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, 2023

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

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, 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, 2023) was $777,074,060. As of January 31, 2024, there were 80,800,062 shares of Common Stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2024 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, 2023, 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, including, without limitation, our launch of QINLOCK in the EU4 (Germany, France, Italy, and Spain) and the United Kingdom (U.K.), which we refer to as key European markets, 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.
- Our pivotal Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line gastrointestinal stromal tumor (GIST) patients with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14, which we also refer to as patients with mutations in KIT exon 11 and 17/18 (the INSIGHT study), may not be successful.
- 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 vimseltinib, and, if applicable, including by a third party, for any related companion diagnostic tests, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates or continue our geographic expansion of QINLOCK, and our ability to generate revenue will be materially impaired.
- 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. 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 drug candidates, such as vimseltinib and DCC-3116, 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 any potential expanded market for our approved drug or drug candidates are smaller than what 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, such as vimseltinib or DCC-3116, if approved, 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 other foreign jurisdictions would prevent QINLOCK and our drug candidates from being marketed more extensively internationally, and any approval we are granted for QINLOCK or our drug candidates in the United States (U.S.) or key European markets would not assure approval of QINLOCK or our drug candidates in other 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. 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 ongoing Phase 3 INSIGHT study and Phase 1/2 study of DCC-3116, 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 retain orphan drug exclusivity for our drug or drug candidates.
- We or the third parties upon whom we depend may be adversely affected by natural disasters or global health crises, including our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.
- We have incurred significant operating losses since our inception and have not generated sufficient revenue to result in a profit 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 vimseltinib, and have not generated sufficient revenue to result in a profit from product sales or profits from our operations. 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.
- We contract with third parties for the manufacture of our drug candidates for preclinical testing, clinical trials, and for the manufacture of QINLOCK. 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 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 commercialize or otherwise provide access to QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, in the U.S., key European markets, and any other jurisdictions where we may receive marketing approval in the future;
- the success and cost of our plans to research, develop, and commercialize our drug candidates, including the timing of our product development activities and clinical trials, and the timing of our investigational new drug (IND) applications, and clearance thereof, for any other drug candidates;
- our ability to successfully complete the pivotal Phase 3 INSIGHT study of QINLOCK for the potential treatment of second line GIST patients with mutations in KIT exon 11 and 17/18, advance our DCC-3116 program through clinical development, and nominate additional drug candidates from our switch control inhibitor platform;
- if we experience delays or difficulties in the enrollment of patients in clinical trials, including in our ongoing INSIGHT study and Phase 1/2 study of DCC-3116, our receipt of necessary marketing approvals could be delayed or prevented;
- the timing or likelihood of regulatory actions, filings, and approvals for our current and future drug candidates, including our ability to obtain and maintain regulatory approval for QINLOCK or obtain and maintain regulatory approval for vimseltinib, or 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 maintain our commercial infrastructure and successfully 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, 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 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;
- our ability to obtain funding for our strategic plans and operations;
- the development of companion diagnostic tests for our drug or any of our current or future drug candidates, if applicable;
- 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 may receive marketing approval;
- the therapeutic benefit, effectiveness, and safety profile of QINLOCK and our drug candidates;
- our commercial preparedness efforts and our ability to successfully commercially launch, or where permitted, otherwise provide access to our drug or drug candidates, if and when they are approved or receive pricing or reimbursement approval;
- the performance and experience of our licensee, Zai Lab (Shanghai) Co., Ltd. (Zai), to successfully develop and commercialize QINLOCK in the People's Republic of China (the PRC), Hong Kong, Taiwan, Macau, and Singapore, these territories collectively referred to as Greater China, under the terms and conditions of our license agreement, and the performance of our distributors in other territories;

- the potential benefits of our combination strategy for DCC-3116;
- our ability to attract additional licensees and/or collaborators or distributors with development, regulatory, and commercialization expertise;
- 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;
- our expectations regarding our ability to obtain, maintain, enforce, and defend our intellectual property protection for QINLOCK or our drug candidates;
- 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, use of proceeds, and need for additional financing; and
- the impact of global economic and political developments on our business, including high inflation and capital market disruptions, the Ukraine-Russia and Israel-Hamas wars, economic sanctions and economic slowdowns or recessions, including any that may result from such developments and the COVID-19 pandemic or other public health concern, which could harm our commercialization efforts for QINLOCK as well as the value of our common stock and our ability to access capital markets.

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 Deciphera logo and the QINLOCK® word mark and logo are registered trademarks and the Deciphera word mark is a trademark 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 commercializing important new medicines to improve the lives of people with cancer. Leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology, we design kinase inhibitors to target the switch pocket region of the kinase with the goal of developing potentially transformative medicines. Through our patient-inspired approach, we seek to develop a broad portfolio of innovative medicines to improve treatment outcomes. QINLOCK, our switch-control tyrosine kinase inhibitor, was discovered using our proprietary drug discovery platform and designed for the treatment of GIST. QINLOCK is approved in Australia, Canada, China, the European Union (EU), Hong Kong, Iceland, Israel, Liechtenstein, Macau, New Zealand, Norway, Singapore, Switzerland, Taiwan, the U.K., and the U.S. for the treatment of fourth-line GIST. 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. In addition to QINLOCK, we have developed a robust pipeline of novel drug candidates using our switch-control kinase inhibitor platform, including vimseltinib and DCC-3116.

Platform Development and Pipeline – 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 expertise in kinase biology 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 switches 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 or that are spectrum-selective against several chosen on-target 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.

In addition to QINLOCK, our platform also enabled the discovery and development of vimseltinib, our inhibitor of the colony stimulating factor 1 receptor (CSF1R) kinase for the potential treatment of TGCT, and DCC-3116, our Phase 1/2 inhibitor of ULK kinases being developed to inhibit autophagy, which is a key process used by cancers for survival and resistance to a variety of anti-tumor therapeutics.

We are also making a focused investment in our next generation of research programs, which are designed to provide first-in-class or best-in-class treatments using our proprietary switch-control inhibitor platform which includes DCC-3084 and DCC-3009.

Our Strategy

Our objective is to discover, develop, and commercialize important new medicines to improve the lives of people with cancer. The principal components of our strategy include:

- With respect to QINLOCK,
  - Build on our successful commercialization in fourth-line GIST in the U.S., where we believe we are the standard of care;
  - Continue our geographic expansion in fourth-line GIST in European and international markets, while working to provide access to QINLOCK to eligible patients in other countries around the world through other channels; and
  - Expand the market opportunity for QINLOCK through our pivotal Phase 3 INSIGHT study in second-line GIST patients with mutations in KIT exon 11 and 17/18.
- With respect to vimseltinib,
  - Rapidly seek approval, and continue commercial preparations, for vimseltinib as a potential therapy for the treatment of TGCT, and leverage potential synergies and experience we have gained from QINLOCK towards this second drug candidate to prepare for a potential launch, if approved; and
  - Initiate a Phase 2 study of vimseltinib for the potential treatment of chronic graft-versus-host disease (cGVHD), subject to the U.S. Food and Drug Administration (FDA) feedback.
- Develop DCC-3116, our inhibitor of ULK kinase, which is currently being studied in a Phase 1/2 study for the potential treatment of advanced or metastatic solid tumors with mutations in the RAS/MAPK pathway and select a recommended Phase 2 dose for potential expansion cohort(s) to maximize the potential of DCC-3116, subject to favorable data.
- Develop DCC-3084, our pan-RAF inhibitor, for which we submitted an IND to FDA in the fourth quarter of 2023 and plan to initiate a Phase 1 study in the first half of 2024.
- Develop DCC-3009, our next generation KIT inhibitor, for which we plan to submit an IND to the FDA in the first half of 2024 and initiate a Phase 1 study in the second half of 2024, each subject to FDA feedback.
- Continue to 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 specific regions of the gene that encodes the kinase, or exons, when referring to particular mutations. 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, wild-type 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 clinical-stage 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. 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).

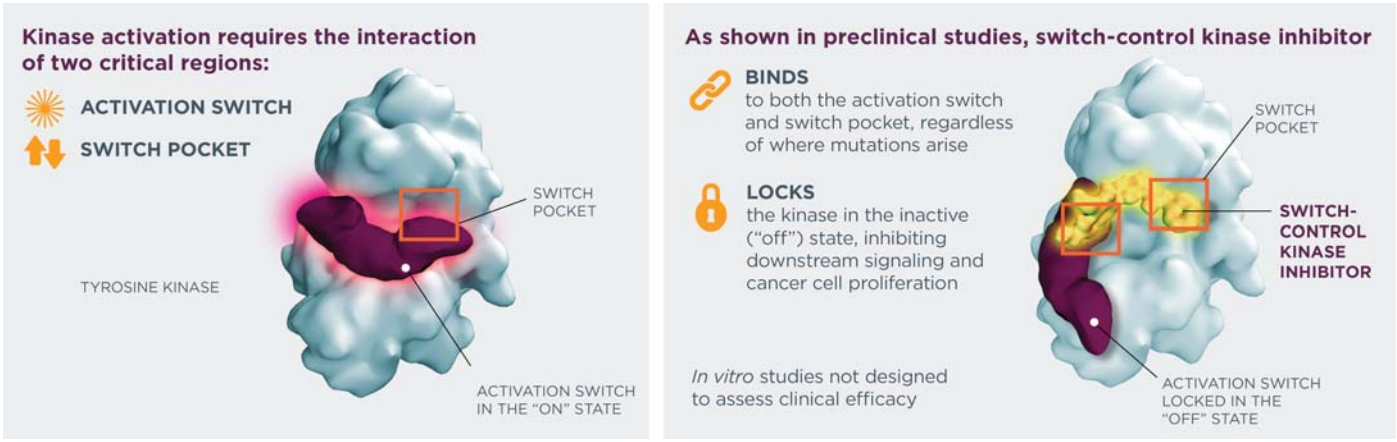
Our proprietary switch-control kinase inhibitor platform includes a library of drug-like, switch-control kinase compounds. We have determined and assessed more than 200 co-crystal structures where our compounds are bound into the switch regions of specific kinases. We use this information to identify and optimize candidate molecules. By directly targeting the switch pocket or other regions that control switch regulation/activation, 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 our approved drug, QINLOCK, and two clinical-stage agents, vimseltinib and DCC-3116, and ongoing research-stage programs, including our pan-RAF inhibitor, DCC-3084, and our next generation KIT inhibitor, DCC-3009. Our switch-control kinase inhibitors are designed to interact at a molecular level that is distinct from other kinase inhibitors and are designed to generate higher and more durable rates of response. We believe our drug candidates may contribute to higher activity than currently available kinase inhibitors.

The figure 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 specific kinases in the MAP kinase family (MEK and ERK), which constitute less than 10% of the over 500 known human kinases 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 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. Our research-stage programs are also wholly-owned:

Notes: ISR=Integrated Stress Response; BRAF=proto-oncogene b-RAF; CSF1R=colony-stimulating factor 1 receptor; EGFR=epidermal growth factor receptor; GCN2=general control nonderepressible 2; GIST=gastrointestinal stromal tumor; G12C=single point mutation with a glycine-to-cysteine substitution at codon 12; KIT=KIT proto-oncogene receptor tyrosine kinase; RAF=rapidly accelerated fibrosarcoma; RAS=rat sarcoma gene; TGCT=tenosynovial giant cell tumor; cGVHD=chronic graft versus host disease; IND=Investigational New Drug. ULK=unc-51-like autophagy-activating kinase; (1) Exclusive development and commercialization license with Zai Lab in Greater China for QINLOCK; (2) The patient population for the INSIGHT study consists of second-line GIST patients with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14 (also referred to as KIT exon 11 + 17/18 patients); (3) The Company expects to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for vimseltinib for the treatment of patients with TGCT in 2Q 2024 and a Marketing Authorisation Application (MAA) to the European Medicines Agency in 3Q 2024.

QINLOCK: A Kinase Inhibitor of KIT and PDGFRA for GIST

QINLOCK is an orally administered switch-control kinase inhibitor developed for the treatment of GIST and is approved in twelve territories for the treatment of fourth-line advanced 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.

Following the Phase 3 INVICTUS study of QINLOCK in fourth-line GIST which met its primary endpoint of improved progression-free survival (PFS) versus placebo, 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 2020, QINLOCK was also approved for the treatment of fourth-line GIST in Canada and Australia. 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 November 2021, we announced that the European Commission (EC) approved QINLOCK in the EU for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The EC decision is applicable to all 27 EU member states plus Iceland, Norway, and Liechtenstein. In 2021, QINLOCK was also approved for the treatment of fourth-line GIST in Switzerland and the U.K. QINLOCK was approved for the treatment of fourth-line GIST in New Zealand in 2022 and Israel, Macau, and Singapore in 2023. In January 2024, we announced that we had entered into an exclusive distribution agreement for QINLOCK in Poland, Czech Republic, Greece, Republic of Cyprus, Malta, Hungary, Romania, Slovenia, Bulgaria, Slovakia, Croatia, Estonia, Lithuania, and Latvia as member states of the EU (Central and Eastern Europe or CEE).

In June 2019, we entered into a license agreement with Zai Lab (Shanghai) Co. Ltd. (Zai) (such agreement, the Zai License Agreement) pursuant to which we granted Zai exclusive rights to develop and commercialize QINLOCK, including certain follow-on compounds (the Licensed Products) in Greater China. QINLOCK was approved for the treatment of adult patients with

advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib by the China National Medical Products Administration (China NMPA) and the Taiwan Food and Drug Administration in 2021 and the Macau Institute for Pharmaceutical Supervision and Administration in 2023. In 2021, the Hong Kong Department of Health approved QINLOCK in Hong Kong for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib.

In November 2021, we announced top-line data from INTRIGUE, our Phase 3 study of QINLOCK for the treatment of second-line GIST. The INTRIGUE study did not meet the primary endpoint of improved PFS compared with the standard of care sunitinib. The Phase 3 INTRIGUE study is an interventional, randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib.

In January 2023, we announced findings from an exploratory circulating tumor DNA (ctDNA) analysis from the Phase 3 INTRIGUE study demonstrating substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18. In August 2023, we announced that we opened the first sites for enrollment in the INSIGHT study of QINLOCK versus sunitinib in this patient population. In 2024, we plan to continue to enroll the INSIGHT pivotal Phase 3 study in second-line GIST patients with mutations in KIT exon 11 and 17/18.

In March 2023, we announced that QINLOCK has been included in the latest National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology as a preferred regimen for second-line GIST patients intolerant to sunitinib. We also announced that the FDA granted Breakthrough Therapy Designation (BTD) for QINLOCK for the treatment of adult patients with unresectable or metastatic GIST who received prior treatment with imatinib, and who harbor a KIT exon 11 mutation and co-occurring KIT exon 17 and/or 18 mutations.

Following QINLOCK's EC approval in fourth-line GIST in November 2021, we have focused our direct commercial efforts in key European markets. We launched QINLOCK in Germany in 2022 and Italy in 2023, and have conducted the post-approval paid access program (AP2) program in France since 2022. In 2024, we plan to continue the geographic expansion of QINLOCK with planned commercial launches following conclusion of pricing and reimbursement negotiations in additional European and international markets. We also plan to provide access to QINLOCK to fourth-line GIST patients in additional countries through other channels with distribution arrangements.

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 95% 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 70% 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.

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 with the most frequent mutations occurring within the kinase ATP-binding pocket (exons 13/14) and the activation loop (exons 17/18).

Treatment Paradigm 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). Although imatinib is effective against KIT mutations in exon 11 and has limited efficacy against exon 9 mutations, 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 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.

Disease progression in advanced GIST is often due to secondary mutations in KIT or PDGFRA that cause resistance to first-line 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 been shown to have 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 13/14 mutations, but is not as active against mutations in exon 17/18. Only about half of GIST patients show benefit on sunitinib therapy and the reported time-to-tumor progression is 6.1 months. The emergence of KIT mutations in exon 17/18 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 17/18.

Although GIST patients may experience periods of disease control with approved 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 with a comparable incidence in the EU4 and the U.K. We estimate that the annual new treatment-eligible population in the U.S. for (i) second-line GIST patients is approximately 2,000, (ii) third-line GIST patients is approximately 1,400 to 1,600, and (iii) fourth-line GIST patients is approximately 1,000 to 1,300. This treatment eligible patient estimate excludes 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. In addition, based on a literature review as well as our ctDNA analysis from INTRIGUE described below, we estimate that approximately 14% of second-line GIST patients will harbor mutations in KIT exon 11 and 17 and/or 18 with exclusions of KIT exon 9, 13, and/or 14. Estimates are inherently uncertain and are subject to a wide variety of assumptions, risks, and uncertainties that can cause actual results to differ materially.

Clinical Development of QINLOCK

Phase 3 INVICTUS Study in Fourth-Line and Fourth-Line Plus GIST; QINLOCK: A Broad Spectrum Inhibitor in Fourth-Line and Fourth-Line Plus GIST

The Phase 3 INVICTUS study was 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 Response Evaluation Criteria In Solid Tumors (RECIST) version 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 August 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved PFS compared to placebo as determined by blinded independent central radiologic review using modified RECIST. In 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% (Hazard Ratio (HR) of 0.15, 95% Confidence Interval (0.09,0.25), p-value <0.0001) compared to placebo. This PFS benefit was consistent across all assessed patient sub-groups.

For the key secondary endpoint of objective response rate (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.

In June 2021, we presented data for QINLOCK patients undergoing intra-patient dose escalation after disease progression in the Phase 3 INVICTUS study at the American Society of Clinical Oncology. An exploratory analysis was conducted to assess the safety and efficacy of QINLOCK dose escalation to 150 mg BID among patients randomized to QINLOCK 150 mg QD in the INVICTUS study. As of the August 10, 2020 cutoff date, of the 85 patients randomized to QINLOCK 150 mg QD in the INVICTUS study, 43 dose escalated to 150 mg BID after disease progression by blinded independent central review using modified RECIST version 1.1.

Among the 43 patients in the QINLOCK arm who dose escalated, initial median PFS, or mPFS1, was 4.6 months (95% CI 2.7–6.4) and the subsequent median PFS, or mPFS2, from the day of dose escalation to second disease progression or death was 3.7 months (95% CI 3.1–5.3). The ratio of mPFS2/mPFS1 was 80%. Median OS was 18.4 months in patients randomized to QINLOCK 150 mg QD with progressive disease and who dose escalated to 150 mg BID (n=43) and 14.2 months in those randomized to QINLOCK 150 mg QD with progressive disease and not dose escalating (n=22) (HR 0.74, 95% CI 0.37–1.49). QINLOCK 150 mg BID was well tolerated with a similar safety profile to QINLOCK 150 mg QD, with new or worsening Grade 3–4 TEAEs of anemia in 6 (14%) and abdominal pain in 3 (7%) patients. In addition, in January 2022, we announced that the NCCN Clinical Practice Guidelines for GIST now includes the use of QINLOCK 150 mg twice daily (BID) after disease progression if previously treated with QINLOCK 150 mg once daily in fourth-line GIST patients.

In September 2021, we announced a long-term update from the Phase 3 INVICTUS study. An exploratory evaluation of primary and secondary endpoints in the Phase 3 INVICTUS study, with a cutoff date of January 15, 2021, an additional 19 months after the primary analysis, demonstrated consistent PFS with no change since the primary data cutoff, and improved median OS among patients receiving ripretinib (median OS 18.2 months with QINLOCK compared to 6.3 months with placebo, HR = 0.41, 95% Confidence Interval (0.26, 0.65)). Safety findings were consistent with the primary analysis results and most TEAEs were Grade 1 or 2. Increases in TEAEs and TEAEs leading to dose modifications in the additional 19 months of follow up were minimal. In addition, a retrospective analysis of the INVICTUS study published in September 2021 demonstrated that QINLOCK provided clinical meaningful benefit across mutation sub-groups, supporting the use of QINLOCK as fourth-line therapy in patients harboring a broad spectrum of mutations. We believe these more mature results continue to support the clinically meaningful benefit in PFS and OS for QINLOCK with an acceptable safety profile in patients with advanced GIST treated with three or more prior lines of therapy.

Phase 3 INTRIGUE Study in Second-Line GIST

In December 2018, we initiated the pivotal Phase 3 INTRIGUE study.

The Phase 3 INTRIGUE 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 were 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 was 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 occurred once a pre-specified number of events, defined as death or disease progression events based on independent radiologic review using modified RECIST, had occurred.

In November 2021, we announced top-line data from our INTRIGUE study, which showed the INTRIGUE study did not meet the primary endpoint of improved PFS compared with the standard of care sunitinib.

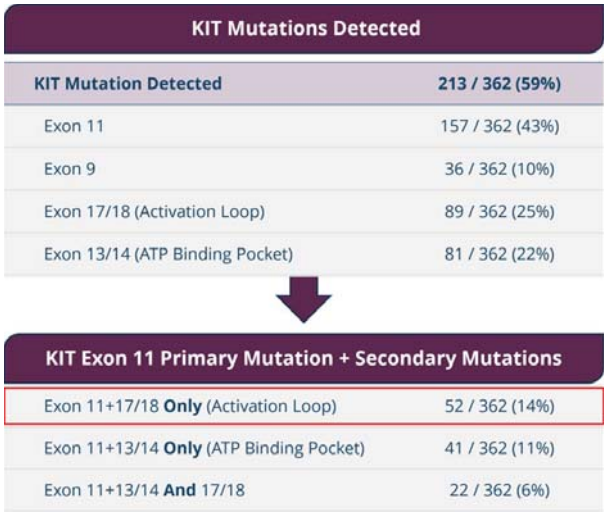
The statistical analysis plan included a hierarchical testing structure that included testing patients with a KIT exon 11 primary mutation and in the all patient intent-to-treat (AP) population. In patients with a KIT exon 11 primary mutation, (n=327), QINLOCK demonstrated a mPFS of 8.3 months compared to 7.0 months for the sunitinib arm (HR of 0.88, p=0.360). Although not formally tested due to the rules of the hierarchical testing sequence, in the AP population QINLOCK demonstrated a mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR of 1.05, nominal p=0.715).

In the INTRIGUE study, QINLOCK was generally well tolerated and the safety profile of QINLOCK was consistent with its existing prescribing information, with the safety population as follows: ripretinib (n=223) and sunitinib (n=221). Any grade 3/4 TEAEs were as follows (n (%)): ripretinib 92 (41.3) and sunitinib 145 (65.6). Any grade 3/4 drug-related TEAEs were as follows (n (%)): ripretinib 59 (26.5) and sunitinib 122 (55.2).

Results from ctDNA Analysis from the Phase 3 INTRIGUE Study in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18

In January 2023, we announced findings of an exploratory analysis using ctDNA from the Phase 3 INTRIGUE study of QINLOCK. An exploratory objective in the Phase 3 INTRIGUE study in GIST patients previously treated with imatinib was to evaluate anti-tumor efficacy of QINLOCK according to baseline KIT primary and secondary mutation status. Baseline peripheral whole blood was analyzed by Guardant360, a 74-gene ctDNA next-generation sequencing liquid biopsy assay.

Of the 453 patients in the overall intent-to-treat population (ITT), baseline ctDNA was analyzed in 362 patients for whom evaluable samples were available. ctDNA was detected in 280 samples and KIT mutations were detected in 213 patients. Primary mutations in KIT were detected in exon 11 in 157 patients and in exon 9 in 36 patients. Common resistance mutations in KIT were detected in exons 17/18 in 89 patients and in exons 13/14 in 81 patients. In patients with a KIT exon 11 primary mutation, 52 patients had mutations in exon 17/18, 41 patients had mutations in exon 13/14 only, and 22 patients had mutations in both exon 13/14 and exon 17/18. The figure below summarizes the KIT primary and secondary mutations that were detected in the 213 patients in which KIT mutations were detected.



Patients with mutations in KIT exon 11 and exon 17/18 had substantially improved PFS, ORR, and OS with QINLOCK versus sunitinib. The table below summarizes these efficacy results. Efficacy results in patients with detectable ctDNA in KIT exon 11 and in the ITT populations were consistent with the primary analysis of the INTRIGUE study based on tumor data used for randomization. The sub-group safety profiles were consistent with the primary analysis. Patients with mutations in KIT exon 11 and 13/14 only derived substantially improved clinical benefit with sunitinib versus QINLOCK.

INTRIGUE Efficacy Results of ctDNA Analysis for Patients with Mutations in KIT Exon 11 and 17/18

	Ripretinib (n=27)	Sunitinib (n=25)	Hazard Ratio/Response Difference (95% CI)
Median Progression-Free Survival[(1)]	14.2 months	1.5 months	0.22 (0.11, 0.44), nominal p value <0.0001
Objective Response Rate[(1)]	44.4%	0%	44.4% (23.0%, 62.7%), nominal p value = 0.0001
Overall Survival[(2)]	Not Estimable	17.5 months	0.34 (0.15, 0.76), nominal p value = 0.0061

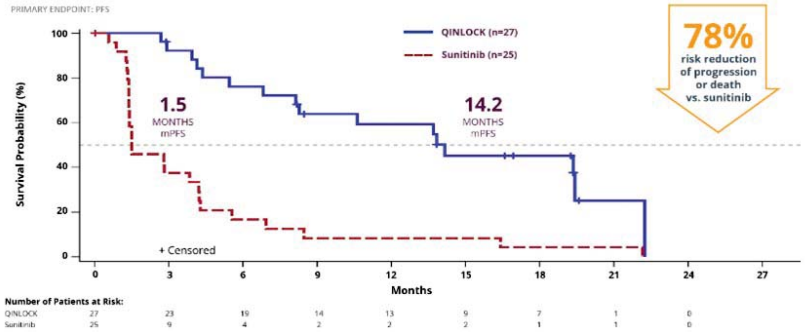
(1) Data cutoff date as of September 1, 2021; (2) Data cutoff date as of September 1, 2022.

The figures below depict the ORR, PFS, and OS for QINLOCK compared with sunitinib in the sub-group analysis.

Objective Response Rate for QINLOCK and sunitinib in KIT Exon 11+17/18 Patients[1,2]

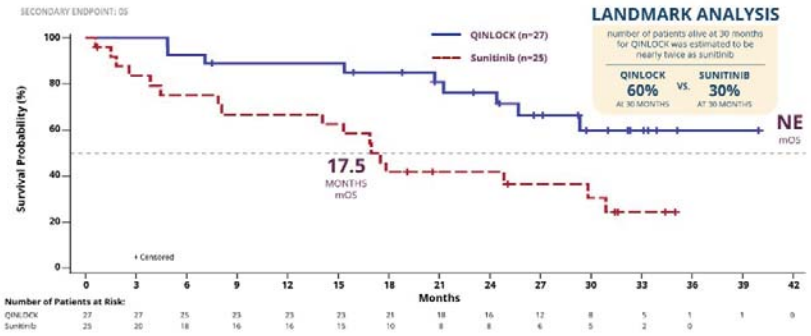
(1) Data cutoff date of September 1, 2021; (2) for 2 patients in the sunitinib arm and 1 patient in the ripretinib arm, no postbaseline disease assessment was available; (3) ORR was confirmed with follow-up imaging; (4) determined using modified RECIST 1.1 criteria; (5) response difference=44.4%, 95% CI (23.0, 62.7), nominal p value 0.0001.

Progression-Free Survival for QINLOCK and sunitinib in KIT Exon 11+17/18 Patients[1]



(median PFS of 14.2 months vs. 1.5 months; HR=0.22, 95% CI [0.11 0.44], nominal p value <0.0001)
(1) Data cutoff date of September 1, 2021.

Overall Survival for QINLOCK and sunitinib in KIT Exon 11+17/18 Patients[1]



(median OS of NE months vs. 17.5 months; HR=0.34, 95% CI [0.15-0.76], nominal p value = 0.0061)
(1) Data cutoff date of September 1, 2022.

Phase 3 INSIGHT Study in Second-Line GIST Patients with Mutations in KIT Exon 11 and 17/18

In August 2023, we announced that we opened the first sites for enrollment in the pivotal Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18. The Phase 3 INSIGHT study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14. In the study, 54 patients will be randomized 2:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary endpoint will be PFS as determined by independent radiologic review using modified RECIST criteria. Secondary endpoints include ORR as determined by independent radiologic review using mRECIST 1.1 criteria and OS. Patients randomized to the sunitinib arm may crossover to the QINLOCK arm after progressive disease. In 2024, we plan to continue to enroll the INSIGHT pivotal Phase 3 study in second-line GIST patients with mutations in KIT exon 11 and 17/18.

QINLOCK Mechanism of Action

KIT and PDGFRA are kinases that each contain both an auxiliary inhibitory switch encoded by KIT exon 11 or PDGFRA exon 12 and 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 Inhibitor 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 tested. This high selectivity for inhibition of CSF1R is attributed to vimseltinib binding into a unique selectivity region of the CSF1R activation switch that is not available in closely related kinases. 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 the pivotal Phase 3 study in patients with TGCT. The MOTION study is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with TGCT who are not amenable to surgery. In October 2023, we announced positive top-line data from the MOTION study. We will continue to engage with regulatory authorities and expect to submit a New Drug Application (NDA) to the FDA in the second quarter of 2024 and a marketing authorization application (MAA) with the European Medicines Agency (EMA) in the third quarter of 2024 for vimseltinib for the treatment of patients with TGCT.

We are also conducting an international, multicenter, ongoing open-label Phase 1/2 study designed to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of vimseltinib in patients with solid tumors and TGCT. In the Phase 2 expansion portion of the study, Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is allowed) and Cohort B includes patients with prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib alone is not allowed). In October 2023, we provided updated data from our Phase 1/2 study of vimseltinib in TGCT patients. The data demonstrated strong clinical benefit with best ORR of 72% (Phase 1) and 64% (Phase 2 Cohort A), an increasing median treatment duration of 25.1 months (Phase 1) and 21.0 months (Phase 2 Cohort A), and a favorable long-term safety profile with no evidence of cholestatic hepatotoxicity.

In November 2021, we announced that vimseltinib had been granted fast track designation by the FDA for the treatment of patients with TGCT who are not amenable to surgery.

In January 2023, we announced that we plan to initiate a Phase 2 study of vimseltinib for the potential treatment of cGVHD in the fourth quarter of 2024, subject to FDA feedback.

Market Opportunity in TGCT

TGCTs are a group of rare, locally aggressive 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. Surgical resection is the primary 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 sub-types based on where they are and how they grow. Localized TGCTs are typically more well-defined and confined to a portion of joints like the fingers, toes, knees, wrists, and ankles. Diffuse-type TGCTs are typically less well-defined and occur most commonly in and around joints such as the knee, hips, ankles, elbows, and shoulders. We estimate that approximately 14,000 to 18,000 patients are diagnosed annually with localized and diffuse-type TGCT in the U.S. Based on our internal analysis of U.S. claims data, we estimate there are approximately 1,400 incident and 9,000 prevalent TGCT patients in the U.S. meeting the following criteria: (i) diagnosed, (ii) drug treated, (iii) may or may not have undergone surgery, and (iv) recently engaged with an oncologist. Further, we estimate an additional opportunity exists for the approximately 1,300 incident TGCT patients in the U.S. who meet the following criteria: (i) diagnosed, (ii) drug-treated, (iii) may or may not have undergone surgery, and (iv) have not recently engaged with an oncologist but who have engaged with a surgeon. We believe a further opportunity exists in Europe, which we estimate has a comparable epidemiology to the U.S. Estimates are inherently uncertain.

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 patients with 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. Many patients are treated with off-label tyrosine kinase inhibitors, in particular imatinib, despite the lack of an approval in TGCT.

Clinical Development of Vimseltinib

Phase 3 MOTION Study in Patients with TGCT

In January 2022, we initiated the pivotal Phase 3 MOTION study in patients with TGCT. The MOTION study is a two-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of vimseltinib in patients with TGCT not amenable to surgery with no prior anti-CSF1/CSF1R therapy (prior therapy with imatinib or nilotinib allowed). In Part 1, patients (n=123) were randomized two-to-one to receive either 30 mg twice weekly of vimseltinib (n=83) or placebo (n=40) for 24 weeks. The primary endpoint of the study is ORR at Week 25 as measured by RECIST version 1.1 by blinded independent radiologic review (IRR). The open-label Part 2 portion of MOTION, in which patients from both the vimseltinib and placebo arms may receive treatment with vimseltinib, remains ongoing. The results for Part 1 of the study are based on a data cutoff date of August 22, 2023.

In October 2023, we announced that the MOTION study met its primary endpoint in the ITT population demonstrating statistically significant and clinically meaningful improvement versus placebo in ORR at Week 25 based on IRR per RECIST v1.1. In the ITT population, the ORR at Week 25 was 40% (95% CI: 29%, 51%) for the vimseltinib arm and 0% (95% CI: 0%, 9%) for the placebo arm resulting in a response difference (vimseltinib vs. placebo) of 40% (95% CI: 29%, 51%) ($p<0.0001$).

In addition to meeting the primary endpoint, the study also achieved statistically significant and clinically meaningful improvements versus placebo for all key secondary endpoints assessed at Week 25 including ORR per tumor volume score (TVS), active range of motion (ROM), physical function, stiffness, quality of life, and pain.

In the ITT population, the ORR at Week 25 based on IRR per TVS was 67% (95% CI: 56%, 77%) for the vimseltinib arm and 0% (95% CI: 0%, 9%) for the placebo arm ($p<0.0001$). Treatment with vimseltinib also demonstrated an improvement in mean change from baseline in active ROM at Week 25 of 18.4% vs. a 3.8% improvement for placebo ($p=0.0077$).

Vimseltinib was well tolerated and the observed adverse events in the MOTION study were consistent with previously disclosed data from the Phase 1/2 study. There was no evidence of cholestatic hepatotoxicity in patients treated with vimseltinib. In the vimseltinib arm, six percent of patients (n=5) experienced TEAEs leading to study treatment discontinuation, 42% of patients (n=35) experienced TEAEs leading to dose reduction and 53% of patients (n=44) had TEAEs leading to dose interruption. The below table lists all TEAEs in greater than or equal to 15% of patients in either arm during Part 1 of the MOTION study:

Preferred Term n (%)	**Vimseltinib (n=83)**		**Placebo (n=39)**	
	All Grades	**Grade 3/4**	**All Grades**	**Grade 3/4**
Periorbital edema^	37 (45%)	3 (4%)	5 (13%)	0
Fatigue ^	27 (33%)	0	6 (15%)	0
Face edema^	26 (31%)	1 (1%)	3 (8%)	0
Pruritus^	24 (29%)	2 (2%)	3 (8%)	0
Headache^	23 (28%)	1 (1%)	10 (26%)	0
Asthenia^	22 (27%)	1 (1%)	9 (23%)	1 (3%)
Nausea ^	21 (25%)	0	8 (21%)	1 (3%)
CPK increased	20 (24%)	8 (10%)	0	0
AST increased	19 (23%)	0	1 (3%)	0
Arthralgia ^	16 (19%)	0	6 (15%)	1 (3%)
Rash ^	16 (19%)	0	2 (5%)	0
Rash maculo-papular^	16 (19%)	1 (1%)	0	0
Edema peripheral ^	15 (18%)	0	3 (8%)	0
Hypertension	14 (17%)	4 (5%)	4 (10%)	1 (3%)

(1) Does not include one patient randomized to placebo that did not receive study drug.
Notes: TEAE incidence is based on maximum grade per CTCAE v5.0. The only Grade 4 adverse events were CPK Increased observed in two patients. ^ Denotes adverse events without Grade 4 criteria per CTCAE v5.0.

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

We have an ongoing open-label Phase 1/2 study designed to evaluate the safety, efficacy, PK, and PD of vimseltinib in patients with solid tumors and TGCT.

In October 2023, we announced an update to the results from our ongoing Phase 1/2 study of vimseltinib in 97 TGCT patients with a cut-off date of June 27, 2023. As of a June 27, 2023 cut-off date, 32 TGCT patients enrolled in the Phase 1 dose escalation portion of the study and 65 TGCT patients enrolled in the two Phase 2 Cohorts (Cohort A and B) in the expansion portion of the study as follows: Phase 1 Cohort 5 (n=8): 30 mg loading dose daily for five days followed by a maintenance dose of 30 mg twice a week; Phase 1 Cohort 8 (n=12): 30 mg loading dose daily for three days followed by a maintenance dose of 10 mg daily; Phase 1 Cohort 9 (n=12): 20 mg loading dose daily for three days followed by a maintenance dose of six mg daily; and Phase 2 Cohorts A (n= 46) and B (n=19): recommended Phase 2 dose of 30 mg twice weekly (no loading dose). We observed a best ORR of 72% in Phase 1, 64% in Phase 2 Cohort A, and 44% in Phase 2 Cohort B, as measured by RECIST version v1.1 by blinded IRR.

Updated interim results for the 93 efficacy evaluable patients are summarized in the below table.

	Phase 1 (n=32)	**Phase 2 Cohort A (n=45)**	**Phase 2 Cohort B (n=16)**
Best ORR per RECIST v1.1 by IRR (%)	72%	64% (38% at Week 25)	44%
Median Duration of Response (months) (Range)	NR (3.8+, 45.2+)	NR (0.03+, 25.4+)	NR (4.0+, 21.0+)
Median Treatment Duration (months) (Range)	25.1 (0.7, 46.9)	21.0 (0.2, 30.3)	7.3 (0.7, 27.4)
Patients Active on Treatment at Cutoff Date (%)	47%	48%	74%

Notes: NR: Not Reached by Kaplan-Meier analysis.

In addition, updated data from Cohorts A and B of the Phase 2 study demonstrated that patients achieved clinically meaningful symptomatic benefit at Week 25 across multiple secondary efficacy measures including best ORR per TVS (Cohort A), active range of motion, physical function, stiffness, and pain.

In the Phase 1/2 study, vimseltinib was well tolerated and the observed adverse events were consistent with previously presented Phase 1/2 data in patients with TGCT. There was no evidence of cholestatic hepatotoxicity in patients treated with vimseltinib. In Phase 2 Cohort A, nine percent of patients (n=4) experienced TEAEs leading to study treatment discontinuation, 52% of patients (n=24) experienced TEAEs leading to dose reduction and 70% of patients (n=32) had TEAEs leading to dose interruption. There were no treatment-related serious adverse events in Phase 2 Cohort A. The TEAEs across all cohorts in the Phase 1/2 study greater than or equal to 15% of TGCT patients (n=95) by all Grades, and the corresponding TEAEs across all cohorts in Grades 3/4, are summarized in the table below.

Preferred Term n (%)	**Phase 1/2 Combined: All Patients (n=95)**	
	All Grades	**Grade 3/4**
Blood CPK increased	63 (66%)	39 (41%)
Periorbital edema^	45 (47%)	0
Headache^	37 (39%)	0
Fatigue^	35 (37%)	2 (2%)
Myalgia^	28 (29%)	3 (3%)
Nausea^	28 (29%)	0
AST increased	27 (28%)	4 (4%)
Arthralgia^	27 (28%)	2 (2%)
Asthenia^	23 (24%)	1 (1%)
Edema peripheral^	23 (24%)	0
Rash maculopapular^	21 (22%)	1 (1%)

Face edema^	21 (22%)	0
Pruritus^	20 (21%)	0
Diarrhea	19 (20%)	1 (1%)
Rash^	18 (19%)	0
COVID-19	18 (19%)	0
Hypertension	15 (16%)	6 (6%)
Lipase increased	15 (16%)	4 (4%)
Amylase increased	15 (16%)	3 (3%)
ALT increased	15 (16%)	1 (1%)

Notes: Results are reported for patients with TGCT with a data cutoff of June 27, 2023. TEAE incidence is based on maximum grade per CTCAE v4.03. TEAEs were summarized in n=95 patients with TGCT across all cohorts in the Phase 1/2 study. One patient from Phase 1 and one patient from Cohort A discontinued and enrolled into Cohort B. The only Grade 4 adverse events were CPK increased. ^ Denotes adverse events without Grade 4 criteria per CTCAE v4.03.

DCC-3116: ULK Kinase Inhibitor for RTK/RAS/MAPK Driven Cancers

DCC-3116 is a potential first-in-class investigational, orally administered, potent, and highly selective switch-control inhibitor of the ULK kinase. DCC-3116 is designed to inhibit autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK kinases, which have been shown to be the initiating factors that activate autophagy. We believe that DCC-3116, in combination with RTK/RAS/MAP kinase signaling pathway inhibition has the potential to change the treatment of RTK/RAS/MAPK driven cancers, if approved.

DCC-3116 is being studied in a Phase 1/2 study designed to evaluate the safety, tolerability, clinical activity, PK, and PD of DCC-3116 as a single agent and in combination with sotorasib in patients with advanced or metastatic solid tumors with $KRAS^{G12C}$ mutations, and QINLOCK, our FDA-approved KIT inhibitor, in patients with GIST. The clinical development plan for DCC-3116 will focus on combination strategies for patients with documented RAS and RAF cancer mutations, which we believe utilize autophagy for tumor growth, survival, and as a resistance mechanism to inhibitors of RTK, RAS, and MAP kinases. In 2024, we plan to select a recommended Phase 2 dose for potential expansion cohort(s), subject to favorable data.

In April 2023, we presented preclinical data on new clinical combinations with DCC-3116 at the American Association for Cancer (AACR) Annual Meeting 2023, including preclinical models in combination with QINLOCK in GIST.

In August 2023, we announced the completion of the single agent DCC-3116 dose escalation portion of the Phase 1/2 study (n=28). We also provided updated data on the PK characteristics of single agent DCC-3116. In addition, we provided an update on the ongoing Phase 1/2 study in combination with trametinib, binimetinib, and sotorasib. In August 2023, we also announced that we opened the first site for enrollment in two new combinations evaluating DCC-3116 in combination cohorts with QINLOCK in patients with GIST and in combination with encorafenib and cetuximab in patients with colorectal cancer.

In January 2024, we announced we are prioritizing the development of DCC-3116 in combination with sotorasib and with QINLOCK and discontinued development of the DCC-3116 cohorts in combination with (i) trametinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; (ii) binimetinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; and (iii) encorafenib and cetuximab in patients with colorectal cancer. As a result, we also terminated the clinical trial collaboration and supply agreement with Pfizer Inc. (Pfizer) for the dose escalation study evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer prior to enrollment in any clinical studies.

Market Opportunity in DCC-3116

Autophagy is a catabolic process in which cells recycle their components as a source of energy. Cancer cells can activate this pathway as an escape mechanism from anti-cancer therapy. Significant scientific evidence exists that inhibition of the MAPK pathway elicits autophagy and protects cancer cells from the cytotoxic effects of targeted inhibition along either pathway. ULK kinases are the initiating factors in autophagy and DCC-3116, a potent and selective inhibitor of ULK kinases, is being studied to explore its potential to inhibit this important mechanism of cancer cell survival. Our preclinical studies have demonstrated the potential for DCC-3116 to inhibit autophagy related resistance to inhibitors of the MAPK pathway.

Inhibition anywhere along the MAPK pathway in cells containing a tumor driver mutation activates ULK and autophagy. These tumor driver mutations may occur within RTKs and multiple nodes along these pathways, such as RAS and RAF. With this

broad potential role of autophagy as a survival/resistance pathway to MAPK and RTK inhibition, there is a significant opportunity for DCC-3116 to provide benefit across a broad spectrum of solid tumors. Specifically, RTK/RAS/RAF mutations are known to occur in approximately 70% of human cancers, although we do not intend to pursue all potential combination approaches within these pathways.

Clinical Development of DCC-3116

DCC-3116 is being studied in a Phase 1/2 study designed to evaluate the safety, tolerability, clinical activity, PK, and PD of DCC-3116 as a single agent and in combination with sotorasib in patients with advanced or metastatic solid tumors with $KRAS^{G12C}$ mutations QINLOCK in patients with GIST.

In September 2022, we presented initial Phase 1 single agent dose escalation data on DCC-3116 in an oral presentation as a Proffered Paper at the ESMO Congress 2022 (ESMO 2022). As of the June 9, 2022 cutoff date, 18 patients with locally advanced or metastatic cancer with a RAF or RAS mutation were enrolled across four dose cohorts treated with DCC-3116 BID: 50 mg BID (n=3); 100 mg BID (n=4); 200 mg BID (n=7); and 300 mg BID (n=4). The median number of prior anti-cancer regimens was three (range 1-10). The most common cancer types were colorectal (56%) and pancreatic (28%) and patients had KRAS (83%) and BRAF (17%) mutations. DCC-3116 exposure appeared to increase dose-proportionally across the four dose levels tested from 50 mg BID to 300 mg BID; at all doses levels, the area under the curve (AUC) of DCC-3116 was at or above the AUC of the lowest tested dose that was active in preclinical studies.

DCC-3116 demonstrated target inhibition with significant decreases in phosphorylation of ATG14, a direct ULK1/2 substrate, in peripheral blood mononuclear cells. At all dose levels, reductions in phosphorylated ATG14 were observed that were associated with anti-tumor activity in preclinical studies combining DCC-3116 and a MEK inhibitor as measured by reductions in phosphorylated ATG13 in tumors. The best overall response was stable disease and the disease control rate at week 16 was 29%. Fourteen patients were evaluable for response per RECIST version 1.1 as of the data cutoff date.

Treatment with DCC-3116 was well tolerated and most TEAEs were Grade 1/2 except for two related asymptomatic and reversible Grade 3 alanine transaminase increases that led to dose interruption and reduction. The most common (≥15%) TEAEs regardless of relatedness reported (all grades) were: fatigue (39%), dehydration (22%), alanine transaminase increases (17%), anemia (17%), aspartate transaminase increases (17%), decreased appetite (17%), hyponatremia (17%), nausea (17%), and vomiting (17%).

In the fourth quarter of 2022, we completed enrollment of the monotherapy dose escalation portion of the Phase 1 study of DCC-3116. Single-agent DCC-3116 did not reach a maximum tolerated dose, and we selected 50 mg BID as the starting dose of DCC-3116 for the combination dose escalation portion of the study. We also opened enrollment for three combination dose escalation cohorts and treated the first patient in the combination dose escalation portion of the study in the fourth quarter of 2022.

In August 2023, we announced the completion of the single agent DCC-3116 dose escalation portion of the Phase 1/2 study (n=28). DCC-3116 was generally well tolerated at doses from 50 mg twice daily (BID) to 300 mg. No maximum tolerated dose was reached. Adverse events observed were generally consistent with prior data disclosed at ESMO 2022, and one dose limiting toxicity (DLT) was observed (Grade 3 ALT increase at 100 mg BID). No treatment-related serious adverse events were observed. We also provided updated data on the PK characteristics of single agent DCC-3116. The updated PK data demonstrated drug exposure associated with anti-tumor activity in preclinical studies. The PK data showed that DCC-3116 exposure increased at doses between 50 and 200 mg BID with associated variability, and DCC-3116 exposure appeared to approach plateau at 300 mg BID. We continued to observe PD effects which were associated with anti-tumor activity in preclinical studies.

We also provided an update on the ongoing Phase 1/2 study in combination with trametinib, binimetinib, and sotorasib. As of August 4, 2023, combination dose escalations of DCC-3116 are ongoing with MEK inhibitors trametinib (n=11) and binimetinib (n=10), and with KRAS G12C inhibitor, sotorasib (n=6) in patients with advanced solid tumors. DLTs were observed at 50 mg BID of DCC-3116 in combination with the approved doses of trametinib (Grade 3 skin rash and diarrhea in one patient and Grade 3 diarrhea in one patient) and binimetinib (Grade 3 decreased ejection fraction in one patient and Grade 2 blurred vision in one patient). Based on these DLTs and the updated PK and PD data from the single agent dose escalation portion of the study, we reduced the dose of DCC-3116 to 50 mg once daily (QD) for both the trametinib and binimetinib cohorts. In addition, the sotorasib cohort at the first dose level of DCC-3116 at 50 mg BID and sotorasib 240 mg QD was well tolerated with no DLTs observed in three patients. We dose escalated DCC-3116 to 200 mg QD and enrollment is ongoing.

In August 2023, we also announced that we opened the first site for enrollment in two new combinations evaluating DCC-3116 in combination cohorts with QINLOCK in patients with GIST and in combination with encorafenib and cetuximab in patients with colorectal cancer.

In January 2024, we announced we are prioritizing the development of DCC-3116 in combination with sotorasib and with QINLOCK and discontinued development of the DCC-3116 cohorts in combination with (i) trametinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; (ii) binimetinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; and (iii) encorafenib and cetuximab in patients with colorectal cancer. As a result, we also terminated the clinical trial collaboration and supply agreement with Pfizer Inc. (Pfizer) for the dose escalation study evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer prior to enrollment in any clinical studies.

Mechanism of Action of DCC-3116

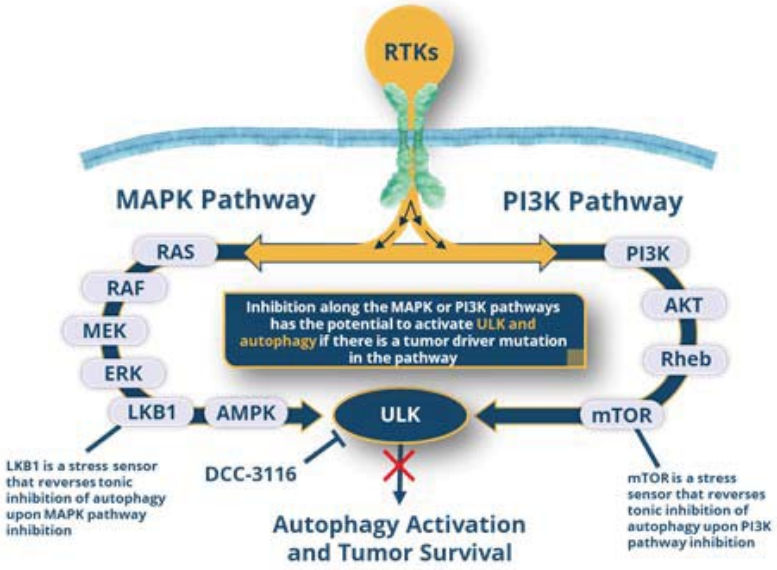
DCC-3116 is designed to treat cancer patients in combination with RTK/RAS/MAP kinase signaling pathway inhibitors. Autophagy is a survival pathway in which cells respond to stress by recycling their own components and/or clearing damaged organelles and proteins from the cell. RTK, RAS, and MAP kinase pathway driven 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. Autophagy has been observed to be upregulated in mutant cancers and is also known to mediate resistance to inhibitors of RTK/RAS/MAP kinase signaling pathways.

Cellular studies in RTK, RAS, and MAP kinase driven cancers have demonstrated that treatment with RTK, RAS, and MAP kinase pathway inhibitors, as well as other signaling pathway inhibitors, can induce ULK activation and autophagic flux as a compensatory survival mechanism. Autophagic flux is the cellular induction of the formation of autophagosomes and their ultimate fusion with lysosomes. Such induction is seen with MAP kinase pathway inhibitors such as RAF, MEK, and ERK inhibitors, direct inhibitors of the RAS pathway including inhibitors of mutant KRAS G12C, as well as RTK inhibitors. In *in vivo* models inhibition of autophagy by DCC-3116 combined with inhibitors of RTK/RAS/MAP kinase signaling has demonstrated additive or synergistic anti-tumor activity.

In the figure below, two key signaling pathways are shown: the MAPK pathway and the PI3K pathway, which are activated in cancer cells by RTK/RAS/RAF mutations. RTK and RAS mutations activate both of these pathways and RAF mutations activate the MAPK pathway in cancer cells. Both the MAPK and PI3K pathways negatively regulate ULK kinase activity, *i.e.* ULK kinase activity is diminished when the MAPK and/or PI3K pathways are activated. Conversely, when the MAPK and/or PI3K pathways are inhibited by targeted therapies, such as with an RTK inhibitor or with a KRAS inhibitor, the negative regulation of ULK kinase is released, which has been shown to result in increased activation of ULK kinase and downstream autophagic flux.

We have shown in preclinical studies that inhibiting the ULK kinase in combination with an inhibitor of key nodes in these pathways results in additive or synergistic inhibition of tumor growth *in vivo*. For example, in *in vivo* studies at the RAS node, DCC-3116 exhibited additivity or synergy with a direct inhibitor of KRAS G12C, sotorasib, resulting in tumor regression in KRAS G12C-mutant non-small cell lung cancer. Also in *in vivo* studies at the MEK node, DCC-3116 exhibited additivity or synergy in combination with the MEK inhibitor, trametinib, inhibiting tumor growth in RAS-mutant pancreatic and lung, and BRAF-mutant melanoma in xenograft tumor models. In composite, inhibition along the MAPK or PI3K pathways has the potential to activate ULK and autophagy if there is a tumor driver mutation upstream of that node in the pathway. We believe

inhibition of ULK by DCC-3116 in combination with an inhibitor of RTK/RAS/RAF is potentially a promising approach for the treatment of mutant RTK/RAS/RAF cancers.



Preclinical Pipeline

We are making a focused investment in our next generation of research programs, which are designed to provide first-in-class or best-in-class treatments using our proprietary switch-control inhibitor platform, which includes DCC-3084 and DCC-3009.

DCC-3084

DCC-3084 is a potential best-in-class RAF inhibitor that is designed to broadly inhibit Class I, II, and III BRAF mutations, BRAF fusions, and BRAF/CRAF heterodimers. DCC-3084 is a potent and selective inhibitor of both BRAF and CRAF kinases and has been shown to target aberrant signaling mechanisms including RAF signaling through monomers, homodimers, and heterodimers. DCC-3084 exhibits high permeability, good central nervous system penetrance, and tumor tissue accumulation. Strong preclinical efficacy in cancer models driven by RAF or RAS mutations support exploration of single agent and combination opportunities.

In April 2023, we presented preclinical data for DCC-3084 at the AACR Annual Meeting 2023, which demonstrated its ability to target the relevant aberrant signaling mechanisms including inhibition of BRAF monomers, BRAF homodimers, and BRAF/CRAF heterodimers. To facilitate tumor access, DCC-3084 possesses desirable pharmaceutical properties including high permeability, CNS penetration, and good solubility at gastric pH. In addition, DCC-3084's optimal properties include a long residency time on RAF kinases, low cellular efflux, and drug-transporter inhibition. Together, the preclinical data on DCC-3084 supports single agent use in tumors driven by RAF and RAS mutations with even deeper responses observed in combination with MEK inhibitors.

In the fourth quarter of 2023, we submitted an IND application to the FDA for DCC-3084 and expect to initiate the Phase 1 study of DCC-3084 in the first half of 2024.

DCC-3009

DCC-3009 is a potential best-in-class next generation KIT inhibitor that is designed to inhibit the broad spectrum of known primary and secondary drug resistant mutations in GIST, spanning KIT exons 9, 11, 13, 14, 17, and 18. Drug-resistant GIST is a complex cancer that has a diverse spectrum of KIT mutations that arise in response to treatment with tyrosine kinase inhibitors. Many patients harbor multiple different drug-resistant mutations in tumors and/or metastatic tumor sites. There remains an unmet medical need for a pan-KIT inhibitor that can broadly and potently inhibit the spectrum of KIT mutations that drive GIST. To

potentially achieve this, we focused on making a drug that can inhibit the spectrum of KIT mutations found in GIST across exons 9, 11, 13, 14, 17, and 18, as well as PDGFRA mutations, while maintaining very high selectivity versus the rest of the kinome.

In April 2023, we presented preclinical data for DCC-3009 at the AACR Annual Meeting 2023, which demonstrated that treatment with DCC-3009 exhibited tumor regressions in multiple drug-resistant preclinical GIST models. DCC-3009 has suitable pharmaceutical and absorption, distribution, metabolism, and excretion (ADME) properties for oral administration, high kinase selectivity, and free drug levels in preclinical models that enable pharmaceutically active exposures needed to suppress the broad spectrum of KIT mutations in GIST.

We expect to submit an IND application to the FDA for DCC-3009 in the first half of 2024 and initiate a Phase 1 study of DCC-3009 in the second half of 2024, each subject to FDA feedback.

In-License Agreement

In August 2021, we entered into an agreement with Sprint Bioscience (Sprint) to exclusively in-license worldwide rights to a research-stage program targeting the VPS34 kinase (the Sprint Agreement). In January 2024, we terminated the Sprint Agreement. For further details on the Sprint Agreement, please read Note 11, *In-License Agreement*, to the consolidated financial statements included in this Form 10-K.

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.

Pursuant to the terms of the Zai License Agreement, as of December 31, 2023, we received an upfront cash payment of $20.0 million and three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 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 annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances. Additionally, certain costs incurred by the Company associated with the Zai License Agreement are reimbursed by Zai.

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 obtained regulatory approval in the Territory. Subject to the Zai Supply Agreement, costs incurred by us for external manufacturing services are reimbursed by Zai. In 2021, QINLOCK was approved by the China NMPA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, and was approved by the Hong Kong Department of Health for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. Also in 2021, QINLOCK was approved by the Taiwan Food and Drug Administration. In 2023, QINLOCK was approved by the Macau Institute for Pharmaceutical Supervision for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Subject to the Zai Supply Agreement, costs incurred by the Company for clinical and commercial supply 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 we have built a targeted infrastructure to commercialize QINLOCK in key European markets, and plan to provide access to QINLOCK in additional countries through other channels with distribution arrangements. In addition, we have entered into distributor arrangements in certain countries including Australia, Canada, and CEE, and may in the future 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. We continuously assess our expansion initiatives and look to strategically utilize all available channels to commercialize QINLOCK globally. In the U.S., we have built a specialist sales force to target physicians who treat GIST, including key opinion leaders at academic centers of excellence, as well as to call on community oncologists and sarcoma doctors with eligible GIST patients. Our sales force is supported by sales management, internal sales support, an internal marketing group, and distribution support. Additionally, our commercial team manages relationships with key accounts such as managed care organizations, group purchasing organizations, hospital systems, physician group networks, and government accounts.

For vimseltinib, we have begun pre-launch planning in patients with TGCT and, if approved, will leverage the potential synergies and experience we have gained from QINLOCK as we believe GIST and TGCT have significant overlap in the key opinion leaders and treating physicians.

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, 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, including vimseltinib, 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 diagnostic tests we may develop. For information regarding the regulation of diagnostic tests, please see "Business—Government Regulation—Regulation of Diagnostic Tests" and for information regarding the risks related to companion diagnostic tests, please see "Risk Factors—Risks Related to the Industry."

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 diagnostic tests, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

QINLOCK, and the drug candidates in our clinical 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 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, followed by ripretinib (QINLOCK) after a patient has received prior treatment with three or more kinase inhibitors, including imatinib. Generic versions of imatinib and sunitinib are also available in the U.S. and certain other major markets. In addition, avapritinib was approved by the FDA in January 2020 for patients with GIST harboring a PDGFRA exon 18 mutation only, including PDGFRA D842V mutations. 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.

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 Medicines Corporation (Blueprint), Novartis AG (Novartis), Pfizer, and Bayer AG (Bayer). We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST including Ascentage Pharma Group Inc. (APGI), Arog Pharmaceuticals, Inc. (Arog), Chia Tai Tianqing Pharmaceutical Group CO., LTD (CTTPG), Cogent Biosciences, Inc. (Cogent), Immunicum AB (Immunicum), Jiangsu HengRui, Inc. (Jiangsu), Ningbo Tai Kang Medical Technology Co. Ltd. (NTKMT), Novartis, Taiho Pharmaceutical Co. Ltd (Taiho), Theseus Pharmaceuticals (Theseus), and IDRx, Inc. (IDRx). Several of these programs are in clinical studies, including but not limited to APGI, Arog, CTTPG, Cogent, Immunicum, Jiangsu, NTKMT, and IDRx.

Competition for Vimseltinib

We are 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 for TGCT, including Abbisko Therapeutics Co., Ltd. (Abbisko), AmMax Bio, Inc. (AmMax), Daiichi Sankyo Company, Limited (Daiichi), Dragonboat Biopharmaceutical Company Limited (DBCL), HX Pharma (HXP), SynOx Therapeutics Ltd (SynOx), and HUTCHMED (China) Limited (HutchMed). These programs are also in clinical studies for TGCT. In addition, pexidartinib is the only FDA approved product, which is indicated for the treatment of adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

Competition for DCC-3116

We are developing DCC-3116, an ULK inhibitor designed to address mutant RAS and RAF cancers. We are aware of other companies that are advancing programs targeting ULK, including Erasca, Inc. (Erasca), Txinno Bioscience Inc. (Txinno), and Ailon Pharma Oy (Ailon).

Competition for DCC-3084

We are developing our pan-RAF inhibitor development candidate, DCC-3084, a broad inhibitor of Class I, II, and III BRAF mutations, BRAF fusions, and BRAF/CRAF heterodimer. We are aware of other companies that are advancing pan-RAF programs, including Day One Biopharmaceuticals, Inc. (Day One), Jazz Pharma Pharmaceuticals, Inc. (Jazz Pharma), F. Hoffmann-La Roche AG (Roche), Kinnate Biopharma Inc. (Kinnate), Erasca, Pfizer, Black Diamond Therapeutics, Inc. (Black Diamond), BeiGene, Inc. (BeiGene), Nested Therapeutics (Nested), METiS Therapeutics (METiS), and Verastem, Inc. (Verastem). Several of these programs are in clinical studies, including but not limited to Day One, Jazz Pharma, Roche, Kinnate, Black Diamond, BeiGene, and Verastem.

Competition for DCC-3009

We are developing DCC-3009, a next generation KIT inhibitor designed to inhibit the broad spectrum of known primary and secondary drug resistant mutations in GIST, spanning KIT exons 9, 11, 13, 14, 17, and 18. We are aware of other companies that are advancing KIT inhibitor programs targeting this patient population, including IDRx, Cogent, and NTKMT.

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 and drug candidates, for example, QINLOCK, vimseltinib, 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, 2024, we own twenty-two issued U.S. patents with composition of matter and, method of use, and drug product claims. Of these, one issued U.S. patent is expected to expire in 2030, one issued U.S. patent is expected to expire in 2034 (inclusive of patent term extension), one issued U.S. patent is expected to expire in 2034, eighteen are expected to expire in 2040, and one is expected to expire in 2042. In addition, we own related patents in Europe, Australia, South America, and Asia that are expected to expire between 2032 and 2040. In addition, we also own twenty-two pending U.S. applications, and related pending applications in Europe, Australia, South America, and Asia, as well as one pending Patent Cooperation Treaty (PCT) patent applications directed to various methods of use, including uses for indications other than GIST, and drug product of QINLOCK (ripretinib). If one or more patents claiming priority to these patent applications is granted, it is expected to expire between 2037 and 2042.

With regard to vimseltinib, as of January 31, 2024, 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 2034 and 2040. In addition, we own one pending U.S. application which, if granted, is expected to expire in 2039, and related patents and pending applications in Australia, Canada, Asia, Europe and South America that are expected to expire between 2034 and 2039. Further, we own one pending PCT application. If one or more patents claiming priority to this PCT application is granted, it is expected to expire in 2043. We also own four pending U.S. provisional applications. If one or more patents claiming priority to these provisional applications is granted, it is expected to expire in 2044.

With regard to DCC-3116, as of January 31, 2024, we own three issued U.S. patents with composition of matter claims and method of use claims that are expected to expire in 2040. We own five pending U.S. applications which, if granted, are expected to expire between 2040 and 2043. In addition, we own related pending applications in Australia, Canada, Asia, Africa, Middle East, Europe, and South America. We also own two pending PCT applications. If one or more patents claiming priority to these PCT applications is granted, it is expected to expire in 2043.

With regard to our early-stage research programs, as of January 31, 2024, we own six pending U.S. applications which, if granted, are expected to expire between 2041 and 2042. We own six pending U.S. provisional applications. If one or more patents claiming priority to these provisional applications is granted, are expected to expire in 2044. We have five pending PCT applications. In addition, we own a related pending application in Europe. If one or more patents claiming priority to these PCT applications is granted, it is expected to expire between 2041 and 2043.

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 the 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. In October 2023, we received a patent term extension that extended the patent term of one of our granted U.S. patents for QINLOCK. As a result, the patent term of one of our composition of matter patents for QINLOCK extends until 2034. We have obtained patent term extensions for two of our issued Australian patents for QINLOCK, extending their expiry dates until 2032 and 2035, respectively. We have obtained a Certificate of Supplementary Protection for our issued patent in Canada, extending the patent expiry date until 2034. We have obtained Supplementary Protection Certificates in several European countries for one of our issued patents in Europe, extending the patent expiry date until 2036. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities 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 1 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.

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, 2023 through September 30, 2024, the user fee for an application requiring clinical data, such as an original NDA, is $4,048,695. The PDUFA also imposes an annual prescription drug product program fee for human drugs ($416,734). 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 sub-groups, 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. The FDA generally requires a

sponsor of a drug receiving accelerated approval to perform post-marketing confirmatory studies with due diligence to verify and describe the predicted effect on irreversible morbidity or mortality, or other clinical endpoint and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after accelerated approval is granted. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency 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 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 MAA with the Australian Therapeutic Goods Administration 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 sub-populations and to support dosing and administration for each pediatric sub-population 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 culminated in November 2023. The FDA established a one-year stabilization period from November 2023 to November 2024 for trading partners to continue to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. 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 other parties involved in the supply chain for prescription drug products must also comply with product tracking and tracking requirements, such as placing 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 EU, the EC, after receiving the opinion of the EMA's Committee for Orphan Medicinal Products (COMP) grants orphan medicinal product designation to also promote the development of orphan products. The relevant EU legislation provides that a product can be designated as an orphan medicinal product by the EC if its sponsor can establish that the product is (1) intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition; (2) either (i) the prevalence of the condition is not more than 5 in 10,000 persons in the EU 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; and (3) exists no satisfactory method of diagnosis, prevention, or treatment of condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000.

In the U.S., Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the EU, orphan 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 EC or any of the competent authorities in the EU 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 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 disapplied in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to an authorized orphan product; (ii) the marketing authorization holder for the authorized orphan product consents to the authorization of a similar medicinal product; or (iii) the marketing authorization holder cannot supply enough of the authorized 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.

As of January 1, 2021, a separate process for orphan drug designation applies in Great Britain (GB). There is no pre-marketing authorization orphan designation (as there is in the EU) and the application for orphan designation is reviewed by the U.K. 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 EU, save that they apply to GB only (e.g. there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in GB).

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 diagnostic tests, 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 EU, *in vitro* medical devices are required to conform with the general safety and performance requirements of the EU Regulation on *in vitro* diagnostic medical devices (Regulation (EU) 2017/746), which became applicable on May 26, 2022 and repealed the previous *in vitro* diagnostic medical devices Directive (Directive No 98/79/EC). To demonstrate compliance with the general safety and performance 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 EU 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 EU. The Regulation provides for a transitional period during which manufacturers of *in vitro* diagnostic medical devices which have a certificate issued under the previous *in vitro* diagnostic medical devices Directive may continue to place their devices on the EU market for a certain period, which depends on the risk class of the device, provided certain requirements of the Regulation (e.g. relating to post-market surveillance and vigilance) are complied with.

Following the U.K.'s departure from the EU on January 31, 2020, the U.K. (which comprises GB 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 GB market. European CE marks for *in vitro* medical devices will continue to be recognized in GB until June 30, 2030, following which a UKCA mark will be required for an *in vitro* medical device to be marketed in GB. The new EU Regulation does not apply in GB, so the regulation of medical devices in GB may diverge further from EU regulations in future. However, the EU regulatory framework on medical devices continues to apply in Northern Ireland under the Northern Ireland Protocol and medical devices in Northern Ireland may either carry a European CE mark or a U.K. and Northern Ireland CE (CE UKNI) mark (although devices bearing the CE UKNI 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. In the EU, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new Clinical Trials Regulation (EU) No 536/2014, which replaced the previous Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System (CTIS) for clinical trial authorization in up to 30 EU/EEA countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States Concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State Concerned. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the Member State Concerned, however overall related timelines are defined by the Clinical Trials Regulation. The new Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

European Drug Review and Approval

In the EU, 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 EC through the centralized procedure, 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 centralized procedure is mandatory for certain types of drugs, including 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 centralized procedure 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 EU and only cover their respective territory, are available for drugs not falling within the mandatory scope of the centralized procedure. Where a drug has already been authorized for marketing in an EU 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 (SmPC), 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, SmPC, 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 EU make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety, and efficacy.

European Chemical Entity Exclusivity

In the EU, innovative medicinal products, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date of which the reference product was first authorized in the EU. 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 eleven 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. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. 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.

The U.K. left the EU on January 31, 2020, and the U.K. and the EU concluded a trade and cooperation agreement (TCA) which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of U.K. and EU pharmaceutical regulations. At present, GB has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in GB therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that GB’s regulatory system is independent from the EU and the TCA does not provide for mutual recognition of U.K. and EU pharmaceutical legislation.

On February 27, 2023, the U.K. government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the U.K. In particular, the MHRA will be responsible for approving all medicinal products destined for the U.K. market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single U.K.-wide MA will be granted by the MHRA for all medicinal products to be sold in the U.K., enabling products to be sold in a single pack and under a single authorization throughout the U.K. The Windsor Framework was approved by the European Union-United Kingdom Joint Committee on March 24, 2023, so the U.K. government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. All existing EU marketing authorization for centrally authorized products were automatically converted (grandfathered) into GB marketing authorizations free of charge on January 1, 2021. Until January 1, 2024, the MHRA could 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. From January 1, 2024 a new international recognition procedure has been put in place, in which the MHRA will take into account decisions on the approval of marketing authorizations made by the EMA and certain other regulators (including the FDA) when determining an application for a new GB marketing authorization through such procedure.

Furthermore, the Data Protection Act 2018 in the U.K. “implements” and complements the EU’s the General Data Protection Regulation (EU) 2016/679 (GDPR), and is effective in the U.K. On June 28, 2021, the EC adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the EU Member States to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EU remain unaffected. The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the EU Member States, plus Norway, Liechtenstein and Iceland.

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. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, QINLOCK and any future approved drugs or assure that coverage and reimbursement will be available for any future approved drug that we may develop. 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.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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.

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. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures have increasingly passed legislation and implemented 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

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. These rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. The data includes the average manufacturer price (AMP) and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results. 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 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, 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. In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other changes discussed in greater detail below, the IRA requires companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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. 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. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. 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. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. 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. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B price calculations and negatively impact our results of operations.

The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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.

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.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter is incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect.

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, 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 Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% 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, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year and, due to subsequent legislative amendments to the statute, will remain in effect through 2031.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility 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.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known.

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.

At the federal level, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On November 3, 2023, the U.S. District Court of South Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is uncertain. We continue to review developments impacting the 340B program.

Individual states in the U.S. and foreign countries 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

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. 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. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. 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 drug 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, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their business associates, that perform services for them that involve the creation, maintenance, receipt, 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), certain other licensed health care practitioners and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- 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, including for example the European Union General Data Protection Regulation, which became effective May 2018, 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 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.

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, our vendors, or our 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.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. 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.

Privacy and Data Security Laws

In the United States, numerous federal, state, and local laws and regulations, including state data breach notification laws, state health information privacy laws, and federal consumer protection laws and regulations (e.g., Section 5 of the FTC Act), and similar laws (e.g., wiretapping laws) govern the collection, use, disclosure, protection, and other processing of health-related and other personal data and may apply to our operations or the operations of our partners upon which we rely. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain health care providers, health plans and health care clearinghouses, known as covered entities and their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities as well as their covered subcontractors. Entities that are found to be in violation of HIPAA as the result of, for example, a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

In addition, U.S. state laws govern the privacy and security of personal data, many of which differ from each other in significant ways and may be subject to different interpretations, thus complicating our compliance efforts. By way of example, the California Consumer Privacy Act (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals. The CCPA provides for administrative fines of up to $7,500 per violation, as well as a private right of action for individuals affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 (CPRA) expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency (CPPA) to implement and enforce the law. Other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These state laws and the CCPA provide individuals with certain rights concerning their personal data, including the right to access, correct, or delete certain personal data, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. While these state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Furthermore, a smaller number of states have passed or proposed legislation that is specifically focused upon the privacy of health-related information.

In the EU and the U.K., 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 the GDPR as incorporated into the laws of the U.K. and the U.K. GDPR. 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. We currently conduct clinical trials and engage in regulatory and commercial operations in the EEA and the U.K. As a result, we are subject to additional privacy laws, including the GDPR and U.K. GDPR (collectively referred to as GDPR). The GDPR imposes a broad range of data protection obligations on companies subject to the GDPR,including, for example, imposing obligations on companies around how they process personal data, stricter requirements relating to processing health and other sensitive data, ensuring there is a legal basis to justify the processing of personal data, stricter requirements relating to obtaining consent of individuals, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, implementing safeguards to protect the security and confidentiality of personal data, taking certain measures on engagement with third parties, 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 European data protection authorities carrying out an investigation or issuing enforcement (for example, monetary penalties of up to €20 million (or £17.5 million in the

U.K.) or 4% of worldwide revenue, whichever is higher). Moreover, data subjects can claim damages resulting from infringement of the GDPR. 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.

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, currently, aligned to the EU's data protection regime. The EC has adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EEA remain unaffected. The U.K. Government has also now introduced a Data Protection and Digital Information Bill (or the U.K. Bill) into the U.K. legislative process with the intention for this bill to reform the U.K.'s data protection regime following Brexit. If passed, the final version of the U.K. Bill may have the effect of further altering the similarities between the U.K. and EU data protection regime and threaten the U.K. adequacy decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk.

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 GDPR. In some cases, we rely upon the recently updated standard contractual clauses (new standard contractual clauses) to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the GDPR). The U.K. is not subject to the EC's new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the U.K. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U.S. have adopted its adequacy decision for the EU U.S. Data Privacy Framework (Framework), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the U.S. are carried out in line with GDPR. The Framework could be challenged like its predecessor frameworks.

In addition, many jurisdictions outside of Europe are also considering and/or enacting comprehensive data protection legislation. For example, as of August 2020, the Brazilian General Data Protection Law imposes stringent requirements similar to GDPR with respect to personal information collected from individuals in Brazil.

In China, there have also been recent significant developments concerning privacy and data security. The Data Security Law of the People’s Republic of China (Data Security Law), which took effect on September 1, 2021, requires data processing (which includes the collection, storage, use, processing, transmission, provision and publication of data), to be conducted in a legitimate and proper manner. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development and the degree of harm it may cause to national security, public interests, or legitimate rights and interests of individuals or organizations if such data are tampered with, destroyed, leaked, illegally acquired or illegally used. The appropriate level of protection measures is required to be taken for each respective category of data.

Also in China, the Personal Information Protection Law, which took effect on November 1, 2021, introduced stringent protection requirements for processing personal information, which are in many ways akin to the requirements of the GDPR. We may be required to make further significant adjustments to our business practices to comply with the personal information protection laws and regulations in China including the Personal Information Protection Law.

We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs.

Human Capital Resources

As of January 31, 2024, we had approximately 355 employees located in approximately 30 states across the United States and five countries in Europe. Approximately 150 employees are located at our headquarters in Waltham, Massachusetts, approximately 40 employees are located at our research facility in Lawrence, Kansas, and approximately 15 employees are located in our European commercial headquarters in Zug, Switzerland.

We believe that our future success largely depends upon our continued ability to attract, retain and engage 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 rewards 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 are committed to continuously building a culture that embraces the uniqueness of our people and finds strength in our differences. We recognize our duty to cultivate diversity within the organization and to ensure that every voice is heard. We understand that varied perspectives lead to the best ideas and outcomes. By creating a workplace where every individual can feel welcome and valued, we will better meet the needs of those we serve. We have a cross-functional Diversity, Equity, and Inclusion (DEI) council comprised of employee volunteers who inform the development of a DEI roadmap with the goal of realizing our vision in 2024 and beyond. 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., key European markets, and in other jurisdictions where we may obtain marketing approval. There is no assurance that our commercialization efforts with respect to QINLOCK including, without limitation, our launch of QINLOCK in key European markets, 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 sufficient revenue to result in a profit from the sale of products. On May 15, 2020, QINLOCK was approved in the U.S. 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., key European markets, and in other jurisdictions where we may obtain marketing approval. In November 2021, we announced that the EC approved QINLOCK in the EU for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We launched QINLOCK in Germany in 2022, Italy in 2023, and have conducted the post-approval paid access program in France since April 2022. We plan to continue the geographic expansion of QINLOCK in 2024, with planned commercial launches following conclusion of pricing and reimbursement negotiations in other key European markets. We also plan to provide access to QINLOCK to fourth-line GIST patients in additional countries through distributorship partnerships. This process is conducted on a country-by-country basis and is time-consuming and complex, and we may not be successful in obtaining reimbursements and other approvals in a timely manner with acceptable terms, or at all. Furthermore, 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 in fourth-line advanced GIST and have a limited history of commercial sales. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the commercialization of QINLOCK in the U.S. in GIST, or those for the commercialization of QINLOCK in key European markets in GIST, will be sufficient for us to achieve success at the levels we expect. Furthermore, there is no guarantee that we will be able to expand patient access to QINLOCK in additional countries through any channels that we may pursue.

We may encounter issues and challenges in commercializing QINLOCK and generating sufficient revenues to result in a profit. 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 sufficient revenues to result in a profit, include:

- the acceptance of QINLOCK by patients and the medical community;
- our ability to successfully complete our Phase 3 INSIGHT study of QINLOCK;
- 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 current good manufacturing practice (cGMP) regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA- or EMA-mandated package insert requirements and successful completion of any related FDA or EMA 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;
- 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 sufficient revenues to result in profit(s) 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 commercialization efforts with respect to QINLOCK in fourth-line advanced GIST. 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., key European markets, and any other international markets where it may subsequently be approved or any significant delay, could have a material adverse impact on our company.

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 are commercializing QINLOCK in the U.S. and continuing our geographic expansion of QINLOCK in key European markets, 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 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 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. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals, and other parties through which we market, sell, and distribute QINLOCK and any other products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. For more information regarding the risks related to such laws, regulations, and patient assistance programs, please see "*Business—Government Regulation—Other Healthcare Laws*" in this Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have 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. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices could, despite efforts to comply, be subject to challenge under 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, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple

jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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. For more information regarding the risks related to insurance coverage and reimbursement, please see "*Business—Government Regulation—Coverage and Reimbursement*" in this Form 10-K.

Our ability to successfully commercialize QINLOCK and other 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 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.

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. Among policy-makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. For more information regarding the risks related to such recently enacted and future legislation, please see "*Business—Government Regulation—U.S. Healthcare Reform*" in this Form 10-K.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations, and prospects.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our drug candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule (FSS) pricing program, and the Tricare Retail Pharmacy program, which require us to disclose average manufacturer pricing, and, in the future may require us to report the average sales price for certain of our drugs to the Medicare program. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. Furthermore, regulatory and legislative changes, and judicial rulings relating to these programs and policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation. For example, in the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements increase our costs and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation. For more information regarding price reporting, please see "*Business—Government Regulation—U.S. Healthcare Reform*" and "*Business—Government Regulation—Coverage and Reimbursement*" in this Form 10-K.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. Additionally, our agreement to participate in the 340B program or our Medicaid drug rebate agreement could be terminated, in which case federal payments may not be available under Medicaid or Medicare Part D for our covered outpatient drugs. Additionally, if we overcharge the government in connection with our arrangements with FSS or Tricare Retail Pharmacy, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

Inadequate funding for the FDA, the SEC, and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and the acceptance of user fees payments, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

QINLOCK or any current drug candidates, such as vimseltinib and DCC-3116, 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 current drug candidates, such as vimseltinib and DCC-3116, or 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. In addition, undesirable side effects caused by our drug candidates 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 drug candidates, such as vimseltinib and DCC-3116, 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 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 advancing clinical development or 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 or any future approved drug 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 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, competent authorities of the Member States in the EU, 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, including promoting unapproved dosing regimens, 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, competent authorities of the Member States of the EU, and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional communications and 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 our current or future international operations 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.

As we expand our operations outside of the U.S. in key European markets, 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. Such 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 European countries, including without limitation, Germany and France, 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 authorization to evaluate the product for reimbursement. 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 approved drug is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

We face increasingly stringent legal requirements with respect to privacy and data security. In the United States, new privacy and data security laws have been passed in numerous states and have been proposed in even more as well as in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate with increasing concerns about individual privacy. The existence of comprehensive privacy laws in different states in the country will make our

compliance obligations more complex and costly 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 and the U.K., 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). The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. 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.

Likewise, many other jurisdictions around the world have enacted or are proposing comprehensive new privacy and data protection laws that can impact our business. For more information regarding these laws and regulations, please see "*Business - Government Regulation—Privacy and Data Security Laws*" in this Form 10-K.

Over the past few years, the number of enforcement actions and the fines have both steadily increased in the U.S. and around the world. U.S. data privacy laws, such as the CCPA, and others that may be passed, similarly introduce requirements with respect to personal information, and non-compliance with the CCPA may result in liability through private actions (subject to defined statutory damages in the event of certain data breaches) and enforcement. Failure to comply with these current and future laws, policies, industry standards, or legal obligations or any security incident resulting in the unauthorized access to, corruption of, or acquisition, release, or transfer of personal information may result in government enforcement actions, litigation, fines, and penalties, or adverse publicity and could cause our customers, business partners, and investors to lose trust in us which could have a material adverse impact on our business and results of our operations. We continue to 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.

Any investigation brought, or penalties issued, by 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 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.

Because the interpretation and application of many privacy and data protection laws (including the GDPR), commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

Unfavorable global economic conditions, including exchange rate fluctuations, could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the U.S. and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Given the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the Euro, may have a significant impact on our results of operations and cash flows from period to period and the price of our common stock. Although we are based in the United States, we sell QINLOCK in the EU and we have also entered into exclusive distributor arrangements to facilitate sales of QINLOCK in select geographies where we do not currently intend to distribute QINLOCK on our own. Currently, we do not have any exchange rate hedging arrangements in place.

The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and high inflation, as well as by the Ukraine-Russia and Israel-Hamas wars and the possibility of a wider global conflict. A severe or prolonged economic

downturn (including inflation or uncertainty caused by political violence and chaos) could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the U.S., possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Although we do not have investments with any financial institution that has experienced such events, if any financial institution with which we have a relationship were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to credit agreements and arrangements with banks in receivership or other financial difficulty, and third parties (such as beneficiaries of letters of credit, among others), may experience direct impacts from the closure or reorganization of such financial institutions and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC, and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC, and Federal Reserve Board will provide access to uninsured funds in the event of the closure of other banks or financial institutions in the future, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have financial arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit, or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations, or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

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. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

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 APGI, Arog, CTTPG, Cogent, Immunicum, Jiangsu, NTKMT, Novartis, Taiho, Theseus, and IDRx. Several of these programs are in clinical studies, including but not limited to APGI, Arog, CTTPG, Cogent, Immunicum, Jiangsu, NTKMT, and IDRx. Further, there are numerous companies marketing or developing antibodies and small molecules targeting CSF1R for TGCT, including Abbisko, AmMax, Daiichi, DBCL, HXP, SynOx, and HutchMed. These programs are also in clinical studies for TGCT. In addition, pexidartinib is the only FDA approved product, which is indicated for the treatment of adult patients with symptomatic TGCT associated with severe morbidity or functional limitations and not amenable to improvement with surgery. With respect to DCC-3116, an ULK inhibitor designed to address mutant RAS and RAF cancers being studied in a Phase 1/2 clinical study, we are aware of other companies that are advancing programs targeting ULK, including Erasca, Txinno, and Ailon. With respect to DCC-3084, we are also aware of pharmaceutical and biotechnology companies developing pan-RAF development candidates, including Day One, Jazz Pharma, Roche, Kinnate, Erasca, Pfizer, Black Diamond, BeiGene, Nested, METiS, and Verastem. Several of these programs are in clinical studies, including but not limited to Day One, Jazz Pharma, Roche, Kinnate, Black Diamond, BeiGene, and Verastem. With respect to DCC-3009, we are aware of other pharmaceutical and biotechnology companies that are developing KIT inhibitors, including IDRx, Cogent, and NTKMT.

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.

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.

If the FDA, EMA, or other foreign regulatory authorities approve generic versions of QINLOCK or any future approved products, or such authorities do not grant any future approved products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of an Abbreviated New Drug Application (ANDA) in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

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. Generic drug manufacturers may seek to launch generic products following the expiration of QINLOCK's exclusivity period or any exclusivity period we obtain for any future approved products even if we still have patent protection for such products. We expect that QINLOCK, and any future approved products will be priced at a significant premium over any competitive generic products. Competition that QINLOCK or any future approved products could face from generic versions could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those products.

The incidence and prevalence for target patient populations of our approved drug or drug candidates and any potential expanded market for our approved drug or drug candidates have not been established with precision. If the market opportunities for our approved drug or any potential expanded market for our approved drug or drug candidates are smaller than what 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, specific mutant RAS and RAF cancers, 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. For example, we have assumed the GIST patient population in our INTRIGUE trial is representative of second-line GIST patients, and that the U.S. market opportunity in second-line GIST patients previously treated with imatinib with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14 will be consistent with the proportion we observed in the INTRIGUE study.

The total addressable market opportunity for QINLOCK, including in the sub-group of the second-line GIST population we are targeting in our INSIGHT study, vimseltinib, and DCC-3116, and any other drug candidates we may develop 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, 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, our expected duration of therapy or treatment 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, such as vimseltinib or DCC-3116, if approved, 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, such as vimseltinib or DCC-3116, if approved, 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, such as vimseltinib or DCC-3116, if approved, do not achieve and maintain 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 drug candidates, such as vimseltinib and DCC-3116, 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, if approved;
- the labeling of our products, including any significant use or distribution restrictions or safety warnings;
- any restrictions on the use of our products together with other medications; and
- the foregoing factors as they apply to any combination drug for which a drug candidate of ours, such as DCC-3116, may be approved to be prescribed with as part of a combination therapy.

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. In addition, even if our Phase 3 INSIGHT study yields positive results and we obtain regulatory approval for QINLOCK in a sub-group of second-line GIST patients, the commercial success of QINLOCK in this indication depends on a number of additional factors, including the adoption of ctDNA testing for GIST patients. Any of the above may cause QINLOCK, or any future approved drugs, such as vimseltinib or DCC-3116, if approved, to be unsuccessful or less successful than anticipated.

Our failure to obtain additional marketing approvals in other foreign jurisdictions would prevent QINLOCK and our drug candidates from being marketed more extensively internationally, and any approval we are granted for QINLOCK or our drug candidates in the U.S., key European markets, or other countries around the world would not assure approval of QINLOCK or our drug candidates in other foreign jurisdictions.

Following the FDA approval of QINLOCK in May 2020, we commenced commercial sales of QINLOCK in the U.S. In addition, our partner, Zai, obtained regulatory approval to market QINLOCK in the PRC, Hong Kong, and Taiwan in 2021 and Israel, Macau, and Singapore in 2023. Following EC approval in November 2021, we launched QINLOCK in Germany in 2022, Italy in 2023, and have conducted the post-approval paid access program in France since April 2022. We plan to continue our geographic expansion of QINLOCK with commercial launches following the conclusion of pricing and reimbursement

negotiations in other key European markets. We also plan to provide access to QINLOCK to fourth-line GIST patients in additional countries through other channels with distribution arrangements.

In order to market and sell QINLOCK, or any future products in other jurisdictions, we or our partners must obtain separate marketing approvals in applicable foreign jurisdictions and comply with numerous and varying regulatory requirements. 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. 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. Except for QINLOCK in select countries where we have received approval, we, or our partners, 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.

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. Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act (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. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. 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 sufficient revenues to result in a profit.

We 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 commercial capabilities in key European markets. 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, training, and motivating a sales force is expensive and time-consuming and could delay any product launch. We will need to commit significant management and other resources to maintain 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, hire, 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;
- 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.

Our product revenues and profitability, if any, are likely to be lower as a result of any partnerships we choose to enter into in markets outside of the U.S. or key European markets than if we were to market and sell the products ourselves in those markets. 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 may 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

Our business could be negatively affected by cyber security threats.

A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. We are dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers, and other business partners, may become the target of cyberattacks or information security compromises or breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of private, proprietary, and other information, or could otherwise lead to the disruption of our business operations. Cyberattacks are becoming more sophisticated and certain cyber incidents, such as surveillance, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss due to remedial actions, loss of business, disruption of operations, damage to our reputation, or potential liability, including litigation and regulatory investigations and enforcement actions. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Furthermore, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks.

We are increasingly dependent on critical, complex, and interdependent information and technology (I&T) systems and data to operate our business. Any failure, inadequacy, interruption, or security lapse of that technology, including security attacks, incidents, and/or breaches, could harm our ability to operate our business effectively.

We have outsourced significant parts of our I&T and business infrastructure to third-party providers, and we currently use these providers to perform business critical I&T and business services for us. We are therefore vulnerable to cybersecurity attacks and incidents on the associated networks and systems, whether they are managed by us directly or by the third parties with whom we contract, and we have experienced and may in the future experience such cybersecurity threats and attacks. The risk of such threats and attacks continues to increase as we are now operating in a hybrid working environment, and sensitive data is accessed by employees working in less secure, home-based environments. The way we work continues to contain a significant remote component in most aspects of the business and we will continue to factor this into our cybersecurity risk management strategy. In addition, due to our reliance on third-party providers, we have experienced and may in the future experience interruptions, delays, or outages related to I&T service availability due to a variety of factors outside of our control, including technical failures, natural disasters, fraud, or security vulnerabilities, compromises, or attacks experienced by or caused by these third-party providers. Interruptions in the service provided by these third-party providers could affect our ability to perform critical tasks.

Because we are a global pharmaceutical company, our systems are subject to frequent cyber-attacks. Due to the nature of a growing number of increasingly sophisticated attacks, there is a risk that they may remain undetected for a period of time. While we have invested in the protection of data and information technology, our efforts may not prevent service interruptions or security compromises, incidents, or breaches (e.g., ransomware or phishing or other social engineering schemes). Any such interruption, compromise, or breach of our systems or data could adversely affect our business operations and/or result in the loss of critical or sensitive protected information, including confidential information, personal information, or intellectual property, and could result in financial, legal, business, and reputational harm to us. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption, compromise, or breach of our systems.

Despite the implementation of security technical and organizational measures, our internal computer systems, and those of third parties with which we contract are vulnerable to damage from security incidents, compromises, breaches, and/or attacks

(e.g., ransomware, computer viruses, worms, social engineering schemes, and other destructive or disruptive software), unauthorized access or misuse, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents, or security attacks, compromises, and/or breaches of our systems or data could result in operational interruptions and/or 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, misuse, or compromised integrity 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 systems disruptions, security compromises, security incidents, or security breaches were to result in a loss of, damage to, or compromised integrity of our data or applications, or inappropriate disclosure of protected information, including confidential, personal, or proprietary information, we could incur liability, and our product research, development, and commercialization efforts could be disrupted or 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 disclosure or loss of information maintained in the information systems and networks of our company, including protected information, such as personal information of our employees and personal health information of our patients. 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 to gain access to our systems and 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 security incidents, breaches, and attacks. The number and complexity of these threats continue to increase over time. Although we have experienced some of the events described above, to date, they have not had a material impact on our operations. Still, the occurrence of any of the events described above in the future could disrupt our business operations and result in enforcement actions or liability, including potential fines and penalties, claims for damages, and/or shareholder litigation.

Security incidents, compromises, and breaches could also include supply chain attacks which, if successful, could cause a delay in the manufacturing and/or distribution of our product or drug candidates. Our key business partners face similar risks, and any security breach or compromise of their systems or data could adversely affect our security posture. In addition, our increased use of cloud technologies could heighten these and other operational risks, and any failure by cloud technology service providers to adequately safeguard their systems and prevent cyber-attacks could disrupt our operations and result in misappropriation, corruption, or loss of protected information, including confidential, personal, or proprietary information.

Finally, 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 third-party providers 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 assets, security controls, and/or information systems. We could also be required to change third-party providers and/or products at significant cost. 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 or compromise of our security measures by third-party actions, employee negligence, misconduct, and/or error, malfeasance, defects, or compromise of 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 potentially causing us to incur legal fees and costs;
- legal or regulatory investigations and 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 business interruption or security incidents, compromises, and/or breaches, 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.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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. 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 clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event 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.

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, 2023, 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."

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 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.

Additionally, an outbreak of any 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. The extent to which an outbreak of any highly infectious or contagious diseases, impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity, and duration of the pandemic, 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 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

Our pivotal Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14, which we also refer to as patients with mutations in KIT exon 11 and 17/18 (the INSIGHT study), may not be successful.

In January 2023, we announced results from an exploratory ctDNA analysis from the Phase 3 INTRIGUE study of QINLOCK in patients with GIST previously treated with imatinib, which showed substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18. Based on these exploratory results, we initiated the pivotal

Phase 3 INSIGHT study of QINLOCK versus sunitinib in this patient population in the second half of 2023. However, our Phase 3 INTRIGUE study for QINLOCK in second-line GIST patients did not meet its primary endpoint and any results from preclinical studies or clinical trials to support the approval of QINLOCK for the treatment of certain second-line GIST patients, including, without limitation, the Phase 3 INTRIGUE study or the exploratory analysis of sub-group mutational data from this study, may not be predictive of results in future clinical trials, including our Phase 3 INSIGHT study.

We cannot be certain that the results from the Phase 3 INSIGHT study for QINLOCK in this population will be consistent with those observed in the exploratory ctDNA analysis from the Phase 3 INTRIGUE study. There is no guarantee that the INSIGHT study will be successful or will generate results that will support marketing approval or any additional revenue, and any revenue generated may be less than what we anticipate. Even if we receive positive results from the Phase 3 INSIGHT study and obtain marketing approval, there is no guarantee that we will be successful in commercializing QINLOCK for second-line GIST patients with mutations in KIT exon 11 and 17/18, and we may encounter issues in commercializing QINLOCK, including, without limitation, if physicians do not broadly adopt ctDNA testing of newly-diagnosed second-line GIST patients as a standard of care, and our ability to generate sufficient revenues to result in a profit. In addition, we may experience difficulties or delays in study conduct and/or enrollment, including, without limitation, study start-up, site initiation, and/or enrollment of patients in the Phase 3 INSIGHT study, which could delay our development plans for the Phase 3 INSIGHT study, increase our costs and limit our ability to obtain marketing approval and successfully commercialize QINLOCK for second-line GIST patients with mutations in KIT exon 11 and 17/18 and generate revenue.

In addition, although we plan to enter into an agreement to validate or develop a companion diagnostic for potential FDA clearance or approval and use in potential marketing and commercialization, we may experience delays in reaching, or fail to reach, agreement on acceptable terms for these services. Companion diagnostic tests are subject to regulation as medical devices and must themselves be cleared or approved for marketing by the FDA or certain other foreign regulatory agencies specifically for use with QINLOCK before we may commercialize QINLOCK in the sub-group we intend to study. We or any third parties whom we engage to validate or develop a companion diagnostic may not be able to validate or develop one that meets such requirements on a timely basis or at all.

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 varying stages of clinical development, including vimseltinib and DCC-3116, and the 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. For example, in November 2021, we announced that the INTRIGUE study did not meet the primary endpoint of improved PFS compared with the standard of care sunitinib despite initially observing encouraging preliminary data in our Phase 1 study of QINLOCK in second-line GIST. Such factors also apply to the earlier-stage trials for our drug candidates, including the Phase 1/2 study of DCC-3116.

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;
- institutional review boards (IRBs) may not authorize us or our investigators to commence or continue a clinical trial at a prospective trial site or an IRB may not approve a protocol amendment to an ongoing clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay planned trials, or abandon product development programs;

- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or the duration of these clinical trials may be longer than we anticipate;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, due to interruptions to their business 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;
- 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 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 that may be conducted in Greater China under our collaboration with Zai;
- the cost of clinical trials for our drug or drug candidates may be greater than we anticipate, including those caused by global economic and political developments; 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.

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. For example, our Phase 3 INSIGHT study is designed to evaluate a specific population of GIST patients with mutations in KIT exon 11 and 17/18. Our INSIGHT study excludes patients with mutations in KIT exon 9, 13, and/or 14 because we observed that this sub-group of patients derived substantially improved clinical benefit with sunitinib versus QINLOCK in our ctDNA analysis from the Phase 3 INTRIGUE study. 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.

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 or require us to conduct additional preclinical studies or clinical trials or to change our development plans and any such requests or requirements could result in development delays. For example, the FDA recently published guidance on "Project Optimus", an initiative to reform dose selection in oncology drug development. If the FDA does not believe we have sufficiently demonstrated that the selected dose maximizes not only the efficacy of the drug candidate, but the safety and tolerability as well, our ability to initiate new studies may be delayed. Even if we conducted the additional studies or generated the additional information requested, the FDA could disagree that we have satisfied their requirements, all of which will cause significant delays and expense to our programs. 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.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our ongoing Phase 3 INSIGHT study and Phase 1/2 study of DCC-3116, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to 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, access restrictions, or disruptions and shortages in the global supply chain resulting from global economic and political developments or other factors. Because the target patient populations for some of our drug candidates and approved drug in clinical development for additional indications are relatively small, it may be difficult to successfully identify patients.

For example, our enrollment for the INSIGHT study requires patients to have the specific KIT exon 11 primary and exon 17/18 secondary mutations. We estimate that we will need to test numerous GIST patients for every one patient that meets the proposed trial criteria and this will require a number of sites. We cannot be certain how many patients will have the requisite mutations for inclusion in the trial or that we will be able to successfully enroll the number of patients required for regulatory approval. If we are unable to locate or identify a sufficient number of eligible patients, or if our vendor for ctDNA analysis does not meet our expected timelines or quality standards, our clinical trial and development plans could be delayed, and our ability to seek participation in the FDA's expedited review and approval programs, including BTD and fast track designation, or otherwise to seek to accelerate clinical development and regulatory timelines could be compromised. 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 in additional indications for our existing drug, 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 and rarity of the disease under investigation;
- the size of the target patient population;
- 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; and
- the patient referral practices of physicians.

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 that could result in slower than expected enrollment may include recruitment challenges for patients with a rare disease and/or a narrow sub-population of patients with required mutations and competing trials 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, or for QINLOCK with respect to label expansion opportunities, which would cause significant harm to our financial position, adversely impact our stock price, and impair our ability to raise capital. In addition, 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.

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 sub-populations 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 or drug candidates, such as DCC-3116, may exacerbate adverse events associated with the therapy as well as result in adverse events from drug-drug interaction. 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 for the treatment of fourth-line advanced GIST. All of our drug candidates, including vimseltinib and DCC-3116, are still in varying stages of clinical development. In August 2023, we also announced that we opened the first sites for enrollment in our Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18.

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 INSIGHT study of QINLOCK;
- receipt and related terms of marketing approvals from applicable regulatory authorities, including for vimseltinib for the potential treatment of TGCT;
- 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;
- successful development, clearance, and/or approval of any companion diagnostic tests for use with our drug and drug candidates, such as those that we intend to develop for QINLOCK in order to identify second-line GIST patients with mutations in KIT exon 11 and 17/18;
- attracting additional licensees and/or collaborators or distributors with development, regulatory, and commercialization expertise; 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 was materially impacted following the preliminary results of our ongoing Phase 3 INTRIGUE study of QINLOCK for second-line GIST, which failed to meet its primary endpoint.

In addition, we may be required or we may seek to develop companion diagnostic tests for our drug or drug candidates in order to select patients most likely to respond to treatment, or to identify appropriate patients for our drug or drug candidates for which we obtain approval. Companion diagnostic tests are subject to regulation as medical devices and must themselves be cleared or approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our drug candidates for use with such companion diagnostics.

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 or drug candidates beyond those that we currently contemplate if we are unable to successfully complete clinical trials for our drug or 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. While we generally plan to conduct only one pivotal Phase 3 trial for each currently anticipated drug candidate, for a single randomized trial to support submission to the FDA of an 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 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. 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.

We may in the future change the manufacturing process we are using to make clinical supplies of any approved drug from that used in our ongoing clinical trials to satisfy greater drug requirements for commercialization. In that event, we will be required to demonstrate comparability, which will include conducting a bioequivalence study, of our approved drug made with the new process from what we have used in clinical trials to date. If we are unable to establish comparability or bioequivalency, or are unable to agree with FDA on a timely basis regarding the study design necessary to do so, the commercialization of our approved drug may be substantially delayed or constrained by supply. If we are unable to manufacture sufficient quantities of our approved drug to meet commercial demand, our business and results of operations will be harmed.

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.

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 or expand our marketing for QINLOCK in additional geographies. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug and drug candidates, including vimseltinib, and, if applicable, including by a third party, for any related companion diagnostic tests, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates or continue our geographic expansion of QINLOCK, and our ability to generate revenue will be materially impaired.

Our drug candidates and any companion diagnostic tests related to our approved drug or 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 and national competent authorities of the Member States in the EU, and the China NMPA and similar regulatory authorities outside the U.S. Before we can commercialize any of our drug candidates, we must obtain marketing approval. We or a third party may also need marketing clearance or approval for any related companion diagnostic tests, including the companion diagnostic tests that we intend to develop for QINLOCK in order to identify second-line GIST patients with mutations in KIT exon 11 and 17/18.

Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. Our drug candidates are in varying stages of clinical development and are subject to the risks of failure inherent in drug development. We have only received marketing authorization for QINLOCK in the U.S., Europe, and other select jurisdictions, and have not received marketing authorization for any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting and managing clinical trials, and in submitting and supporting the applications necessary to seek marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the

submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our drug candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the U.S. and internationally, 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. Further, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, changes in regulatory review for each submitted product application, or pre-market approval application for a companion diagnostic test or equivalent application types, may cause delays in the approval or rejection of an application. For example, now that the UK has left the EU, a separate marketing authorization application is required in order to market a product in the UK and the requirements and procedures for obtaining marketing approval in the UK and the EU could diverge further now that the regulatory system in the UK is independent from the EU. 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 and we or a third party fails to obtain approval of companion diagnostic tests related to our approved drug and drug candidates, or we fail to expand the approval for QINLOCK in additional 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 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 fourth-line GIST in the U.S. In the EU, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (ii) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention, or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000.

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 the EU. 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. Similarly, the EMA may grant a marketing authorization to a similar medicinal product for the same indication as an authorized orphan product at any time if it is established that the second product, although similar, is safer, more effective or otherwise clinically superior to the authorized product. The FDA and EMA also can approve a different drug for the same orphan indication, or the same drug for a different indication, during the orphan exclusivity period.

The FDA Reauthorization Act of 2017 (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 its regulations and policies under the Orphan Drug Act. 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. For more information regarding the risks related to orphan drug designation and orphan drug exclusivity, please see "*Business-Government Regulation—Orphan Drug Designation*" in this Form 10-K.

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, including the companion diagnostic test that we intend to develop for QINLOCK in order to identify second-line GIST patients with mutations in KIT exon 11 and 17/18. 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 diagnostic tests 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 will and may in the future rely on third parties for the design, development, and manufacture of companion diagnostic tests for our therapeutic drug candidates that require such tests. We have limited experience in the development and commercialization of companion diagnostic tests with third parties and may not be successful in developing and commercializing appropriate companion diagnostic tests with third parties to pair with our drug candidates that receive marketing approval. If these parties are unable to successfully develop companion diagnostic tests 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. For more information regarding the risks related to development of companion diagnostic tests, please see "*Business-Government Regulation of Diagnostic Tests*" in this Form 10-K.

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, including the companion diagnostic tests that we intend to develop for QINLOCK in order to identify second-line GIST patients with mutations in KIT exon 11 and 17/18. We will and may in the future rely on third parties for the development, testing, and manufacturing of these companion diagnostic tests, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostic tests. 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. Current commercially available diagnostic tests may become unavailable in the future.

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.

In November 2021, we announced that vimseltinib had been granted fast track designation by the FDA for the treatment of patients with TGCT who are not amenable to surgery. We intend to and may in the future seek fast track designation for some of our other 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 an unmet medical need 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. For more information regarding the risks related to fast track designation, please see "*Business-Government Regulation-Special FDA Expedited Review and Approval Programs*" in this Form 10-K.

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.

In March 2023, the FDA granted BTD for QINLOCK for the treatment of adult patients with unresectable or metastatic GIST who received prior treatment with imatinib, and who harbor a KIT exon 11 mutation and co-occurring KIT exon 17 and/or 18 mutations (KIT exon 11+17/18 mutations). We have in the past received and may in the future seek a BTD for some of our drug candidates. For more information regarding the risks related to BTD, please see "*Business-Government Regulation-Special FDA Expedited Review and Approval Programs*" in this Form 10-K

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

Results of preclinical studies and early clinical trials of drug candidates may not be predictive of results of later studies or trials. Our drug candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any program or drug candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for programs or drug candidates in our industry is high. The results from preclinical studies or early clinical trials may not be predictive of the results from later preclinical studies or clinical trials, and interim results of a clinical trial are not necessarily indicative of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials.

Many companies in the biopharmaceutical industry have suffered significant setbacks at later stages of development after achieving positive results in early stages of development. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their drug candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. A program may fail to result in a designated compound for many reasons, including inability to achieve desired candidate profile properties, chemistry or patent challenges, or inconclusive or conflicting in vitro and/or in vivo studies. Designated compounds undergoing IND-enabling studies, including animal toxicity studies, may fail at that stage. Moreover, even if an IND is filed, regulatory authorities may not clear the candidate as safe to proceed for human studies. Even if any drug candidates progress to clinical trials, these drug candidates may fail to achieve clinical-proof-of-concept or show the safety and efficacy in clinical development required to obtain regulatory approval, despite the observation of positive results in animal studies. Our or our collaborators' failure to replicate positive results from early research programs and preclinical studies may prevent us from further developing and commercializing those or other drug candidates, which would limit our potential to generate revenues from them and harm our business and prospects.

For the foregoing reasons, we cannot be certain that any ongoing or future preclinical studies or clinical trials, including our ongoing Phase 1/2 study of DCC-3116, our Phase 3 INSIGHT study, or our pan-RAF research program, will be successful. Any safety or efficacy concerns observed in any one of our preclinical studies or clinical trials in a targeted area could limit the prospects for regulatory approval of drug candidates in that and other areas, which could have a material adverse effect on our business and prospects.

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 the 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 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 drug 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 U.S. Patent and Trademark Office (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 sufficient revenue to result in a profit 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 sufficient revenue to result in a profit 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, 2023, 2022, and 2021, we reported net losses of $194.9 million, $178.9 million, and $300.0 million, respectively. As of December 31, 2023, we had an accumulated deficit of $1.4 billion.

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. Except for QINLOCK, all of our drug candidates, including vimseltinib and DCC-3116, are still in clinical stages of development. To date, we have not generated sufficient revenue to result in a profit from the product sales of QINLOCK and have funded our operations primarily with proceeds from the sales of our common stock in public offerings and through at-the-market offerings, sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, upfront and milestones 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 $1.6 billion in net proceeds from such transactions. As of December 31, 2023, our cash, cash equivalents, and marketable securities were $352.9 million.

We expect to incur operating losses for the foreseeable future, particularly as we commercialize QINLOCK, seek marketing approval for vimseltinib, 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 future clinical trials of QINLOCK in the Phase 3 INSIGHT study, vimseltinib, 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 key European markets and other countries around the world in connection with the marketing approval for QINLOCK in these select jurisdictions. 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 sufficient revenue to result in a profit and we do not know when, or if, we will generate profits or positive operating cash flows. We also have only obtained marketing approval for QINLOCK for the treatment of fourth-line advanced GIST in the U.S. and other select jurisdictions, and have not obtained marketing approval for any other indications or 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 commercialize or otherwise provide access to QINLOCK for the treatment of fourth-line advanced GIST in the U.S., key European markets, and any other jurisdictions where we may receive marketing approval in the future;
- the timing or likelihood of regulatory actions, filings, and approvals for our current and future drug candidates, including our ability to obtain and maintain regulatory approval for QINLOCK or obtain and maintain regulatory approval for vimseltinib, or any of our current or future drug candidates;
- successfully complete our Phase 3 INSIGHT study of QINLOCK, advance our DCC-3116 program through clinical development, and nominate additional drug candidates from our switch control inhibitor platform;
- 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;
- 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;
- 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 may 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 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. Our expenses could increase materially if we are required by the FDA, the EMA, or other regulatory authorities to perform studies in addition to those currently expected, 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 global economic instability or global political developments, including historically high inflation, rising interest rates, and political unrest.

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 vimseltinib, and have not generated sufficient revenue to result in a profit from product sales or profits from our operations. 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 in the U.S. and key European markets. 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. Except for QINLOCK, all of our drug candidates, including vimseltinib and DCC-3116, are still in clinical stages of development.

We have not yet demonstrated our ability to complete Phase 3 clinical trials other than for QINLOCK for the treatment of fourth-line GIST and vimseltinib for the potential treatment of TGCT, or the ability to complete the development of any companion diagnostic tests, and we have not generated sufficient revenue to result in a profit from product sales or 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 or unknown factors. While we have transitioned from a company with a research and development focus to a company supporting commercial activities, we continue to have limited experience with activities designed to conduct large-scale sales, marketing, and distribution activities necessary for continued successful product commercialization.

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 global economic and political developments. 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 conduct our Phase 3 INSIGHT study, and advance our drug candidates, vimseltinib and DCC-3116, and seek to identify lead drug candidates in our research 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 related to our commercial launch in key European markets and any current or future drug candidate for which we may receive marketing approval, including vimseltinib. 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, 2023, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestones received under our collaboration or license agreements will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2026. 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 drug discovery, preclinical development, and clinical trials for our drug candidates;
- our ability to obtain regulatory approval and support the commercialization of vimseltinib, if approved, for the treatment of TGCT;
- 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 market acceptance, success, costs and timing associated with our commercialization activities for QINLOCK or any of our future approved drugs, including product manufacturing, marketing, sales, and distribution, as well as

infrastructure costs in the U.S. and key European markets 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, which may require up-front, milestone and/or royalty payments to the seller or licensor.

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 geographies, and achieve sufficient revenues to result in a profit for QINLOCK or any of our drug candidates that receive marketing approval. 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 sufficient product revenues to result in a profit, 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, the ownership of our stockholders' interest will be diluted, and the terms of our securities may include liquidation or other preferences that adversely affect the rights of our 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, 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, 2024, our executive officers and directors, and, combined with our stockholders who own more than 10% of our outstanding capital stock based on filings required by Section 13 of the Exchange Act through February 1, 2024, 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, 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 by-laws 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 by-laws.

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 by-laws 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 by-laws 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 by-laws, or (iv) any action asserting a claim governed by the internal affairs doctrine (collectively, 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 by-laws 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, our amended and restated by-laws provide that 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 in pursuing any such claims. Additionally, these forum selection clauses in our amended and restated by-laws 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 and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, 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 $6.51 per share and as high as $71.11 per share through January 31, 2024. 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 success of our corporate strategy and goals;

- 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, including our combination strategy with DCC-3116;
- 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 or global conditions; and
- the other factors described in this "Risk Factors" section.

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.

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 DCC-3116, and do not plan to independently conduct any clinical trials for our future drug candidates. 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 global economic and political developments, 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 drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize 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. 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 do not currently own any or operate any manufacturing facilities for the production of QINLOCK or any drug candidates that may be approved in the future. 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 sole source third-party suppliers for the manufacture and supply of QINLOCK and certain of our drug candidates for preclinical and clinical testing, and for the commercial manufacture of any of our current and future drugs. 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. 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. Further, there can be no assurance that our supply of QINLOCK and our other drug candidates will not be limited, interrupted, or of satisfactory quality. 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. Although we actively manage these third-party relationships to ensure continuity, quality, and compliance with regulations, some events beyond our control, including global economic or political developments, 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 ceases 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 have scaled up and validated our manufacturing process for QINLOCK, and may continue to scale up as needed to satisfy greater drug requirements for commercialization. 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.

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, or future third-party manufacturers, 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 and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. We will also need to verify, such as through a manufacturing comparability study, that any new supplier will produce our drug candidate or product according to the specifications previously submitted to the FDA or another regulatory authority. In addition, changes in suppliers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new supplier. The delays associated with the verification of a new supplier or comparability of new manufacturing processes could negatively affect our ability to develop drug candidates or commercialize our product in a timely manner or within budget.

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 manufacturers' ability to make changes or respond to address any FDA concerns. Moreover, the facility that our supplier of QINLOCK uses to manufacture commercial supply has limited experience manufacturing a commercial 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 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhanced the 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 active pharmaceutical ingredient 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 drug candidates, if approved, if we are not able to negotiate commercial supply terms with any third-party manufacturers, we may be unable to commercialize our drug candidates 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 do not currently have a validated manufacturing process for any of our drug candidates, other than our approved drug, QINLOCK. In addition, we have not yet scaled-up our manufacturing process for any of our drug candidates, other than vimseltinib. 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. Zai received regulatory approval to market QINLOCK in the PRC, Hong Kong, and Taiwan in 2021 and Israel, Macau, and Singapore in 2023. We will not derive product revenue from Zai's sales of QINLOCK in Greater China 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 during a specified period. In addition, our clinical development plan for DCC-3116 is focused on combination strategies for patients with documented RAS and RAF cancer mutations. We currently have and may in the future choose to enter into collaboration arrangements with other pharmaceutical companies for arrangements with DCC-3116.

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 and/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 our 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, including DCC-3116. 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, collaboration, or distribution agreement 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 global economic instability.

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 Russia do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology products and/or intellectual property rights owned by U.S. entities, 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, 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. A patent term extension application was granted in the U.S. on a patent 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 United States Congress, the United States 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.

Our issued European patents could be subject to the jurisdiction of the recently formed Unified Patent Court (UPC).

Our European patents and patent applications could be challenged in the recently created UPC for the EU. We decided to remove, i.e., opt out, our European patents and European patent applications from the jurisdiction of the UPC. However, if certain formalities and requirements were not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, even after we decided to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. Although such patent rights would apply to numerous European countries, a successful challenge to a European patent under the UPC could result in loss of patent protection in numerous European countries. Accordingly, a single proceeding under the UPC addressing the validity and infringement of the European patent could result in loss of patent protection in numerous European countries rather than in each validated country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and drug candidates.

Our intellectual property licenses from third parties could limit our ability to control certain decisions relating to our licensed European patents and applications.

We may enter into license agreements where we may not have the final or sole decision on whether we are able to opt out certain of our in-licensed European patents and patent applications from the recently created UPC for the European Union. While our licensors may decide to opt out of the UPC, we cannot guarantee that any of our current or future in-licensed European patents and patent applications will be challenged for non-compliance during the opt-out procedure and if successful, brought under the jurisdiction of the UPC, nor that our licensors will decide to opt back into the UPC at a later time. Thus, we cannot be certain that any of our current or future in-licensed European patents and patent applications will not fall under the jurisdiction of the UPC. Under the UPC, a single European patent would be valid and enforceable in numerous European countries. A challenge to the validity of a European patent under the UPC, if successful, could result in a loss of patent protection in numerous European countries which could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cyber Risk Management and Strategy

We have developed and maintain an information security program designed to assess, identify, and manage risks from cybersecurity threats. As part of this program, we conduct periodic assessments of our assets to evaluate the effectiveness of applicable security controls. These assessments are informed by industry standard frameworks and include a review of our information security controls to assess cybersecurity maturity compared to our peers and other highly regulated industries. The results of these assessments are reported to the board of directors as part of a cybersecurity update report conducted at least annually.

We also engage vendors to assist with enterprise managed detection and response, global security operations center, security information and event management, and enterprise vulnerability management. In addition, we have implemented a cybersecurity third party risk management process to assess mission and business critical third parties for cyber risks and to assist the business in making risk-informed technology product and services decisions. Our practice is to perform due diligence, including the completion of security questionnaires and risk assessments, as appropriate, on third parties who maintain material data or information to help us evaluate and verify third party information security capabilities.

We have adopted an Incident Response Management Procedure (the Procedure) that outlines the legal and governance processes for identifying and managing material risks to privacy and security. An incident response team is responsible for carrying out the Procedure and is led by our information & technology (I&T) department, and includes members from our legal and compliance, privacy, investor relations, finance, and quality departments. In addition, our enterprise information security program describes our capabilities and processes for the preparation, detection, analysis, containment, recovery, and reporting of incidents. We also manage and maintain business continuity and disaster recovery capabilities to help ensure the availability of business-critical technology resources during adverse conditions.

Governance Related to Cybersecurity Risks

Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through committees, has responsibility for the oversight of risk management. Our board of directors oversees the management of our risks from cybersecurity threats. In addition, the full board discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them.

Our Vice President of I&T is responsible for developing, implementing, and maintaining our cybersecurity risk management policies and procedures. The individual currently serving in the role of Vice President of I&T has over twenty-five years of experience in cybersecurity, information security, data protection, privacy, regulatory compliance and risk management within complex and international business verticals such as pharmaceutical/biotech, technology, financial services, and retail. The Vice President of I&T reports to our Chief Financial Officer, and provides periodic cybersecurity updates to our board on at least an annual basis. Our incident response process contemplates that the executive team will notify the board of a material cybersecurity incident.

Our cybersecurity steering committee (the Steering Committee) oversees technical matters regarding cybersecurity through periodic meetings and frequent communications. When formal meetings are held, attending committee members include representatives from the I&T, regulatory affairs, quality, finance, and legal and compliance departments. The Steering Committee has a charter that is reviewed internally to ensure it is aligned with our business strategy. As outlined in its charter, the Steering Committee has three key roles: (i) systems assurance: to oversee the establishment and maintenance of effective cybersecurity mechanisms throughout the Company; (ii) documentation: review of documented policies, standards, processes, and procedures that will have a direct or indirect impact on the security and privacy of our information; and (iii) management of information security risk: identify and manage significant cybersecurity risks across the Company, including escalating to our executive leadership team where appropriate.

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), of which 44,343 is subleased until May 2025. 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, regulatory, business development, and administrative functions.

Additionally, we lease 47,262 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 we are entitled to two five-year options to extend the leases. The described leased space in Lawrence, Kansas includes space for leases that are less than 12 months, and as a result, these leases are not reflected within the consolidated balance sheets.

We also lease 861 square feet of space in Zug, Switzerland for our European headquarters, to accommodate our needs for office space in supporting our European commercialization efforts. The lease terms for such space are generally less than 12 months.

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, 2024, 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

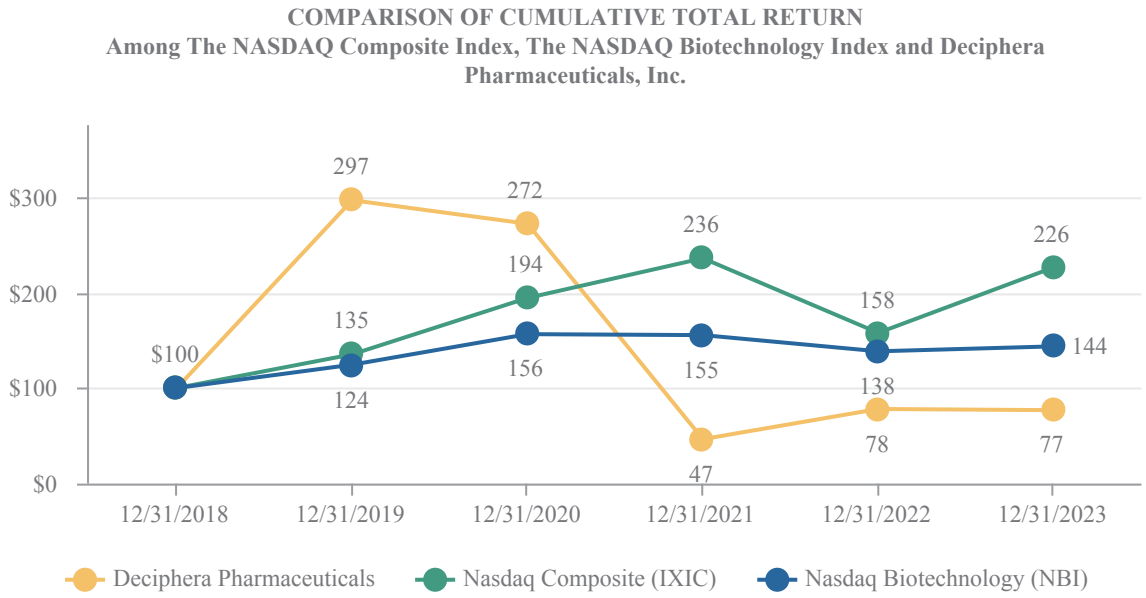
Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

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 December 31, 2018 through December 31, 2023. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on December 31, 2018, 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.



ITEM 6. RESERVED

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 commercializing important new medicines to improve the lives of people with cancer. Leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology, we design kinase inhibitors to target the switch pocket region of the kinase with the goal of developing potentially transformative medicines. Through our patient-inspired approach, we seek to develop a broad portfolio of innovative medicines to improve treatment outcomes. QINLOCK, our switch-control tyrosine kinase inhibitor, was discovered using our proprietary drug discovery platform and designed for the treatment of GIST. QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Iceland, Israel, Liechtenstein, Macau, Norway, New Zealand, Singapore, Switzerland, Taiwan, the U.K., and the U.S. for the treatment of fourth-line advanced GIST. 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. In addition to QINLOCK, we have developed a robust pipeline of novel drug candidates using our switch-control kinase inhibitor platform, including vimseltinib and DCC-3116.

Our Drug and Drug Candidates

QINLOCK

QINLOCK, an orally administered kinase switch control inhibitor of the KIT and PDGFRA kinases, is approved in sixteen territories for the treatment of fourth-line advanced GIST.

In June 2019, we entered into the Zai License Agreement, pursuant to which we granted Zai exclusive rights to develop and commercialize QINLOCK, including the Licensed Products, in Greater China. In March and September 2021, the China NMPA and the Taiwan Food and Drug Administration, respectively, 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 March 2021, the Hong Kong Department of Health approved QINLOCK in Hong Kong for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib.

In November 2021, we announced top-line data from INTRIGUE, our Phase 3 study of QINLOCK for the treatment of second-line GIST. The INTRIGUE study did not meet the primary endpoint of improved PFS compared with the standard of care sunitinib. The Phase 3 INTRIGUE study is an interventional, randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. In the study, 453 patients were randomized 1:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib.

In January 2023, we announced findings from an exploratory analysis using ctDNA analysis from the Phase 3 INTRIGUE study demonstrating substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17 and/or 18 and the absence of mutations in KIT exon 9, 13, and/or 14, which we also refer to as patients with mutations in KIT exon 11 and 17/18. Based on the results of the ctDNA analysis and discussions with the FDA, in August 2023, we announced that we opened the first sites for enrollment in the pivotal Phase 3 INSIGHT study of QINLOCK versus sunitinib in this patient population. Following QINLOCK's EC approval in fourth-line GIST in November 2021, we have focused our direct commercial efforts in key European markets. We launched QINLOCK in Germany in 2022 and Italy in 2023, and have conducted the AP2 program in France since 2022. We also plan to continue the geographic expansion of QINLOCK in 2024, with planned commercial launches following conclusion of pricing and reimbursement negotiations in additional European and international markets. We also plan to provide access to QINLOCK to fourth-line GIST patients in additional European countries through other channels with distribution arrangements.

Vimseltinib

Vimseltinib is an investigational, orally administered, potent, and highly-selective switch-control kinase inhibitor of the CSF1R.

We are currently studying vimseltinib in the pivotal Phase 3 study in patients with TGCT (MOTION study). The MOTION study is a two-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of vimseltinib in patients with TGCT who are not amenable to surgery. In Part 1 of the study, eligible study participants will be assigned to receive either vimseltinib or matching placebo for 24 weeks. Participants assigned to placebo in Part 1 will have the option to receive vimseltinib in Part 2 of the study. Part 2 is a long-term treatment phase in which all participants will receive open-label vimseltinib. The primary endpoint of the study is ORR at 25 weeks as measured by RECIST v1.1 by blinded independent radiological review.

In October 2023, we announced positive top-line data from the MOTION study. The study met its primary endpoint in the intent-to-treat population demonstrating statistically significant and clinically meaningful improvement versus placebo in objective response rate at Week 25 based on blinded independent radiologic review per Response Evaluation Criteria in Solid Tumors version 1.1. In addition to meeting the primary endpoint, the study also achieved statistically significant and clinically meaningful improvements versus placebo in all key secondary endpoints including TVS, ROM, physical function, stiffness, quality of life, and pain. Vimseltinib was well-tolerated and the observed adverse events in the MOTION study were consistent with previously presented Phase 1/2 study results, including the data discussed below.

We are also conducting an international, multicenter, ongoing open-label Phase 1/2 study designed to evaluate the safety, efficacy, PK, and PD of vimseltinib in patients with solid tumors and TGCT. Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is allowed) and cohort B includes patients with prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib alone is not allowed). In October 2023, we provided updated data from our Phase 1/2 study of vimseltinib in TGCT patients. The data demonstrated strong clinical benefit with best objective response rates of 72% (Phase 1) and 64% (Phase 2 Cohort A), an increasing median treatment duration of 25.1 months (Phase 1) and 21.0 months (Phase 2 Cohort A), and a favorable long-term safety profile with no evidence of cholestatic hepatotoxicity.

We will continue to engage with regulatory authorities and expect to submit an NDA to the FDA in the second quarter of 2024 and a MAA with the EMA in the third quarter of 2024 for vimseltinib for the treatment of patients with TGCT.

In January 2023, we announced that we plan to initiate a Phase 2 study of vimseltinib for the potential treatment of cGVHD in the fourth quarter of 2024, subject to FDA feedback.

DCC-3116

DCC-3116 is a potential first-in-class investigational, orally administered, potent, and highly selective switch-control inhibitor of the ULK kinase. DCC-3116 is designed to inhibit autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK kinases, referred to collectively as ULK or ULK kinases, which have been shown to be the initiating factors that activate autophagy. We believe that DCC-3116, in combination with RTK/RAS/MAP kinase signaling pathway inhibition, has the potential to change the treatment of mutant RTK/RAS/RAF cancers, if approved.

DCC-3116 is being studied in a Phase 1/2 study designed to evaluate the safety, tolerability, clinical activity, PK, and PD of DCC-3116 as a single agent and in combination with sotorasib, an FDA-approved $KRAS^{G12C}$ inhibitor, in patients with advanced or metastatic solid tumors with $KRAS^{G12C}$ mutation, QINLOCK, our FDA-approved KIT inhibitor, in patients with GIST. In 2024, we plan to select a recommended Phase 2 dose for at least one potential expansion cohort, subject to favorable data.

In August 2023, we announced the completion of the single agent DCC-3116 dose escalation portion of the Phase 1/2 study (n=28). We also provided updated data on the PK characteristics of single agent DCC-3116.

In addition, in August 2023, we provided an update on the ongoing Phase 1/2 study in combination with trametinib, binimetinib, and sotorasib.

In January 2024, we announced that we are prioritizing the development of DCC-3116 in combination with sotorasib and with QINLOCK and discontinued development of the DCC-3116 cohorts in combination with (i) trametinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; (ii) binimetinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; and (iii) encorafenib and cetuximab in patients with colorectal cancer. As a result, we also terminated the clinical trial collaboration and supply agreement with Pfizer Inc. (Pfizer) for the dose escalation study evaluating DCC-3116 in combination with encorafenib and cetuximab in patients with colorectal cancer prior to enrollment in any clinical studies.

Preclinical Pipeline

We are also making a focused investment in our next generation of research programs, which are designed to provide first-in-class or best-in-class treatments using our proprietary switch-control inhibitor platform.

In November 2022, we announced the nomination of DCC-3084 as our pan-RAF inhibitor development candidate. DCC-3084 is a potential best-in-class pan-RAF inhibitor that is designed to broadly inhibit Class I, II, and III BRAF mutations, BRAF fusions, and BRAF/CRAF heterodimers. In April 2023, we presented preclinical data for DCC-3084 at the AACR Annual Meeting 2023. In the fourth quarter of 2023, we submitted an IND application to the FDA for DCC-3084 and expect to initiate the Phase 1 study of DCC-3084 in the first half of 2024.

In April 2023, we announced the nomination of DCC-3009 as our next generation KIT inhibitor. DCC-3009 is a potential best-in-class next generation KIT inhibitor that is designed to inhibit the broad spectrum of known primary and secondary drug resistant mutations in GIST, spanning KIT exons 9, 11, 13, 14, 17, and 18. In April 2023, we presented preclinical data for DCC-3009 at the AACR Annual Meeting 2023. We expect to submit an IND application to the FDA for DCC-3009 in the first half of 2024 and initiate a Phase 1 study of DCC-3009 in the second half of 2024, each subject to FDA feedback.

COVID-19

We continue to closely monitor the impact of the COVID-19 pandemic on our business operations in an effort to mitigate interruption to our clinical programs, research efforts, commercialization 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 trials. In addition, we 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. While all of our studies remain open for enrollment, we have experienced some delays or disruptions in enrollment and enrollment may in the future be temporarily paused for new patients at some sites. We will continue to assess the duration, scope, and severity of the COVID-19 pandemic as it evolves and monitor local COVID-19 trends and government guidance for each of our site and office locations. However, 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 COVID-19 on our business and the duration for which it may have an impact cannot be

determined at this time. For further information regarding the impact of the COVID-19 pandemic on us, see "Part I. Item 1A—Risk Factors" included in this Annual Report on Form 10-K.

Components of Our Results of Operations

Revenues

QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Iceland, Israel, Liechtenstein, Macau, Norway, New Zealand, Singapore, Switzerland, Taiwan, the U.K., and the U.S. for the treatment of fourth-line GIST. 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 owed to us under the Zai License Agreement and Zai Supply Agreement agreements we entered into with Zai in June 2019 and February 2020, respectively, including royalty revenues under the Zai License Agreement following the approvals of QINLOCK in the PRC and Hong Kong in March 2021. 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, including vimseltinib, for which we may receive marketing approval, if any. Additionally, we cannot provide assurance as to the extent of future royalty payments, the timing of future milestone payments, or that we will achieve and receive any future milestone payments at all. We may never succeed in obtaining regulatory approval for any of our drug candidates other than QINLOCK.

Product Revenues, Net

During the years ended December 31, 2023, 2022, and 2021, our only source of product revenues was from the sales of QINLOCK. Product revenues are recorded net of estimates of variable consideration. Please read Note 2, *Summary of Significant Accounting Policies* and Note 3, *Revenues*, of these consolidated financial statements included in this Form 10-K for further details of the reserves recorded for variable considerations.

Collaboration Revenues

For the years ended December 31, 2023, 2022, and 2021, collaboration revenues were associated with the Zai License Agreement and Zai Supply Agreement.

Zai License Agreement

Pursuant to the terms of the Zai License Agreement, we received an upfront cash payment of $20.0 million and three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 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 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.

During the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we began recognizing royalty revenues under the Zai License Agreement.

Zai Supply Agreement

Pursuant to the terms of the Zai Supply Agreement, costs incurred by us for external manufacturing services associated with the production of QINLOCK for use in the Territory for clinical trials and commercial inventory are reimbursed by Zai. During the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we began recognizing revenues associated with sales of commercial inventory of QINLOCK under the Zai Supply Agreement.

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. Further, cost of sales includes the external costs of producing and distributing commercial inventories sold under the Zai Supply Agreement. Cost of sales also includes charges related to inventory written down as a result of excess, obsolescence, unmarketability, or other reasons.

Cost of sales for newly launched products will not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. The gross margin on sales of QINLOCK for the years ended December 31, 2022 and 2021 was enhanced by sales of the initial pre-launch inventory, and therefore, use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the launch of QINLOCK, referred to as zero cost inventories. However, we do not expect that the cost of sales as a percentage of net sales of QINLOCK will increase significantly after we have sold all zero cost inventories and commenced the sales of inventories which will reflect the full cost of manufacturing. We began selling inventory with the full cost of manufacturing in the fourth quarter of 2022.

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:

- successfully commercializing or otherwise providing access to QINLOCK for the treatment of fourth-line advanced GIST in the U.S., key European markets, and any other jurisdictions where we may receive marketing approval in the future;
- the timing or likelihood of regulatory actions, filings, and approvals for our current and future drug candidates, including our ability to obtain and maintain regulatory approval for QINLOCK or obtain and maintain regulatory approval for vimseltinib, or any of our current or future drug candidates;
- successful completion of our Phase 3 INSIGHT study of QINLOCK, advancing our DCC-3116 program through clinical development, and nominating additional drug candidates from our switch control inhibitor platform;
- achieving and maintaining market acceptance of QINLOCK, or any current or future drug candidate for which we may receive marketing approval, in the medical community and with third-party payors;
- developing and implementing marketing and reimbursement strategies;
- raising additional funds necessary to fund ongoing operations and capital expenditure requirements, including to complete clinical development of and commercialize any current or future drug candidates for which we receive approval;
- making or maintaining and expanding arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;
- maintaining a continued acceptable safety profile of our products following approval.
- obtaining and maintaining patent, trade secret and other intellectual property protection, and regulatory exclusivity for our drug and drug candidates;
- protecting and enforcing our rights in our intellectual property portfolio;
- effectively competing with other therapies; and
- attracting additional licensees and/or collaborators or distributors with development, regulatory, and commercialization expertise.

A change in the outcome of any of these variables with respect to the commercialization of QINLOCK or the development of our drug or any of our drug candidates would significantly change the costs and timing associated with the commercialization of QINLOCK or development of our drug or that drug candidate. We may never succeed in obtaining regulatory approval for any of our drug candidates, including vimseltinib, 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 vimseltinib, if approved; 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. Additionally, during the year ended December 31, 2021, certain costs incurred in connection with our corporate restructuring were included in research and development expense. 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 expenses associated with our drug and drug candidate programs will increase in 2024 as these programs progress and as we support regulatory filing submissions for vimseltinib. 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. Additionally, during the year ended December 31, 2021, certain costs incurred in connection with our corporate restructuring were included in selling, general, and administrative expenses.

We anticipate that our selling, general, and administrative expenses will increase modestly overall due to increased selling, general, and administrative expenses to be incurred related to the continued planned launches of QINLOCK in new jurisdictions in 2024 and supporting commercial preparations for a potential launch of vimseltinib. We also anticipate that we will continue to incur accounting, audit, legal, regulatory, compliance, and investor and public relations expenses associated with the business and continued operations as a public company.

Restructuring

We have made estimates and judgments regarding the amount and timing of our restructuring expense and liability, including current and future period termination benefits, pipeline program termination costs and other exit costs to be incurred when related actions take place. Restructuring charges are reflected in our consolidated statements of income within research and development expense and selling, general, and administrative expense. Actual results may differ from these estimates.

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, including the impacts of foreign currency exchange differences.

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. We have considered our history of cumulative net losses incurred since inception and have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets. Accordingly, a full valuation allowance has been established against our deferred tax assets as of December 31, 2023.

Since the Conversion in October 2017, we have not recorded any U.S. federal, state or foreign 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, 2023, we had NOL carryforwards for federal income tax purposes of $827.3 million, of which all may be carried forward indefinitely but are subject to an 80% limitation. As of December 31, 2023, we had NOL carryforwards for state income tax purposes of $733.4 million, which begin to expire in 2027. We also had federal and state research and orphan drug credits of $55.7 million and $4.8 million, respectively, as of December 31, 2023, which begin to expire in 2037 and 2032, respectively. We also had foreign NOL carryforwards of $29.8 million as of December 31, 2023, which will begin to expire in 2026.

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, revenues, 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*, of these consolidated financial statements included in this Form 10-K, 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, Medicaid, and other governmental rebates in the U.S. and other similar programs in other countries, including countries in which we are accruing for estimated rebates because final pricing has not yet been negotiated. 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 account for forfeitures as they occur.

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, 2023, 2022, and 2021

The following table summarizes our results of operations for the years ended December 31, 2023, 2022, and 2021:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Revenues:			
Product revenues, net	$ 159,074	$ 125,504	$ 87,389
Collaboration revenues	4,282	8,532	8,759
Total revenues	163,356	134,036	96,148
Cost and operating expenses:			
Cost of sales	3,732	8,770	2,932
Research and development	234,123	187,821	257,040
Selling, general, and administrative	136,459	120,167	136,253
Total cost and operating expenses	374,314	316,758	396,225
Loss from operations	(210,958)	(182,722)	(300,077)
Other income (expense):			
Interest and other income, net	16,447	4,513	113
Total other income (expense), net	16,447	4,513	113
Loss before income tax expense	(194,511)	(178,209)	(299,964)
Income tax expense	431	722	—
Net loss	$ (194,942)	$ (178,931)	$ (299,964)

Revenues

Product Revenues, Net

During the years ended December 31, 2023, 2022, and 2021, our only source of product revenues was from the sales of QINLOCK.

During the years ended December 31, 2023, 2022, and 2021, net product revenues by geography consisted of the following:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
U.S.	$ 121,546	$ 97,216	$ 81,476
Rest of world	37,528	28,288	5,913
Total product revenues, net	$ 159,074	$ 125,504	$ 87,389

For the year ended December 31, 2023 compared to the same period in 2022, U.S. net product revenues increased $24.3 million, primarily due to a $19.5 million increase in sales volume and a $4.8 million increase in net price. The increase in sales volume was driven primarily by increased demand, including new patient acquisition, new prescriber growth, and increasing average duration of therapy. In addition to strength in QINLOCK's fourth-line GIST indication, we believe recent demand growth has been positively impacted by an increase in unpromoted use in earlier lines of therapy based on physician decision. The increase in net price was primarily driven by price increases, partially offset by an increase in chargebacks and administrative fees and government rebates and other incentives.

For the year ended December 31, 2022 compared to the same period in 2021, U.S. net product revenues increased $15.7 million, primarily due to $12.0 million in increased sales volume and a $3.7 million increase in net price. The increase in volume was primarily driven by an increase in the average duration of therapy as the real-world persistency curve continues to mature and more fully reflects the impact of patients who receive a prolonged clinical benefit from QINLOCK. The increase in net price was primarily driven by price increases, partially offset by an increase in chargebacks and administrative fees and government rebates and other incentives.

For the year ended December 31, 2023 compared to the same period in 2022, rest of world net product revenues increased $9.2 million, primarily due to increased sales volume of QINLOCK in Germany, which launched in January 2022, in France, where we have conducted a post-approval paid access program since April 2022, in Italy, which launched in the third quarter of 2023, and other jurisdictions as we continued our commercialization efforts, partially offset by a decrease in net price in Germany as price negotiations were completed in 2023.

For the year ended December 31, 2022 compared to the same period in 2021, rest of world net product revenues increased $22.4 million, primarily due to increased sales volume of QINLOCK in Germany, which launched in January 2022, and in France, where we have conducted a AP2 program since April 2022, as we continued our commercialization efforts

Collaboration Revenues

For the year ended December 31, 2023 compared to the same period in 2022, collaboration revenues decreased $4.3 million primarily due to a decrease in supply revenues under the Zai Supply Agreement, partially offset by an increase in royalty revenues under the Zai License Agreement.

For the year ended December 31, 2022 compared to the same period in 2021, collaboration revenues decreased $0.2 million primarily due to the recognition of a $5.0 million development milestone in the first quarter of 2021 associated with the approval of QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, by the China NMPA in March 2021, partially offset by an increase in revenues under the Zai Supply Agreement and an increase in royalty revenues recognized under the Zai License Agreement.

Cost of Sales

We began incurring costs of collaboration sales during the year ended December 31, 2021 upon commencing sales of commercial inventory of QINLOCK under the Zai Supply Agreement.

During the years ended December 31, 2023, 2022, and 2021, cost of sales by type consisted of the following:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
Cost of product sales	$ 2,079	$ 2,674	$ 1,305
Cost of collaboration sales	1,653	6,096	1,627
Total cost of sales	$ 3,732	$ 8,770	$ 2,932

For the year ended December 31, 2023 compared to the same period in 2022, cost of sales decreased $5.0 million primarily due to a decrease in cost of sales recognized under the Zai Supply Agreement as a result of a decrease in sales and a decrease in cost of sales in the U.S. due to the write down of inventory in the prior year period. During the year ended December 31, 2022, cost of sales included charges of $0.9 million for inventory written down as a result of excess, obsolescence, unmarketability, or other reasons. There were no inventory amounts written down and charged to cost of sales during the year ended December 31, 2023.

For the year ended December 31, 2022 compared to the same period in 2021, cost of sales increased $5.8 million primarily due to costs associated with the commercial inventory of QINLOCK sold under the Zai Supply Agreement and increased product sales of QINLOCK in Germany and France. During the year ended December 31, 2022 and 2021, cost of sales also included charges of $0.9 million and less than $0.1 million, respectively, for inventory written down as a result of excess, obsolescence, unmarketability, or other reasons.

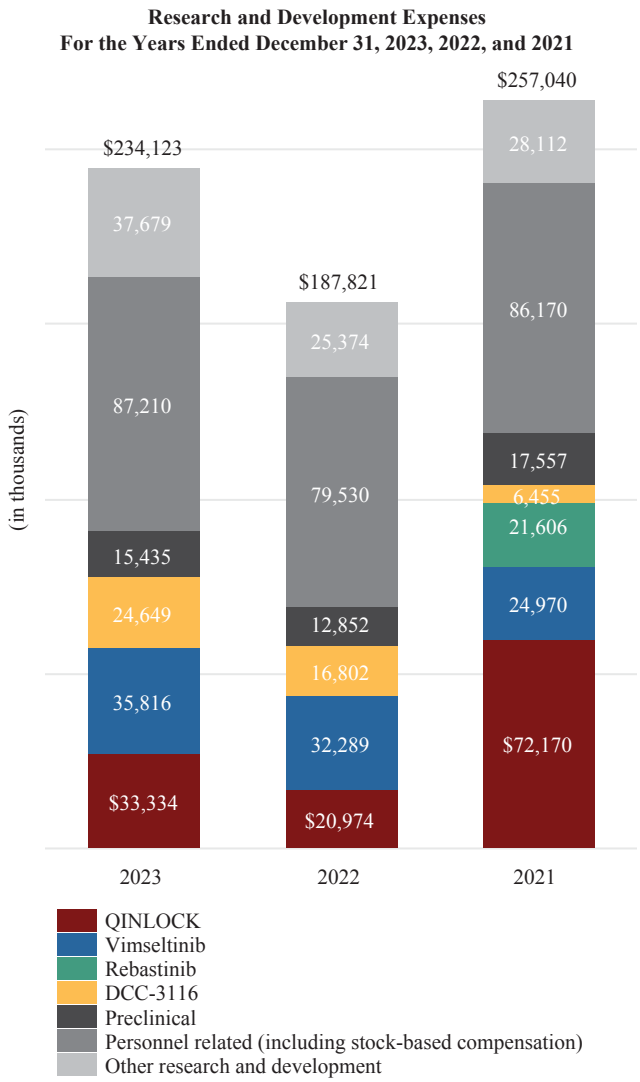
Prior to the fourth quarter of 2022, cost of sales associated with product sales of QINLOCK were primarily related to the sales of zero cost inventories, which consisted of packaging, labeling, shipping, and distribution costs. As a result, the full costs of manufacturing QINLOCK inventory are not included in cost of sales during the years ended December 31, 2022 and 2021.

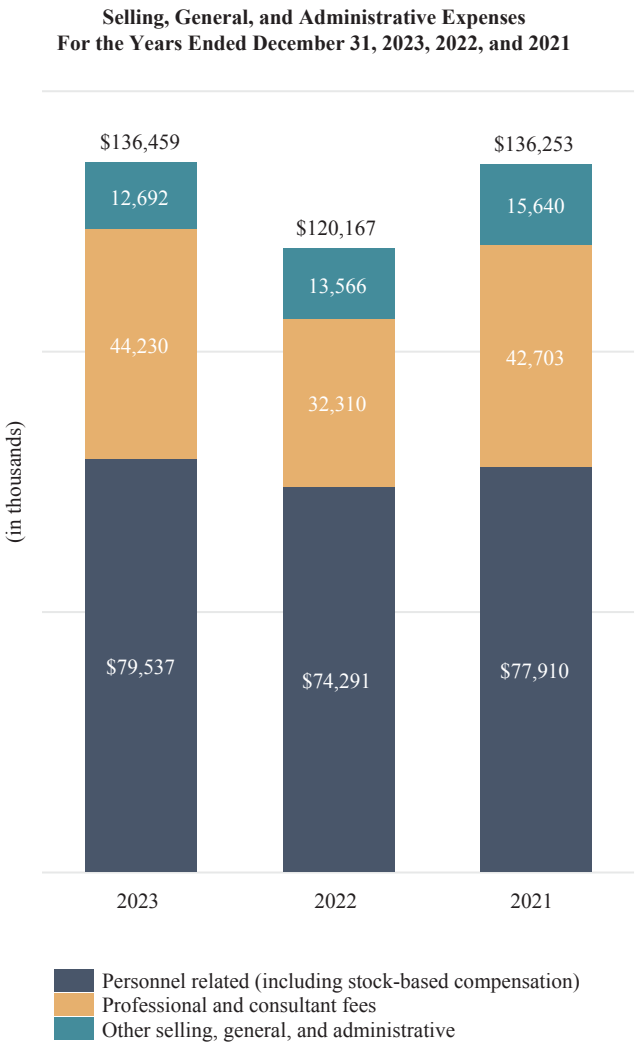
Prior to receiving FDA approval for QINLOCK in May 2020, we manufactured inventory to be sold and recorded approximately $6.0 million related to this inventory build-up as research and development expense. We did not record any such costs related to the build-up of this inventory as research and development expense during the years ended December 31, 2023, 2022, and 2021.

Utilizing the actual direct costs to manufacture QINLOCK prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the years ended December 31, 2022 and 2021 would have increased by approximately $1.9 million each year.

We do not expect our cost of sales for QINLOCK to increase significantly 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. We continued to sell the zero cost inventories of QINLOCK in the U.S. through the third quarter of 2022, and began selling inventory with the full cost of manufacturing in the fourth quarter of 2022.

Operating Expenses





Research and Development Expenses

QINLOCK

For the year ended December 31, 2023 compared to the same period in 2022, research and development expenses related to QINLOCK increased primarily as a result of increased clinical trial expenses of $11.6 million and increased manufacturing expenses of $1.1 million. Clinical trial expenses for QINLOCK increased primarily as a result of increased expenses associated with our Phase 3 INSIGHT study of QINLOCK versus sunitinib in patients with mutations in KIT exon 11 and 17/18, our Phase 3 INTRIGUE study of QINLOCK for the treatment of second-line GIST, our ongoing Phase 1 study of QINLOCK, and an increase in clinical pharmacology study activities, partially offset by a decrease in expenses associated with INVICTUS, our Phase 3 study of QINLOCK for the treatment of fourth-line GIST. Manufacturing costs increased primarily due to timing of processing of inventory for clinical and commercial use.

For the year ended December 31, 2022 compared to the same period in 2021, research and development expenses related to QINLOCK decreased primarily as a result of decreased clinical trial expenses of $26.7 million, decreased manufacturing expenses of $8.4 million, and a decrease due to the restructuring charges incurred in the fourth quarter of 2021 of $10.9 million related to the termination of agreements and the discontinuation of the Phase 1b/2 study of QINLOCK in combination with a MEK inhibitor, which we discontinued in 2021. Clinical trial expenses for QINLOCK decreased primarily as a result of decreased expenses associated with INTRIGUE, our Phase 3 study of QINLOCK for the treatment of second-line GIST, which we initiated in December 2018 and for which enrollment was completed in December 2020, and our ongoing Phase 1 study of QINLOCK. Manufacturing costs decreased primarily due to timing of processing of inventory for clinical and commercial use.

Vimseltinib

For the year ended December 31, 2023 compared to the same period in 2022, research and development expenses related to our vimseltinib program increased primarily as a result of increased manufacturing expenses of $1.8 million, preclinical expenses of $1.0 million, and clinical trial expenses of $0.7 million. Manufacturing expenses increased primarily due to process validation activities. Preclinical expenses increased primarily due to an increase in biology and toxicology activities. Clinical trial expenses increased primarily due to increased activities associated with our Phase 3 study of vimseltinib in patients with TGCT, MOTION, and Phase 1/2 study of vimseltinib to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in patients with TGCT, both of which we presented data from during the fourth quarter of 2023, partially offset by decreased activities associated with clinical pharmacology study activities.

For the year ended December 31, 2022 compared to the same period in 2021, research and development expenses related to our vimseltinib program increased primarily as a result of increases in clinical trial expenses of $7.8 million. Clinical trial expenses increased primarily due to increased activities associated with our Phase 3 study of vimseltinib in patients with TGCT, MOTION, which was initiated in the fourth quarter of 2021 and increased clinical pharmacology study activities, partially offset by a decrease in clinical trial expense associated with our Phase 1/2 study of vimseltinib to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in patients with TGCT.

Rebastinib

For the year ended December 31, 2022 compared to the same period in 2021, research and development expenses related to our rebastinib program decreased primarily as a result of the discontinuation of our Phase 1/2 rebastinib program in the fourth quarter of 2021 following the corporate restructuring implemented in the fourth quarter of 2021.

DCC-3116

For the year ended December 31, 2023 compared to the same period in 2022, research and development expenses related to our DCC-3116 program increased primarily as a result of increases in clinical trial expenses of $7.8 million. Clinical trial expenses increased primarily due to increased activities associated with our Phase 1/2 studies evaluating DCC-3116 as a single agent and in combination cohorts.

For the year ended December 31, 2022 compared to the same period in 2021, research and development expenses related to our DCC-3116 program increased primarily as a result of increases in manufacturing costs of $7.5 million and increases in clinical trial expenses of $3.2 million, associated with our Phase 1 study of DCC-3116, which we initiated in June 2021, partially offset by a decrease in preclinical expense of $0.4 million, due to the program moving from the preclinical to clinical stage in June 2021.

Preclinical

For the year ended December 31, 2023 compared to the same period in 2022, the increase in preclinical costs of $2.6 million, was primarily due to increased activities related to toxicology and biology studies for our early-stage drug discovery programs, including for DCC-3084 and DCC-3009.

For the year ended December 31, 2022 compared to the same period in 2021, the decrease in preclinical costs of $4.7 million, was primarily due to a $4.0 million upfront payment to Sprint pursuant to the Sprint Agreement, an agreement to exclusively in-license worldwide rights to a research-stage program targeting VPS34, a key kinase in the autophagy pathway for the potential treatment of cancer, during the third quarter of 2021. For further details on the Sprint Agreement, please read Note 11, *In-License Agreement*, to the consolidated financial statements included in this Form 10-K.

Unallocated expenses

For the year ended December 31, 2023 compared to the same period in 2022, the increase in personnel-related and other research and development expenses were primarily associated with increased other research and development expenses of $12.3 million and increased personnel-related costs of $7.7 million. The other research and development expenses increase primarily related to manufacturing and development expenses for DCC-3084 and DCC-3009, consulting and professional services to support the research and development functions not allocated to specific projects, and temporary employment services. The increase in personnel-related was primarily due to an increase in headcount, partially offset by a decrease in stock-based compensation expense of $0.5 million primarily as a result of the completion of vesting associated with grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. The decrease in stock-based compensation was partially offset by $1.0 million of expenses recognized as a result of the achievement of multiple vesting events associated with performance-based restricted stock units during the fourth quarter of 2023 as well as headcount increases. Additionally, unallocated research and

development increased $2.3 million primarily due to a change in estimate made during the prior year as certain of our clinical trials were closing.

For the year ended December 31, 2022 compared to the same period in 2021, the decrease in unallocated research and development expenses were primarily associated with a decrease due the restructuring charges incurred in the fourth quarter of 2021 of $5.9 million and a decrease in personnel-related costs of $0.8 million. The decrease in personnel-related costs was primarily due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021, partially offset by an increase in employee expenses related to our international employees, who were primarily hired in the second half of 2021, and an increase in stock-based compensation expense of $1.5 million, primarily due to stock-based compensation grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. Additionally, unallocated research and development expenses decreased $3.1 million due to a change in estimate as certain of our clinical trials are closing.

We expect research and development expenses associated with our drug and drug candidate programs will increase in 2024 as these programs progress and as we support regulatory filing submissions for vimseltinib.

Selling, General, and Administrative Expenses

For the year ended December 31, 2023 compared to the same period in 2022, the increase in selling, general, and administrative expenses was primarily associated with increased professional and consultant fees of $11.9 million and an increase in personnel-related costs of $5.2 million, partially offset by a decrease in other selling, general, and administrative expenses of $0.9 million. The increase in professional and consultant fees is primarily due to an increase in professional, consulting, and other expenses related to the commercialization of QINLOCK, preparations for a potential commercial launch of vimseltinib, temporary employment services, and an increase in third-party legal services. The increase in personnel-related costs was primarily due to an increase in headcount, partially offset by a decrease in stock-based compensation of $0.9 million primarily as a result of the completion of vesting associated with grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. The decrease in stock-based compensation was partially offset by $2.9 million of expenses recognized as a result of the achievement of multiple vesting events associated with performance-based restricted stock units during the fourth quarter of 2023. The decreases in other selling, general, and administrative expenses is primarily due to an increase in sublease income, which began during the second quarter of 2022.

For the year ended December 31, 2022 compared to the same period in 2021, the decrease in selling, general, and administrative expenses was primarily associated with decreases in professional and consultant fees of $10.4 million, the absence of restructuring charges incurred in the fourth quarter of 2021 of $4.0 million, partially offset by an increase in personnel-related costs of $0.4 million. The decreases in professional and consultant fees were primarily due to a decrease in various advisory fees related to establishing, in the prior year period, a targeted commercial infrastructure and commercialization preparedness in key European markets to support the launch of QINLOCK in Germany in January 2022 and to conduct the AP2 program in France which began in April 2022. The increases in personnel-related costs were primarily due an increase in stock-based compensation expense of $4.3 million, primarily due to stock-based compensation grants issued in the fourth quarter of 2021 in connection with our corporate restructuring, and an increase in employee expenses related to our international employees, who were primarily hired in the second half of 2021, partially offset by the cost reduction measures included in our corporate restructuring implemented in the fourth quarter of 2021.

We anticipate that our selling, general, and administrative expenses will increase modestly overall due to increased selling, general, and administrative expenses to be incurred related to the continued launch of QINLOCK in additional jurisdictions in 2024 and supporting commercial preparations for a potential launch of vimseltinib.

Interest and Other Income, Net

For the years ended December 31, 2023 and 2022 compared to the same periods in 2022 and 2021, the increase in interest and other income, net, was primarily due to increased interest income on our cash equivalents and marketable securities associated with an increase in interest rates resulting in higher yield investments. Additionally, during the year ended December 31, 2022 compared to the same period in 2021, the increase in interest income on our cash equivalents and marketable securities was associated with higher investment balances.

Income tax expense

For the year ended December 31, 2023 compared to the same period in 2022, the decrease in income tax expense was primarily due to a decrease in U.S. state taxes and changes in transfer pricing resulting in a decrease in taxes due in international jurisdictions.

For the year ended December 31, 2022 compared to the same period in 2021, the increase in income tax expense was primarily due to increased revenue recorded in international jurisdictions.

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, 2023, 2022, and 2021.

Restructuring

In November 2021, we announced a corporate restructuring intended to prioritize clinical development of select programs, streamline commercial operations, maintain a focus on discovery research, and extend our cash runway.

As a result of the restructuring, we recognized a one-time charge in the fourth quarter of 2021 of approximately $26.2 million. This charge included approximately $9.8 million of employee-related termination costs and approximately $16.4 million of discontinuation costs such as contract termination fees and non-cancellable commitments related to the rebastinib and ripretinib programs. These amounts were incurred and paid by the end of 2022.

The following table summarized the charges and spending related to our restructuring efforts during the year ended December 31, 2022:

(in thousands)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2021	$ 7,383	$ 13,408	$ 20,791
Adjustments to previous estimates, net	(374)	192	(182)
Payments	(7,009)	(13,600)	(20,609)
Restructuring reserve as of December 31, 2022	$ —	$ —	$ —

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, and we have not generated sufficient revenues to result in a profit.

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 under the Zai License Agreement and Zai Supply Agreement. QINLOCK is approved in 16 territories for the treatment of fourth-line advanced GIST. During the years ended December 31, 2023, 2022 and 2021, our product revenues were primarily derived from sales of QINLOCK in the U.S. Additionally, we launched QINLOCK in Germany in January 2022, have conducted the AP2 program in France since April 2022, and launched QINLOCK in Italy in the third quarter of 2023. 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. During the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we also began to recognize royalty revenues under the Zai License Agreement. However, we cannot provide assurance as to what extent we will generate revenue from the commercialization of QINLOCK by us or our partners. 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, including vimseltinib. We may never generate revenues that are significant enough to achieve profitability.

On October 2, 2017, we completed the IPO of our common stock. Since October 2017, we have primarily supported our operations by completing issuances of our common stock through our IPO, subsequent follow-on offerings, including our underwritten public offerings in April 2022 and January 2023, and Open Market Sale Agreements℠ (the August 2020 Sales

Agreement and as amended, the Amended Sales Agreement, and the May 2023 Sales Agreement) with Jefferies LLC (Jefferies). Through such issuances, we have issued and sold 46,160,921 shares of our common stock and pre-funded warrants to purchase 9,748,761 shares of our common stock resulting in net proceeds of $1.3 billion, after deducting underwriting discounts and commissions and other offering expenses.

In April 2022, we entered into an underwriting agreement with J.P. Morgan Securities LLC and Jefferies, as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,501,239 shares of our common stock at a public offering price of $10.00 per share to certain investors. In addition, we issued and sold pre-funded warrants to purchase 9,748,761 shares of our common stock at a purchase price of $9.99 per pre-funded warrant, which equals the public offering price per share of the common stock less the $0.01 exercise price per share of each pre-funded warrant. The offering closed on April 29, 2022, resulting in net proceeds of $163.4 million, after deducting underwriting discounts and commissions and other offering expenses.

During the years ended December 31, 2023 and 2022, 2,427,693 and 892,798 shares of pre-funded warrants exercised, respectively, resulting in net proceeds of less than $0.1 million in each year. As of December 31, 2023, there were 6,428,270 pre-funded warrants outstanding.

In August 2022, we entered into an amendment to our existing August 2020 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 Amended 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 Amended Sales Agreement, but we have no obligation to sell any Shares under the Amended Sales Agreement. We 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, 2021, we issued 172,094 shares resulting in net proceeds of $8.5 million after deducting commissions and other offering expenses, under the August 2020 Sales Agreement. During the years ended December 31, 2023 and 2022, we did not issue any shares under the August 2020 Sales Agreement or the Amended Sales Agreement.

On January 18, 2023, we delivered written notice to Jefferies that we were suspending and terminating the prospectus related to the Shares issuable pursuant to the terms of the Amended Sales Agreement. The Amended Sales Agreement was superseded by the May 2023 Sales Agreement.

In January 2023, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies, Cowen and Company, LLC, and Guggenheim Securities, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,986,111 shares of our common stock at a public offering price of $18.00 per share. The offering closed on January 24, 2023, resulting in net proceeds of $134.5 million, after deducting underwriting discounts and commissions and other offering expenses.

In May 2023, we entered into the May 2023 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 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 May 2023 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 May 2023 Sales Agreement, but we have no obligation to sell any Shares under the May 2023 Sales Agreement. We 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, 2023, we issued 1,004,185 shares resulting in net proceeds of $14.6 million, after deducting commissions and other offering expenses, under the May 2023 Sales Agreement. As of December 31, 2023, there was up to $185.0 million available for future issuance under the May 2023 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 August 2020 and May 2023 Sales Agreements 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 August 2020 Sales Agreement, as amended[3]	Various[3]	Various[3]	466,369	26.4		Not applicable		466,369	26.4
April 2022 Follow-on Public Offering	10.00	April 26, 2022	5,251,239	142.0	April 29, 2022	2,250,000	21.4	7,501,239	163.4
January 2023 Follow-on Public Offering	18.00	January 24, 2023	6,944,445	116.9	January 24, 2023	1,041,666	17.6	7,986,111	134.5
Issuances Pursuant to the May 2023 Sales Agreement[3]	Various[3]	Various[3]	1,004,185	14.6		Not applicable		1,004,185	14.6
							Total	46,160,921	$1,269.0

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. Information presented above represents the total number of shares of our common stock issued, and total net proceeds from issuances of shares of our common stock, pursuant to the August 2020 Sales Agreement and May 2023 Sales Agreement through December 31, 2023. Shares issued pursuant to the August 2020 Sales Agreement and May 2023 Sales Agreement can be sold over multiple days, months, and years at varying prices.

Cash Flows

As of December 31, 2023, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $352.9 million, which consisted of cash, money market funds, U.S. government securities, corporate debt securities, commercial paper, 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)	2023	2022	2021
Net cash flows used in operating activities	$ (146,697)	$ (152,862)	$ (240,824)
Net cash flows provided by (used in) investing activities	12,549	(34,309)	176,848
Net cash flows provided by financing activities	152,004	164,994	14,890
Net (decrease) increase in cash and cash equivalents	$ 17,856	$ (22,177)	$ (49,086)

Operating Activities

During the year ended December 31, 2023 compared to the same period in 2022, net cash flows used in operating activities decreased $6.2 million, primarily resulting from increases in net cash flows related to changes in our operating assets and liabilities of $30.1 million, partially offset by an increase in our net loss of $16.0 million, an increase in discount accretion associated with our marketable securities of $6.1 million, and a decrease in share-based compensation of $1.3 million. The increase in net cash flows related to changes in our operating assets and liabilities were generally due to the timing of vendor invoicing and payments.

During the year ended December 31, 2022 compared to the same period in 2021, net cash flows used in operating activities decreased $88.0 million, primarily resulting from a decrease in our net loss of $121.0 million, as well as an increase in share-based compensation of $5.9 million, partially offset by increases in net cash flows related to changes in our operating assets and liabilities of $32.5 million. The increase in net cash flows related to changes in our operating assets and liabilities were generally due to the timing of vendor invoicing and payments.

Investing Activities

During the year ended December 31, 2023 compared to the same period in 2022, net cash flows provided by investing activities increased $46.9 million, primarily resulting from a net increase in proceeds from maturities and sales of marketable securities of $46.6 million.

During the year ended December 31, 2022 compared to the same period in 2021, net cash flows used in investing activities increased $211.2 million, primarily resulting from a decrease in proceeds from maturities and sales of marketable securities of $228.9 million, partially offset by a decrease in purchases of marketable securities of $12.6 million, a decrease in purchases of property and equipment of $1.1 million and a $4.0 million upfront payment pursuant to the Sprint Agreement during the third quarter of 2021. For further details on the Sprint Agreement, please read Note 11, *In-License Agreement*, to the consolidated financial statements included in this Form 10-K.

Financing Activities

During the year ended December 31, 2023 compared to the same period in 2022, net cash flows provided by financing activities decreased $13.0 million, primarily resulting from a decrease in net proceeds from offerings of our common stock and pre-funded warrants of $14.0 million. Net of underwriting discounts and commissions and other offering costs, the decrease in proceeds from offerings was primarily due to our issuance of common stock in a follow-on public offering in January 2023 of $134.5 million as compared to our issuance of common stock and pre-funded warrants in a follow-on public offering in April 2022 of $163.4 million, partially offset by $14.6 million of net proceeds from issuances under the May 2023 Sales Agreement during 2023 compared to no issuances under the August 2020 Sales Agreement during 2022.

During the year ended December 31, 2022 compared to the same period in 2021, net cash flows provided by financing activities increased $150.1 million, primarily resulting from an increase in net proceeds from offerings of our common stock and pre-funded warrants of $154.8 million, partially offset by a decrease in proceeds from stock option exercises and employee stock purchase plan activity of $4.7 million. Net of underwriting discounts and commissions and other offering costs, the increase in proceeds from offerings was due to our issuance of common stock and pre-funded warrants in a follow-on public offering in April 2022 of $163.4 million as compared to our issuances under the August 2020 Sales Agreement during the year ended December 31, 2021 of $8.5 million.

Funding Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of QINLOCK and eventual commercialization of one or more of our drug candidates. Our net loss was $194.9 million, $178.9 million, and $300.0 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $1.4 billion. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses and capital requirements will continue to 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 capabilities to bring QINLOCK to eligible patients around the world, including in key European markets;
- conduct our Phase 3 INSIGHT study of QINLOCK, the development of companion diagnostic tests related to INSIGHT, and other expenses that may be borne as a result of the new trial;
- seek regulatory approval and support the commercialization of vimseltinib, if approved, as a therapy for the treatment of TGCT;
- develop DCC-3116, our ULK kinase inhibitor, for the potential treatment of mutant RAS or RAF 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;
- make payments, if any, pursuant to any license or collaboration agreement we may enter into;
- maintain, expand, protect, and enforce our intellectual property portfolio; and
- maintain our operational, financial, and management systems and personnel, including to support our clinical development and commercialization efforts and our operations as a public company, including international operations in key European markets and other potential geographies.

As we continue to seek regulatory approval for our drug candidates, 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. 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, product, royalty, and supply revenues, 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. Market volatility resulting from global economic developments, political unrest, and high inflation, 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.

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 the Zai License Agreement), 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.

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 further 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 diagnostic tests 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;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK, including our commercial launch of QINLOCK in key European markets, 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, 2023 of $352.9 million, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestones received under our collaboration or license agreements will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2026. We have based these estimates on assumptions that may not be achieved, and we could utilize our available capital resources sooner than we expect.

Contractual Obligations and Commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods. Such arrangements include those related to our lease commitments and commercial supply agreements.

Lease Commitments

Our lease commitments reflect payments due for our lease agreements for office space at the Premises that expire in November 2029, laboratory, office, and storage space in Lawrence, Kansas under lease agreements that expire in December 2030, and office space in key European markets to support European commercialization which have terms of less than 12 months. As of December 31, 2023, our contractual commitments for our leases were $30.6 million, of which $4.8 million is expected to be paid within one year, and $25.8 million will be paid over the remaining term of such leases. For additional information on our leases and timing of future payments, please read Note 7, *Leases*, to the consolidated financial statements included in this Form 10-K.

Commercial Supply Agreements

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. As of December 31, 2023, our contractual commitments for such obligations were $11.0 million, which are expected to be paid within one year.

Other Obligations

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 generally 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 have not been included separately within these contractual and other obligations disclosures.

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 Policies*, 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, 2023 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 both December 31, 2023 and 2022, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $2.7 million to our interest rate sensitive instruments.

We do not believe that our cash, cash equivalents, and marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value, 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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

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.

Recognition of Net Product Revenues

As described in Note 2 to the consolidated financial statements, 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 variable consideration. Product revenues, net totaled $159.1 million for the year ended December 31, 2023

The principal consideration for our determination that performing procedures relating to the recognition of net product revenues is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's revenue recognition.

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 the recognition of net product revenues, including controls over the recording of revenue at the transaction price once the customer takes control of the product. These procedures also included, among others, (i) testing the completeness, accuracy, and occurrence of revenue for a sample of transactions by obtaining and inspecting source documents, such as invoices, customer purchase orders, shipping documents, and cash receipts; and (ii) testing, on a sample basis, the completeness, accuracy, and occurrence of product revenue reserves activity by recalculating and evaluating the variable consideration for consistency with the contractual terms of management's arrangements and policies.

/s/Pricewaterhousecoopers LLP

Boston, Massachusetts
February 7, 2024

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,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 83,507	$ 64,741
Short-term marketable securities	222,709	259,745
Accounts receivable, net	31,952	22,429
Inventory	21,210	20,561
Prepaid expenses and other current assets	21,718	25,482
Total current assets	381,096	392,958
Long-term marketable securities	46,699	14,550
Long-term investments—restricted and other long-term assets	8,277	3,277
Property and equipment, net	5,421	6,707
Operating lease assets	32,073	36,547
Total assets	$ 473,566	$ 454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 26,476	$ 18,612
Accrued expenses and other current liabilities	70,295	64,622
Operating lease liabilities	3,504	3,235
Total current liabilities	100,275	86,469
Operating lease liabilities, net of current portion	22,375	25,879
Total liabilities	122,650	112,348
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 80,503,338 shares and 67,637,351 shares issued and outstanding as of December 31, 2023 and 2022, respectively	805	676
Additional paid-in capital	1,777,839	1,575,361
Accumulated other comprehensive income	577	(983)
Accumulated deficit	(1,428,305)	(1,233,363)
Total stockholders' equity	350,916	341,691
Total liabilities and stockholders' equity	$ 473,566	$ 454,039

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,		
	2023	2022	2021
Revenues:			
Product revenues, net	$ 159,074	$ 125,504	$ 87,389
Collaboration revenues	4,282	8,532	8,759
Total revenues	163,356	134,036	96,148
Cost and operating expenses:			
Cost of sales	3,732	8,770	2,932
Research and development	234,123	187,821	257,040
Selling, general, and administrative	136,459	120,167	136,253
Total cost and operating expenses	374,314	316,758	396,225
Loss from operations	(210,958)	(182,722)	(300,077)
Other income (expense):			
Interest and other income, net	16,447	4,513	113
Total other income (expense), net	16,447	4,513	113
Loss before income tax expense	(194,511)	(178,209)	(299,964)
Income tax expense	431	722	—
Net loss	$ (194,942)	$ (178,931)	$ (299,964)
Net loss per share—basic and diluted	$ (2.29)	$ (2.37)	$ (5.16)
Weighted average common shares outstanding—basic and diluted	85,059,962	75,500,148	58,084,325
Comprehensive loss:			
Net loss	$ (194,942)	$ (178,931)	$ (299,964)
Other comprehensive income (loss):			
Unrealized gains (losses) on marketable securities	1,043	(992)	(278)
Currency translation adjustment	517	(42)	318
Total other comprehensive income (loss)	1,560	(1,034)	40
Total comprehensive loss	$ (193,382)	$ (179,965)	$ (299,924)

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, 2020	57,596,144	$ 576	$ 1,297,557	$ 11	$ (754,468)	$ 543,676
Issuance of common stock sold in public offering, net of underwriting discounts, commissions, and offering costs	172,094	2	8,547	—	—	8,549
Issuance of common stock under stock option and incentive plan and employee stock purchase plans	781,406	7	6,334	—	—	6,341
Stock-based compensation expense	—	—	46,078	—	—	46,078
Other comprehensive income	—	—	—	40	—	40
Net loss	—	—	—	—	(299,964)	(299,964)
Balance, December 31, 2021	58,549,644	585	1,358,516	51	(1,054,432)	304,720
Issuance of common stock sold in public offering, net of underwriting discounts, commissions, and offering costs	7,501,239	75	163,278	—	—	163,353
Issuance of common stock upon pre-funded warrant exercise	892,798	9	—	—	—	9
Issuance of common stock under stock option and incentive and employee stock purchase plans	693,670	7	1,625	—	—	1,632
Stock-based compensation expense	—	—	51,942	—	—	51,942
Other comprehensive loss	—	—	—	(1,034)	—	(1,034)
Net loss	—	—	—	—	(178,931)	(178,931)
Balance, December 31, 2022	67,637,351	676	1,575,361	(983)	(1,233,363)	341,691
Issuance of common stock and pre-funded warrants, net of underwriting discounts, commissions and offering costs	8,990,296	90	149,023	—	—	149,113
Issuance of common stock upon pre-funded warrant exercise	2,427,693	24	—	—	—	24
Issuance of common stock under stock option and incentive and employee stock purchase plans	1,447,998	15	2,852	—	—	2,867
Stock-based compensation expense	—	—	50,603	—	—	50,603
Other comprehensive income	—	—	—	1,560	—	1,560
Net loss	—	—	—	—	(194,942)	(194,942)
Balance, December 31, 2023	80,503,338	$ 805	$ 1,777,839	$ 577	$ (1,428,305)	$ 350,916

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,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (194,942)	$ (178,931)	$ (299,964)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	50,603	51,942	46,078
Depreciation expense	2,100	2,946	3,014
Noncash lease expense	4,475	4,126	3,446
Acquired in-process research and development	—	—	4,000
Net amortization (accretion) of premiums (discounts) on marketable securities	(7,397)	(1,297)	1,782
Changes in operating assets and liabilities:			
Accounts receivable	(9,345)	(1,784)	(6,699)
Inventory	(386)	(7,109)	(10,155)
Prepaid expenses and other current assets	3,808	(9,510)	(7,934)
Other long-term assets	(4,996)	(168)	—
Accounts payable	7,777	5,319	833
Accrued expenses and other current liabilities	4,411	(16,184)	27,285
Income tax liabilities	431	722	—
Operating lease liabilities	(3,236)	(2,934)	(2,510)
Net cash flows used in operating activities	(146,697)	(152,862)	(240,824)
Cash flows from investing activities:			
Purchases of marketable securities	(322,572)	(322,767)	(335,375)
Maturities of marketable securities	335,114	289,299	468,587
Sales of marketable securities	785	—	49,613
Purchases of property and equipment	(778)	(841)	(1,970)
Acquired in-process research and development	—	—	(4,000)
Increase in restricted investments	—	—	(7)
Net cash flows provided by (used in) investing activities	12,549	(34,309)	176,848
Cash flows from financing activities:			
Proceeds from offerings of common stock, net of underwriting discounts and commissions	149,747	163,778	8,589
Proceeds from pre-funded warrants	24	9	—
Payments of public offering costs	(634)	(425)	(40)
Proceeds from stock option exercises and employee stock purchase plan	2,867	1,632	6,341
Net cash flows provided by financing activities	152,004	164,994	14,890
Net (decrease) increase in cash and cash equivalents	17,856	(22,177)	(49,086)
Effect of exchange rate changes on cash and cash equivalents	910	(145)	252
Cash and cash equivalents at beginning of period	64,741	87,063	135,897
Cash and cash equivalents at end of period	$ 83,507	$ 64,741	$ 87,063

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

1. Nature of the Business and Basis of Presentation

Nature of the Business

Deciphera Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer. Leveraging its proprietary switch-control inhibitor platform and deep expertise in kinase biology, the Company designs kinase inhibitors to target the switch pocket region of the kinase with the goal of developing potentially transformative medicines. Through its patient-inspired approach, the Company seeks to develop a broad portfolio of innovative medicines to improve treatment outcomes. QINLOCK, the Company's switch-control tyrosine kinase inhibitor, was discovered using its proprietary drug discovery platform and designed for the treatment of gastrointestinal stromal tumor (GIST). QINLOCK is approved in Australia, Canada, China, the European Union (EU), Hong Kong, Iceland, Israel, Liechtenstein, Macau, Norway, New Zealand, Singapore, Switzerland, Taiwan, the United Kingdom (U.K.), and the United States (U.S.) for the treatment of fourth-line GIST. 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 Greater China. In addition to QINLOCK, the Company has developed a robust pipeline of novel drug candidates using its switch-control kinase inhibitor platform, including vimseltinib and DCC-3116.

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, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, compliance with government regulations, 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 commercialization of QINLOCK, the Company's first 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 sufficient revenue to result in a profit from product sales of QINLOCK or any current or future drug candidates for which it receives marketing approval.

In April 2022, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC and Jefferies, LLC (Jefferies), as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,501,239 shares of its common stock at a public offering price of $10.00 per share to certain investors. In addition, the Company issued and sold pre-funded warrants to purchase 9,748,761 shares of its common stock at a public offering price of $9.99 per pre-funded warrant, which equals the public offering price per share of the common stock less the $0.01 exercise price per share of each pre-funded warrant. The offering closed on April 29, 2022, resulting in net proceeds of $163.4 million, after deducting underwriting discounts and commissions and other offering expenses.

As the pre-funded warrants are indexed to the Company’s common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the pre-funded warrants as additional paid-in capital on the Company’s consolidated balance sheets.

The pre-funded warrants are exercisable at any time. Certain holders of pre-funded warrants may not exercise the pre-funded warrant if the holder, together with its affiliates, would beneficially own more than 4.99%, 9.99% or 28.22% of the number of shares of the Company’s common stock outstanding immediately after giving effect to such exercise. A holder of pre-funded warrants may increase or decrease this percentage not in excess of 19.99%, with the exception of one holder, by providing at least 61 days’ prior notice to the Company.

During the years ended December 31, 2023 and 2022, 2,427,693 and 892,798 shares of pre-funded warrants were exercised, respectively, resulting in net proceeds of less than $0.1 million in each year. As of December 31, 2023, there were 6,428,270 pre-funded warrants outstanding.

In August 2022, the Company entered into an amendment to its existing Open Market Sale Agreement℠ (the August 2020 Sales Agreement and as amended, Amended Sales Agreement) with 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 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 Amended 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 Amended Sales Agreement, but it has no obligation to sell any Shares under the Amended 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, 2021, the Company issued 172,094 shares resulting in net proceeds of $8.5 million after deducting commissions and other offering expenses, under the August 2020 Sales Agreement. During the years ended, December 31, 2023 and 2022, the Company did not issue any shares under the August 2020 Sales Agreement or the Amended Sales Agreement.

On January 18, 2023, the Company delivered written notice to Jefferies that it was suspending and terminating the prospectus related to the common stock issuable pursuant to the terms of the Amended Sales Agreement. As a result, the Company will not make any sales of its securities pursuant to the Amended Sales Agreement, unless and until a new prospectus, prospectus supplement, or a new registration statement is filed. The Amended Sales Agreement was superseded by an Open Market Sale Agreement[SM] entered into in May 2023 (the May 2023 Sales Agreement) with Jefferies.

In January 2023, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies, Cowen and Company, LLC, and Guggenheim Securities, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,986,111 shares of its common stock at a public offering price of $18.00 per share. The offering closed on January 24, 2023, resulting in net proceeds of $134.5 million, after deducting underwriting discounts and commissions and other offering expenses.

In May 2023, the Company entered into the May 2023 Sales Agreement with Jefferies, pursuant to which the Company may issue and sell the Shares having aggregate offering proceeds of up to $200.0 million 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 May 2023 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 May 2023 Sales Agreement, but it has no obligation to sell any Shares under the May 2023 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, 2023, the Company issued 1,004,185 shares resulting in net proceeds of $14.6 million, after deducting commissions and other offering expenses, under the May 2023 Sales Agreement. As of December 31, 2023, there was up to $185.0 million available for future issuance under the May 2023 Sales Agreement.

Basis of Presentation

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 $194.9 million, $178.9 million, and $300.0 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, the Company had an accumulated deficit of $1.4 billion. 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 $352.9 million as of December 31, 2023, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestones received under its collaboration or license agreements 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 further terminate 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.

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, and the Company's chief operating decision maker views the Company's business, as a single segment for the purposes of making decisions on how to allocate resources and assessing performance. The Company's focus is discovering, developing, and commercializing important new medicines to improve the lives of people with cancer by leveraging its proprietary switch-control inhibitor platform and deep expertise in kinase biology. The Company designs kinase inhibitors to target the switch pocket region of the kinase with the goal of developing potentially transformative medicines and develop a broad portfolio of innovative medicines to improve treatment outcomes. The Company operates in the U.S. and Europe. Primarily all of the Company's long-lived assets reside in the U.S.

Revenues

The Company 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 Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, 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 Company 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

QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Iceland, Israel, Liechtenstein, Macau, Norway, New Zealand, Singapore, Switzerland, Taiwan, the U.S. and the U.K. for the treatment of fourth-line GIST.

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, Medicaid, and other governmental rebates in the U.S. and other similar programs in other countries, including countries in which the Company is accruing for estimated rebates because final pricing has not yet been negotiated. 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 supplies the Licensed Products to Zai for use in the Territory for commercial inventory and clinical trials. Subject to the Zai Supply Agreement, costs incurred by the Company for external manufacturing services are reimbursed by Zai.

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 Zai License Agreement and Zai Supply Agreement, please read Note 3, *Revenues*, to these consolidated financial statements.

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, 2023 and 2022, the Company's marketable securities were comprised of debt securities, commercial paper, U.S. government 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 during the years ended December 31, 2023, 2022 or 2021.

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.

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 commercial and research and development activities associated with its drug and drug candidates, as applicable. 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 the Company's drug and drug candidate activities. These activities, including the commercialization of QINLOCK, 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 partner 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, 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 years ended December 31, 2023 and 2022, the Company did not record any expected credit losses related to outstanding accounts receivable.

Inventory and Cost of Sales

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. The Company classifies its inventory costs as long-term when it expects to utilize the inventory beyond its normal operating cycle and includes these costs in long-term investments—restricted and other long-term assets in the consolidated balance sheets. Cost of sales for both product revenues, net and collaboration revenues are based on the sale of inventory used in commercial products.

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 initial 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, as the maturities of these instruments are more than one year from the balance sheet date, 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 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.

The Company has made an accounting policy election to not recognize short-term leases, or leases that have a lease term of 12 months or less at commencement date, within its consolidated balance sheets and to recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Sublease

All of the Company's leases are operating leases. The Company determines the classification of a sublease at inception. If the sublease is determined to be an operating lease, the Company will recognize sublease income on a straight-line basis over the lease term in the consolidated statement of operations and comprehensive loss as a reduction of the related operating expense. If the sublease is determined to be a sales-type lease or direct financing lease, the Company will derecognize the right-of-use asset from the Company's original lease and record a net investment in the sublease and evaluate for impairment. The Company will account for the lease liability of the original lease based on the accounting for a lease liability in a finance lease.

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, 2023, 2022, or 2021.

Acquired In-Process Research and Development (IPR&D)

Acquired IPR&D represents the value assigned to research and development assets that have not reached technological feasibility. Upon the acquisition of IPR&D, the Company completes an assessment of whether the acquisition constitutes the purchase of a single asset or group of assets. The Company considers multiple factors in this assessment, including the nature of the technology acquired, the presence or absence of separate cash flows, the development process and stage of completion, quantitative significance, and the Company's rationale for entering into the transaction.

If the Company acquires a business as defined under applicable accounting standards, then the acquired IPR&D is capitalized as an intangible asset on the consolidated balance sheets and recorded at fair value. If the Company acquires an asset or group of assets that do not meet the definition of a business under applicable accounting standards, then the acquired IPR&D is expensed as research and development in the consolidated statements of operations and comprehensive loss on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred until such time that the asset or group of assets reaches technological feasibility, if ever.

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, facility- and technology-related costs, depreciation, manufacturing expenses, external costs of outside vendors engaged to conduct preclinical development activities and trials, and upfront fees paid to third-parties associated with acquired IPR&D that has not reached technological feasibility. 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. 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 and Accumulated Other Comprehensive Income (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, 2023 and 2022, the Company's other comprehensive income (loss) consisted of foreign currency translation adjustments and unrealized gains (losses) on marketable securities. For the year ended December 31, 2021, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities.

As of December 31, 2023 and 2022, accumulated other comprehensive income (loss) primarily consisted of foreign currency translation adjustments and unrealized gains (losses) on marketable securities.

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, including pre-funded warrants, for the years ended December 31, 2023, 2022, and 2021. 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. Potential common shares that are issuable for little or no cash consideration, such as the Company's pre-funded warrants issued in April 2022, are considered outstanding common shares are included in the calculation of basic and diluted net income (loss) per share in all circumstances.

3. Revenues

Net 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 U.S. Food and Drug Administration (FDA) on May 15, 2020, and during 2023, 2022, and 2021 in certain other jurisdictions following regulatory approval or on a named patient basis.

Net product revenues by geography consisted of the following and are attributable to individual countries based on the location of the customer:

(in thousands)	Year Ended December 31, 2023	2022	2021
U.S.	$ 121,546	$ 97,216	$ 81,476
Rest of world	19,570	13,947	5,913
Germany	17,958	14,341	—
Total product revenues, net	$ 159,074	$ 125,504	$ 87,389

The Company primarily sells QINLOCK through specialty distributors and specialty pharmacies. The Company recognized revenues from two customers accounting for 44% and 12% of gross product revenues for the year ended December 31, 2023, respectively, two customers accounting for 40% and 12% of gross product revenues for the year ended December 31, 2022, respectively, and three customers accounting for 57%, 18% and 10% of gross product revenues for the year ended December 31, 2021, respectively. As of December 31, 2023, two customers individually accounted for approximately 53% and 16% of accounts receivable associated with the Company's product sales. As of December 31, 2022, three customers individually accounted for approximately 47%, 15%, and 14% 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, 2022	$ 475	$ 656	$ 15,825	$ 1,375	$ 18,331
Provision related to sales in the current year	4,529	10,757	17,984	4,636	37,906
Adjustments related to prior period sales	(31)	—	80	—	49
Credits and payments made during the period	(4,219)	(10,533)	(9,023)	(4,916)	(28,691)
Balance as of December 31, 2023	$ 754	$ 880	$ 24,866	$ 1,095	$ 27,595

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

(in thousands)	December 31, 2023	December 31, 2022
Reduction of accounts receivable, net	$ 1,528	$ 1,082
Component of accrued expenses and other current liabilities	26,067	17,249
Total revenue-related reserves	$ 27,595	$ 18,331

Collaboration Revenues

Zai License Agreement

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 three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 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 annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances. Additionally, certain costs incurred by the Company associated with the Zai License Agreement are reimbursed by Zai.

During the years ended December 31, 2023, 2022, and 2021, the Company recognized royalty revenues under the Zai License Agreement, which the Company began recognizing in the second quarter of 2021 following the approval from the China National Medical Products Administration (China NMPA).

During the year ended December 31, 2021, revenues recognized under the Zai License Agreement also included the achievement of a $5.0 million development milestone in the first quarter of 2021.

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.

In the first quarter of 2021, the Company determined that the $5.0 million development milestone was probable of achievement and that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, and constitute consideration to be included in the transaction price 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.

Zai Supply Agreement

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 obtained regulatory approval in the Territory. QINLOCK was approved in the PRC, Hong Kong, and Taiwan in 2021, and Macau and Singapore in 2023. Subject to the Zai Supply Agreement, costs incurred by the Company for clinical and commercial supply are reimbursed by Zai.

During the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, the Company began recognizing revenues associated with sales of commercial inventory of QINLOCK under the Zai Supply Agreement.

4. Marketable Securities and Fair Value Measurements

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

As of December 31, 2023 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
U.S. government securities	97,889	15	(93)	$ 97,811
Corporate debt securities	82,934	26	(123)	82,837
Commercial paper	39,542	30	(11)	39,561
Certificates of deposit	2,500	—	(1)	2,499
Due after one year through five years:				
U.S. government securities	31,698	34	(151)	31,581
Corporate debt securities	15,060	64	(5)	15,119
Total	$ 269,623	$ 169	$ (384)	$ 269,408

As of December 31, 2022 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Corporate debt securities	$ 113,939	$ 2	$ (571)	$ 113,370
Commercial paper	81,344	12	(336)	81,020
Certificates of deposit	33,877	14	(152)	33,739
U.S. government securities	31,761	15	(160)	31,616
Due after one year through five years:				
Corporate debt securities	11,278	—	(38)	11,240
U.S. government securities	3,349	—	(39)	3,310
Total	$ 275,548	$ 43	$ (1,296)	$ 274,295

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, 2023 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 29,829	$ —	$ 29,829
Marketable securities:				
U.S. government securities	—	129,392	—	129,392
Corporate debt securities	—	97,956	—	97,956
Commercial paper	—	39,561	—	39,561
Certificates of deposit	—	2,499	—	2,499
Total	$ —	$ 299,237	$ —	$ 299,237

As of December 31, 2022 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 27,787	$ —	$ 27,787
Certificates of deposit	—	14,167	—	14,167
Corporate debt securities	—	4,945	—	4,945
Marketable securities:				
Corporate debt securities	—	124,610	—	124,610
Commercial paper	—	81,020	—	81,020
U.S. government securities	—	34,926	—	34,926
Certificates of deposit	—	33,739	—	33,739
Total	$ —	$ 321,194	$ —	$ 321,194

The tables above exclude certificates of deposit of $3.1 million as of both December 31, 2023 and 2022 that the Company held to secure a letter of credit associated with its leases and to secure a credit card account. The certificates of deposit 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. The Company performs validation procedures to ensure the reasonableness of this data. The Company performs its own review of prices received from the independent pricing services by comparing these prices to other sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2023 and 2022.

5. Inventory

Capitalized inventory consisted of the following:

(in thousands)	December 31, 2023	December 31, 2022
Raw materials	$ 4,934	$ 6,844
Work in process	18,253	11,125
Finished goods	2,957	2,592
Total inventory	$ 26,144	$ 20,561

Long-term inventory, which consists of raw materials, is included in long-term investments—restricted and other long-term assets in the consolidated balance sheets. As of December 31, 2023, $4.9 million was classified as non-current.

Inventory written down as a result of excess, obsolescence, unmarketability, or other reasons is charged to cost of sales, and totaled $0.9 million during the year ended December 31, 2022. There were less than $0.1 million in inventory amounts written

down and charged to cost of sales during the year ended December 31, 2021. There were no inventory amounts written down and charged to cost of sales during the year ended December 31, 2023.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
(in thousands)	2023	2022
Laboratory equipment	$ 6,517	$ 5,515
Computer equipment	5,035	5,018
Furniture and fixtures	3,922	3,919
Leasehold improvements	2,113	2,113
Construction in progress	31	226
Total cost	17,618	16,791
Less: Accumulated depreciation	(12,197)	(10,084)
Total property and equipment, net	$ 5,421	$ 6,707

Depreciation expense was $2.1 million, $2.9 million, and $3.0 million for the years ended December 31, 2023, 2022, and 2021, 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. The Premises became the Company's new headquarters in October 2019.

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.

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 as of both December 31, 2023 and 2022 were classified as long-term investment—restricted in the consolidated balance sheets.

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. Additionally, new leases associated with the 2020 Lawrence Lease Agreements commenced during the first and fourth quarters of 2021 resulting in the additions of operating lease assets of $0.5 million and $3.4 million and corresponding lease liabilities of $0.5 million and $1.7 million, respectively. Further, a new lease associated with the 2020 Lawrence Lease Agreements commenced during the second quarter of 2022 resulting in the addition of operating lease assets of $3.8 million and corresponding lease liability of $1.1 million, respectively.

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, 2023, 2022, and 2021 the Company was subject to certain lease agreements with terms of less than 12 months to accommodate short-term or temporary needs and its office space needs to support

commercialization efforts in key European markets. The expenses associated with such lease agreements are included in short-term lease costs for the years ended December 31, 2023, 2022, and 2021, 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, 2023, 2022, and 2021.

Sublease

In May 2022, the Company entered into a sublease agreement to sublease 44,343 square feet of space at 200 Smith Street, Waltham, MA, for a term of three years for $8.9 million over the term of the sublease. The Company determined the sublease to be an operating lease. Therefore the Company will recognize sublease income on a straight-line basis over the lease term in its consolidated statement of operations and comprehensive income. The Company will continue to account for the right-of-use asset and related liability of the original lease as it did prior to the commencement of the sublease.

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)	**2023**	**2022**
Operating lease right of use assets	$ 32,073	$ 36,547
Current operating lease liabilities	$ 3,504	$ 3,235
Operating lease liabilities, net of current portion	22,375	25,879
Total operating lease liabilities	$ 25,879	$ 29,114

The components of lease expense were as follows:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Operating lease cost	$ 6,012	$ 5,809	$ 5,178
Short-term lease cost	60	455	357
Variable lease cost	1,738	1,468	1,225
Sublease income	(2,926)	(1,736)	—
Total lease expense, net	$ 4,884	$ 5,996	$ 6,760

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

(in thousands)	**As of December 31, 2023**
2024	$ 4,854
2025	4,936
2026	5,019
2027	5,101
2028	5,183
Thereafter	5,535
Total future minimum lease payments	30,628
Less: imputed interest	(4,749)
Total operating lease liabilities	$ 25,879

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

	As of December 31,	
	2023	2022
Weighted-average remaining lease term in years	6.08	6.97
Weighted-average discount rate	5.55%	5.59%

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)	2023	2022	2021
Cash paid for amounts included in the measurement of operating lease liabilities	$ 4,772	$ 4,617	$ 4,243
Operating lease liabilities arising from obtaining operating lease assets	$ —	$ 1,188	$ 2,150

8. Other Consolidated Financial Detail

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
(in thousands)	2023	2022
External research and development expenses	$ 16,095	$ 17,411
Payroll and related expenses	20,519	21,971
Revenue-related reserves	26,067	17,249
Professional fees	5,669	4,275
Other	1,945	3,716
Total accrued expenses and other current liabilities	$ 70,295	$ 64,622

Interest Income

For the years ended December 31, 2023, 2022, and 2021, interest income was $16.7 million, $5.1 million, and $0.6 million, respectively.

9. Stockholders' Equity

Undesignated Preferred Stock

The Company's board of directors has the authority, without further action by its stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon the Company's liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action. There are no shares of preferred stock outstanding as of December 31, 2023.

Common Stock

In April 2022, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC and Jefferies, as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,501,239 shares of its common stock at a public offering price of $10.00 per share to certain investors. In addition, the Company issued and sold pre-funded warrants to purchase 9,748,761 shares of its common stock at a public offering price of $9.99 per pre-funded warrant,

which equals the public offering price per share of the common stock less the $0.01 exercise price per share of each pre-funded warrant. The offering closed on April 29, 2022, resulting in net proceeds of $163.4 million, after deducting underwriting discounts and commissions and other offering expenses. Additionally, during the years ended December 31, 2023 and 2022, 2,427,693 and 892,798 shares of pre-funded warrants exercised, respectively, resulting in net proceeds of less than $0.1 million in each year. For additional information on the pre-funded warrants, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements.

On August 4, 2022, the Company entered into the Amended Sales Agreement, 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, 2021, the Company issued 172,094 shares resulting in net proceeds of $8.5 million after deducting commissions and other offering expenses, under the August 2020 Sales Agreement. During the years ended, December 31, 2023 and 2022, the Company did not issue any shares under the August 2020 Sales Agreement or the Amended Sales Agreement. For additional information on the August 2020 Sales Agreement and Amended Sales Agreement, please read Note 1, *Nature of the Business and Basis of Presentation*, to these consolidated financial statements.

On January 18, 2023, the Company delivered written notice to Jefferies that it was suspending and terminating the prospectus related to the common stock issuable pursuant to the terms of the Amended Sales Agreement. As a result, the Company will not make any sales of its securities pursuant to the Amended Sales Agreement, unless and until a new prospectus, prospectus supplement, or a new registration statement is filed. The Amended Sales Agreement was superseded by the May 2023 Sales Agreement.

In January 2023, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC, Jefferies, Cowen and Company, LLC, and Guggenheim Securities, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale of an aggregate of 7,986,111 shares of its common stock at a public offering price of $18.00 per share. The offering closed on January 24, 2023, resulting in net proceeds of $134.5 million, after deducting underwriting discounts and commissions and other offering expenses.

In May 2023, the Company entered into the May 2023 Sales Agreement with Jefferies, pursuant to which the Company may issue and sell the Shares having aggregate offering proceeds of up to $200.0 million 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, 2023, the Company issued 1,004,185 shares resulting in net proceeds of $14.6 million, after deducting commissions and other offering expenses, under the May 2023 Sales Agreement. As of December 31, 2023, there was up to $185.0 million available for future issuance under the May 2023 Sales Agreement.

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, 2023, 1,471,244 remained available for issuance under the 2017 Plan. The number of shares reserved for issuance under the 2017 Plan was increased by 3,220,133 shares effective January 1, 2024.

Inducement Plan

In January 2022, the Company adopted the Inducement Plan pursuant to which the Company initially reserved 800,000 shares of common stock to be used exclusively for grants of equity-based awards to individuals who were not previously

employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. The Inducement Plan provides for the grant of equity-based awards in the form of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, unrestricted stock awards, and dividend equivalent rights. The Inducement Plan was adopted by the Company without stockholder approval pursuant to Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. In February 2023, the Inducement Plan was amended and the number of shares reserved for issuance under the Inducement Plan was increased by 270,000 to return the number of shares available for issuance to the amount initially reserved. As of December 31, 2023, 444,400 shares of common stock were available for issuance under the Inducement Plan. In February 2024, the Inducement Plan was amended and the number of shares reserved for issuance under the Inducement Plan was increased by 355,600.

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 typically vest over four years and directors over one year.

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, 2023, 2,219,550 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, 2024.

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 113,019, 148,619, and 90,947 shares of common stock issued under the ESPP during the years ended December 31, 2023, 2022, and 2021, respectively.

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,		
	2023	2022	2021
Risk-free interest rate	4.0%	2.0%	1.0%
Expected term (in years)	6.0	6.0	5.8
Expected volatility	85.5%	78.2%	77.8%
Expected dividend yield	0%	0%	0%

The following table summarizes the Company's option activity from January 1, 2023 to December 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	8,279,217	$ 24.26		
Granted	1,489,555	$ 15.36		
Exercised	(190,126)	$ 8.42		
Forfeited	(156,603)	$ 22.04		
Expired	(162,575)	$ 36.29		
Outstanding as of December 31, 2023	9,259,468	$ 22.98	6.7	$ 27,665
Options vested and expected to vest as of December 31, 2023	9,259,468	$ 22.98	6.7	$ 27,665
Options exercisable as of December 31, 2023	6,879,959	$ 24.96	6.1	$ 20,792

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, 2023, 2022, and 2021 was $1.0 million, $0.4 million, and $15.7 million, respectively.

The weighted average grant-date fair value per share of options granted during the years ended December 31, 2023, 2022, and 2021 was $11.30, $6.48, and $17.95, respectively.

Restricted Stock Units

The 2017 Plan provides for the award of restricted stock units. During the years ended December 31, 2023, 2022, and 2021, 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. From time to time, the Company may also grant restricted stock units that are subject to performance-based vesting conditions.

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, 2023 to December 31, 2023:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	2,077,988	$	18.09
Granted	1,743,194	$	15.14
Vested	(892,882)	$	19.02
Forfeited	(393,995)	$	16.92
Unvested at December 31, 2023	2,534,305	$	15.91

The fair value of time-based restricted stock units that vested during the years ended December 31, 2023, 2022, and 2021 were $14.7 million, $6.2 million, and $4.7 million respectively.

During 2023, the Company granted restricted stock units that were subject to performance-based vesting conditions. Vesting of such performance-based restricted stock units is contingent upon meeting any of three specific performance obligations associated with the achievement of certain research and development activities and continued employment through the service period. During the year ended December 31, 2023, two of the performance obligations became probable and were achieved during the fourth quarter of 2023. The table below summarizes the Company's performance-based restricted stock unit activity from January 1, 2023 to December 31, 2023:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	—	$	—
Granted	377,949	$	15.48
Vested	(251,971)	$	15.48
Forfeited	(5,575)	$	15.48
Unvested at December 31, 2023	120,403	$	15.48

The Company granted no performance-based restricted stock units in 2022 or 2021. The fair value of performance-based restricted stock units that vested during the year ended December 31, 2023 was $3.2 million. No performance-based restricted stock units vested in 2022 or 2021 and no performance-based restricted stock units were outstanding as of December 31, 2022 and 2021.

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)	**2023**	**2022**	**2021**
Research and development	$ 21,775	$ 22,238	$ 20,698
Selling, general, and administrative	28,828	29,704	25,380
Total stock-based compensation	$ 50,603	$ 51,942	$ 46,078

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

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Stock options	$ 26,685	$ 34,861	$ 36,263
Time-based restricted stock units	19,526	16,537	9,047
Performance-based restricted stock units	3,900	—	—
Employee stock purchase plan	492	544	768
Total stock-based compensation expense	$ 50,603	$ 51,942	$ 46,078

As of December 31, 2023, total unrecognized compensation cost related to the unvested share-based awards was $54.5 million, which is expected to be recognized over a weighted average of 2.0 years.

During the year ended December 31, 2023, of the $3.9 million charged to stock-based compensation expense associated with performance-based restricted stock units, $2.9 million and $1.0 million were classified as selling, general, and administrative and research and development, respectively, within the consolidated statements of operations and comprehensive loss.

11. In-License Agreement

In August 2021, the Company entered into an agreement with Sprint Bioscience (Sprint) to exclusively in-license worldwide rights to a research-stage program targeting VPS34, a key kinase in the autophagy pathway for the potential treatment of cancer (the Sprint Agreement).

The Company accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single IPR&D asset. Pursuant to the terms of the Sprint Agreement, the Company made an upfront payment of $4.0 million during the third quarter of 2021, which was recorded as research and development expense within the consolidated statements of operations and comprehensive loss during the year ended December 31, 2021 as the acquired asset had not yet reached technological feasibility.

In January 2024, the Company terminated the Sprint Agreement, pursuant to which Sprint received a reversion license to VPS34. No amounts were due upon the termination of the Sprint Agreement.

12. 401(k) Savings Plan

Effective January 1, 2018, the Company adopted the 2018 401(k) Plan, a defined contribution plan under Section 401(k) of the Internal Revenue Code, whereby the Company provides matching contributions of 100% of each employee's contribution up to a maximum matching contribution of 3% of the employee's eligible compensation and at a rate of 50% of each employee's contribution in excess of 3% up to a maximum of 5% of the employee's eligible compensation.

Total employer matching contributions related to the 2018 401(k) Plan were $2.4 million, $2.7 million, and $2.8 million for the years ended December 31, 2023, 2022, and 2021, respectively.

13. Restructuring

In November 2021, the Company announced a corporate restructuring intended to prioritize clinical development of select programs, streamline commercial operations, maintain a focus on discovery research, and extend its cash runway. The corporate restructuring included a workforce reduction of approximately 35%, or approximately 140 positions, as well as discontinuation

costs such as contract termination fees and non-cancellable commitments related to the rebastinib and ripretinib programs. These amounts were incurred and paid by the end of 2022.

The Company recognized a one-time charge in the fourth quarter of 2021 of approximately $26.2 million. This charge included approximately $9.8 million of employee-related termination costs and approximately $16.3 million of discontinuation costs such as contract termination fees and non-cancellable commitments related to the rebastinib and ripretinib programs. For the year ended December 31, 2021, approximately $22.2 million and $4.0 million was recognized in research and development expenses and selling, general, and administrative expenses, respectively, on the Company's consolidated statements of operations and comprehensive loss. The restructuring reserve was included in accrued expenses and other current liabilities in the Company's consolidated balance sheets.

The following table summarized the charges and spending related to the Company's restructuring efforts during 2021 and 2022:

(in thousands)	Workforce Reduction	Pipeline Programs	Total
Restructuring charges incurred during the fourth quarter of 2021	$ 9,835	$ 16,335	$ 26,170
Amounts previously included in prepaid and other current assets	—	(2,927)	(2,927)
Reserves established	9,835	13,408	23,243
Amounts paid through December 31, 2021	(2,452)	—	(2,452)
Restructuring reserve as of December 31, 2021	$ 7,383	$ 13,408	$ 20,791
Adjustments to previous estimates, net	(374)	192	(182)
Amounts paid during the year ended December 31, 2022	(7,009)	(13,600)	(20,609)
Restructuring reserve as of December 31, 2022	$ —	$ —	$ —

14. 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, including pre-funded warrants, 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 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)	2023	2022	2021
Numerator:			
Net loss	$ (194,942)	$ (178,931)	$ (299,964)
Denominator:			
Weighted average common shares outstanding—basic and diluted	85,059,962	75,500,148	58,084,325
Net loss per share—basic and diluted	$ (2.29)	$ (2.37)	$ (5.16)

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,		
	2023	2022	2021
Options to purchase common stock	9,259,468	8,279,217	7,439,508
Unvested restricted stock units	2,534,305	2,077,988	1,537,732
Unvested employee stock purchase plan shares	84,623	61,307	211,822
Total	11,878,396	10,418,512	9,189,062

Restricted stock units that are outstanding and contain performance-based vesting criteria for which the performance conditions have not been met are excluded from the presentation of common stock equivalents outstanding in the chart above.

15. 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, 2023, 2022, and 2021, 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.

Net loss before income tax expense by jurisdiction is as follows:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
U.S.	$ (191,378)	$ (173,072)	$ (281,129)
Foreign	(3,133)	(5,137)	(18,835)
Net loss before income tax expense	$ (194,511)	$ (178,209)	$ (299,964)

The provision for income taxes consisted of the following:

	Year Ended December 31,		
(in thousands)	2023	2022	2021
Current provision:			
Federal	$ —	$ —	$ —
State	—	166	—
Foreign	431	556	—
Total current provision	431	722	—
Total provision for income taxes	$ 431	$ 722	$ —

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,		
	2023	2022	2021
Federal statutory income tax rate	21.0%	21.0%	21.0%
State taxes, including credits, net of federal benefit	2.4	4.4	3.2
Federal research and orphan drug credit	6.1	4.2	2.5
Stock-based compensation	(2.2)	(3.6)	0.1
Permanent adjustments and other	(1.9)	(1.3)	(0.3)
Increase in deferred tax asset valuation allowance	(25.6)	(25.1)	(26.5)
Effective income tax rate	(0.2%)	(0.4%)	—%

During 2022, 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 2022 increase of $0.8 million in the deferred tax asset balances have been completely offset by an increase in the Company's valuation allowance which is included in the change in deferred tax asset valuation allowance line in the reconciliation above.

The Tax Cuts and Jobs Act (TCJA) requires taxpayers to capitalize and amortize research and experimental (R&D) expenditures under section 174 for tax years beginning after December 31, 2021. These rules became effective for the Company during the year ended December 31, 2022 and the rules are also in effect for its foreign subsidiaries and the calculation of global intangible low-taxes income (GILTI) for the Company. As a result, the Company has capitalized worldwide R&D costs of $223.4 million and $176.9 million for the years ended December 31, 2023 and 2022, respectively. The Company will amortize these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

Net deferred tax assets consisted of the following:

	December 31,	
(in thousands)	2023	2022
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 210,790	$ 213,710
Research and orphan drug credit carryforwards	59,495	47,418
Stock-based compensation	23,371	20,134
Accrued expenses	7,484	6,944
Operating lease liabilities	7,563	8,699
Property and equipment	(149)	(131)
Operating lease assets	(7,042)	(8,158)
Research and development capitalization	74,551	37,797
Other	1,004	893
Total gross deferred tax assets	377,067	327,306
Valuation allowance	(377,067)	(327,306)
Net deferred tax assets	$ —	$ —

The change in the valuation allowance was as follows:

	Year Ended December 31,	
(in thousands)	2023	2022
Valuation allowance as of beginning of year	$ (327,306)	$ (282,536)
Net increases recorded to income tax provision	(49,761)	(44,770)
Valuation allowance as of end of year	$ (377,067)	$ (327,306)

As of December 31, 2023, the Company had NOL carryforwards for federal income tax purposes of $827.3 million, of which all may be carried forward indefinitely but are subject to an 80% limitation. As of December 31, 2023, the Company had NOL carryforwards for state income tax purposes of $733.4 million, which begin to expire in 2027. As of December 31, 2023, the Company also had available research and orphan drug credit carryforwards for federal and state income tax purposes of $55.7

million and $4.8 million, respectively, which begin to expire in 2037 and 2032, respectively. We also had foreign NOL carryforwards of $29.8 million as of December 31, 2023, which will begin to expire in 2026. 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 performed an analysis of ownership changes through December 31, 2023. Based on this analysis, the Company does not believe that any of its tax attributes through December 31, 2023 will expire unutilized due to Section 382 limitations.

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, 2023. Management reevaluates the positive and negative evidence at each reporting period.

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, state, and foreign jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years that are open under statute are from December 31, 2020 to the present, although carryforward attributes that were generated prior to 2020 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

As of December 31, 2023, the unremitted earnings of the Company's foreign subsidiaries are not material. The Company has not provided for U.S. income taxes or foreign withholding taxes on these earnings as it is the Company's current intention to permanently reinvest these earnings outside the U.S. The tax liability on these earnings is also not material. Events that could trigger a tax liability include, but are not limited to, distributions, reorganizations or restructurings and/or tax law changes.

Uncertain tax positions represent tax positions for which reserves have been established. As of December 31, 2023, the Company has certain gross unrecognized tax benefits primarily related to the Company's federal and state research and orphan drug credit carryforwards. 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, 2023 and 2022, 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. A reconciliation of the beginning and ending amount of uncertain tax positions is summarized as follows:

	Year Ended December 31,	
(in thousands)	**2023**	**2022**
Beginning Balance	$ 1,857	$ 2,355
Additions based on tax positions for the current period	1,284	635
Additions (reductions) for tax positions of prior periods	—	(1,133)
Ending Balance	$ 3,141	$ 1,857

16. 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, 2023, the Company's contractual commitments for its commercial supply agreements were $11.0 million, which is expected to be paid within one year. During the years ended

December 31, 2023, 2022, and 2021, the Company made $10.0 million, $9.6 million, and $9.1 million, respectively, 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, 2023 or 2022.

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, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, 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, 2023, our internal control over financial reporting was effective.

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.

The effectiveness of our internal control over financial reporting as of December 31, 2023 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, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the quarter ended December 31, 2023, Steven L. Hoerter, our Chief Executive Officer and an executive officer, terminated a trading arrangement for the sale of securities of the Company's common stock (terminated Rule 10b5-1 Trading Plan) that was intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). The terminated Rule 10b5-1 Trading Plan was adopted on June 13, 2023 and would have continued until June 30, 2024 if not earlier terminated. Under the terminated Rule 10b5-1 Trading Plan, an aggregate number of 237,500 securities could be sold or purchased during the duration of the terminated Rule 10b5-1 Trading Plan, which includes any shares sold to cover mandatory tax withholding obligations. No shares were triggered under the terminated Rule 10b5-1 Trading Plan prior to termination.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTION THAT PREVENTS INSPECTIONS

Not applicable.

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 2024 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 2024 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 2024 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 2024 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 2024 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 (Incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.4#*	Form of Non-Qualified Stock Option Agreement for Company Employees under 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).

Exhibit Number	Description
10.5#*	Form of Restricted Stock Unit Award Agreement for Company Employees under 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.6#*	Form of Non-Qualified Stock Option Agreement for Non-U.S. Optionees under 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.7#*	Form of Restricted Stock Unit Award Agreement for Non-U.S. Grantees under 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.8#*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.9#	2022 Inducement Plan, as amended.
10.10#*	Form of Non-Qualified Stock Option Agreement for Company Employees under 2022 Inducement Plan (Incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K filed on February 8, 2022).
10.11#*	Form of Restricted Stock Unit Award Agreement for Company Employees under 2022 Inducement Plan (Incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K filed on February 8, 2022).
10.12#*	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).
10.13#*	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).
10.14#*	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).
10.15#*	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).
10.16#*	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 (Incorporated by reference to Exhibit 10.16(a) to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.17#*	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn (Incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K filed on February 9, 2021).
10.17(a)#*	Amendment No. 1 to Employment Agreement, between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn (Incorporated by reference to Exhibit 10.17(a) to the Registrant's Annual Report on Form 10-K filed on February 9, 2021)
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#*	Deciphera Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed on February 7, 2023).
10.21#*	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
10.22*	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).
10.22(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).
10.22(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).
10.22(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).
10.23*	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).
10.24*	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).
10.25*	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).
10.26*	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).
10.27*	Open Market Sale Agreement℠, dated May 3, 2023, by and between Deciphera Pharmaceuticals, LLC and Jefferies LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2023).
10.28*	Transition Agreement between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn, Ph.D., dated August 1, 2023 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on October 30, 2023).
10.29*	Consulting Agreement between Deciphera Pharmaceuticals, LLC and Daniel L. Flynn, Ph.D., dated August 1, 2023 (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on October 30, 2023).
10.30	Compensation Recovery Policy.
10.31	Employment Agreement, between Deciphera Pharmaceuticals, LLC and Dashyant Dhanak.
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 Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.

Exhibit Number	Description
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 7, 2024

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 7, 2024
/s/ Thomas P. Kelly Thomas P. Kelly	Chief Financial Officer (Principal Financial and Accounting Officer)	February 7, 2024
/s/ Patricia L. Allen Patricia L. Allen	Director	February 7, 2024
/s/ Edward J. Benz, Jr., M.D. Edward J. Benz, Jr., M.D.	Director	February 7, 2024
/s/ James A. Bristol, Ph.D. James A. Bristol, Ph.D.	Director	February 7, 2024
/s/ Frank S. Friedman Frank S. Friedman	Director	February 7, 2024
/s/ Susan L. Kelley, M.D. Susan L. Kelley, M.D.	Director	February 7, 2024
/s/ John R. Martin John R. Martin	Director	February 7, 2024
/s/ Ron Squarer Ron Squarer	Director	February 7, 2024
/s/ Dennis L. Walsh Dennis L. Walsh	Director	February 7, 2024

Deciphera Pharmaceuticals, Inc.

CORPORATE INFORMATION

BOARD OF DIRECTORS

James A. Bristol, Ph.D.*
Senior Advisor at Frazier Healthcare Partners

Frank S. Friedman*
President and Chief Executive Officer of IPFS Inc.

Ron Squarer*
Former Chief Executive Officer of Array BioPharma, Inc.

Steven L. Hoerter
President and Chief Executive Officer

Susan L. Kelley, M.D.
Former Chief Medical Officer of the Multiple Myeloma Research Consortium

John R. Martin
Chief Financial Officer for City Wide Franchise Company, Inc.

Patricia L. Allen
Former Chief Financial Officer of Vividion Therapeutics, Inc.

Edward J. Benz, Jr., M.D.
President and Chief Executive Officer Emeritus of the Dana-Farber Cancer Institute, Richard and Susan Smith Distinguished Professor of Medicine, professor of Pediatrics, professor of Genetics, and faculty dean for Oncology Emeritus at Harvard Medical School

Dennis L. Walsh
Senior Vice President and Chief Financial Officer of Americo Life, Inc.

EXECUTIVE OFFICERS

Steven L. Hoerter
Director, President and Chief Executive Officer

Dashyant Dhanak, Ph.D.
Executive Vice President and Chief Scientific Officer

Thomas P. Kelly
Executive Vice President, Chief Financial Officer and Treasurer

Matthew L. Sherman, M.D.
Executive Vice President and Chief Medical Officer

Daniel C. Martin
Senior Vice President and Chief Commercial Officer

Jama Pitman
Senior Vice President and Chief Development Officer

CORPORATE ADDRESS

200 Smith Street
Waltham, MA 02451

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP

TRANSFER AGENT

Computershare Trust Company, N.A.
250 Royall St.
Canton, MA 02021

INVESTOR RELATIONS

Jennifer Larson
jlarson@deciphera.com

* Nominee for re-election at the 2024 Annual Meeting of Stockholders.