launch in Europe, if approved, and any current or future drug candidate for which we receive marketing approval. 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 our commercialization efforts.

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2020, together with anticipated product revenues, but excluding any potential future milestone payments or other payments under our collaboration or license agreements, if any, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. 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 trial of QINLOCK for the treatment of second-line GIST;
- the scope, progress, costs, and results of drug discovery, preclinical development, and clinical trials for our drug candidates;
- the cost of maintaining, expanding, or contracting for sales, marketing, and distribution capabilities in connection with commercialization of QINLOCK or any future drugs for which we receive marketing approval;
- the success of our commercialization efforts and market acceptance for QINLOCK or any of our future approved drugs;
- the number and development requirements of 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 commercial supplies of QINLOCK and our drug candidates;
- the costs, timing, and outcome of regulatory review of our drug candidates and for QINLOCK for additional indications or in additional geographies, including Europe;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK and any of our drug candidates for which we obtain marketing approval, as well as infrastructure costs in the U.S. and Europe, and in other jurisdictions where we may seek marketing approval and choose to sell or enter into distribution arrangements;
- the revenue received from commercial sales of QINLOCK and our 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, distribution, or other license agreements that we have entered into or 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 additional license, distributor, 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 drug candidates, technologies, and associated intellectual property rights.

Identifying potential drug candidates and conducting preclinical testing and clinical trials and, for any drug candidates that receive marketing approval, establishing and maintaining a commercial infrastructure, 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 additional marketing approvals, including for QINLOCK in additional indications or geographies, and achieve substantial revenues for any of our drug candidates that receive marketing approval, including for QINLOCK. In addition, QINLOCK and any of our drug candidates that receive marketing approval may not achieve commercial success. 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.

Risks Related to Ownership of Our Common Stock

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 at least such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs primarily through a combination of equity, debt, or other 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, drug 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 commercialization efforts, or grant rights to develop and market drugs and drug candidates that we would otherwise prefer to develop and market ourselves.

We expect our operating results to fluctuate in future periods, which may adversely affect our stock price.

Our quarterly operating results have fluctuated in the past, and we believe they will continue to do so in the future. Our operating results may fluctuate due to the level of success of our commercial efforts, as well as the variable nature of our operating expenses as a result of the timing and magnitude of expenditures. In one or more future periods, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline.

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 January 31, 2021, our executive officers and directors, and, based on filings required by Section 13 of the Exchange Act through February 4, 2021, our stockholders who own more than 10% of our outstanding capital stock, beneficially own shares, in the aggregate, representing approximately 32% 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 specific courts as the 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 any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim against us or any of our current or former directors, officers, employees, or stockholders 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 governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal executive offices are located in Waltham, Massachusetts. In addition, 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 the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general litigation costs in pursuing any such

claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, these forum selection clauses in our amended and restated bylaws 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 the filing of such lawsuits against us and our directors, officers, and employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is unenforceable, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts 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.

The market price of our common stock may be volatile and fluctuate substantially upon the occurrence of future events, 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. Our common stock is currently quoted on the Nasdaq Global Select Market under the symbol "DCPH." 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 January 31, 2021. 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;
- the success of commercialization of our drug and drug candidates, if approved;
- 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 or those of companies that are perceived to be similar to us;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally;
- the degree of success of competitive products or technologies;
- results of clinical trials and preclinical studies, of our drug or 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 our drug or 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;
- rumors or announcements regarding transactions involving our company or our drug 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 other national conditions; and
- the other factors described in this "Risk Factors" section.

Effective as of December 31, 2020, we are a large accelerated filer, which will increase our costs and demands on management.

As a result of our public float (the market value of our common shares held by non-affiliates) as of June 30, 2020, we have become a large accelerated filer as of December 31, 2020 and therefore no longer qualify as an "emerging growth company," as defined in the JOBS Act. Additionally, due to our public float as of June 30, 2020, we no longer qualify as a "smaller reporting company" as defined in the Exchange Act. However, we are not required to reflect the change in our smaller reporting company status, and comply with the associated increased disclosure obligations, until our first quarterly report in our next fiscal year (i.e., the quarterly report for the three-month period ended March 31, 2021).

As a large accelerated filer, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance 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;
- the requirement that we provide full and more detailed disclosures regarding executive compensation; and
- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

We expect that compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. Preparing such attestation report and the cost of compliance with reporting requirements that we had not previously implemented has and will continue to increase our expenses and require significant management time. Investors may find our common stock less attractive because of the additional compliance costs. 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.

The rules governing the standards that must be met for management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm's evaluations of our internal control over financial reporting, we may need to upgrade systems, including information technology, implement additional financial and management controls, reporting systems, and procedures, and hire additional accounting and finance staff.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third-party litigation, as well as investigations by the SEC, the Nasdaq Global Select Market, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. Further, any delay in compliance with the auditor attestation provisions of Section 404 could subject us to a variety of administrative sanctions, including ineligibility for short-form resale registration, action by the SEC and the

suspension or delisting of our common stock, which could reduce the trading price of our common stock and could harm our business.

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 as a large accelerated filer, 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.

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.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials and preclinical studies, and those third parties may not perform satisfactorily, or may experience delays in performing these services, including failing to meet deadlines for the completion of such trials or studies, which may harm our ability to obtain regulatory approval for or commercialize our approved drug and drug candidates and our business could be substantially harmed.

We currently rely on various third-party CROs to conduct our ongoing clinical trials for QINLOCK, vimseltinib, 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. We also rely on CROs, including third-party laboratories, to conduct some of our preclinical studies. 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 and commercialization 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 good clinical practices, 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. In addition, these third parties could experience business interruptions, for example in connection with COVID-19, that could hinder their ability to meet their contractual obligations to us or may delay their performance of the services they conduct for us. 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 approved drug for additional indications or our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our approved drug for additional indications or our drug candidates, if approved.

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 for the manufacture of QINLOCK for commercialization and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug or drug candidates 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 commercial manufacture of any of our current and future drugs. 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 or drug candidates 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 partners. 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 COVID-19, could result in supply chain disruptions or the complete or partial failure of these manufacturing services. Any such failure or disruptions 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, including sole source suppliers, 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 QINLOCK. We acquire many key materials on a purchase order basis. As a result, while we have commercial supply arrangements for our drug substance and finished drug product for QINLOCK, we do not have long term supply arrangements with respect to our drug candidates and other materials. We do not currently have arrangements in place for redundant supply or a second source for drug substance or drug product. We rely on our sole source suppliers to manufacture all of our drug substance and finished drug product for commercialization of QINLOCK unless and until we add additional sources. If we obtain marketing approval for any of our drug candidates, we will need to establish an agreement for commercial manufacture with a third party. Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval, or commercial supply, including with respect to QINLOCK. If our current sole source suppliers cannot perform as agreed, or if such contract manufacturers choose to terminate their agreements with us, we would be required to replace such manufacturers. We may incur added costs, delays, and difficulties in identifying and qualifying any such replacement manufacturer or in reaching an agreement with any such alternative manufacturers. In addition, we depend on the proprietary technology of our third-party manufacturers for QINLOCK and certain of our drug candidates.

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 any drug candidate, 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 a drug candidate, 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 QINLOCK will initially use to manufacture commercial supply has limited experience manufacturing commercial finished drug product.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), drafted in response to the U.S. COVID-19 pandemic, became law. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed product, our results could be materially impacted.

For our other potential products, if we are not able to negotiate commercial supply terms with any 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 the FDA's cGMP regulations or similar regulatory requirements outside of the U.S., including in Europe. 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 drug or drug candidates. 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 and drug candidates may compete with other drugs and drug candidates 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 our approved drug, QINLOCK. 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 or drug candidates or in the manufacturing facilities in which our drug or drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

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

We may enter into license and/or collaborations with third parties for the development and commercialization of our approved drug or drug candidates. If those license and/or collaborations, including, without limitation, our license arrangement with Zai for the development and commercialization of QINLOCK in Greater China, are not successful, we may not be able to capitalize on the market potential of our approved drug or 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 certain approved drugs or 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 QINLOCK 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 QINLOCK 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 QINLOCK 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 or 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 or 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 approved drug or 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 an approved drug or 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 approved drug 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 and/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 and/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 approved drug 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 approved drug or drug candidates;
- license or collaboration agreements may not lead to development or commercialization of our approved drug or drug candidates in the most efficient manner, or at all; and
- if a licensee and/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 licenses and/or collaborations, or distribution arrangements with distributors, we may have to alter our development and commercialization plans.

Our drug development programs and the commercialization of QINLOCK and any drug candidates for which we obtain marketing approval 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 QINLOCK in Greater China. We may in the future decide to enter into additional licenses for QINLOCK or license to or collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our drug candidates. We currently have, and may in the future 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 or drug candidate;
- the costs and complexities of manufacturing and delivering such drug or 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, including due to the impact of COVID-19.

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 or 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, collaborators, or distributors. 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, 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 commercialization of such drug or drug candidate, if approved, or reduce the scope of any sales or marketing activities for such drug or 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.

Risks Related to Our Intellectual Property

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

Filing, prosecuting, and defending patents with respect to our drug and 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, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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.

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 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 our drug and 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 switch-control kinase 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 switch-control kinase 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 or 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 and 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 drugs or 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 or 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 commercialization of the relevant drug, or 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 our approved drug or any of our 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 Patents

If we are unable to obtain and maintain sufficient patent protection for our approved drug or 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 approved drug or 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 approved drug and drug candidates, for example, QINLOCK, vimseltinib, 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 switch-control kinase 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 and market competition may increase, which could harm our business, reduce our potential revenues, and adversely affect our 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 approved drug or 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 approved drug, 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 drugs or drug candidates might expire before or shortly after such drugs or 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, including generic versions of such products. 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 approved drug or 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, drug candidates, or technology could have an adverse impact on our business.

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 our approved drug or any of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. We have applied for patent term extension in the U.S. on patents covering QINLOCK and we expect to seek extensions of patent terms in the U.S. for other drug candidates and, if available, in other countries where we are prosecuting patents. In the U.S., the Hatch-Waxman Act permits 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 non-compliance 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 or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease a total of 82,346 rentable square feet of office space for our headquarters at 200 Smith Street, Waltham, Massachusetts (the Premises). The initial term of our leases at the Premises will expire in November 2029 unless terminated earlier in accordance with the terms of the leases and we are entitled to two five-year options to extend the leases. Our existing space is used primarily for our clinical development and operations, medical affairs, commercial launch preparation, regulatory, business development, and administrative functions.

We also lease 42,514 square feet of laboratory, office, and storage space in Lawrence, Kansas, which is used primarily for discovery research, preclinical research and non-clinical functions. The initial term of the leases in Lawrence, Kansas will expire on December 31, 2030 unless terminated earlier in accordance with the terms of the lease and the Company is entitled to two five-year options to extend the leases. The described leased space in Lawrence, Kansas includes space for leases which had not commenced under Accounting Standards Codification (ASC) Topic 842, *Leases* (ASC 842), as of December 31, 2020, and as a result, these leases are not reflected within the consolidated balance sheets. We expect these leases to commence in 2021. We also lease 3,909 square feet of space in Lawrence, Kansas to accommodate short-term needs.

We believe that our existing office and laboratory space is sufficient to meet our needs for the foreseeable future and that suitable additional space will be available as and when needed.

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 January 31, 2021, 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

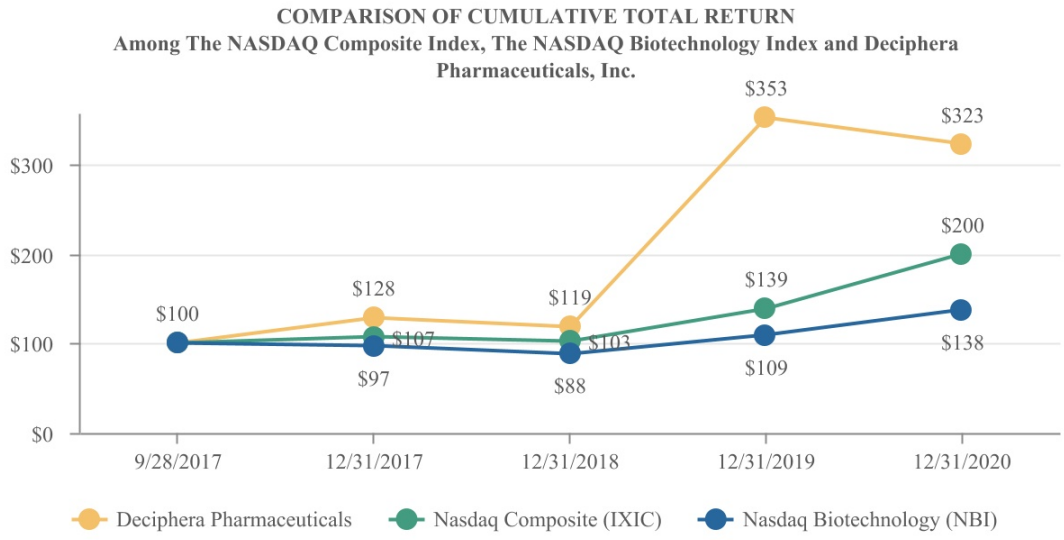
Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

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, 2020. 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the periods covered by this 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 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, 2020, 2019, and 2018 and the balance sheet data as of December 31, 2020 and 2019 from our audited consolidated financial statements appearing at the end of this Form 10-K. The selected statements of operations data for the years ended December 31, 2017 and 2016 and the balance sheet data as of December 31, 2018, 2017, and 2016 is derived from our audited consolidated financial statements not

included in this 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)	**2020**	**2019**	**2018**	**2017**	**2016**
Statement of Operations Data:					
Revenues:					
Product revenues, net[1]	$ 39,461	$ —	$ —	$ —	$ —
Collaboration revenues[2]	2,626	25,000	—	—	—
Total revenues	42,087	25,000	—	—	—
Cost and operating expenses:					
Cost of sales[3]	225	—	—	—	—
Research and development[4]	198,970	157,610	82,887	39,514	20,163
Selling, general, and administrative[4]	114,082	68,116	21,212	11,421	5,675
Total cost and operating expenses	313,277	225,726	104,099	50,935	25,838
Loss from operations	(271,190)	(200,726)	(104,099)	(50,935)	(25,838)
Other income (expense):					
Interest and other income, net	4,701	8,537	4,329	746	4
Interest expense	—	(67)	(84)	(95)	(106)
Total other income (expense), net	4,701	8,470	4,245	651	(102)
Net loss	$ (266,489)	$ (192,256)	$ (99,854)	$ (50,284)	$ (25,940)
Net loss per share—basic and diluted	$ (4.78)	$ (4.48)	$ (2.82)	$ (2.99)	$ (2.23)
Weighted average common shares outstanding—basic and diluted	55,780,982	42,869,058	35,390,480	16,792,179	11,626,287

(1) Amount includes revenues recognized associated with the sales of QINLOCK, which commenced in the U.S. in May 2020. For additional information, please read Note 3, *Revenues*, to these consolidated financial statements.

(2) Amounts primarily include revenues recognized associated with the Zai License Agreement. For additional information, please read Note 3, *Revenues*, to these consolidated financial statements.

(3) Cost of sales did not reflect the full cost of manufacturing QINLOCK for the year ended December 31, 2020 due to the use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the launch of QINLOCK.

(4) 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)	**2020**	**2019**	**2018**	**2017**	**2016**
Research and development	$ 17,443	$ 7,934	$ 4,021	$ 1,320	$ 541
Selling, general, and administrative	19,694	12,476	5,667	3,546	946
Total share-based compensation	$ 37,137	$ 20,410	$ 9,688	$ 4,866	$ 1,487

(in thousands)	As of December 31, 2020	2019	2018	2017	2016
Balance Sheet Data:					
Cash and cash equivalents	$ 135,897	$ 120,320	$ 293,764	$ 196,754	$ 57,461
Marketable securities	425,408	459,256	—	—	—
Working capital[(1)]	514,039	533,370	278,294	184,367	53,695
Total assets	642,432	622,409	315,559	199,095	58,945
Notes payable to related party, including current portion	—	—	1,294	1,481	1,668
Convertible preferred shares	—	—	—	—	192,667
Total stockholders' equity/members' (deficit)	543,676	546,467	279,981	183,973	(139,760)

(1) We define working capital as current assets less current liabilities.

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 Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this 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 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 biopharmaceutical company focused on discovering, developing, and delivering important new medicines to patients for the treatment of cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to execute our strategy to develop a broad portfolio of innovative medicines. We have one approved drug, QINLOCK, which was developed through our proprietary platform. Beyond QINLOCK, we are developing three clinical-stage drug candidates and advancing our research-stage programs. We wholly own QINLOCK and all of our drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. We are preparing for a potential launch of QINLOCK in Europe and we have entered, and intend in the future to enter, into select distributor arrangements to offer QINLOCK in geographies where we do not intend to distribute QINLOCK on our own, such as Australia and Canada.

Our Drug and Drug Candidates

QINLOCK

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following FDA approval of QINLOCK, in May 2020, we launched QINLOCK commercially in the U.S. Additionally, in November 2020, we announced that we had entered into exclusive distribution agreements for QINLOCK in Canada, Israel, Australia, New Zealand, Singapore, Malaysia, and Brunei.

In July 2020, Zai, our licensee for QINLOCK in Greater China, announced that the China NMPA accepted the NDA submission for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

In October 2020, an EU MAA for QINLOCK in fourth-line GIST was accepted for review by the EMA. In January 2021, we announced that Swissmedic accepted a Swiss MAA for QINLOCK in fourth-line GIST. We also announced plans to file a marketing application in the U.K. for QINLOCK in fourth-line GIST. In preparation for a potential European approval of QINLOCK, we are actively engaged in building a direct commercial presence in key European markets and building a targeted infrastructure to commercialize QINLOCK, if approved. In January 2021, we also announced commencement of planning efforts for a bridging study for QINLOCK in Japan.

In addition, we successfully completed enrollment of our global pivotal Phase 3 study in second-line GIST patients, INTRIGUE, and expect to announce top-line results from INTRIGUE in the second half of 2021. We are also studying QINLOCK in an ongoing Phase 1 study in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib. We believe QINLOCK has the potential to play an even broader role than in the fourth-line setting in the treatment of GIST, and we are planning further clinical development to explore this potential.

Vimseltinib

We are currently studying vimseltinib in an open-label Phase 1/2 study designed to evaluate the safety, efficacy, PK, and PD of vimseltinib in patients with malignant solid tumors as well as patients with TGCT. In November 2020, we announced the selection of a Phase 2 dose and initiated the expansion portion of the study with vimseltinib in patients with symptomatic TGCT not suitable for surgery. We are continuing to enroll TGCT patients in cohort 9 of the dose escalation portion of the study to complete enrollment in this cohort. We expect to present updated data for vimseltinib in the second half of 2021.

Rebastinib

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, PK, and efficacy in patients with advanced or metastatic solid tumors. 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 the Phase 1b/2 study of rebastinib in combination with carboplatin. In May 2020, we announced that in Part 2 of the study of rebastinib in combination with paclitaxel, we observed the required number of responses in the first stage in both the endometrial and platinum-resistant ovarian cancer cohorts, triggering the expansion of enrollment in these cohorts. In addition, based on the clinical activity observed in Part 1, we added a cohort for patients with carcinosarcoma in Part 2 of the study of rebastinib in combination with paclitaxel. We expect to present updated data from the study of rebastinib in combination with paclitaxel in patients with endometrial cancer in the second quarter of 2021 and in patients with PROC in the second half of 2021.

DCC-3116

In January 2021, we announced our plans to initiate a Phase 1 study of DCC-3116 in the second quarter of 2021, subject to FDA authorization to proceed under our IND for DCC-3116, submitted in the fourth quarter of 2020 and cleared by the FDA.

Coronavirus (COVID-19)

The full extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact our business, including our preclinical studies, clinical trial operations, or commercialization efforts will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted at this time, such as the duration of such pandemic including future waves of infection, new strains of the virus that causes COVID-19, or the broad availability of effective vaccines, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic but it could have a material adverse effect on our business, financial condition, and results of operations. The COVID-19 pandemic may also have the effect of heightening the risks to which we are subject, including various aspects of our preclinical studies and ongoing clinical trials, the reliance on third parties in our supply chain for materials and manufacturing of our drug and drug candidates, disruptions in health regulatory agencies' operations globally, the volatility of our common stock, our ability to access capital markets, and our ability to successfully launch, commercialize, and generate revenue from QINLOCK.

We are continuing to assess the long-term impact of COVID-19 on our business operations in an effort to mitigate interruption to our clinical programs, research efforts, commercial launch of QINLOCK, and other business activities and to ensure the safety and well-being of our employees, as well as the physicians and patients participating in our clinical studies. Because COVID-19 infections have been reported throughout the U.S. and worldwide, certain national, state, and local governmental authorities have issued orders, proclamations, and/or directives aimed at minimizing the spread of COVID-19. Although some of these restrictions were eased or lifted, in response to local surges and new waves of infection, some countries, states, and local governments have reinstituted these restrictions, and additional, more restrictive orders, proclamations, and/or directives may be issued in the future. In response to the COVID-19 pandemic, we have implemented precautionary measures to protect the health and safety of our employees, partners, and patients, including encouraging all employees, other than those engaged in laboratory research activities, to work-from-home, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines.

Our ability to successfully launch, commercialize, and generate revenue from QINLOCK may be adversely affected by the impact of the COVID-19 pandemic. For example, limited hospital access for non-patients, social distancing requirements, and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. In response, we have implemented a virtual launch model, which may adversely affect the ability of our sales professionals to effectively market QINLOCK to physicians, which may have a negative impact on our sales and our market penetration. In addition, in the U.S. we are utilizing various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and rising unemployment caused by the COVID-19 pandemic may lead to increased utilization of our patient assistance programs, which could reduce revenues.

In addition, we continue to actively monitor risks associated with potential interruptions to our clinical studies due to the impact of COVID-19 and are in frequent communication with clinical study sites and CROs. Some clinical trial sites have maintained or reinstituted restrictions on site visits by sponsors and CROs, initiation of new trials, patient visits, and new patient enrollment as a result of COVID-19. While all of our studies remain open for enrollment, we have provided guidance to our clinical trial sites that new patient enrollment may occur at sites where resources allow these patients to be safely enrolled and closely monitored and enrollment has slowed at, or has been or may in the future be temporarily paused for new patients in some sites. In addition, we continue to work closely with our study sites and CROs to allow for utilization of remote and local assessments, such as televisits, in accordance with FDA guidance, as well as to ensure availability of study drug for patients. While study activities are continuing in the clinical trials we have underway in sites across the globe, and although some of these restrictions may from time to time be eased or lifted, we cannot guarantee that COVID-19 precautions, either now or in the future, or the impact of the pandemic, will not directly or indirectly affect the expected timelines for some of our clinical trials.

In light of the changing circumstances surrounding the COVID-19 pandemic, the operating environment remains fluid and uncertain, and the full significance of the impact of the COVID-19 outbreak on our business and the duration for which it may have an impact cannot be determined at this time.

Components of Our Results of Operations

Revenues

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following FDA approval of QINLOCK, in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. We may generate revenue in the future from a combination of product sales or payments from collaboration, distribution, or any potential additional license agreements that we may enter into with third parties. We expect that our revenue in the foreseeable future will be derived primarily from sales of QINLOCK and, payments, if any, made under the Zai License and Zai Supply Agreements we entered into in June 2019 and February 2020, respectively. 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 provide assurance as to what extent we will generate revenue from the commercialization of QINLOCK or if, when, or to what extent we will generate revenue from the commercialization and sale of our drug candidates for which we receive marketing approval, if any. We may never succeed in obtaining regulatory approval for any of our drug candidates other than QINLOCK.

Net Product Revenues

Following the FDA approval of QINLOCK in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. During the year ended December 31, 2020, our only source of product revenues were from the sales of QINLOCK. Product revenues are recorded net of estimates of variable consideration. Please read Note 2, *Summary of Significant Accounting Policies*, of these consolidated financial statements for further details of the reserves recorded for variable considerations.

Collaboration Revenues

For the years ended December 31, 2020 and 2019, collaboration revenues were associated with our license and supply agreements with Zai, as applicable.

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. Additionally, certain costs we incur associated with the Zai License Agreement are reimbursed by Zai.

As of December 31, 2020, QINLOCK had not received regulatory approval in the Territory, and it is not possible to estimate when, or if, we may receive royalty payments or commercial milestones under the Zai License Agreement.

Pursuant to the terms of the Zai Supply Agreement, costs we incur for external manufacturing services are reimbursed by Zai.

Cost of Sales

Our cost of sales includes external costs of producing and distributing inventories that are related to product revenue during the respective period of the associated sales. In addition, shipping and handling costs for product shipments are recorded in cost of sales as incurred.

Cost of sales for newly launched products, such as QINLOCK, will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. As a result, the gross margin on sales of QINLOCK for the year ended December 31, 2020 was enhanced by the use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the launch of QINLOCK.

Operating Expenses

The successful development and commercialization of our drug and 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 QINLOCK and any current or future drug candidates for which we receive approval;
- obtaining and maintaining patent, trade secret and other intellectual property protection, and regulatory exclusivity for our drug and drug candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;
- developing and implementing marketing and reimbursement strategies;
- continuing to establish sales, marketing, and distribution capabilities to support the commercial launch of QINLOCK or our drug candidates, if and when approved, whether alone or in collaboration with others such as Zai, our licensee for QINLOCK in Greater China;
- acceptance of QINLOCK or our drug candidates, 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 our products following approval.

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

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 and 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 pre-launch manufacturing of commercial inventory of QINLOCK prior to FDA approval; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, supplies, and technology-related costs.

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 switch-control kinase inhibitor platform technology or facility expenses, including depreciation or other indirect costs, to specific drug or drug candidate development programs because these costs are deployed across multiple drug or drug candidate development programs and, as such, are not separately classified.

Research and development activities are central to our business model. Drugs and 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 as our drug and 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 our drug and 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, legal, finance, commercial, human resources, and administrative functions. Selling, general, and administrative expenses also include direct and allocated facility- and technology-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 as we continue to support the commercial launch of QINLOCK in the U.S., the potential launch of QINLOCK in Europe, if approved, and the establishment of a targeted commercial infrastructure in key European markets. We also anticipate that we will continue to incur accounting, audit, legal, regulatory, compliance, and investor and public relations expenses associated with growth of the business and continued operations 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 for the years ended December 31, 2019 and 2018 consisted of interest expense associated with a previously outstanding construction loan from a related party. The outstanding balance of the construction loan from a related party was repaid in December 2019, and there was therefore no interest expense during the year ended December 31, 2020.

Income Taxes

On October 2, 2017, immediately prior to the completion of our initial public offering (IPO), we engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation (the Conversion). 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. Upon the Conversion, we became subject to typical corporate U.S. federal and state income taxation; however, we do not have net operating loss (NOL) 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, 2020, we had NOL carryforwards for federal income tax purposes of $643.6 million, of which $16.6 million begin to expire in 2037 and $627.0 million may be carried forward indefinitely. As of December 31, 2020, we had NOL carryforwards for state income tax purposes of $479.2 million, which begin to expire in 2037. We also had federal and state research and orphan drug credits of $28.8 million and $3.0 million, respectively, as of December 31, 2020, 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.

Product Revenue Reserves

We recognize product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. We record product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, trade discounts and allowances, product returns, and other incentives, which are described below.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, forecasted customer buying, and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Chargebacks and administrative fees: Chargebacks for discounts represent our estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list

prices charged to the customers who directly purchase the product from us. The customers charge us for the difference between what the customers pay us for the product and the customer's ultimate contractually committed or government required lower selling price to the qualified healthcare providers. As part of our contractual commitments to sell product to qualified healthcare providers, we pay fees for administrative services, such as account management and data reporting.

Government rebates: Government rebates consist of Medicare, Tricare, and Medicaid rebates. These reserves are recorded in the same period the related revenue is recognized. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe a rebate under the Medicare Part D program.

Trade discounts and allowances: We provide customers with discounts that are explicitly stated in contracts and recorded in the period the related product revenue is recognized. In addition, we also receive sales order management, inventory management, and data services from customers in exchange for certain fees.

Product returns: We estimate the amount of our product sales that may be returned by our customers and record this estimate in the period the related product revenue is recognized. We currently estimate product return liabilities based on available industry data and our visibility into the inventory remaining in the distribution channel.

Other incentives: Other incentives include co-payment assistance provided to qualified patients, whereby we may provide financial assistance to patients with prescription drug co-payments required by the patient's insurance provider. Reserves for co-payment assistance are recorded in the same period the related revenue is recognized.

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 associated cost incurred for the services 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 as well as the limited historical 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. 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.

Results of Operations

Comparison of the Years Ended December 31, 2020, 2019, and 2018

The following table summarizes our results of operations for the years ended December 31, 2020, 2019, and 2018:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Revenues:			
Product revenues, net	$ 39,461	$ —	$ —
Collaboration revenues	2,626	25,000	—
Total revenues	42,087	25,000	—
Cost and operating expenses:			
Cost of sales	225	—	—
Research and development	198,970	157,610	82,887
Selling, general, and administrative	114,082	68,116	21,212
Total cost and operating expenses	313,277	225,726	104,099
Loss from operations	(271,190)	(200,726)	(104,099)
Other income (expense):			
Interest and other income, net	4,701	8,537	4,329
Interest expense	—	(67)	(84)
Total other income (expense), net	4,701	8,470	4,245
Net loss	$ (266,489)	$ (192,256)	$ (99,854)

Revenues

Net Product Revenues

During the year ended December 31, 2020, our only source of product revenues were from the sales of QINLOCK, which commenced in the U.S. in May 2020 following the FDA approval of QINLOCK on May 15, 2020. For the year December 31, 2020, product revenues were $39.5 million, which consisted of $38.0 million of revenues in the U.S. and $1.5 million of revenues outside of the U.S.

Collaboration Revenues

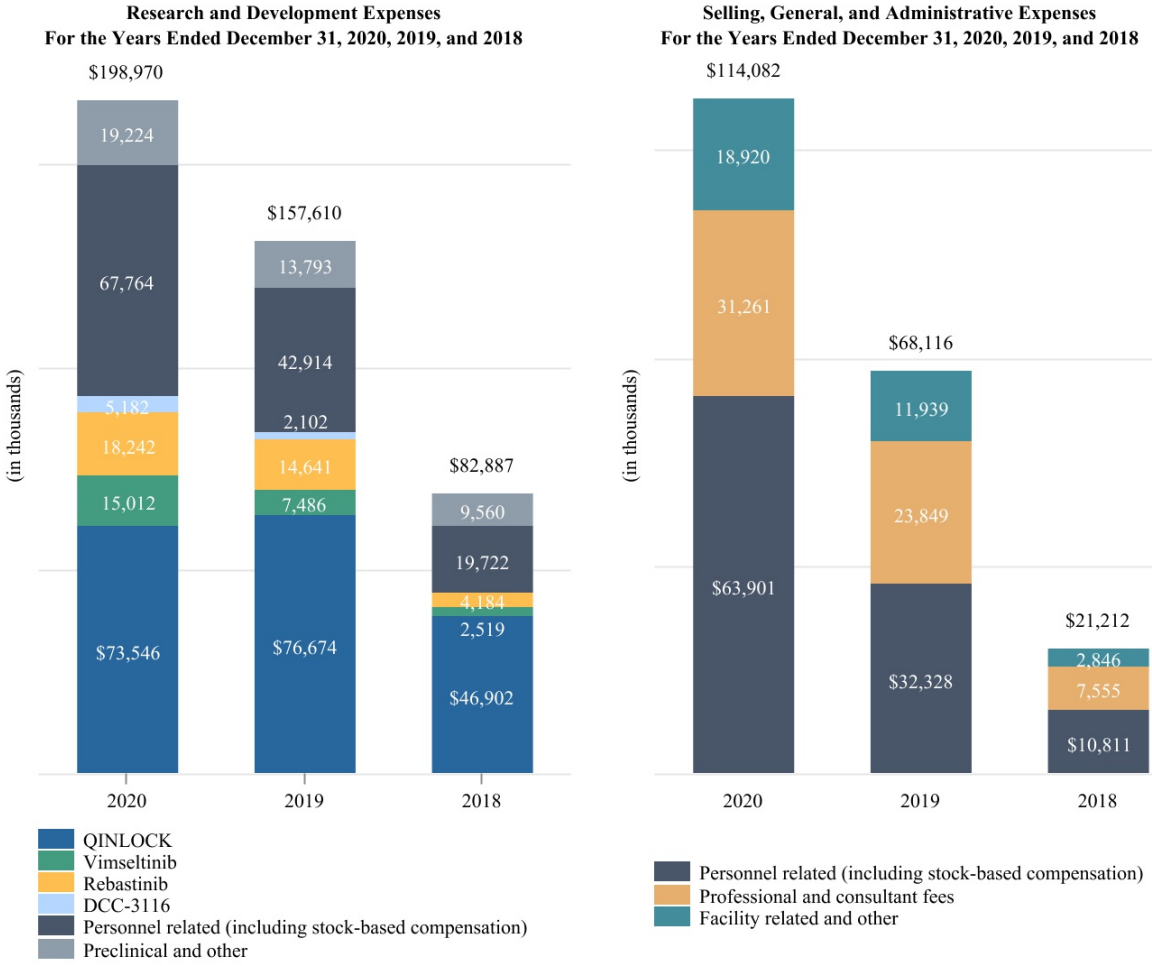
For the year ended December 31, 2020 compared to the same period in 2019, collaboration revenues decreased $22.4 million, primarily driven by the recognition of up-front and development milestone payments of $20.0 million and $5.0 million, respectively, associated with the Zai License Agreement, entered into in June 2019, in the second quarter of 2019 as compared to the recognition of a $2.0 million development milestone payment associated with the Zai License Agreement in the second quarter of 2020. The decrease in up-front and milestone payments were partially offset by $0.6 million of revenues recognized associated with reimbursements under the Zai License and Supply Agreements during the year ended December 31, 2020.

Cost of Sales

Cost of sales were $0.2 million for the year ended December 31, 2020 and were primarily related to packaging, labeling, shipping, and distribution costs associated with sales of QINLOCK. External manufacturing costs associated with QINLOCK inventory prior to FDA approval were previously expensed as research and development expenses and, therefore, are not included in cost of sales during the year ended December 31, 2020.

We expect our cost of sales for QINLOCK to increase as a percentage of net sales in future periods as we continue to produce inventory for future sales, which will reflect the full cost of manufacturing, and then sell such inventory.

Operating Expenses



Research and Development Expenses

QINLOCK

For the year ended December 31, 2020 compared to the same period in 2019, research and development expenses related to QINLOCK decreased primarily as a result of a decrease in clinical trial expenses of $6.1 million. The decrease in clinical trial expenses was primarily due to decreased expenses associated with our pivotal Phase 3 study in fourth-line and fourth-line plus GIST, INVICTUS, which we initiated in January 2018 and announced top-line results from in August 2019. In addition, clinical trial expenses decreased due to decreased expenses associated with our ongoing Phase 1 study of QINLOCK and decreased expenses associated with clinical pharmacology studies. These decreases were partially offset by increased expenses related to our pivotal Phase 3 study in second-line GIST, INTRIGUE, which we initiated in December 2018 and completed enrollment of which in December 2020.

For the year ended December 31, 2019 compared to the same period in 2018, expenses related to QINLOCK increased primarily as a result of increases in clinical trial expenses of $28.0 million and manufacturing costs of $2.0 million. The increase in clinical trial expenses was due to our pivotal INTRIGUE Phase 3 study in second-line GIST, which we initiated in December 2018, and expenses related to our pivotal INVICTUS Phase 3 study 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 expenses increased due to increased expenses associated with clinical pharmacology studies that commenced in 2019. Manufacturing costs for QINLOCK increased primarily as a result of increased 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.

Vimseltinib

For the year ended December 31, 2020 compared to the same period in 2019, expenses related to our vimseltinib program increased primarily as a result of increases in clinical trial expenses of $4.1 million, manufacturing costs of $2.7 million, and preclinical costs of $0.8 million. The increase in clinical trial expenses was primarily due to increased activities associated with the dose escalation portion of our ongoing Phase 1/2 study of vimseltinib to assess the safety, tolerability, PK, and PD in patients with TGCT. Manufacturing costs for the vimseltinib program increased as a result of increased activities to support clinical trials. The increase in preclinical costs was primarily due to increased ongoing studies.

For the year ended December 31, 2019 compared to the same period in 2018, expenses related to our vimseltinib program increased primarily as a result of an increase in preclinical costs of $2.5 million and clinical trial expenses of $1.8 million. The increase in preclinical costs was primarily due to additional studies and the increase in clinical trial expenses was primarily due to increased activities associated with the dose escalation portion of our ongoing Phase 1/2 study of vimseltinib to assess the safety, tolerability, PK, and PD in patients with malignant solid tumors and TGCT.

Rebastinib

For the year ended December 31, 2020 compared to the same period in 2019, expenses related to our rebastinib program increased primarily as a result of increases in manufacturing costs of $1.9 million and clinical trial expenses of $1.7 million. Manufacturing costs for the rebastinib program increased as a result of increased activities to support clinical trials. The increases in clinical trial expenses were due to our Phase 1b/2 study of rebastinib in combination with paclitaxel, which we initiated in October 2018 and moved to Part 2 of the Phase 1b/2 study in the second quarter of 2019, and our second Phase 1b/2 study of rebastinib in combination with carboplatin, which we initiated in January 2019 and moved to Part 2 of the Phase 1b/2 study in January 2020.

For the year ended December 31, 2019 compared to the same period in 2018, expenses related to our rebastinib program increased primarily as a result of increases in clinical trial expenses of $9.3 million. The increases in clinical trial expenses were due to our Phase 1b/2 study of rebastinib in combination with paclitaxel, which we initiated in October 2018 and moved to Part 2 of the Phase 1b/2 study in the second quarter of 2019, and our second Phase 1b/2 clinical study of rebastinib in combination with carboplatin, which we initiated in January 2019.

DCC-3116

For the year ended December 31, 2020 compared to the same period in 2019, expenses related to our DCC-3116 program increased primarily as a result of an increase in preclinical activities of $1.4 million, including IND-enabling studies, associated with a full year of activities for this drug candidate, which we announced as an addition to our pipeline in June 2019, and increased manufacturing costs of $1.1 million to support our Phase 1 study of DCC-3116, which we expect to initiate in the second quarter of 2021. This addition of DCC-3116 to our pipeline in June 2019 also resulted in increased research and development expenses during the year ended December 31, 2019 compared to the same period in 2018.

Unallocated expenses

For the year ended December 31, 2020 compared to the same period in 2019, the increase in unallocated research and development expenses was related to personnel-related costs and preclinical and other costs. The increase in personnel-related costs was primarily due to an increase in headcount and stock-based compensation expense in our research and development functions. Personnel-related costs for the years ended December 31, 2020 and 2019 included stock-based compensation expense of $17.4 million and $7.9 million, respectively. The increase in stock-based compensation expense was primarily related to headcount increases, a higher value of our common stock resulting in increased valuations of share-based awards granted to our employees, and $1.9 million of expenses related to the achievement of vesting events associated with performance-based restricted stock units during the year ended December 31, 2020. The increase in preclinical and other costs was primarily due to increased costs of $3.3 million in connection with increased activities for our early-stage drug discovery programs and increased costs for temporary staffing of $2.5 million to support our research and development functions.

For the year ended December 31, 2019 compared to the same period in 2018, the increase in unallocated research and development expenses was related to personnel-related costs and preclinical and other costs. The increase in personnel-related costs was primarily due to an increase in headcount and stock-based compensation expense in our research and development functions. 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 associated with headcount increases and a higher value of our common stock resulting in increased valuations of share-based awards granted to our employees. The increase in preclinical and other costs was primarily due to increased consultant fees of $2.5 million and increased costs of $0.5 million in connection with our early-stage drug discovery programs.

We expect research and development expenses will increase in 2021 as compared to 2020 as we continue to invest in the development of our clinical pipeline.

Selling, General, and Administrative Expenses

For the year ended December 31, 2020 compared to the same period in 2019, the increase in selling, general, and administrative expenses was related to personnel-related costs, professional and consultant fees, and facility related and other costs. The increase in personnel-related costs was primarily a result of an increase in headcount and an increase in stock-based compensation expense in our selling, general, and administrative functions. Personnel-related costs for the years ended December 31, 2020 and 2019 included stock-based compensation expense of $19.7 million and $12.5 million, respectively. The increase in stock-based compensation expense was primarily related to increased headcount and a higher value of our common stock resulting in increased valuations of share-based awards granted to our employees, partially offset by the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer resulting in $2.4 million of expenses during the year ended December 31, 2019. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness and the launch of QINLOCK. The increase in facility related and other costs was primarily due to a full year of expenses, including those related to rent and depreciation expenses, associated with our new headquarters (the Premises) that commenced in October 2019 (the Initial Space) and rent, depreciation, and moving expenses associated with our lease at the Premises that commenced in July 2020 (the Additional Space) as well as technology-related costs to support the growth of the business. For additional information on our leases at the Premises, please read Note 7, *Leases*, to the consolidated financial statements included elsewhere herein.

For the year ended December 31, 2019 compared to the same period in 2018, the increase in selling, general, and administrative expenses was related to personnel-related costs, professional and consultant fees, and facility related and other costs. The increase in personnel-related costs was primarily a result of an increase in headcount and an increase in stock-based compensation expense in our selling, general, and administrative functions. 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 an increase in headcount, a higher value of our common stock resulting in increased valuations of share-based awards granted to our employees, and the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer resulting in $2.4 million of expenses during the year ended December 31, 2019. 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 expenses incurred in connection with the move to the Initial Space in October 2019 as well as technology-related costs to support the growth of the business. For additional information on our leases at the Premises, please read Note 7, *Leases*, to the consolidated financial statements included elsewhere herein.

We expect selling, general, and administrative expenses will increase in 2021 as compared to 2020 as we continue to execute on the commercial launch of QINLOCK in the U.S. and prepare for a potential commercial launch in Europe, if approved.

Interest and Other Income, Net

For the year ended December 31, 2020 compared to the same period in 2019, the decrease in interest and other income, net, was primarily due to decreases in interest income earned on our cash equivalents and marketable securities associated with our holdings of lower yield investments during the year ended December 31, 2020.

For the year ended December 31, 2019 compared to the same period in 2018, the increase in interest and other income, net, was primarily due to increases in interest income earned on our invested 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 9, *Common Stock*, to the consolidated financial statements included elsewhere herein.

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, 2020, 2019, and 2018.

Liquidity and Capital Resources

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, building a commercial and marketing organization, and commercializing our first approved product, QINLOCK. Our only product approved for sale is QINLOCK, which only recently received approval, and we have not generated substantial revenue from product sales.

As a result, we have incurred significant operating losses since our inception. We have generated limited revenue to date primarily from our product sales and license and supply agreements with Zai. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following the FDA approval of QINLOCK, in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. During the year ended December 31, 2020, our product revenues were primarily derived from sales of QINLOCK in the U.S. We have also entered into exclusive distributor arrangements to facilitate product sales of QINLOCK in select geographies where we do not currently intend to distribute QINLOCK on our own. We do not expect to generate revenue from sales of any drug candidates in the near future, if at all, unless and until we obtain marketing approval for, and begin to sell, such drug candidates.

On October 2, 2017, we completed the IPO of our common stock. Since October 2017, we have primarily supported our operations by completing public issuances of our common stock through our IPO, subsequent follow-on offerings, and an Open Market Sale Agreement℠ (the Sales Agreement) with Jefferies LLC (Jefferies). Through such issuances, we have sold and issued 29,497,292 shares of our common stock resulting in net proceeds of $948.0 million after deducting underwriting discounts and commissions and other offering expenses.

In August 2020, we entered into the Sales Agreement with Jefferies, pursuant to which we may issue and sell shares of our common stock having aggregate offering proceeds of up to $200.0 million (the Shares) from time to time through Jefferies as our sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. We may sell the Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any Shares under the Sales Agreement. We or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. As of December 31, 2020, there was $181.3 million available for future issuance under the Sales Agreement.

Public issuances of our common stock and shares issued pursuant to the underwriters' partial or full exercises of options to purchase additional shares of common stock, if applicable, associated with our IPO, subsequent follow-on offerings, and issuances of shares pursuant to the Sales Agreement have been summarized in the following table:

		Shares Issued in Public Offering			Shares Issued Pursuant to The Underwriters' Exercise of Options to Purchase Additional Shares of Common Stock (if applicable)			Total	
(in millions, except share and per share amounts)	Price per Share[1]	Date	Shares Issued	Net Proceeds[2]	Date	Shares Issued	Net Proceeds[2]	Shares Issued	Net Proceeds[2]
IPO	$ 17.00	October 2, 2017	7,500,000	$ 114.1	October 4, 2017	666,496	$ 10.5	8,166,496	$ 124.6
June 2018 Follow-on Public Offering	40.00	June 11, 2018	4,300,000	161.0	June 20, 2018	645,000	24.3	4,945,000	185.3
Third Quarter of 2019 Follow-on Public Offering	37.00	August 19, 2019	10,810,810	375.4	September 3, 2019	1,621,621	56.4	12,432,431	431.8
February 2020 Follow-on Public Offering	55.00	February 19, 2020	3,181,818	163.7	February 25, 2020	477,272	24.7	3,659,090	188.4
Issuances Pursuant to the Sales Agreement - Fourth Quarter of 2020	Various[3]	Fourth Quarter of 2020[3]	294,275	17.9		Not applicable		294,275	17.9
							Total	29,497,292	$ 948.0

1. The price per share presented above represents the price per share at which shares were sold for both the public offering of shares and the underwriters' exercise of options to purchase additional shares, if applicable.
2. Proceeds are presented net of underwriting discounts and commissions and other offering expenses.
3. Shares issued pursuant to the Sales Agreement were sold in multiple lots at varying prices over the course of several days during the quarter indicated in the table above.

Cash Flows

As of December 31, 2020, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $561.3 million, which consisted of cash, money market funds, U.S. government securities, commercial paper, corporate debt securities, and certificates of deposit. 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)	2020	2019	2018
Net cash flows used in operating activities	$ (239,683)	$ (149,296)	$ (86,783)
Net cash flows provided by (used in) investing activities	28,459	(460,522)	(2,194)
Net cash flows provided by financing activities	226,801	436,374	185,987
Net increase (decrease) in cash and cash equivalents	$ 15,577	$ (173,444)	$ 97,010

Operating Activities

During the year ended December 31, 2020 compared to the same period in 2019, net cash used by operating activities increased $90.4 million, primarily resulting from an increase in our net loss of $74.2 million and increases in net cash outflows related to changes in our operating assets and liabilities of $38.6 million, partially offset by increases in net non-cash charges of $22.5 million. The increase in net cash outflows related to changes in our operating assets and liabilities was primarily due to an increase in accounts receivable of $13.9 million and an increase in inventory of $3.2 million. The increases in accounts receivable and inventory were primarily associated with sales of QINLOCK and the commencement of the capitalization of QINLOCK inventory, respectively, following the FDA approval of QINLOCK in May 2020. Other net cash outflows related to changes in our operating assets and liabilities were generally due to the timing of vendor invoicing and payments. Net non-cash charges increased primarily due to an increase in share-based compensation of $16.7 million.

During the year ended December 31, 2019 compared to the same period in 2018, net cash used by operating activities increased $62.5 million, primarily resulting from an increase in our net loss of $92.4 million, partially offset by increases in non-

cash charges of $8.2 million and cash provided by changes in our operating assets and liabilities of $21.7 million. Net non-cash charges increased primarily due to an increase in share-based compensation of $10.7 million. Net cash provided by changes in our operating assets and liabilities increased primarily due to increases of $26.6 million in accounts payable and accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses and other current assets of $4.6 million. Changes in accounts payable, accrued expenses and other current liabilities, and prepaid expenses and other current assets were generally due to growth in our business.

Investing Activities

During the year ended December 31, 2020 compared to the same period in 2019, net cash flows from investing activities increased $489.0 million, resulting from an increase in proceeds from sales and maturities of marketable securities of $770.1 million, partially offset by an increase in purchases of marketable securities of $279.6 million. The increase in net sales and maturities of marketable securities was partially offset by increases in our restricted investments of $1.2 million, which was made up of a $1.0 million increase to the letter of credit for our leases at the Premises associated with the commencement of the Additional Space and a $0.6 million increase to our Company credit card limit to support the growth of our business during the year ended December 31, 2020 compared to an increase of $0.4 million to secure a Company credit card during the same period in 2019, and an increase in purchases of property and equipment of $0.4 million primarily associated with moving into the Additional Space.

During the year ended December 31, 2019 compared to the same period in 2018, net cash flows from investing activities decreased $458.3 million, resulting from the net purchases of marketable securities of $455.1 million during the year ended December 31, 2019 to build our initial marketable securities portfolio, an increase in purchases of property and equipment of $3.8 million, primarily associated with moving to the Premises, partially offset by a decrease in the amount that we increased our restricted investments of $0.6 million, which was due to an increase of $0.4 million to secure a Company credit card during the year ended December 31, 2019 compared to an increase of $1.1 million to secure a letter of credit associated with our lease of the Initial Space at the Premises during the same period in 2018.

Financing Activities

During the year ended December 31, 2020 compared to the same period in 2019, net cash flows from financing activities decreased $209.6 million, primarily resulting from a decrease in net proceeds from public offerings of our common stock of $225.2 million, partially offset by an increase in proceeds from the exercise of stock options and employee stock purchase plans of $14.5 million, which was primarily due to increased stock option exercises associated with vesting of increased share-based awards as a result of headcount growth, and a $1.3 million decrease in repayments associated with a previous note payable to a related party, which was not outstanding during the year ended December 31, 2020 due to the early repayment of the outstanding balance of the note payable to a related party in December 2019. Net of underwriting discounts and commissions and other offering costs, the decrease in proceeds from our public offerings was due our issuance in the third quarter of 2019 of $431.8 million as compared to our issuance in February 2020 of $188.4 million and our issuance in the fourth quarter of 2020 under the Sales Agreement of $17.9 million.

During the year ended December 31, 2019 compared to the same period in 2018, net cash flows from financing activities increased $250.4 million, primarily resulting from an increase in net proceeds from public offerings of our common stock of $246.5 million and an increase in proceeds from the exercise of stock options of $5.0 million, which was primarily due to vesting of increased share-based awards associated with headcount growth, partially offset by an increase of $1.1 million in repayments associated with a previous note payable to a related party, primarily due to the early repayment of the outstanding balance of the note payable to a related party in December 2019. Net of underwriting discounts and commissions and other offering costs, the increase in proceeds from our public offerings was due our issuance in the third quarter of 2019 of $431.8 million as compared to our issuance in June 2018 of $185.3 million.

Funding Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of QINLOCK and the development and eventual commercialization of one or more of our drug candidates. Our net loss was $266.5 million, $192.3 million, and $99.9 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $754.5 million. We expect to continue to incur

significant expenses and operating losses for the foreseeable future. We expect that our expenses and capital requirements will increase in connection with our ongoing activities, particularly as we:

- continue to commercialize QINLOCK in the U.S., and continue to build our global commercial capability as we actively prepare to bring QINLOCK to eligible patients around the world, including in Europe, if approved;
- continue with our ongoing pivotal Phase 3 study of QINLOCK in second-line GIST and potentially other areas of GIST treatment;
- continue with our ongoing and planned clinical programs for vimseltinib as a potential single agent therapy for the treatment of TGCT and rebastinib as a combination therapy in solid tumor cancers;
- develop DCC-3116, our ULK kinase inhibitor, for the potential treatment of RAS or RAF mutant cancers;
- continue research and development and drug discovery activities and initiate additional clinical trials;
- seek marketing approval for our drug or any of our drug candidates that successfully complete clinical development;
- 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;
- maintain, expand, protect, and enforce our intellectual property portfolio; 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 international operations in Europe and other potential geographies.

As we continue to seek regulatory approval for our drug and drug candidates, including QINLOCK for the treatment of second-line GIST patients, we expect to incur significant expenses related to our ongoing clinical development efforts and activities related to maintaining and expanding 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. We may not be successful in our commercialization of QINLOCK. Even if we are able to generate substantial product sales of QINLOCK, we may not become profitable. Until we become profitable, if ever, we expect to finance our operations primarily through a combination of equity, debt, or other 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.

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, drugs, or drug candidates, or grant licenses on terms that may not be favorable to us. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. 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 commercialization efforts or grant rights to develop and market drugs and drug candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses and capital requirements or when or if we will be able to achieve or maintain profitability. 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. 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 success of our commercialization efforts and market acceptance for QINLOCK or any of our future approved drugs;
- the timing and outcome of regulatory review of our drug and 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 commercial manufacturing;
- addition and retention of key research and development and commercial, including sales and marketing, personnel;
- our efforts to enhance operational, financial, and information management systems and hire additional personnel, including personnel to support the business;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK, including our planned commercial launch of QINLOCK in Europe, if approved, and any of our drug candidates for which we obtain marketing approval;
- 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, distribution, or other arrangement, including the terms and timing of any upfront, milestone, and/or royalty payments thereunder.

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2020 of $561.3 million, together with anticipated product revenues, but excluding any potential future milestone payments or other payments under our collaboration or license agreements, if any, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. 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.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 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]	$ 44,573	$ 4,635	$ 9,429	$ 9,758	$ 20,751
Commercial supply agreements[3]	8,815	6,994	1,821	—	—
Total	$ 53,388	$ 11,629	$ 11,250	$ 9,758	$ 20,751

(1) Lease commitments reflect payments due for our lease agreements at the Premises in Waltham, Massachusetts that expire in November 2029 and our lease agreements in Lawrence, Kansas that expire in December 2030.

(2) In addition, lease commitments reflect payments due for leases in Lawrence, Kansas that had not commenced under ASC 842 as of December 31, 2020, and as a result, these leases are not reflected within the consolidated balance sheets. We expect these leases to commence in 2021.

(3) We have entered into commercial supply agreements related to the supply of QINLOCK that require us to make binding forecasts for a certain amount of purchases. The related cancellation clauses would as a general matter require us to pay the full amount of these binding forecasts.

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.

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 Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash, cash equivalents, and marketable securities as of December 31, 2020 consisted of cash, money market funds, U.S. government securities, commercial paper, corporate debt securities, and certificates of deposit. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. 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 general 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, 2020 and 2019, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $4.3 million and $4.6 million, respectively, 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, including changes resulting from the impact of the COVID-19 pandemic. 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.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Deciphera Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

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 Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally

accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued External Research and Development Expenses

As described in Notes 2 and 8 to the consolidated financial statements, the Company has entered into various research and development contracts with research institutions and other companies both inside and outside of the U.S. Management records accruals for estimated ongoing research costs. Within accrued expenses and other current liabilities, management has accrued $31.3 million of external research and development expenses as of December 31, 2020. When evaluating the adequacy of the accrued liabilities, management analyzes progress of the studies or trials, including the phase or completion of events, invoices received, and contracted costs. As disclosed by management, this process involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify services that have been performed, and estimating the associated cost incurred for the services when the Company has not yet been invoiced or otherwise notified of actual costs. Significant judgments and estimates are made in determining the accrued balances at the end of the reporting period.

The principal considerations for our determination that performing procedures relating to accrued external research and development expenses is a critical audit matter are the significant judgment by management in developing the estimate of costs incurred; this in turn led to significant auditor judgment and effort in performing procedures to evaluate management's estimate of the cost incurred for the research and development activities and in evaluating the audit evidence obtained for these accrued external research and development expenses.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to accrued external research and development expenses. These procedures also included, among others (i) testing management's process for estimating accrued research and development expenses, (ii) testing the completeness and accuracy of the data used to develop the estimate related to actual invoiced expenses, contractual rates for services, and patient services received, and (iii) evaluating the reasonableness of the estimated cost incurred for the services which have not been invoiced.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 9, 2021

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,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 135,897	$ 120,320
Short-term marketable securities	416,033	459,256
Accounts receivable, net	13,896	—
Inventory	5,716	—
Prepaid expenses and other current assets	12,489	13,832
Total current assets	584,031	593,408
Long-term marketable securities	9,375	—
Long-term investments—restricted	3,102	1,510
Property and equipment, net	9,583	6,333
Operating lease assets	36,341	21,158
Total assets	$ 642,432	$ 622,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,308	$ 19,575
Accrued expenses and other current liabilities	55,227	38,716
Operating lease liabilities	2,457	1,747
Total current liabilities	69,992	60,038
Operating lease liabilities, net of current portion	28,764	15,904
Total liabilities	98,756	75,942
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 57,596,144 shares and 51,617,639 shares issued and outstanding as of December 31, 2020 and 2019, respectively	576	516
Additional paid-in capital	1,297,557	1,033,819
Accumulated other comprehensive income (loss)	11	111
Accumulated deficit	(754,468)	(487,979)
Total stockholders' equity	543,676	546,467
Total liabilities and stockholders' equity	$ 642,432	$ 622,409

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,		
	2020	2019	2018
Revenues:			
Product revenues, net	$ 39,461	$ —	$ —
Collaboration revenues	2,626	25,000	—
Total revenues	42,087	25,000	—
Cost and operating expenses:			
Cost of sales	225	—	—
Research and development	198,970	157,610	82,887
Selling, general, and administrative	114,082	68,116	21,212
Total cost and operating expenses	313,277	225,726	104,099
Loss from operations	(271,190)	(200,726)	(104,099)
Other income (expense):			
Interest and other income, net	4,701	8,537	4,329
Interest expense	—	(67)	(84)
Total other income (expense), net	4,701	8,470	4,245
Net loss	$ (266,489)	$ (192,256)	$ (99,854)
Net loss per share—basic and diluted	$ (4.78)	$ (4.48)	$ (2.82)
Weighted average common shares outstanding—basic and diluted	55,780,982	42,869,058	35,390,480
Comprehensive loss:			
Net loss	$ (266,489)	$ (192,256)	$ (99,854)
Other comprehensive income (loss):			
Unrealized gains (losses) on marketable securities	(100)	111	—
Total other comprehensive income (loss)	(100)	111	—
Total comprehensive loss	$ (266,589)	$ (192,145)	$ (99,854)

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

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Issuance of common stock sold in public offering, net of underwriting discounts, commissions, and offering costs	3,953,365	40	206,236	—	—	206,276
Issuance of common stock under stock option and incentive and employee stock purchase plans	2,025,140	20	20,365	—	—	20,385
Stock-based compensation expense	—	—	37,137	—	—	37,137
Unrealized gains (losses) on marketable securities	—	—	—	(100)	—	(100)
Net loss	—	—	—	—	(266,489)	(266,489)
Balance, December 31, 2020	57,596,144	$ 576	$ 1,297,557	$ 11	$ (754,468)	$ 543,676

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,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (266,489)	$ (192,256)	$ (99,854)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	37,137	20,410	9,688
Depreciation expense	2,305	830	317
Noncash lease expense	2,834	958	—
Gain on disposal of equipment	(7)	—	—
Net accretion of discounts on marketable securities	(1,611)	(3,999)	—
Changes in operating assets and liabilities:			
Accounts receivable	(13,896)	—	—
Inventory	(3,241)	—	—
Prepaid expenses and other current assets	(1,772)	(10,321)	(5,770)
Accounts payable	(7,533)	10,862	3,991
Accrued expenses and other current liabilities	13,923	24,189	4,477
Operating lease liabilities	(1,333)	(319)	—
Other long-term liabilities	—	350	368
Net cash flows used in operating activities	(239,683)	(149,296)	(86,783)
Cash flows from investing activities:			
Purchases of marketable securities	(1,096,769)	(817,142)	—
Maturities of marketable securities	627,913	261,216	—
Sales of marketable securities	504,216	100,780	—
Purchases of property and equipment	(5,316)	(4,935)	(1,125)
Proceeds from sale of equipment	7	—	—
Increase in restricted investments	(1,592)	(441)	(1,069)
Net cash flows provided by (used in) investing activities	28,459	(460,522)	(2,194)
Cash flows from financing activities:			
Proceeds from public offerings, net of underwriting discounts and commissions	207,231	432,400	185,933
Repayment of notes payable to related party	—	(1,294)	(187)
Payments of public offering costs	(815)	(620)	(674)
Proceeds from stock option exercises and employee stock purchase plan	20,385	5,888	915
Net cash flows provided by financing activities	226,801	436,374	185,987
Net increase (decrease) in cash and cash equivalents	15,577	(173,444)	97,010
Cash and cash equivalents at beginning of period	120,320	293,764	196,754
Cash and cash equivalents at end of period	$ 135,897	$ 120,320	$ 293,764
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 67	$ 84
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	$ 239	$ 661	$ —
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 biopharmaceutical company focused on discovering, developing, and delivering important new medicines to patients for the treatment of cancer. The Company is leveraging its proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. The Company has one approved drug, QINLOCK® (ripretinib), referred to as QINLOCK, which was developed through its proprietary platform. Beyond QINLOCK, the Company is developing three clinical stage drug candidates and advancing its research-stage programs. The Company wholly owns QINLOCK and all of its drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in the People's Republic of China, Hong Kong, Macau, and Taiwan, referred to as Greater China. The Company is preparing for a potential launch of QINLOCK in Europe and the Company has entered, and intends in the future to enter, into select distributor arrangements to offer QINLOCK in geographies where the Company does not intend to distribute QINLOCK on its own, such as Australia and Canada.

On May 15, 2020, QINLOCK was approved by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. Following FDA approval of QINLOCK, in May 2020, the Company launched QINLOCK commercially in the U.S. In June 2020, QINLOCK was authorized for sale in Canada by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In July 2020, the Australian Therapeutic Goods Administration approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

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, market acceptance and the successful commercialization of QINLOCK or any of the Company's current or future drug candidates for which it receives marketing approval, competition for QINLOCK or any of the Company's current or future drug candidates for which it receives marketing approval, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, compliance with government regulations, the impact of the novel coronavirus (COVID-19) pandemic on its operations, and the ability to secure additional capital to fund operations. QINLOCK and the Company's drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval. In addition to supporting its research and development efforts, the Company will be required to invest in the Company's commercial capabilities and infrastructure, to support its launch and commercialization of QINLOCK, the Company's first and recently approved drug, and any current or future drug candidate for which the Company obtains marketing approval. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's drug development and commercialization efforts are successful, it is uncertain when, if ever, the Company will realize substantial revenue from product sales of QINLOCK or any current or future drug candidates for which it receives marketing approval.

The full extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact the Company's business, including its preclinical studies, clinical trial operations, or commercialization efforts will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted at this time, such as the duration of such pandemic including future waves of infection, new strains of the virus that causes COVID-19, or the broad availability of effective vaccines, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The Company is continuing to monitor the long-term impact of COVID-19, if any, on its financial condition and results of operations. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic but it could have a material adverse effect on the Company's business, financial condition, and results of operations. The COVID-19 pandemic may also have the effect of heightening the risks to which the Company is subject, including various aspects of the Company's preclinical studies and ongoing clinical trials, the reliance on third parties in the Company's supply chain for materials and manufacturing of the Company's drug and drug candidates, disruptions in health regulatory agencies' operations globally, the volatility of the Company's common stock, and its ability to access capital markets, and the Company's ability to successfully launch, commercialize, and generate revenue from sales of QINLOCK.

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.

In August 2020, the Company entered into an Open Market Sale Agreement℠ (the Sales Agreement) with Jefferies LLC (Jefferies), pursuant to which the Company may issue and sell shares of its common stock having aggregate offering proceeds of up to $200.0 million (the Shares) from time to time through Jefferies as its sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell the Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any Shares under the Sales Agreement. The Company or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. During the year ended December 31, 2020, the Company issued 294,275 shares resulting in net proceeds of $17.9 million after deducting underwriting discounts and commissions and other offering expenses under the Sales Agreement. As of December 31, 2020, there was up to $181.3 million available for future issuance under the Sales Agreement.

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 $266.5 million, $192.3 million, and $99.9 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, the Company had an accumulated deficit of $754.5 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents, and marketable securities of $561.3 million as of December 31, 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 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 certain 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 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, product revenue reserves, the accrual for research and development expenses, and the valuation of stock-based option 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 discovering, developing, and delivering important new medicines to patients for the treatment of cancer by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Substantially all of the Company's tangible assets are held in the U.S.

Revenues

In accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (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, 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.

Product Revenues

In May 2020, the Company began generating product revenue from sales of QINLOCK to specialty distributors and specialty pharmacies in the U.S. following the approval of QINLOCK by the FDA on May 15, 2020 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

The Company recognizes product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. The Company records product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, trade discounts and allowances, product returns, and other incentives, which are described below.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Company's customer) or a liability (if the amount is payable to a party other than the Company's customer, other than product returns, which are recorded as liabilities). The Company's estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, forecasted customer buying, and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

Chargebacks and administrative fees: Chargebacks for discounts represent the Company's estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list prices charged to the customers who directly purchase the product from the Company. The customers charge the Company for the difference between what the customers pay the Company for the product and the customer's ultimate contractually committed or government required lower selling price to the qualified healthcare providers. As part of the Company's contractual commitments to sell product to qualified healthcare providers, the Company pays fees for administrative services, such as account management and data reporting.

Government rebates: Government rebates consist of Medicare, Tricare, and Medicaid rebates. These reserves are recorded in the same period the related revenue is recognized. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom it will owe a rebate under the Medicare Part D program.

Trade discounts and allowances: The Company provides the customers with discounts that are explicitly stated in the contracts and recorded in the period the related product revenue is recognized. In addition, the Company also receives sales order management, inventory management, and data services from the customers in exchange for certain fees.

Product returns: The Company estimates the amount of its product sales that may be returned by its customers and records this estimate in the period the related product revenue is recognized. The Company currently estimates product return liabilities based on available industry data and its visibility into the inventory remaining in the distribution channel.

Other incentives: Other incentives include co-payment assistance provided to qualified patients, whereby the Company may provide financial assistance to patients with prescription drug co-payments required by the patient's insurance provider. Reserves for co-payment assistance are recorded in the same period the related revenue is recognized.

Collaboration Revenues

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 QINLOCK, including certain follow-on compounds (the Licensed Products), in Greater China (the Territory). In February 2020, the Company entered into a Supply Agreement (the Zai Supply Agreement), as required by terms in the Zai License Agreement, pursuant to which the Company will supply the Licensed Products to Zai for use in the Territory for clinical trials as well as commercial inventory, if QINLOCK obtains regulatory approval in the Territory. Subject to the Zai Supply Agreement, costs incurred by the Company for external manufacturing services are reimbursed by Zai. The Company accounts for its license and supply agreements with Zai under ASC 606.

The Zai License Agreement includes development and regulatory milestone payments. Therefore, 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 cumulative 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.

The Zai License Agreement also includes sales-based royalties for the license of intellectual property, including milestone payments based on the level of sales. As 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.

The Company 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.

For additional information on the Company's license and supply agreements, please read Note 3, *Revenues*, to these consolidated financial statements.

Cash and 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, 2020 and 2019, the 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 securities are classified as current or non-current based on each instrument's underlying effective maturity date and for which the Company has the intent and ability to hold the investment for a period of greater than 12 months. Marketable securities with maturities of less than 12 months from the balance sheet date are classified as current and are included in short-term marketable securities in the consolidated balance sheets. Marketable securities with maturities greater than 12 months from the balance sheet date for which we have the intent and ability to hold the investment for greater than 12 months are classified as non-current and are included in long-term marketable securities in the consolidated balance sheets.

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, except for the changes in allowance for expected credit losses, which are recorded in other income (expense), net, within the consolidated statements of operations and comprehensive loss. 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 to determine whether a credit loss exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis.

A credit loss is estimated by considering available information relevant to the collectability of the security and information about past events, current conditions, and reasonable and supportable forecasts. Any credit loss is recorded as a charge to other income (expense), net, not to exceed the amount of the unrealized loss. Unrealized losses other than the credit loss are recognized in accumulated other comprehensive income (loss). When determining whether a credit loss exists, the Company considers several factors, including whether the Company has the intent to sell the security or 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. If the Company has an intent to sell, or if it is more likely than not that the Company will be required to sell a debt security in an unrealized loss position before recovery of its amortized cost basis, the Company will write down the security to its fair value and record the corresponding charge as a component of other income (expense), net. No declines in value were deemed to be credit losses or other than temporary during the years ended December 31, 2020 or 2019, respectively.

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 accredited financial institutions, in amounts that exceed federally insured limits. The Company attempts to minimize the risks related to cash, cash equivalents, and marketable securities by investing in a 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.

Accounts Receivable

Accounts receivable arise from product sales and amounts due from the Company's collaboration partners and have standard payment terms that generally require payment within 30 to 90 days. The amount from product sales represents amounts due from specialty distributors and specialty pharmacies in the U.S., which are recorded net of reserves for customer chargebacks, trade discounts and allowances, and other incentives to the extent such amounts are payable to the customer by the Company. The Company monitors economic conditions to identify facts or circumstances that may indicate that its receivables are at risk of collection. The Company provides reserves against accounts receivable for estimated losses, if any, that may result from a customer's inability to pay based on the composition of its accounts receivable, current economic conditions, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve. During the year ended December 31, 2020, the Company did not record any expected credit losses related to outstanding accounts receivable.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the regulatory approval of its drug candidates, the Company incurs expenses for the manufacture of drug product supplies to support clinical development that could potentially be available to support the commercial launch of those drugs. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses.

The Company performs an assessment of the recoverability of capitalized inventories during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of sales in the Company's consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

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.

Leases

The Company adopted ASC Topic 842, *Leases* (ASC 842), 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.

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.

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, 2020, 2019, or 2018.

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.

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 and drug candidates 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 cancellable, 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. The Company has 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

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 years ended December 31, 2020 and 2019, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities. For the year ended December 31, 2018, 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, 2020, 2019, and 2018. 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.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the

Company does not believe that the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13). The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2020. This standard requires entities to estimate an expected lifetime credit loss on financial assets and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases.

This standard became effective for the Company on January 1, 2020, and adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

3. Revenues

Product Revenues

To date, the Company's only source of product revenues has been from the sales of QINLOCK, which began in May 2020, following the approval of QINLOCK by the FDA on May 15, 2020 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

For the year ended December 31, 2020, product revenues were $39.5 million, which consisted of $38.0 million of revenues in the U.S. and $1.5 million of revenues outside of the U.S.

The Company primarily sells QINLOCK through specialty distributors and specialty pharmacies. The Company recognized revenues from three customers accounting for 57%, 24%, and 10% of gross product revenues for the year ended December 31, 2020. As of December 31, 2020, two customers individually accounted for approximately 59% and 20% of accounts receivable associated with the Company's product sales.

Activity in each of the product revenue allowance and reserve categories is summarized as follows:

(in thousands)	Trade discounts and allowances	Chargebacks and administrative fees	Government rebates and other incentives	Returns	Total
Balance as of December 31, 2019	$ —	$ —	$ —	$ —	$ —
Provision related to sales in the current year	556	1,663	2,923	856	5,998
Credits and payments made	(404)	(1,399)	(490)	(324)	(2,617)
Balance as of December 31, 2020	$ 152	$ 264	$ 2,433	$ 532	$ 3,381

The total reserves described above are summarized as components of the Company's consolidated balance sheets as follows:

(in thousands)	December 31, 2020
Reduction of accounts receivable, net	$ 363
Component of accrued expenses and other current liabilities	3,018
Total revenue-related reserves	$ 3,381

Collaboration Revenues

In June 2019, the Company entered into the Zai License Agreement, pursuant to which the Company granted Zai exclusive rights to develop and commercialize 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 revenues of $2.3 million during the year ended December 31, 2020, which consisted of the achievement of a $2.0 million development milestone in the second quarter of 2020 and $0.3 million in reimbursable costs.

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 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 and commercial 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. Additionally, in the second quarter of 2020, the Company determined that the $2.0 million development milestone was probable of achievement and that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, and constitutes consideration to be included in the transaction of the arrangement. 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 fully recognized in the period.

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.

In February 2020, the Company entered into the Zai Supply Agreement, as required by terms in the Zai License Agreement, pursuant to which the Company will supply the Licensed Products to Zai for use in the Territory for clinical trials as well as commercial inventory, if QINLOCK obtains regulatory approval in the Territory. Subject to the Zai Supply Agreement, costs incurred by the Company for external manufacturing services are reimbursed by Zai.

Under the Zai Supply Agreement, the Company recognized revenues of $0.4 million for external manufacturing services provided during the year ended December 31, 2020.

4. Marketable Securities and Fair Value Measurements

The following tables present marketable securities by contractual maturity and security type:

As of December 31, 2020 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
U.S. government securities	$ 298,335	$ 49	$ (1)	$ 298,383
Commercial paper	62,037	9	(15)	62,031
Corporate debt securities	38,309	—	(34)	38,275
Certificates of deposit	17,344	1	(1)	17,344
Due after one year through five years:				
U.S. government securities	9,370	5	—	9,375
Total	$ 425,395	$ 64	$ (51)	$ 425,408

As of December 31, 2019 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	$ 314,292	$ 74	$ (23)	$ 314,343
U.S. government securities	78,612	48	(3)	78,657
Certificates of deposit	66,241	17	(2)	66,256
Total	$ 459,145	$ 139	$ (28)	$ 459,256

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, 2020 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 46,676	$ —	$ 46,676
U.S. government securities	—	30,000	—	30,000
Marketable securities:				
U.S. government securities	—	307,758	—	307,758
Commercial paper	—	62,031	—	62,031
Corporate debt securities	—	38,275	—	38,275
Certificates of deposit	—	17,344	—	17,344
Total	$ —	$ 502,084	$ —	$ 502,084

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

The tables above exclude certificates of deposit of $3.1 million and $1.5 million as of December 31, 2020 and December 31, 2019, respectively, that the Company held to secure a letter of credit associated with its leases and to secure a credit card account. The Company increased its credit card limit and corresponding certificate of deposit in the first quarter of 2020. The Company also increased its letter of credit and corresponding certificate of deposit associated with its leases in the fourth quarter of 2020. The certificates of deposit are Level 2 instruments and are measured at carrying value in the consolidated balance sheets in long-term investments—restricted and approximate fair value. For additional information on the letter of credit associated with the Company's leases, please read Note 7, *Leases*, to these consolidated financial statements.

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. Inventory

The Company commenced the capitalization of QINLOCK inventory in May 2020 upon receiving FDA approval of QINLOCK.

Capitalized inventory consisted of the following:

(in thousands)	December 31, 2020
Raw materials	$ 1,352
Work in process	4,142
Finished goods	222
Total inventory	$ 5,716

There were no inventory amounts written down as a result of excess, obsolescence, unmarketability, or other reasons charged to cost of sales during the year ended December 31, 2020.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2020	December 31, 2019
Laboratory equipment	$ 3,631	$ 2,195
Computer equipment	4,795	2,950
Furniture and fixtures	3,187	1,941
Leasehold improvements	1,895	908
Construction in progress	197	169
Total cost	13,705	8,163
Less: Accumulated depreciation	(4,122)	(1,830)
Total property and equipment, net	$ 9,583	$ 6,333

Depreciation expense was $2.3 million, $0.8 million, and $0.3 million for the years ended December 31, 2020, 2019, and 2018, respectively.

7. Leases

The Company leases real estate, including office and laboratory space.

In May 2018, the Company entered into a lease for office space (the Initial 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. In October 2019, the lease for the Initial Space commenced under ASC 842 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 in October 2019.

Prior to the adoption of ASC 842, the Company was deemed to be the owner of the Initial 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 Initial Space) as construction-in-progress within property and equipment, net and recorded a corresponding build-to-suit facility lease financing obligation. Under ASC 842, the Company was no longer considered the owner of the Initial Space and therefore the build-to suit asset and corresponding liabilities at December 31, 2018 were reversed as of the date of adoption of ASU 2016-02 on January 1, 2019 as the lease commencement date had not yet been met.

In April 2019, the Company amended its lease for office space at the Premises to add an additional 38,003 square feet of space (the Additional Space) for a total of 82,346 square feet of space. 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. In July 2020, the lease for the Additional Space commenced under ASC 842 and resulted in the addition of an operating lease asset of $16.5 million and a corresponding lease liability of $13.5 million in the third quarter of 2020.

The Company is required to maintain a letter of credit associated with its leases at the Premises. The balances of the Company's certificate of deposit associated with the letter of credit for its leases at the Premises of $2.1 million and $1.1 million as of December 31, 2020 and 2019, respectively, were classified as long-term investment—restricted in the consolidated balance sheets. The Company increased the letter of credit and associated certificate of deposit by $1.0 million pursuant to the terms of the lease agreement for the Additional Space during the fourth quarter of 2020.

In August 2020, the Company amended and restated its real estate leases primarily for office and laboratory space in Lawrence, Kansas (the 2020 Lawrence Lease Agreements). The initial term of the 2020 Lawrence Lease Agreements will expire on December 31, 2030 unless terminated earlier in accordance with the terms of the lease and the Company is entitled to two five-year options to extend the leases. The 2020 Lawrence Lease Agreements modified a previously existing operating lease which resulted in an additional operating lease asset of $1.4 million and a corresponding lease liability of $1.4 million during the third quarter of 2020. Additionally, as a result of the 2020 Lawrence Lease Agreements, some previously existing operating leases

terminated as of December 31, 2020. The Company expects that additional new operating leases associated with additional lease space included in the 2020 Lawrence Lease Agreements will commence under ASC 842 in 2021.

The Company's leases contain options to extend the lease terms; however, these extensions were not included in the operating lease assets and lease liabilities recorded on the consolidated balance sheets as they were not reasonably certain of being exercised.

During the years ended December 31, 2020 and 2019, the Company was subject to certain lease agreements to accommodate short-term or temporary needs. The expenses related to the Company's short-term or temporary lease agreements are included in short-term lease costs for the years ended December 31, 2020 and 2019, as applicable.

The Company's leases require the Company to pay for its share of certain operating expenses, taxes, and other 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 years ended December 31, 2020 and 2019. Payment escalations specified in the leases 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:

	December 31,	
(in thousands)	**2020**	**2019**
Operating lease assets	$ 36,341	$ 21,158
Current operating lease liabilities	$ 2,457	1,747
Operating lease liabilities, net of current portion	28,764	15,904
Total operating lease liabilities	$ 31,221	$ 17,651

The components of lease expense were as follows:

	Year Ended December 31,	
(in thousands)	**2020**	**2019**
Operating lease cost	$ 4,167	$ 1,223
Short-term lease cost	354	520
Variable lease cost	461	427
Total lease expense	$ 4,982	$ 2,170

Additionally, as previously disclosed in the Company's 2018 Form 10-K and under the previous lease accounting standard, ASC 840, *Leases,* the Company recorded rent expense of $1.1 million during the year ended December 31, 2018.

Future annual minimum lease payments under operating leases are as follows:

(in thousands)	**As of December 31, 2020**
2021	$ 4,143
2022	4,225
2023	4,308
2024	4,390
2025	4,472
Thereafter	18,520
Total future minimum lease payments	40,058
Less: imputed interest	(8,837)
Total operating lease liabilities	$ 31,221

The weighted-average remaining lease term and weighted-average discount rate of the Company's operating leases are as follows:

	As of December 31,	
	2020	2019
Weighted-average remaining lease term in years	8.97	9.63
Weighted-average discount rate	5.60 %	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:

	Year Ended December 31,	
(in thousands)	2020	2019
Cash paid for amounts included in the measurement of operating lease liabilities	$ 2,666	$ 532
Operating lease liabilities arising from obtaining operating lease assets	$ 14,902	$ 17,144

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
(in thousands)	2020	2019
External research and development expenses	$ 31,259	$ 20,462
Payroll and related expenses	17,255	12,902
Professional fees	3,306	3,810
Revenue-related reserves	3,018	—
Other	389	1,542
Total accrued expenses and other current liabilities	$ 55,227	$ 38,716

9. 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.

In August 2020, the Company entered into the Sales Agreement with Jefferies, pursuant to which the Company may issue and sell shares of its common stock in "at-the-market" offerings having aggregate offering proceeds of up to $200.0 million from time to time through Jefferies as its sales agent. During the year ended December 31, 2020, the Company issued 294,275 shares

resulting in net proceeds of $17.9 million under the Sales Agreement. As of December 31, 2020, there was up to $181.3 million available for future issuance under the Sales Agreement. For additional information on the Sales Agreement, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements.

10. 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, 2020, 1,828,021 remained available for issuance under the 2017 Plan. The number of shares reserved for issuance under the 2017 Plan was increased by 2,303,845 shares effective January 1, 2021.

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, 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, 2020, 1,372,135 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, 2021.

The purchase price of common stock under the ESPP is equal to 85% of the lesser of (i) the fair market value per share of the common stock on the first business day of an offering period and (ii) the fair market value per share of the common stock on the purchase date. The fair value of the discounted purchases made under the ESPP is calculated using the Black-Scholes option-pricing model, which is described in further detail within the "Stock Option Valuation" section below, on the date of the first day of the offering period. The fair value of the look-back provision plus the 15% discount is recognized as stock-based compensation expense in the consolidated statements of operations and comprehensive loss over the 6-month purchase period. Employees began participating in the ESPP program during the first offering period of the ESPP program in the second quarter of 2020. There were 37,298 shares of common stock issued under the ESPP during the year ended December 31, 2020.

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 as well as the limited historical 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. 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,		
	2020	2019	2018
Risk-free interest rate	1.2 %	2.2 %	2.8 %
Expected term (in years)	6.1	6.2	6.1
Expected volatility	77.2 %	74.5 %	73.3 %
Expected dividend yield	0 %	0 %	0 %

The following table summarizes the Company's option activity from January 1, 2020 to December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	6,750,939	$ 19.36		
Granted	1,331,148	$ 54.79		
Exercised	(1,881,892)	$ 9.96		
Forfeited/Expired	(487,856)	$ 33.27		
Outstanding as of December 31, 2020	5,712,339	$ 29.53	7.8	$ 158,204
Options vested and expected to vest as of December 31, 2020	5,712,339	$ 29.53	7.8	$ 158,204
Options exercisable as of December 31, 2020	2,873,038	$ 20.60	7.1	$ 104,889

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, 2020, 2019, and 2018 was $86.0 million, $53.2 million, and $4.4 million, respectively.

The weighted average grant-date fair value per share of options granted during the years ended December 31, 2020, 2019, and 2018 was $36.71, $19.22, and $19.68, respectively.

Restricted Stock Units

The 2017 Plan provides for the award of restricted stock units. During the years ended December 31, 2020, 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 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 was contingent upon meeting a specific performance obligation and continued employment through the service period. The performance criteria associated with the performance-based restricted stock units became probable and was achieved during the second quarter of 2020. As a result, 55,200 performance-based restricted units at a weighted average grant date fair value of $34.43 vested during 2020 and the fair value of the performance-based restricted units that vested during 2020 was $3.6 million. 2,200 performance-based restricted units at a weighted average grant date fair value of $34.43 were forfeited during 2020. The Company granted no performance-based restricted units in 2020 or 2018. As of December 31, 2020, there were no unvested performance-based restricted units.

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 table below summarizes the Company's time-based restricted stock unit activity from January 1, 2020 to December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2019	99,500	$ 29.58
Granted	426,155	$ 51.74
Vested	(50,750)	$ 28.93
Forfeited	(36,280)	$ 52.66
Unvested at December 31, 2020	438,625	$ 49.28

The fair value of time-based restricted stock units that vested during the years ended December 31, 2020 and 2019 were $2.3 million and $0.5 million, respectively. No restricted stock units vested during the year ended December 31, 2018.

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)	**2020**	**2019**	**2018**
Research and development	$ 17,443	$ 7,934	$ 4,021
Selling, general, and administrative	19,694	12,476	5,667
Total stock-based compensation	$ 37,137	$ 20,410	$ 9,688

The following table summarizes share-based compensation expense associated with each of our share-based compensation arrangements:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Stock options	$ 29,925	$ 19,328	$ 9,578
Time-based restricted stock units	4,424	1,082	110
Performance-based restricted stock units	1,907	—	—
Employee stock purchase plan	881	—	—
Total stock-based compensation expense	$ 37,137	$ 20,410	$ 9,688

As of December 31, 2020, total unrecognized compensation cost related to the unvested share-based awards was $85.0 million, which is expected to be recognized over a weighted average of 2.5 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.

11. 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.

Total employer matching contributions related to the 2018 401(k) Plan were $2.3 million, $0.9 million, and $0.4 million for the years ended December 31, 2020, 2019, and 2018, respectively.

12. 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 period. 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 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 anti-dilutive. The Company reported a net loss for during each of the periods presented.

Basic and diluted net loss per share was calculated as follows:

	Year Ended December 31,		
(in thousands, except share and per share amounts)	**2020**	**2019**	**2018**
Numerator:			
Net loss	$ (266,489)	$ (192,256)	$ (99,854)
Denominator:			
Weighted average common shares outstanding—basic and diluted	55,780,982	42,869,058	35,390,480
Net loss per share—basic and diluted	$ (4.78)	$ (4.48)	$ (2.82)

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,		
	2020	**2019**	**2018**
Options to purchase common stock	5,712,339	6,750,939	5,787,151
Unvested restricted stock units	438,625	156,900	25,000
Unvested employee stock purchase plan shares	30,826	—	—
Total	6,181,790	6,907,839	5,812,151

13. Income Taxes

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).

Prior to the Conversion on October 2, 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 2, 2017 or for earned research and orphan drug credits as the operating losses incurred by the Company had been passed through to its members. Upon consummation of the Conversion on October 2, 2017, the Company became subject to Corporate U.S. federal and state income taxes.

During the years ended December 31, 2020, 2019, and 2018, the Company reported net losses, and as a result, recorded no income tax benefits for the net operating losses (NOLs), 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,		
	2020	2019	2018
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	2.4	7.0	6.1
Research and orphan drug credit	2.1	5.4	9.6
Stock-based compensation	5.4	4.7	0.7
Permanent adjustments and other	0.5	(0.9)	—
Increase in deferred tax asset valuation allowance	(31.4)	(37.2)	(37.4)
Effective income tax rate	— %	— %	— %

During 2020, the Company completed a detailed study of its research and development and orphan drug credits. As a result, the Company adjusted its deferred tax asset balances and the impacts are included in the research and orphan drug credit line in the effective rate reconciliation above. The impacts of the decreases in the deferred tax asset balances have been completely offset by a decrease in the Company's valuation allowance which is included in the increase in deferred tax asset valuation allowance line in the reconciliation above.

Net deferred tax assets consisted of the following:

	December 31,	
(in thousands)	2020	2019
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 159,192	$ 85,632
Research and orphan drug credit carryforwards	31,142	25,267
Stock-based compensation	8,928	5,535
Accrued expenses	3,779	2,951
Operating lease liabilities	9,321	5,841
Property and equipment	(387)	—
Operating lease assets	(8,811)	(5,515)
Other	16	(64)
Total gross deferred tax assets	203,180	119,647
Valuation allowance	(203,180)	(119,647)
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 NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely).

Further, on March 27, 2020, the previous U.S. President signed into law the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) in response to the U.S. COVID-19 pandemic, which, among other things, suspends the 80% limitation on the deduction for NOLs in taxable years beginning before January 1, 2021, permits a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. In addition, the CARES Act raises the corporate charitable deduction limit to 25% of taxable income and makes qualified improvement property generally eligible for 15-year cost-recovery and 100% bonus depreciation. The enactment of the CARES Act did not result in any material adjustments to the Company's income tax provision for the year ended December 31, 2020, or to its net deferred tax assets and related allowances as of December 31, 2020.

The change in the valuation allowance was as follows:

	Year Ended December 31,	
(in thousands)	2020	2019
Valuation allowance as of beginning of year	$ (119,647)	$ (48,191)
Net increases recorded to income tax provision	(83,533)	(71,456)
Valuation allowance as of end of year	$ (203,180)	$ (119,647)

As of December 31, 2020, the Company had NOL carryforwards for federal income tax purposes of $643.6 million, of which $16.6 million begin to expire in 2037 and $627.0 million may be carried forward indefinitely. As of December 31, 2020, the Company had NOL carryforwards for state income tax purposes of $479.2 million, which begin to expire in 2037. As of December 31, 2020, the Company also had available research and orphan drug credit carryforwards for federal and state income tax purposes of $28.8 million and $3.0 million, respectively, which begin to expire in 2037 and 2032, respectively. Utilization of the NOL 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 could occur in the future.

These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. If the Company experiences 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 NOL 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 NOL 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 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, 2020. 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, 2020. 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, 2020 and 2019, 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.

14. Commitments and Contingencies

Purchase Commitments Associated with Commercial Supply Agreements

The Company has entered into commercial supply agreements related to the supply of QINLOCK that require the Company to make binding forecasts for a certain amount of purchases. The related cancellation clauses would as a general matter require the Company to pay the full amount of these binding forecasts. As of December 31, 2020, the Company's contractual commitments for its commercial supply agreements were $8.8 million, of which $7.0 million is expected to be paid within one year and $1.8 million is expected to be paid between one and three years. During the year ended December 31, 2020, the Company made $3.7 million of payments for purchases associated with its commercial supply agreements.

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, 2020 or 2019.

15. 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, 2020	Sep 30, 2020	Jun 30, 2020	Mar 31, 2020	Dec 31, 2019	Sep 30, 2019	Jun 30, 2019	Mar 31, 2019
Statements of Operations Data:								
Revenues	$ 19,486	$ 15,449	$ 7,090	$ 62	$ —	$ —	$ 25,000	$ —
Gross profit [1]	19,359	15,359	7,082	62	—	—	25,000	—
Loss from operations	(62,999)	(63,997)	(68,932)	(75,262)	(70,373)	(58,353)	(22,975)	(49,025)
Net loss	(62,740)	(63,701)	(67,241)	(72,807)	(67,216)	(56,196)	(21,460)	(47,384)
Net loss per share—basic and diluted	$ (1.10)	$ (1.13)	$ (1.20)	$ (1.36)	$ (1.31)	$ (1.28)	$ (0.56)	$ (1.25)

(1) Gross profit is calculated as total revenues less cost of sales.

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, 2020. 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 provide reasonable assurance 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 provide reasonable assurance 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, 2020, 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 internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP. 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, 2020, our internal control over financial reporting was effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their audit report, which is included herein.

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, 2020 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 2021 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 2021 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 2021 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 2021 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 2021 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 Stockholders' Equity
- 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 3.1 to the Registrant's Current Report on Form 8-K filed on June 12, 2020)
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 (Incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K filed on March 9, 2020)
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 (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#	Form of Incentive Stock Option Agreement under 2017 Stock Option and Incentive Plan.

Exhibit Number	Description
10.4#	Form of Non-Qualified Stock Option Agreement for Company Employees under 2017 Stock Option and Incentive Plan.
10.5#	Form of Restricted Stock Unit Award Agreement for Company Employees under 2017 Stock Option and Incentive Plan.
10.6#	Form of Non-Qualified Stock Option Agreement for Non-U.S. Optionees under 2017 Stock Option and Incentive Plan.
10.7#	Form of Restricted Stock Unit Award Agreement for Non-U.S. Grantees under 2017 Stock Option and Incentive Plan.
10.8#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under 2017 Stock Option and Incentive Plan.
10.9#*	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).
10.10#*	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).
10.11#*	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).
10.12#*	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).
10.13#*	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).
10.14#*	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).
10.15#*	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).
10.16#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Thomas P. Kelly (Incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 10-K filed on March 14, 2019)
10.16(a)#	Amendment No. 1 to Employment Agreement, between Deciphera Pharmaceuticals, LLC and Thomas P. Kelly
10.17#	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn
10.17(a)#	Amendment No. 1 to Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn
10.18#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Matthew L. Sherman (Incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 10-K filed on March 9, 2020)
10.19#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel C. Martin (Incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 10-K filed on March 14, 2019)
10.20#	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Stephen Ruddy
10.21#*	Deciphera Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 5, 2020)
10.22#*	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).

Exhibit Number	Description
10.23*	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).
10.23(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 (Incorporated by reference to Exhibit 10.11(a) to the Registrant's Annual Report on Form 10-K filed on March 19, 2019).
10.23(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 (Incorporated by reference to Exhibit 10.11(a) to the Registrant's Annual Report on Form 10-K filed on March 19, 2019).
10.23(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).
10.24*	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)
10.25*	Letter Agreement, made as of January 17, 2020, 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 May 5, 2020)
10.26*	Commercial Manufacturing Services and Supply Agreement, made as of April 3, 2019, by and between Deciphera Pharmaceuticals, LLC and Lonza (2) (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2020)
10.27*	Supply Agreement, made as of February 28, 2020, by and between Deciphera Pharmaceuticals, LLC and Cambrex (2) (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2020)
10.28*	Open Market Sale Agreement℠, dated August 4, 2020, by and between Deciphera Pharmaceuticals, Inc. and Jefferies LLC. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 4, 2020)
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.
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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

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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.

(2) Portions of this exhibit (indicated by asterisk) have been omitted in accordance with the rules of the Securities and Exchange Commission.

† 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: February 9, 2021

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)	February 9, 2021
/s/ Thomas P. Kelly Thomas P. Kelly	Chief Financial Officer (Principal Financial and Accounting Officer)	February 9, 2021
/s/ Patricia L. Allen Patricia L. Allen	Director	February 9, 2021
/s/ Edward J. Benz, Jr., M.D. Edward J. Benz, Jr., M.D.	Director	February 9, 2021
/s/ James A. Bristol, Ph.D. James A. Bristol, Ph.D.	Director	February 9, 2021
/s/ Frank S. Friedman Frank S. Friedman	Director	February 9, 2021
/s/ Susan L. Kelley, M.D. Susan L. Kelley, M.D.	Director	February 9, 2021
/s/ John R. Martin John R. Martin	Director	February 9, 2021
/s/ Ron Squarer Ron Squarer	Director	February 9, 2021
/s/ Michael D. Taylor, Ph.D. Michael D. Taylor, Ph.D.	Director	February 9, 2021
/s/ Dennis L. Walsh Dennis L. Walsh	Director	February 9, 2021

FORM OF INCENTIVE STOCK OPTION AGREEMENT UNDER THE DECIPHERA PHARMACEUTICALS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

Grant Date:

Expiration Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.01 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall vest and become exercisable with respect to the following number of Option Shares on the dates indicated; provided that the Optionee continues to have a Service Relationship at such time. For purposes of this Agreement, "Vesting Commencement Date" shall mean .

[INSERT VESTING SCHEDULE]

***** If an Option Shares Exercisable vesting tranche is -0-, you have reached the ISO $100,000 vesting limit in the calendar year. You will receive a corresponding Non-Qualified Stock Option in a separate agreement.

[#] If Vest Type equals "Monthly," the number of shares shown as exercisable will vest ratably per month from the previous date exercisable until the final date exercisable.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

The vesting of this Stock Option shall accelerate in full if, on or within 12 months following, the consummation of a Change in Control Event, the Optionee's Service Relationship

with the Company, any Subsidiary or the acquiring or succeeding entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause.

"Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee, willful misconduct by the Optionee or willful failure by the Optionee to perform his or her responsibilities to the Company or any Subsidiary (including, without limitation, breach by the Optionee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Optionee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Optionee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Optionee's resignation, that termination for Cause was warranted.

"Change in Control Event" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a "Person") of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a "Sale"), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns

the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the "Acquiring Entity") in substantially the same proportions as their ownership of the equity or membership interest in the Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A-3(i)(5).

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) to the extent permitted by the Administrator, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; or (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full

purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares of Stock attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Service Relationship. If the Optionee's Service Relationship is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee's Service Relationship terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination, may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that

is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

(a) Termination for Cause. If the Optionee's Service Relationship terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect.

(c) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, the Optionee's disability, or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's Service Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Status of the Stock Option. This Stock Option is intended to qualify as an “incentive stock option” under Section 422 of the Internal Revenue Code of 1986, as amended (the “Code”), but the Company does not represent or warrant that this Stock Option qualifies as such. The Optionee should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. To the extent any portion of this Stock Option does not so qualify as an “incentive stock option,” such portion shall be deemed to be a non-qualified stock option. If the Optionee intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Option Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will so notify the Company within 30 days after such disposition.

7. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any

Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

8. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Optionee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[Remainder of page intentionally left blank.]

DECIPHERA PHARMACEUTICALS, INC.

By:
Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated:

Optionee's Signature

Optionee's name and address:

FORM OF NON-QUALIFIED STOCK OPTION AGREEMENT FOR COMPANY EMPLOYEES UNDER DECIPHERA PHARMACEUTICALS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

Grant Date:

Expiration Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.01 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall vest and become exercisable with respect to the following number of Option Shares on the dates indicated; provided that the Optionee continues to have a Service Relationship at such time. For purposes of this Agreement, "Vesting Commencement Date" shall mean .

[INSERT VESTING SCHEDULE]

[#] If Vest Type equals "Monthly," the number of shares shown as exercisable will vest ratably per month from the previous date exercisable until the final date exercisable.

If the Non-Qualified ("NQ") option is a "sister" grant to an Incentive Stock Option ("ISO") due to the IRS ISO grant limitations being exceeded, the vesting schedule applies cumulatively to the combined ISO and NQ grant.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

The vesting of this Stock Option shall accelerate in full if, on or within 12 months following, the consummation of a Change in Control Event, the Optionee's Service Relationship with the Company, any Subsidiary or the acquiring or succeeding entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause.

"Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee, willful misconduct by the Optionee or willful failure by the Optionee to perform his or her responsibilities to the Company or any Subsidiary (including, without limitation, breach by the Optionee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Optionee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Optionee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Optionee's resignation, that termination for Cause was warranted.

"Change in Control Event" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a "Person") of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a "Sale"), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to

direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the "Acquiring Entity") in substantially the same proportions as their ownership of the equity or membership interest in the Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A-3(i)(5).

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) to the extent permitted by the Administrator, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a

combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares of Stock attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Service Relationship. If the Optionee's Service Relationship is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee's Service Relationship terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination, may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Service Relationship terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect.

(d) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, the Optionee's disability or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's Service Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

7. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Optionee at any time.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[Remainder of page intentionally left blank.]

DECIPHERA PHARMACEUTICALS, INC.

By:
Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____

Optionee's Signature

Optionee's name and address:

FORM OF RESTRICTED STOCK UNIT AWARD AGREEMENT FOR COMPANY EMPLOYEES UNDER DECIPHERA PHARMACEUTICALS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Grantee:

No. of Restricted Stock Units:

Grant Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.01 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in a Service Relationship on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

[INSERT VESTING SCHEDULE]

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service. If the Grantee's Service Relationship terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

Notwithstanding the foregoing, the vesting of the Restricted Stock Units shall accelerate in full if, on or within 12 months following, the consummation of a Change in Control Event, the Grantee's Service Relationship with the Company, any Subsidiary or the acquiring or succeeding

entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause.

"Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Grantee, willful misconduct by the Grantee or willful failure by the Grantee to perform his or her responsibilities to the Company or any Subsidiary (including, without limitation, breach by the Grantee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Grantee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Grantee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Grantee's resignation, that termination for Cause was warranted.

"Change in Control Event" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Grantee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a "Person") of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a "Sale"), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns

the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the "Acquiring Entity") in substantially the same proportions as their ownership of the equity or membership interest in the Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A3(i)(5).

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding; Mandatory Sell to Cover. In connection with the settlement of vested Restricted Stock Units, the Company shall issue the shares of Stock referred to in Paragraph 4 to a broker designated by the Company and acting on behalf and for the account of the Grantee with instructions to (i) sell a number of shares of such Stock sufficient to satisfy the applicable withholding taxes which arise in connection with such settlement; provided, that the amount sold does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment, along with any applicable third-party commission, and (ii) remit the proceeds of such sale to the Company. In the event the sale proceeds are insufficient to fully satisfy the applicable withholding taxes, the Grantee authorizes withholding from payroll and any other amounts payable to the Grantee, in the same calendar year, and otherwise agrees to make adequate provision through the submission of cash, a check or its equivalent for any sums required to satisfy the applicable withholding taxes. Unless the

withholding tax obligations of the Company and/or any Affiliate thereof are satisfied, the Company shall have no obligation to issue any shares of Stock on the Grantee's behalf pursuant to the vesting of the Restricted Stock Units.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

8. No Obligation to Continue Service. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee's Service Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Grantee's Service Relationship at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[Remainder of page intentionally left blank]

DECIPHERA PHARMACEUTICALS, INC.

By:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

Grantee's Signature

Grantee's name and address:

Address:

FORM OF NON-QUALIFIED STOCK OPTION AGREEMENT FOR NON-U.S. OPTIONEES UNDER DECIPHERA PHARMACEUTICALS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

Grant Date:

Expiration Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.01 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein this Non-Qualified Stock Option Agreement for Non-U.S. Optionees, including the additional terms and conditions for certain countries, as set forth in the appendix attached hereto (the "Appendix" and, together, the "Agreement") and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the U.S. Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall vest and become exercisable with respect to the following number of Option Shares on the dates indicated; provided that the Optionee continues to have a Service Relationship at such time. For purposes of this Agreement, "Vesting Commencement Date" shall mean .

[INSERT VESTING SCHEDULE]

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

The vesting of this Stock Option shall accelerate in full if, on or within 12 months following, the consummation of a Change in Control Event, the Optionee's Service Relationship with the Company, any Subsidiary or the acquiring or succeeding entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause.

“Cause” shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee, willful misconduct by the Optionee or willful failure by the Optionee to perform his or her responsibilities to the Company or any Subsidiary (including, without limitation, breach by the Optionee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Optionee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Optionee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Optionee's resignation, that termination for Cause was warranted.

“Change in Control Event” shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a “Person”) of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a “Sale”), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the “Acquiring Entity”) in substantially the same proportions as their ownership of the equity or membership interest in the

Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A-3(i)(5).

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) to the extent permitted by the Administrator, through the delivery (or attestation to the ownership) or shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full

purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares of Stock attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Service Relationship. If the Optionee's Service Relationship is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee's Service Relationship terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination, may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that

is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Service Relationship terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect.

(d) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, the Optionee's disability or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

For the avoidance of doubt, for purposes of this Section 3, the Optionee's service during any portion of a vesting period will not entitle the Optionee to vest in a pro rata portion of the Stock Option if the Optionee's Service Relationship terminates prior to the next vesting date.

For purposes of this Stock Option, the Optionee's Service Relationship will be deemed terminated as of the date the Optionee is no longer actively providing services to the Company or any Subsidiary (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Optionee is providing service or the terms of the Optionee's employment or service agreement, if any) and such date will not be extended by any notice period (*e.g.*, the Optionee's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where the Optionee is providing service or the terms of the Optionee's employment or service agreement, if any). The Company shall have the exclusive discretion to determine when the Optionee is no longer actively providing services for purposes of this Stock Option (including whether the Optionee may still be considered to be providing services while on a leave of absence).

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Responsibility for Taxes.

(a) The Optionee acknowledges and agrees that, regardless of any action taken by the Company or, if different, the Subsidiary to which the Optionee is providing services (the "Employer"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to the Optionee's participation in the Plan and legally applicable or deemed applicable to the Optionee ("Tax-Related Items") is and remains the Optionee's responsibility and may exceed the amount, if any, actually withheld by the Company or the Employer. The Optionee further acknowledges that the Company and/or the Employer (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Stock Options or the underlying shares of Stock, including, but not limited to, the grant, vesting or exercise of the Stock Options, or the subsequent sale of shares of Stock purchased at exercise and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Stock Options to reduce or eliminate the Optionee's liability for Tax-Related Items or achieve any particular tax result. Further, if the Optionee is subject to Tax-Related Items in more than one jurisdiction, the Optionee acknowledges that the Company and/or the Employer (or former service recipient, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Prior to any relevant taxable or tax withholding event, as applicable, the Optionee agrees to make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items. In this regard, the Optionee authorizes the Company and/or the Employer, or their respective agents, at their discretion, to satisfy any applicable withholding obligations with regard to all Tax-Related Items by one or a combination of the following: (i) withholding from the Optionee's salary, wages or other compensation payable to the Optionee by the Company and/or the Employer, (ii) withholding from proceeds of the sale of the shares of Stock underlying the Stock Options either through a voluntary sale or through a broker-assisted "same day sale" arranged by the Company (on the Optionee's behalf pursuant to this authorization without further consent), (iii) requiring the Optionee to make a payment in cash, (iv) withholding from shares of Stock otherwise deliverable to the Optionee, provided that if the Optionee is a Section 16 officer of the Company under the Exchange Act, then the Company will withhold from proceeds of the sale of shares of Stock acquired upon exercise of the Stock Option or (v) any method determined by the Administrator to be in compliance with applicable laws.

(c) The Company and/or the Employer may withhold or account for Tax-Related Items by considering statutory or other applicable withholding rates, including minimum or maximum rates applicable in the Optionee's jurisdiction(s), provided that in the case of shares of Stock being withheld, the rate used is consistent with the Stock Option being subject to equity account treatment. In the event of over-withholding, the Optionee may receive a refund of any over-withheld amount in cash

(with no entitlement to the equivalent in shares of Stock), or if not refunded, the Optionee may seek a refund from local tax authorities. In the event of under-withholding, the Optionee may be required to pay any additional Tax-Related Items directly to the applicable tax authority or to the Company and/or the Employer.

(d) The Optionee agrees to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold or account for as a result of the Optionee's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue or deliver the shares of Stock or the proceeds of the sale of the shares of Stock acquired upon exercise of the Stock Options, if the Optionee fails to comply with his or her obligations in connection with the Tax-Related Items

7. Nature of Grant. By accepting the Stock Option, the Optionee acknowledges, understands, and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and may be amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the Stock Option is exceptional, voluntary and occasional and does not create any contractual or other right to receive future grants of stock options, the same number of stock options, or benefits in lieu of stock options, even if stock options or a certain number of stock options have been granted in the past;

(c) all decisions with respect to future stock option or other grants, if any, will be at the sole discretion of the Company;

(d) the Optionee is voluntarily participating in the Plan;

(e) the Stock Option and any Stock subject to the Stock Option, and the income from and value of same, are not intended to replace any pension rights or compensation;

(f) unless otherwise agreed with the Company, the Stock Option and the Stock subject to the Stock Option, and the income from and value of same, are not granted as consideration for, or in connection with, the service the Optionee may provide as a director of a Subsidiary;

(g) the Stock Option and any shares of Stock subject to the Stock Option, and the income from and value of same, are not part of normal or expected compensation for any purpose, including, without limitation to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, holiday pay, pension or retirement or welfare benefits or similar mandatory payments;

(h) the future value of the shares of Stock underlying the Stock Option is unknown, indeterminable, and cannot be predicted with certainty;

(i) if the underlying shares of Stock subject to the Stock Option do not increase in value, the Stock Option will have no value;

(j) if the Optionee exercises the Stock Option and acquires shares of Stock, the value of such Stock may increase or decrease, even below the Option Exercise Price per Share;

(k) no claim or entitlement to compensation or damages shall arise from forfeiture of the Stock Option resulting from the termination of the Optionee's Service Relationship (for any reason whatsoever, whether or not later found to be invalid or in breach of labor laws in the jurisdiction where the Optionee is employed or otherwise rendering services or the terms of the Optionee's employment or service agreement, if any);

(l) unless otherwise provided in the Plan or by the Company in its discretion, the Stock Option and the benefits evidenced by this Agreement do not create any entitlement to have the Stock Option or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the shares of Stock; and

(m) neither the Company, the Employer nor any other Subsidiary shall be liable for any foreign exchange rate fluctuation between the Optionee's local currency and the U.S. dollar that may affect the value of the Stock Option or of any amounts due to the Optionee pursuant to the exercise of the Stock Option or the subsequent sale of any shares of Stock acquired upon exercise.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. ***The Company and the Employer hold certain personal information about the Optionee, including, but not limited to, the Optionee's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of Stock or directorships held in the Company, details of all Stock Option or any other entitlement to shares of Stock awarded, canceled, exercised, vested, unvested or outstanding in the Optionee's favor ("Data").***

The Optionee hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of the Optionee's Data as described in this Agreement and any other Stock Option grant materials by and among, as applicable, the Employer, the Company and its other Subsidiaries for the exclusive purpose of implementing, administering and managing the Optionee's participation in the Plan

For Optionees residing in the EU/EEA and United Kingdom, the processing of Optionee's data is exclusively performed in accordance with the Data Privacy Notice as set out in the Appendix below. In the latter case, the Company relies on the legal basis that the processing of the Optionee's Data is necessary (i) in order to take steps for entering into or the performance of this Agreement and other contractual obligations in connection with Stock Options and (ii) for the Company's legitimate business interests of managing the Plan and generally administering employee equity awards.

The Optionee understands that Data will be transferred to [INSERT] ("[PROVIDER]"), or such other stock plan service provider as may be selected by the Company in the future, which is assisting the Company with the implementation, administration and management of the Plan. The Optionee understands that the recipients of the Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than the Optionee's country. The Optionee acknowledges that the Company, PROVIDER and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan will process the Data, in electronic or other form, for the sole purpose of implementing, administering and managing the Optionee's participation in the Plan.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

11. Governing Law and Venue. The Stock Option grant and the provisions of this Agreement are governed by, and subject to, the laws of the State of Delaware, without regard to the conflict of law provisions, as provided in the Plan. For purposes of litigating any dispute that arises under this grant or the Agreement, the parties hereby submit to and consent to the jurisdiction of the Commonwealth of Massachusetts, agree that such litigation shall be conducted in the courts of Middlesex County, Massachusetts or the federal courts for the United States for the District of Massachusetts, where this grant is made and/or to be performed.

12. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding the Optionee's participation in the Plan, or the Optionee's acquisition or sale of the underlying shares of Stock. The Optionee should consult with his or her own personal tax, legal and financial advisors regarding the Optionee's participation in the Plan before taking any action related to the Plan.

13. Compliance with Law. Notwithstanding any other provision of the Plan or this Agreement, unless there is an exemption from any registration, qualification or other legal requirement applicable to the shares of Stock, the Company shall not be required to deliver any shares of Stock issuable upon exercise of this Stock Option prior to the completion of any registration or qualification of the shares under any local, state, federal or foreign securities or exchange control law or under rulings or regulations of the U.S. Securities and Exchange Commission ("SEC") or of any other governmental regulatory body, or prior to obtaining any

approval or other clearance from any local, state, federal or foreign governmental agency, which registration, qualification or approval the Company shall, in its absolute discretion, deem necessary or advisable. The Optionee understands that the Company is under no obligation to register or qualify the Stock with the SEC or any state or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the shares of Stock. Further, the Optionee agrees that the Company shall have unilateral authority to amend the Agreement without the Optionee's consent to the extent necessary to comply with securities or other laws applicable to the issuance of shares of Stock.

14. Language. The Optionee acknowledges that he or she is sufficiently proficient in English, or has consulted with an advisor who is sufficiently proficient in English, so as to allow the Optionee to understand the terms and conditions of this Agreement. If the Optionee has received this Agreement, or any other documents related to the Option and/or the Plan translated into a language other than English and if the meaning of the translated version is different from the English version, the English version will control.

15. Electric Delivery and Participation. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. The Optionee hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

16. Severability. The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

17. Appendix. Notwithstanding any provisions in this Agreement, this Stock Option grant shall be subject to any additional terms and conditions set forth in any Appendix to this Agreement for the Optionee's country. Moreover, if the Optionee relocates to one of the countries included in the Appendix, the additional terms and conditions for such country will apply to the Optionee, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

18. Imposition of Other Requirements. The Company reserves the right to impose other requirements on the Optionee's participation in the Plan, on this Stock Option and on any shares of Stock acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require me to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

19. Waiver. The Optionee acknowledges that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by the Optionee or any other optionee.

20. Insider Trading/Market Abuse. By accepting the Stock Option, the Optionee acknowledges that he or she is bound by all the terms and conditions of the Company's insider

trading policy as may be in effect from time to time. The Optionee further acknowledges that, depending on the Optionee's or his or her broker's country or the country in which the shares of Stock are listed, he or she may be subject to insider trading restrictions and/or market abuse laws which may affect the Optionee's ability to accept, acquire, sell or otherwise dispose of shares of Stock, rights to shares of Stock (*e.g.*, Options) or rights linked to the value of shares of Stock during such times as the Optionee is considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders the Optionee placed before the Optionee possessed inside information. Furthermore, the Optionee could be prohibited from (i) disclosing the inside information to any third party, which may include fellow employees and (ii) "tipping" third parties or causing them otherwise to buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. the Optionee acknowledges that it is the Optionee's responsibility to comply with any applicable restrictions, and the Optionee should speak to his or her personal advisor on this matter.

21. Foreign Asset/Account, Exchange Control and Tax Reporting. The Optionee may be subject to foreign asset/account, exchange control, tax reporting or other requirements which may affect the Optionee's ability acquire or hold Stock Options or shares of Stock or cash received from participating in the Plan (including the proceeds arising from the sale of Stock) in a brokerage/bank account outside the Optionee's country. The applicable laws of the Optionee's country may require that he or she report such Stock Options, shares of Stock, accounts, assets or transactions to the applicable authorities in such country and/or repatriate funds received in connection with the Plan to the Optionee's country within a certain time period or according to certain procedures. the Optionee acknowledges that he or she is responsible for ensuring compliance with any applicable requirements and should consult his or her personal legal advisor to ensure compliance with applicable laws.

DECIPHERA PHARMACEUTICALS, INC.

By:

Name:

Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____

Optionee's Signature

Optionee's name and address:

APPENDIX TO
NON-QUALIFIED STOCK OPTION AGREEMENT
FOR NON-U.S. OPTIONEES
UNDER DECIPHERA PHARMACEUTICALS, INC.
2017 STOCK OPTION AND INCENTIVE PLAN

[INSERT COUNTRY/REGION SPECIFIC NOTIFICATIONS, TERMS AND CONDITIONS]

FORM OF RESTRICTED STOCK UNIT AWARD AGREEMENT FOR NON-U.S. GRANTEES UNDER DECIPHERA PHARMACEUTICALS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Grantee:

No. of Restricted Stock Units:

Grant Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.01 per share (the "Stock") of the Company pursuant to this Restricted Stock Unit Award Agreement for Non-U.S. Grantees, including the additional terms and conditions for certain countries, as set forth in the appendix attached hereto (the "Appendix" and, together, the "Agreement").

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in a Service Relationship on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

[INSERT VESTING SCHEDULE]

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service. If the Grantee's Service Relationship terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units. For the avoidance of doubt, service during any portion of the vesting period will not entitle the Grantee to vest in a pro rata portion of unvested Restricted Stock Units.

For purposes of the Restricted Stock Units, the Grantee's Service Relationship will be deemed terminated as of the date the Grantee is no longer actively providing services to the Company or any Subsidiary (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Grantee is providing service or the terms of the Grantee's employment or service agreement, if any) and such date will not be extended by any notice period (*e.g.*, the Grantee's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where the Grantee is providing service or the terms of the Grantee's employment or service agreement, if any). The Company shall have the exclusive discretion to determine when the Grantee is no longer actively providing services for purposes of the Restricted Stock Units (including whether the Grantee may still be considered to be providing services while on a leave of absence).

Notwithstanding the foregoing, the vesting of the Restricted Stock Units shall accelerate in full if, on or within 12 months following, the consummation of a Change in Control Event, the Grantee's Service Relationship with the Company, any Subsidiary or the acquiring or succeeding entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause.

"Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Grantee, willful misconduct by the Grantee or willful failure by the Grantee to perform his or her responsibilities to the Company or any Subsidiary (including, without limitation, breach by the Grantee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Grantee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Grantee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Grantee's resignation, that termination for Cause was warranted.

"Change in Control Event" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Grantee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a "Person") of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company,

unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a "Sale"), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the "Acquiring Entity") in substantially the same proportions as their ownership of the equity or membership interest in the Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A3(i)(5).

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including

the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Responsibility for Taxes; Mandatory Sell to Cover. The Grantee acknowledges that, regardless of any action taken by the Company or, if different, the Grantee's employer (the "Employer"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to the Grantee's participation in the Plan and legally applicable or deemed applicable to the Grantee ("Tax-Related Items") is and remains the Grantee's responsibility and may exceed the amount, if any, actually withheld by the Company or the Employer. The Grantee further acknowledges that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Restricted Stock Units or the underlying shares of Stock, including, but not limited to, the grant, vesting or settlement of the Restricted Stock Units, the subsequent sale of shares of Stock acquired pursuant to such settlement and the receipt of any dividends; and (2) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Restricted Stock Units to reduce or eliminate the Grantee's liability for Tax-Related Items or achieve any particular tax result. Further, if the Grantee is subject to Tax-Related Items in more than one jurisdiction, the Grantee acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

In connection with the settlement of vested Restricted Stock Units, the Company and/or the Employer shall issue the shares of Stock referred to in Paragraph 4 to a broker designated by the Company and/or the Employer and acting on behalf and for the account of the Grantee with instructions to (i) sell a number of shares of such Stock sufficient to satisfy any Tax-Related Items which arise in connection with such settlement; provided, that the amount sold does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment, along with any applicable third-party commission, and (ii) remit the proceeds of such sale to the Company and/or the Employer. In the event that such withholding by sale of shares of Stock is problematic under applicable tax or securities law or has materially adverse accounting consequences, the Grantee authorizes the Company or the Employer to satisfy any applicable withholding obligations or rights with regard to all Tax-Related Items by withholding from the Grantee's wages or other cash compensation paid to the Grantee by the Company and/or the Employer or requiring the Grantee to make a cash payment in an amount equal to the withholding obligations or rights for Tax-Related Items.

In the event of over-withholding, the Grantee may receive a refund of any over-withheld amount in cash (with no entitlement to the equivalent in shares of Stock), or if not refunded, the Grantee may seek a refund from the local tax authorities. In the event the sale proceeds are insufficient to fully satisfy any Tax-Related Items, the Grantee authorizes withholding from payroll and any other amounts payable to the Grantee, in the same calendar year, and otherwise agrees to make adequate provision through the submission of cash, a check or its equivalent for any sums required to satisfy any Tax-Related Items. Unless the withholding tax obligations of the Company and/or the Employer thereof are satisfied, the Company shall have no obligation to

issue any shares of Stock on the Grantee's behalf pursuant to the vesting of the Restricted Stock Units.

7. Section 409A of the Code. To the extent applicable to U.S. taxpayers, this Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

8. Nature of Grant. By accepting the Restricted Stock Units, the Grantee acknowledges, understands, and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and may be amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the Restricted Stock Units is exceptional, voluntary and occasional and does not create any contractual or other right to receive any future restricted stock units, the same number of restricted stock units, or benefits in lieu of restricted stock units, even if restricted stock units or a certain number of restricted stock units have been granted in the past;

(c) all decisions with respect to future restricted stock units or other grants, if any, will be at the sole discretion of the Company;

(d) the Grantee is voluntarily participating in the Plan;

(e) the Restricted Stock Units and any shares of Stock subject to the Restricted Stock Units, and the income from and value of same, are not intended to replace any pension rights or compensation;

(f) unless otherwise agreed with the Company, the Restricted Stock Units and the shares of Stock subject to the Restricted Stock Units, and the income from and value of same, are not granted as consideration for, or in connection with, the service the Grantee may provide as a director of a Subsidiary;

(g) the Restricted Stock Units and any shares of Stock subject to the Restricted Stock Units, and the income from and value of same, are not part of normal or expected compensation for any purpose, including, without limitation to, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, holiday pay, pension or retirement or welfare benefits or similar mandatory payments;

(h) the future value of the shares of Stock underlying the Restricted Stock Units is unknown, indeterminable, and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the Restricted Stock Units resulting from the termination of the Grantee's Service Relationship (for any reason whatsoever, whether or not later found to be invalid or in breach of

labor laws in the jurisdiction where the Grantee is employed or otherwise rendering services or the terms of the Grantee's employment or service agreement, if any);

(j) unless otherwise provided in the Plan or by the Company in its discretion, the Restricted Stock Units and the benefits evidenced by this Agreement do not create any entitlement to have the Restricted Stock Units or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the shares of Stock; and

(k) neither the Company, the Employer nor any other Subsidiary shall be liable for any foreign exchange rate fluctuation between the Grantee's local currency and the U.S. dollar that may affect the value of the Restricted Stock Units or the subsequent sale of any shares of Stock acquired upon vesting.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Information. ***The Company and the Employer hold certain personal information about the Grantee, including, but not limited to, the Grantee's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company, details of all Restricted Stock Units or any other entitlement to shares of Stock awarded, canceled, exercised, vested, unvested or outstanding in the Grantee's favor ("Data").***

The Grantee hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of the Grantee's Data as described in this Agreement and any other Restricted Stock Unit grant materials by and among, as applicable, the Employer, the Company and its other Subsidiaries for the exclusive purpose of implementing, administering and managing the Grantee's participation in the Plan. For Grantees residing in the EU/EEA and United Kingdom, the processing of Grantee's data is exclusively performed in accordance with the Data Privacy Notice as set out in the Appendix below. In the latter case, the Company relies on the legal basis that the processing of the Grantee's Data is necessary (i) in order to take steps for entering into or the performance of this Agreement and other contractual obligations in connection with Restricted Stock Units and (ii) for the Company's legitimate business interests of managing the Plan and generally administering employee equity awards.

The Grantee understands that Data will be transferred to [INSERT PROVIDER]. ("PROVIDER"), or such other stock plan service provider as may be selected by the Company in the future, which is assisting the Company with the implementation, administration and management of the Plan. The Grantee understands that the recipients of the Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than the Grantee's country. The Grantee acknowledges that the Company, PROVIDER and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and

managing the Plan will process the Data, in electronic or other form, for the sole purpose of implementing, administering and managing the Grantee's participation in the Plan. The Grantee understands that Data will be held only as long as is necessary to implement, administer and manage the Grantee's participation in the Plan.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

12. Governing Law and Venue. The Restricted Stock Units grant and the provisions of this Agreement are governed by, and subject to, the laws of the State of Delaware, without regard to the conflict of law provisions, as provided in the Plan. For purposes of litigating any dispute that arises under this grant or the Agreement, the parties hereby submit to and consent to the jurisdiction of the Commonwealth of Massachusetts, agree that such litigation shall be conducted in the courts of Middlesex County, Massachusetts or the federal courts for the United States for the District of Massachusetts, where this grant is made and/or to be performed.

13. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding the Grantee's participation in the Plan, or the Grantee's acquisition or sale of the underlying shares of Stock. The Grantee should consult with his or her own personal tax, legal and financial advisors regarding the Grantee's participation in the Plan before taking any action related to the Plan.

14. Compliance with Law. Notwithstanding any other provision of the Plan or this Agreement, unless there is an exemption from any registration, qualification or other legal requirement applicable to the shares of Stock, the Company shall not be required to deliver any shares of Stock issuable upon settlement of the Restricted Stock Units prior to the completion of any registration or qualification of the shares of Stock under any local, state, federal or foreign securities or exchange control law or under rulings or regulations of the U.S. Securities and Exchange Commission ("SEC") or of any other governmental regulatory body, or prior to obtaining any approval or other clearance from any local, state, federal or foreign governmental agency, which registration, qualification or approval the Company shall, in its absolute discretion, deem necessary or advisable. The Grantee understands that the Company is under no obligation to register or qualify the shares of Stock with the SEC or any state or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the shares of Stock. Further, the Grantee agrees that the Company shall have unilateral authority to amend the Agreement without The Grantee's consent to the extent necessary to comply with securities or other laws applicable to the issuance of shares of Stock.

15. Language. The Grantee acknowledges that he or she is sufficiently proficient in English, or has consulted with an advisor who is sufficiently proficient in English, so as to allow the Grantee to understand the terms and conditions of this Agreement. If the Grantee has received this Agreement, or any other documents related to the Restricted Stock Units and/or the

Plan translated into a language other than English and if the meaning of the translated version is different from the English version, the English version will control.

16. Electric Delivery and Participation. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. The Grantee hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

17. Severability. The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

18. Appendix. Notwithstanding any provisions in this Agreement, the Restricted Stock Units grant shall be subject to any additional terms and conditions set forth in any Appendix to this Agreement for the Grantee's country. Moreover, if the Grantee relocates to one of the countries included in the Appendix, the additional terms and conditions for such country will apply to the Grantee, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

19. Imposition of Other Requirements. The Company reserves the right to impose other requirements on the Grantee's participation in the Plan, on the Restricted Stock Units and on any shares of Stock acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require me to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

20. Waiver. The Grantee acknowledges that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by the Grantee or any other grantee.

21. Insider Trading/Market Abuse. By accepting the Restricted Stock Units, the Grantee acknowledges that he or she is bound by all the terms and conditions of the Company's insider trading policy as may be in effect from time to time. The Grantee further acknowledges that, depending on the Grantee or his or her broker's country or the country in which the shares of Stock are listed, he or she may be subject to insider trading restrictions and/or market abuse laws which may affect the Grantee's ability to accept, acquire, sell or otherwise dispose of the shares of Stock, rights to the shares of Stock (*e.g.*, Restricted Stock Units) or rights linked to the value of the shares of Stock during such times as the Grantee is considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders the Grantee placed before the Grantee possessed inside information. Furthermore, the Grantee could be prohibited from (i) disclosing the inside information to any third party, which may include fellow employees and (ii) "tipping" third parties or causing them otherwise to buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in

effect from time to time. The Grantee acknowledges that it is the Grantee's responsibility to comply with any applicable restrictions, and the Grantee should speak to his or her personal advisor on this matter.

22. Foreign Asset/Account, Exchange Control and Tax Reporting. The Grantee may be subject to foreign asset/account, exchange control, tax reporting or other requirements which may affect the Grantee's ability acquire or hold Restricted Stock Units or the shares of Stock or cash received from participating in the Plan (including dividends and the proceeds arising from the sale of the shares of Stock) in a brokerage/bank account outside the Grantee's country. The applicable laws of the Grantee's country may require that he or she report such Restricted Stock Units, shares of Stock, accounts, assets or transactions to the applicable authorities in such country and/or repatriate funds received in connection with the Plan to the Grantee's country within a certain time period or according to certain procedures. The Grantee acknowledges that he or she is responsible for ensuring compliance with any applicable requirements and should consult his or her personal legal advisor to ensure compliance with applicable laws.

[Remainder of page intentionally left blank.]

DECIPHERA PHARMACEUTICALS, INC.

By: /Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

Grantee's Signature

Grantee's name and address:

Address:

APPENDIX TO
RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR NON-U.S. GRANTEES
UNDER DECIPHERA PHARMACEUTICALS, INC.
2017 STOCK OPTION AND INCENTIVE PLAN

[INSERT COUNTRY/REGION SPECIFIC NOTIFICATIONS, TERMS AND CONDITIONS]

FORM OF NON-QUALIFIED STOCK OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS UNDER DECIPHERA PHARMACEUTICS, INC. 2017 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

Grant Date:

Expiration Date:

Pursuant to the Deciphera Pharmaceuticals, Inc. 2017 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), Deciphera Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above, who is a Director of the Company but is not an employee of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.01 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall vest and become exercisable with respect to the following number of Option Shares on the dates indicated; provided that the Optionee continues to have a Service Relationship at such time.

[INSERT VESTING SCHEDULE]

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

The vesting of this Stock Option shall accelerate in full if, following the consummation of a Change in Control Event, the Optionee's Service Relationship with the Company, any Subsidiary or the acquiring or succeeding entity (or an affiliate thereof) is terminated by the Company, any Subsidiary or such entity without Cause, or by the Optionee with Good Reason.

"Cause" shall mean, unless otherwise provided in an employment or other service agreement between the Company, any Subsidiary and the Optionee, willful misconduct by the Optionee or willful failure by the Optionee to perform his or her responsibilities to the Company

or any Subsidiary (including, without limitation, breach by the Optionee of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Optionee and the Company or any Subsidiary), as determined by the Company or any Subsidiary, which determination shall be conclusive. The Optionee shall be considered to have been terminated for Cause if the Company or any Subsidiary determines, within 30 days after the Optionee's resignation, that termination for Cause was warranted.

"Change in Control Event" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee:

(i) the acquisition after the date hereof by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (a "Person") of (x) beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of any equity or membership interest in the Company if, after (but not before) such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the combined voting power of the then-outstanding equity or membership interests of the Company having the right to elect directors of the Company (or otherwise having the right to direct the operation and management of the Company), or (y) the sole power, by the terms of the organizational documents of the Company or by contract, to direct the operation and management of the Company; provided, however, that for purposes of this subsection (1), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlling or controlled by the Company, or (iv) any acquisition by any entity pursuant to a Sale (as defined below) which complies with clauses (x) and (y) of subsection (ii) of this definition; or

(ii) the consummation of a sale or other disposition of all or substantially all of the assets of the Company (a "Sale"), unless, immediately following such Sale, each of the following two conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the equity or membership interests in the Company immediately prior to such Sale beneficially own, directly or indirectly, more than 50% of the then-outstanding equity or membership interests and the combined voting power of the then-outstanding securities having the right to elect directors (or otherwise having the right to direct the operation and management), respectively, of the resulting or acquiring entity in such Sale (which shall include, without limitation, an entity which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring entity is referred to herein as the "Acquiring Entity") in substantially the same proportions as their ownership of the equity or membership interest in the Company immediately prior to such Sale and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Entity) beneficially owns, directly or indirectly, 50% or more of the then-outstanding equity or

membership interests in the Acquiring Entity or of the combined voting power of the then-outstanding securities of such entity having the right to elect directors (or otherwise having the right to direct the operation and management of such entity) (except to the extent that such ownership existed prior to the Sale).

Notwithstanding any other provision in this definition, where required to avoid additional taxation under Section 409A of the Code, the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treas. Reg. Section 1.409A-3(i)(5).

"Good Reason" shall mean, unless otherwise provided in an employment or other service agreement between the Company or any Subsidiary and the Optionee, any of the following: (i) a material diminution in the Optionee's authority, duties or responsibilities or (ii) a material diminution in the Optionee's annual cash compensation except for across-the-board reductions similarly affecting all or substantially all of the directors of the Company.

"Service Relationship" means any relationship as an employee, director or consultant of the Company or any Subsidiary (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or consultant).

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) to the extent permitted by the Administrator, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares of Stock attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Service Relationship. If the Optionee's Service Relationship is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of six

months from the date of such termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee's Service Relationship terminates shall terminate immediately and be of no further force or effect.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Optionee at any time.

7. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

8. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file

with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[Remainder of page intentionally left blank.]

DECIPHERA PHARMACEUTICALS, INC.

By:
Name:
Title:

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated:

Optionee's Signature

Optionee's name and address:

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

THIS AMENDMENT NO. 1 ("**Amendment 1**") is made effective as of **June 10, 2020** ("**Amendment 1 Effective Date**") by and between **Deciphera Pharmaceuticals, LLC** with offices located at 200 Smith Street, Waltham, MA 02451 ("**Company**") and Thomas P. Kelly ("**Executive**")**.**

BACKGROUND. Company and Executive have entered into and executed an Employment Agreement dated October 17, 2017 (the "**Agreement**") and following a review of executive compensation by the Board of Directors of Deciphera Pharmaceuticals, Inc., the Parties desire to amend the Agreement to revise certain Change in Control benefits.

NOW THEREFORE, intending to be legally bound, the Parties agree as follows:

1. Section 5(a)(i) of the Agreement is hereby deleted and replaced in its entirety as follows: "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 Base Salary plus (ii) the Executive's Target Annual Cash Incentive Compensation for the then-current year."

2. The reference to "12 months" of COBRA health continuation payments in Section 5(a)(ii)(i) of the Agreement shall be changed to "18 months."

3. All capitalized terms used, but not otherwise defined, in this Amendment 1 will have the same meaning given to them in the Agreement. All references to "Agreement" in the Agreement and this Amendment 1 are deemed to include this Amendment 1.

4. Except as specifically set forth in this Amendment 1, the Agreement remains unchanged and in full force and effect.

IN WITNESS WHEREOF, each Party has caused this Amendment 1 to be executed as of the Amendment 1 Effective Date.

Deciphera Pharmaceuticals, LLC

By: /s/ Steven Hoerter
Name: Steven Hoerter
Title: President and Chief Executive Officer

EXECUTIVE

/s/ Thomas P. Kelly
Name: Thomas P. Kelly

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of the 13th day of October, 2017, by and between Daniel L. Flynn, Ph.D. (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 shall be effective as of the closing of the first underwritten public offering of the equity securities of Deciphera Pharmaceuticals, Inc. ("Parent") pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

RECITALS

WHEREAS, the Company and the Executive are parties to that certain Employment Agreement dated November 6, 2003 (the "Prior Agreement"), which the Company and the Executive intend to replace with this Agreement;

WHEREAS, the Company desires to continue to employ the Executive and the Executive desires to continue to be employed by the Company on 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 this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions of Section 3 (the "Term").

(b) Position and Duties. During the Term, the Executive shall serve as the Chief Scientific Officer of the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer of the Company or the Board of Directors of Parent (the "Board"), provided that such duties are consistent with the Executive's position, or other positions that the Executive may hold from time to time. The Executive shall devote 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 approval of 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 Executive's duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's initial annual base salary shall be $355,000. The base salary shall be evaluated periodically by the Board or the Compensation Committee of the Board (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 executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Executive's target annual incentive compensation shall be 35 percent of Executive's Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as "Target Annual Cash Incentive Compensation." To earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Employee Benefits. During the Term, the Executive will 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.

(d) 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 then in effect and established by the Company for its senior executive officers.

(e) Paid Time Off. During the Term, the Executive shall be entitled to paid time off in accordance with the Company's policies and procedures. 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 the Company 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 the Company or any of its subsidiaries and affiliates if the Executive was retained in his 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 this Agreement, or in any Agreement between the parties; (v) a material violation by the Executive of the Company'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 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 his 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) material reduction of the Executive's annual 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) material diminution in the Executive's duties, authority or responsibilities without the prior consent of the Executive, other than changes in duties, authority or responsibilities resulting from the Executive's 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 (A) the Executive reasonably determines in good faith that a Good Reason Condition has occurred; (B) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within sixty (60) days of the first occurrence of such Good Reason Condition; (C) the Executive cooperates in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (D) notwithstanding such efforts, the Good Reason Condition continues to exist; and (E) the Executive terminates his employment within sixty (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 his death, the date of his 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; (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) Compensation 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 his authorized representative or estate) (i) any Base Salary earned through the Date of Termination and unpaid expense reimbursements (subject to, and in accordance with, Section 2(d) 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 (collectively, the "Accrued Benefit").

(b) Termination by the Company without Cause or by the Executive with 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 his employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive his Accrued Benefit. In addition, subject to the Executive signing a separation and general release agreement in a form and manner satisfactory to the Company (the "Separation and General Release Agreement"), the Separation and General Release Agreement becoming irrevocable 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), and the Executive not breaching any of his post-employment contractual obligations to the Company:

(i) the Company shall pay the Executive an amount equal to 12 months of the Executive's then current Base Salary; and

(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 Executive a monthly cash payment until the earlier of (i) 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) 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 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); and

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. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within 12 months after a Change in Control, 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 times the sum of (A) the Executive's then current Base Salary plus (ii) the Executive's Target Annual Cash Incentive Compensation for the then-current 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 Executive a monthly cash payment until the earlier of (i) 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 Date of Termination; 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 the Company 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 the Company representing 50 percent or more of the combined voting power of the Company'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 the Company); 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 the Company where the stockholders of the Company, 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 the Company 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 the Company.

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 the Company 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 the Company) 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 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 will 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 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. Nondisclosure/Confidentiality.

(a) Confidential Information. As used in this Agreement, "Confidential Information" shall mean information belonging to the Company or any of its subsidiaries or affiliates or related entities, as applicable (together, the "Protected Parties" and each of them, a "Protected Party") which is of value to any of the Protected Parties in the course of conducting its business and the disclosure of which could result in a competitive or other disadvantage to a Protected Party. Confidential Information includes, without limitation:

(i) the identity of any current or prospective customers, clients, suppliers or vendors of any of the Protected Parties;

(ii) information relating to the business, products, affairs and finances of any of the Protected Parties;

(iii) information relating to the manufacture, production, distribution, marketing, or sale of any product sold by any of the Protected Parties;

(iv) technical data and know-how relating to the business of any of the Protected Parties;

(v) any information relating to technology, marketing and business plans or strategies of any of the Protected Parties;

(vi) any management accounting or other similar financial information that would typically be included in the financial statements of any of the Protected Parties, including without limitation, the amount of the assets, liabilities, net worth, revenues or net income of any of the Protected Parties;

(vii) names and addresses of any of the customers, clients, suppliers, vendors and employees of any of the Protected Parties, and details of any independent contractor or agency arrangements of any of the Protected Parties;

(viii) information relating to legal and professional dealings, equity structure, real property, tangible property, finances, business, and investment activities, and other personal affairs of any of the Protected Parties; and

(ix) any and all books, notes, memoranda, records, correspondence, documents, computer and other discs and tapes, data listings, codes, designs, drawings and other documents and materials (whether made or created by the Executive or otherwise) relating to the business of any of the Protected Parties;

Notwithstanding the foregoing, Confidential Information does not include information in the public domain prior to the time of disclosure, unless due to breach of the Executive's duties under Section 7(b).

(b) Confidentiality. The Executive understands and agrees that the Executive's employment with the Company will create a relationship of confidence and trust between the Executive and the Company with respect to all Confidential Information. At all times, both during the Executive's employment with the Company and after his termination of employment, the Executive will keep in confidence and trust all such Confidential Information, and will not use or disclose any such Confidential Information without the written consent of the Company, except as may be necessary in the ordinary course of performing the Executive's duties to the Company, or as may be required by applicable law. For the avoidance of doubt, the Executive understands that 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 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. The Executive further understands that nothing contained in this Agreement limits the Executive's ability to (A) communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company, or (B) share compensation information concerning the Executive or others, except that this does not permit the Executive to disclose compensation information concerning others that the Executive has obtained because the Executive's job responsibilities require or allow access to such information.

(c) Company Property. All documents, records, data, apparatus, equipment and other physical property, whether or not pertaining to Confidential Information, which are furnished to the Executive by the Company or any other Protected Party or are produced by the Executive in connection with the Executive's employment will be and remain the sole property of the Company. The Executive will return to the Company all such materials and property as and when requested by the Company. In any event, the Executive will return all such materials and property immediately upon termination of the Executive's employment for any reason. The Executive will not retain any such material or property or any copies thereof after such termination.

(d) Work Product. As used in this Agreement, the term "Work Product" means all inventions, innovations, improvements, technical information, systems, software developments, methods, designs, analyses, drawings, reports, service marks, trademarks, trade names, logos and all similar or related information (whether patentable or unpatentable, copyrightable, registerable as a trademark, reduced to writing, or otherwise), or any part thereof, which relates to the Company's or any of its affiliates' actual or anticipated business, research and development or existing or future products or services and which are or were conceived, developed or made by the Executive (whether or not during usual business hours, whether or not by the use of the facilities of the Company or any of its affiliates, and whether or not alone or in conjunction with any other person) while employed by the Company together with all patent applications, letters patent, trademark, trade name and service mark applications or registrations, copyrights and reissues thereof that may be granted for or upon any of the foregoing. All Work Product that the Executive may discover, invent or originate during the Term of Employment shall be the exclusive property of the Company, and its affiliates, as applicable, and the Executive hereby assigns all of the Executive's right, title and interest in and to such Work Product to the Company or its applicable affiliate, including all intellectual property rights therein. The Executive shall promptly disclose all Work Product to the Company, shall execute at the request of the Company any assignments or other documents the Company may deem necessary to protect or perfect its (or any of its affiliate's, as applicable) rights therein, and shall assist the Company, at the Company's expense, in obtaining, defending and enforcing the Company's (or any of its affiliate's, as applicable) rights therein. The Executive hereby appoints the Company as his attorney-in-fact to execute on his behalf any assignments or other documents deemed necessary by the Company to protect or perfect the Company's (and any of its affiliate's, as applicable) rights to any Work Product.

(e) 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 Paragraph.

8. Third-Party Agreements and Rights. 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 duties for the Company as contemplated under this Agreement will not violate any obligations the Executive may have to any other party. In the Executive's work for the Company, the Executive will not disclose or make use of any

information in violation of any agreements with or rights of any such other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such other party.

9. Non-Competition; Non-Solicitation.

(a) The Executive understands and acknowledges that the Executive is being hired as a key employee with the Company, and is being placed in an executive position which includes the Executive's involvement and discretion in decisions and matters of importance for the Company. The Executive understands that the nature of the Executive's position gives the Executive access to and knowledge of Confidential Information and places the Executive in a position of trust and confidence with the Company. The Executive further understands and acknowledges that the Company's ability to safeguard its Confidential Information for the exclusive knowledge and use of the Company is of great competitive importance and commercial value to the Company, and that improper use or disclosure by the Executive may result in unfair or unlawful competitive activity.

(b) Because of the Company's legitimate business interest as described herein, and the good and valuable consideration offered to the Executive, during the Executive's employment with the Company and continuing through twelve (12) months after the Date of Termination (the "Restricted Period"), the Executive (i) will not, directly or indirectly, whether as owner, partner, investor, operator, manager, officer, director, consultant, agent, employee, co- venturer, advisor, representative or otherwise, engage, participate, assist or invest or actively prepare to engage, participate, assist or invest or actively prepare to engage, participate, assist or invest in any Competing Business (as hereinafter defined); (ii) will refrain from directly or indirectly employing, attempting to employ, recruiting, hiring or otherwise soliciting, inducing or influencing any person to leave employment with any of the Protected Parties; and (iii) will refrain from soliciting or encouraging any customer, supplier, consultant or vendor to terminate or otherwise modify adversely its business relationship with any of the Protected Parties. The Executive understands that the restrictions set forth in this Section 9 are intended to protect the interest of each of the Protected Parties in its Confidential Information, goodwill and established employee, customer, supplier, consultant and vendor relationships and goodwill, and agrees that such restrictions are reasonable and appropriate for this purpose.

(c) For purposes of this Agreement, the term "Competing Business" shall mean engaged (or seeking to engage) in any way in developing, manufacturing, offering, producing, providing, marketing, performing, licensing, or soliciting business for pre-clinical, clinical or commercial stage products or product candidates in oncology that: (i) in the case of pre-clinical assets are focused on specific molecular targets, that are identified by the Company as the primary intended molecular targets (e.g. the primary intended molecular targets of DCC- 2618 would be the KIT and PDGFRa kinases) or (ii) in the case of clinical-stage or commercial assets that are in active development for a particular label or indication (as defined by an active clinical protocol or prescribing information) that the Company is actively pursuing on the Termination Date or is the subject of active planning by the Company, its subsidiaries and/or its affiliates as of the Date of Termination (irrespective of whether such business is carried on by the

Company and/or any of its subsidiaries or affiliates as of the Effective Date). Notwithstanding the foregoing, "Competing Business" shall not include any investment by the Executive, directly or indirectly, solely as an investor (x) in publicly traded stock of a company representing less than two percent (2%) of the stock of such company, or (y) in mutual funds, exchange traded funds or similar investment or alternative investment vehicles, in each case, investing in public market securities.

(d) The restrictions in this Section 9 shall apply to any conduct in (i) the United States of America; (ii) any geographic area in which the Company or its subsidiaries or affiliates has sold, is then selling, or is actively planning to sell its products or services as of the Date of Termination; and (iii) any other geographic area in which the Company or its subsidiaries or affiliates has operated, is then operating or is actively planning to operate its business.

(e) The parties acknowledge and agree that these restrictive covenants set forth in this Section 9 shall not supersede or be superseded by, and shall be read in conjunction with, any non-solicitation, non-competition and confidentiality agreement or other restrictive covenants entered into between the parties to effect the greatest restriction.

10. 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 will 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.

11. Remedies. The Executive acknowledges that the restrictions contained in this Agreement are reasonable and necessary to protect the Company's legitimate business interests and that any violation of the provisions contained herein may result in irreparable injury to the Company and that monetary damages may not be sufficient to compensate the Company for any economic loss which may be incurred by reason of breach of the restrictions contained herein. In the event of a breach or a threatened breach by the Executive of any provision contained herein, the Company shall be entitled to a temporary restraining order and injunctive relief restraining the Executive from the commission of any breach, shall not be required to provide any bond or other security in connection with obtaining any such equitable remedy and shall be entitled to recover the Company's reasonable attorneys' fees, costs and expenses related to the breach or threatened breach. Nothing contained in this Section 119 shall be construed as prohibiting the Company from pursuing any other remedies available to it for any breach or threatened breach, including, without limitation, the recovery of money damages. In the event of a breach by Executive of any covenants contained herein, the term of such covenant shall be tolled until such breach has been duly cured.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. Governing Law. 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 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.

19. 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.

20. 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.

21. Integration. This 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, the Prior Agreement and any offer letter between the Company and the Executive; provided that any restrictive covenant obligation shall remain in full force and effect.

22. 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.

[Remainder of Page Left Intentionally Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

DECIPHERA PHARMACEUTICALS, LLC

Dated: October 13, 2017

By: /s/ Michael D. Taylor, Ph.D.
Name: Michael D. Taylor, Ph.D.
Title: President and Chief Executive Officer

Dated: October 12, 2017

/s/ Daniel L. Flynn, Ph.D.
Daniel L. Flynn, Ph.D.

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

THIS AMENDMENT NO. 1 ("**Amendment 1**") is made effective as of **June 10, 2020** ("**Amendment 1 Effective Date**") by and between **Deciphera Pharmaceuticals, LLC** with offices located at 200 Smith Street, Waltham, MA 02451 ("**Company**") and Daniel L. Flynn, Ph.D. ("**Executive**")**.**

BACKGROUND. Company and Executive have entered into and executed an Employment Agreement dated October 13, 2017 (the "**Agreement**") and following a review of executive compensation by the Board of Directors of Deciphera Pharmaceuticals, Inc., the Parties desire to amend the Agreement to revise certain Change in Control benefits.

NOW THEREFORE, intending to be legally bound, the Parties agree as follows:

1. Section 5(a)(i) of the Agreement is hereby deleted and replaced in its entirety as follows: "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 Base Salary plus (ii) the Executive's Target Annual Cash Incentive Compensation for the then-current year."

2. The reference to "12 months" of COBRA health continuation payments in Section 5(a)(ii)(i) of the Agreement shall be changed to "18 months."

3. All capitalized terms used, but not otherwise defined, in this Amendment 1 will have the same meaning given to them in the Agreement. All references to "Agreement" in the Agreement and this Amendment 1 are deemed to include this Amendment 1.

4. Except as specifically set forth in this Amendment 1, the Agreement remains unchanged and in full force and effect.

IN WITNESS WHEREOF, each Party has caused this Amendment 1 to be executed as of the Amendment 1 Effective Date.

Deciphera Pharmaceuticals, LLC

By: /s/ Steven Hoerter
Name: Steven Hoerter
Title: President and Chief Executive Officer

EXECUTIVE

/s/ Daniel L. Flynn, Ph.D.
Name: Daniel L. Flynn, Ph.D.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of the _the day of_, 2018, by and between Stephen Ruddy (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").

RECITALS

WHEREAS, the Company desires to employ the Executive and the Executive desires to be employed by the Company commencing on or about May 29, 2018, upon the terms contained herein. The date when Executive's employment with the Company commences is referred to as the "Effective Date."

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 this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions of Section 3 (the "Term").

(b) Position and Duties. During the Term, the Executive shall serve as the Chief Technical Officer of the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer of the Company or the Board of Directors (the "Board") of Deciphera Pharmaceuticals, Inc. ("Parent"), provided that such duties are consistent with the Executive's position, or other positions that the Executive may hold from time to time. The Executive shall devote 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 approval of 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 Executive's duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's initial annual base salary shall be $350,000. The base salary shall be evaluated periodically by the Board or the Compensation Committee of the Board (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 executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Executive's target annual incentive compensation shall be 35 percent of Executive's Base Salary. The target annual incentive compensation in effect at any

given time is referred to herein as "Target Annual Cash Incentive Compensation." To earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid. For the avoidance of doubt, the annual incentive compensation shall not be pro-rated for 2018.

(c) Signing Bonus. The Executive will be eligible to receive a one-time signing bonus of $75,000 (the "Signing Bonus") upon the three-month anniversary of the Effective Date, subject to the Executive's continuous employment with the Company through such date. The Signing Bonus will be paid on the first regular payroll date occurring on or after the three-month anniversary of the Effective Date.

(d) Equity Compensation. Promptly after the Effective Date, the Executive shall be granted an option to purchase 90,000 shares of Common Stock of Parent (the "Initial Option") with an exercise price equal to the then fair market value of the Common Stock. The Initial Option shall be granted under, and shall be subject to, the terms of the Company's current equity incentive plan and applicable equity incentive agreements.

(e) Employee Benefits. During the Term, the Executive will 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.

(f) 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 then in effect and established by the Company for its senior executive officers.

(g) Paid Time Off. During the Term, the Executive shall be entitled to paid time off in accordance with the Company's policies and procedures. 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 the Company 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 the Company or any of its subsidiaries and affiliates if the Executive was retained in his 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 this Agreement, or in any Agreement between the parties; (v) a material violation by the Executive of the Company'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 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 his 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) material reduction of the Executive's annual 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) material diminution in the Executive's duties, authority or responsibilities without the prior consent of the Executive, other than changes in duties, authority or responsibilities resulting from the Executive's 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 (A) the Executive reasonably determines in good faith that a Good Reason Condition has occurred; (B) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within sixty (60) days of the first occurrence of such Good Reason Condition; (C) the Executive cooperates in good faith with the

Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (D) notwithstanding such efforts, the Good Reason Condition continues to exist; and (E) the Executive terminates his employment within sixty (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 his death, the date of his 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; (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) Compensation 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 his authorized representative or estate) (i) any Base Salary earned through the Date of Termination and unpaid expense reimbursements (subject to, and in accordance with, Section 2(f) 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 (collectively, the "Accrued Benefit").

(b) Termination by the Company without Cause or by the Executive with 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 his employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive his Accrued Benefit. In addition, subject to the Executive signing a separation and general release agreement in a form and manner satisfactory to the Company (the "Separation and General Release Agreement"), the Separation and General Release Agreement becoming irrevocable 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), and the Executive not breaching any of bis post-employment contractual obligations to the Company:

(i) the Company shall pay the Executive an amount equal to 12 months of the Executive's then current Base Salary; and

(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 Executive a monthly cash payment until the earlier of (i) 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) 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 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 l.409A-2(b)(2); and

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. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within 12 months after a Change in Control, 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 (1) times the sum of (A) the Executive's then current Base Salary plus (B) the Executive's Target Annual Cash Incentive Compensation for the then-current 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 Executive a monthly cash payment until the earlier of (i) 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 Date of Termination; 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- l, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-l, 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 the Company 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 the Company representing 50 percent or more of the combined voting power of the Company'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 the Company); 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 the Company where the stockholders of the Company, 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 the Company 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 the Company.

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 the Company 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 the Company) 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 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 l.409A-l(h).

(d) The Parties intend that this Agreement will 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 is intended to constitute a separate payment for purposes of Treasury Regulation Section l.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. Nondisclosure/Confidentiality.

(a) Confidential Information. As used in this Agreement, "Confidential Information" shall mean information belonging to the Company or any of its subsidiaries or affiliates or related entities, as applicable (together, the "Protected Parties" and each of them, a "Protected Party") which is of value to any of the Protected Parties in the course of conducting its business and the disclosure of which could result in a competitive or other disadvantage to a Protected Party. Confidential Information includes, without limitation:

(i) the identity of any current or prospective customers, clients, suppliers or vendors of any of the Protected Parties;

(ii) information relating to the business, products, affairs and finances of any of the Protected Parties;

(iii) information relating to the manufacture, production, distribution, marketing, or sale of any product sold by any of the Protected Parties;

(iv) technical data and know-how relating to the business of any of the Protected Parties;

(v) any information relating to technology, marketing and business plans or strategies of any of the Protected Parties;

(vi) any management accounting or other similar financial information that would typically be included in the financial statements of any of the Protected Parties, including without limitation, the amount of the assets, liabilities, net worth, revenues or net income of any of the Protected Parties;

(vii) names and addresses of any of the customers, clients, suppliers, vendors and employees of any of the Protected Parties, and details of any independent contractor or agency arrangements of any of the Protected Parties;

(viii) information relating to legal and professional dealings, equity structure, real property, tangible property, finances, business, and investment activities, and other personal affairs of any of the Protected Parties; and

(ix) any and all books, notes, memoranda, records, correspondence, documents, computer and other discs and tapes, data listings, codes, designs, drawings and other documents and materials (whether made or created by the Executive or otherwise) relating to the business of any of the Protected Parties;

Notwithstanding the foregoing, Confidential Information does not include information in the public domain prior to the time of disclosure, unless due to breach of the Executive's duties under Section 7(b).

(b) Confidentiality. The Executive understands and agrees that the Executive's employment with the Company will create a relationship of confidence and trust between the Executive and the Company with respect to all Confidential Information. At all times, both during the Executive's employment with the Company and after his termination of employment, the Executive will keep in confidence and trust all such Confidential Information, and will not use or disclose any such Confidential Information without the written consent of the Company, except as may be necessary in the ordinary course of performing the Executive's duties to the Company, or as may be required by applicable law. For the avoidance of doubt, the Executive understands that 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 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. The Executive further understands that nothing contained in this Agreement limits the Executive's ability to (A) communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company, or (B) share compensation information concerning the Executive or others, except that this does not permit the Executive to disclose compensation information concerning others that the Executive has obtained because the Executive's job responsibilities require or allow access to such information.

(c) Company Property. All documents, records, data, apparatus, equipment and other physical property, whether or not pertaining to Confidential Information, which are furnished to the Executive by the Company or any other Protected Party or are produced by the Executive in connection with the Executive's employment will be and remain the sole property of the Company. The Executive will return to the Company all such materials and property as and when requested by the Company. In any event, the Executive will return all such materials and property immediately upon termination of the Executive's employment for any reason. The Executive will not retain any such material or property or any copies thereof after such termination.

(d) Work Product. As used in this Agreement, the term "Work Product" means all inventions , innovations, improvements, technical information, systems, software developments, methods, designs, analyses, drawings, reports, service marks, trademarks, trade names, logos and all similar or related information (whether patentable or unpatentable, copyrightable, registerable as a trademark, reduced to writing, or otherwise), or any part thereof, which relates to the Company's or any of its affiliates' actual or anticipated business, research and development or existing or future products or services and which are or were conceived, developed or made by the Executive (whether or not during usual business hours, whether or not by the use of the facilities of the Company or any of its affiliates, and whether or not alone or in conjunction with any other person) while employed by the Company together with all patent applications, letters patent, trademark, trade name and service mark applications or registrations, copyrights and reissues thereof that may be granted for or upon any of the foregoing. All Work Product that the Executive may discover, invent or originate during the Term of Employment shall be the exclusive property of the Company, and its affiliates, as applicable, and the Executive hereby assigns all of the Executive's right, title and interest in and to such Work Product to the Company or its applicable affiliate, including all intellectual property rights therein. The Executive shall promptly disclose all Work Product to the Company, shall execute at the request of the Company any assignments or other documents the Company may deem necessary to protect or perfect its (or any of its affiliate's, as applicable) rights therein, and shall assist the Company, at the Company's expense, in obtaining, defending and enforcing the Company's (or any of its affiliate's, as applicable) rights therein. The Executive hereby appoints the Company as his attorney-in-fact to execute on his behalf any assignments or other documents deemed necessary by the Company to protect or perfect the Company's (and any of its affiliate's, as applicable) rights to any Work Product.

(e) 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 Paragraph.

8. Third-Party Agreements and Rights. 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 duties for the Company as contemplated under this Agreement will not violate any obligations the Executive may have to any other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such other party.

9. Non-Competition; Non-Solicitation.

(a) The Executive understands and acknowledges that the Executive is being hired as a key employee with the Company, and is being placed in an executive position which includes the Executive's involvement and discretion in decisions and matters of importance for the Company. The Executive understands that the nature of the Executive's position gives the Executive access to and knowledge of Confidential Information and places the Executive in a position of trust and confidence with the Company. The Executive further understands and acknowledges that the Company's ability to safeguard its Confidential Information for the exclusive knowledge and use of the Company is of great competitive importance and commercial value to the Company, and that improper use or disclosure by the Executive may result in unfair or unlawful competitive activity.

(b) Because of the Company's legitimate business interest as described herein, and the good and valuable consideration offered to the Executive, during the Executive's employment with the Company and continuing through twelve (12) months after the Date of Termination (the "Restricted Period"), the Executive (i) will not, directly or indirectly, whether as owner, partner, investor, operator, manager, officer, director, consultant, agent, employee, co-venturer, advisor, representative or otherwise, engage, participate, assist or invest or actively prepare to engage, participate, assist or invest or actively prepare to engage, participate, assist or invest in any Competing Business (as hereinafter defined); (ii) will refrain from directly or indirectly employing, attempting to employ, recruiting, hiring or otherwise soliciting, inducing or influencing any person to leave employment with any of the Protected Parties; and (iii) will refrain from soliciting or encouraging any customer, supplier, consultant or vendor to terminate or otherwise modify adversely its business relationship with any of the Protected Parties. The Executive understands that the restrictions set forth in this Section 9 are intended to protect the interest of each of the Protected Parties in its Confidential Information, goodwill and established employee, customer, supplier, consultant and vendor relationships and goodwill, and agrees that such restrictions are reasonable and appropriate for this purpose.

(c) For purposes of this Agreement, the term "Competing Business" shall mean engaged (or seeking to engage) in any way in developing, manufacturing, offering, producing, providing, marketing, performing, licensing, or soliciting business for pre-clinical, clinical or commercial stage products or product candidates in oncology that: (i) in the case of pre-clinical assets are focused on specific molecular targets, that are identified by the Company as the primary intended molecular targets (e.g. the primary intended molecular targets of DCC- 2618 would be the KIT and PDGFRa kinases) or (ii) in the case of clinical-stage or commercial assets that are in active development for a particular label or indication (as defined by an active clinical protocol or prescribing information) that the Company is actively pursuing on the Termination Date or is the subject of active planning by the Company, its subsidiaries and/or its affiliates as of the Date of Termination (irrespective of whether such business is carried on by the Company and/or any of its subsidiaries or affiliates as of the Effective Date). Notwithstanding

the foregoing, "Competing Business" shall not include any investment by the Executive, directly or indirectly, solely as an investor (x) in publicly traded stock of a company representing less than two percent (2%) of the stock of such company, or (y) in mutual funds, exchange traded funds or similar investment or alternative investment vehicles, in each case, investing in public market securities.

(d) The restrictions in this Section 9 shall apply to any conduct in [(i) the United States of America; (ii) any geographic area in which the Company or its subsidiaries or affiliates has sold, is then selling, or is actively planning to sell its products or services as of the Date of Termination; and (iii) any other geographic area in which the Company or its subsidiaries or affiliates has operated, is then operating or is actively planning to operate its business.

(e) The parties acknowledge and agree that these restrictive covenants set forth in this Section 9 shall not supersede or be superseded by, and shall be read in conjunction with, any non-solicitation, non-competition and confidentiality agreement or other restrictive covenants entered into between the parties to effect the greatest restriction.

10. 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 will 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.

11. Remedies. The Executive acknowledges that the restrictions contained in this Agreement are reasonable and necessary to protect the Company's legitimate business interests and that any violation of the provisions contained herein may result in irreparable injury to the Company and that monetary damages may not be sufficient to compensate the Company for any economic loss which may be incurred by reason of breach of the restrictions contained herein. In the event of a breach or a threatened breach by the Executive of any provision contained herein, the Company shall be entitled to a temporary restraining order and injunctive relief restraining the Executive from the commission of any breach, shall not be required to provide any bond or other security in connection with obtaining any such equitable remedy and shall be entitled to recover the Company's reasonable attorneys' fees, costs and expenses related to the breach or threatened breach. Nothing contained in this Section 119 shall be construed as prohibiting the Company from pursuing any other remedies available to it for any breach or threatened breach, including, without limitation, the recovery of money damages. In the event of a breach by Executive of any covenants contained herein, the term of such covenant shall be tolled until such breach has been duly cured.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. Governing Law. 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 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.

19. 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.

20. 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.

21. Integration. This 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.

22. 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.

[Remainder of Page Left Intentionally Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

DECIPHERA PHARMACEUTICALS, LLC

Dated: 2018.04.24 By: /s/ Michael D. Taylor, Ph.D.
Name: Michael D. Taylor, Ph.D.
Title: President & CEO

Dated: 26 April 2018 /s/ Stephen Ruddy
STEPHEN RUDDY

[Signature Page to Ruddy Employment Agreement]

DECIPHERA PHARMACEUTICALS, INC.

The following is a list of significant subsidiaries of Deciphera Pharmaceuticals, Inc. as of December 31, 2020.

SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Deciphera Pharmaceuticals, LLC	Delaware
Deciphera Pharmaceuticals Securities Corporation	Massachusetts

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, 333-230270, 333-237031) and Form S-3 (No. 333-236389) of Deciphera Pharmaceuticals, Inc. of our report dated February 9, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 9, 2021

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: February 9, 2021

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: February 9, 2021

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, 2020 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: February 9, 2021

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, 2020 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: February 9, 2021

By: /s/ Thomas P. Kelly

Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)