Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to _____

Commission file number: 001-38219

decīphera™

DECIPHERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(781) 209-6400

(Registrant's telephone number, including area code)

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

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

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 Exchange Act. ☐

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

As of May 6, 2024, there were 86,475,972 shares of Common Stock, $0.01 par value per share, outstanding.

Deciphera Pharmaceuticals, Inc.

INDEX

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:

- We may not complete the pending transaction with Ono Pharmaceutical Co., Ltd. (Ono) within the time frame we anticipate, or at all, which could have an adverse effect on our business, financial results and/or operations.
- While the Merger Agreement (as defined below) is in effect, we are subject to restrictions on our business activities.
- In certain instances, the Merger Agreement requires us to pay a termination fee to Ono, which could require us to use available cash that would have otherwise been available for general corporate purposes and other uses.
- 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.
- 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 any future approved drugs, such as vimseltinib or DCC-3116, if approved, will depend upon 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, 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 enrollment of patients in clinical trials, including 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 inception and have not generated sufficient revenue to result in a profit from product sales. We expect to incur continued losses 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 Quarterly Report on Form 10-Q (Form 10-Q), 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). 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-Q 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-Q, 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 expectations regarding the time frame of the pending transaction with Ono and our ability to complete the transaction within the time frame we anticipate, or at all;
- 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-Q and our prior filings with the SEC. You should read this Form 10-Q and the documents that we have filed as exhibits to this Form 10-Q 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-Q are made as of the date of this Form 10-Q, 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-Q. Nevertheless, all rights to such trademarks are reserved. These and other trademarks referenced in this Form 10-Q are the property of their respective owners.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Deciphera Pharmaceuticals, Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 91,228	$ 83,507
Short-term marketable securities	181,299	222,709
Accounts receivable, net	32,684	31,952
Inventory	21,098	21,210
Prepaid expenses and other current assets	23,628	21,718
Total current assets	349,937	381,096
Long-term marketable securities	26,778	46,699
Other long-term assets and long-term investments—restricted	8,133	8,277
Property and equipment, net	5,155	5,421
Operating lease assets	30,925	32,073
Total assets	$ 420,928	$ 473,566
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 19,459	$ 26,476
Accrued expenses and other current liabilities	60,396	70,295
Operating lease liabilities	3,574	3,504
Total current liabilities	83,429	100,275
Operating lease liabilities, net of current portion	21,449	22,375
Total liabilities	104,878	122,650
Commitments and contingencies (Note 7)		
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; 82,158,670 shares and 80,503,338 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	821	805
Additional paid-in capital	1,788,519	1,777,839
Accumulated other comprehensive income (loss)	98	577
Accumulated deficit	(1,473,388)	(1,428,305)
Total stockholders' equity	316,050	350,916
Total liabilities and stockholders' equity	$ 420,928	$ 473,566

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

Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Product revenues, net	$ 42,550	$ 33,222
Collaboration revenues	2,449	223
Total revenues	44,999	33,445
Cost and operating expenses:		
Cost of sales	2,088	488
Research and development	57,834	54,765
Selling, general, and administrative	33,924	31,449
Total cost and operating expenses	93,846	86,702
Loss from operations	(48,847)	(53,257)
Other income:		
Interest and other income, net	3,764	3,648
Total other income, net	3,764	3,648
Net loss	$ (45,083)	$ (49,609)
Net loss per share—basic and diluted	$ (0.52)	$ (0.60)
Weighted average common shares outstanding—basic and diluted	87,388,106	82,676,624
Comprehensive loss:		
Net loss	$ (45,083)	$ (49,609)
Other comprehensive income (loss):		
Unrealized gains (losses) on marketable securities	(206)	709
Currency translation adjustment	(273)	93
Total other comprehensive income (loss)	(479)	802
Total comprehensive loss	$ (45,562)	$ (48,807)

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

Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
(Unaudited, in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2023	80,503,338	$ 805	$ 1,777,839	$ 577	$ (1,428,305)	$ 350,916
Issuance of common stock upon pre-funded warrant exercise	914,001	9	—	—	—	9
Issuance of common stock under stock option and incentive plans	741,331	7	506	—	—	513
Stock-based compensation expense	—	—	10,174	—	—	10,174
Other comprehensive income (loss)	—	—	—	(479)	—	(479)
Net loss	—	—	—	—	(45,083)	(45,083)
Balance, March 31, 2024	82,158,670	$ 821	$ 1,788,519	$ 98	$ (1,473,388)	$ 316,050

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2022	67,637,351	$ 676	$ 1,575,361	(983)	$ (1,233,363)	$ 341,691
Issuance of common stock, net of underwriting discounts, commissions and offering costs	7,986,111	80	134,411	—	—	134,491
Issuance of common stock upon pre-funded warrant exercise	2,427,693	24	—	—	—	24
Issuance of common stock under stock option and incentive plans	456,597	5	166	—	—	171
Stock-based compensation expense	—	—	12,514	—	—	12,514
Other comprehensive income (loss)	—	—	—	802	—	802
Net loss	—	—	—	—	(49,609)	(49,609)
Balance, March 31, 2023	78,507,752	$ 785	$ 1,722,452	$ (181)	$ (1,282,972)	$ 440,084

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

Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (45,083)	$ (49,609)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	10,174	12,514
Depreciation expense	450	608
Noncash lease expense	1,147	1,102
Net (accretion) amortization of (discounts) premium on marketable securities	(1,653)	(1,566)
Changes in operating assets and liabilities:		
Accounts receivable	(878)	77
Inventory	(918)	(1,258)
Prepaid expenses and other current assets	(1,967)	(4,061)
Other long-term assets	140	—
Accounts payable	(6,944)	993
Accrued expenses and other current liabilities	(8,196)	(7,464)
Operating lease liabilities	(857)	(791)
Net cash flows used in operating activities	(54,585)	(49,455)
Cash flows from investing activities:		
Purchases of marketable securities	(20,264)	(122,860)
Maturities of marketable securities	83,041	87,021
Sales of marketable securities	—	785
Purchases of property and equipment	(146)	(360)
Net cash flows provided by (used in) investing activities	62,631	(35,414)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of underwriting discounts and commissions	—	135,125
Proceeds from pre-funded warrant exercise	9	24
Payments of offering costs	—	(634)
Proceeds from stock option exercises and employee stock purchase plan	513	171
Net cash flows provided by financing activities	522	134,686
Net (decrease) increase in cash and cash equivalents	8,568	49,817
Effect of exchange rate changes on cash and cash equivalents	(847)	79
Cash and cash equivalents at beginning of period	83,507	64,741
Cash and cash equivalents at end of period	$ 91,228	$ 114,637

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

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

1. Nature of the Business and Summary of Significant Accounting Policies

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, New Zealand, Norway, 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.

During the three months ended March 31, 2024 and 2023, 914,001 and 2,427,693 shares of pre-funded warrants were exercised, respectively, resulting in net proceeds of less than $0.1 million during each period. As of March 31, 2024, there were 5,514,269 pre-funded warrants outstanding.

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 an Open Market Sale Agreement[SM] (the Sales Agreement) with Jefferies, pursuant to which the Company may issue and sell 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 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 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 three months ended March 31, 2024, no shares were issued by the Company under the Sales Agreement. As of March 31, 2024, there was up to $185.0 million available for future issuance under the 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 $45.1 million and $194.9 million for the three months ended March 31, 2024 and the year ended December 31, 2023, respectively. As of March 31, 2024, the Company had an accumulated deficit of $1.5 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 $299.3 million as of March 31, 2024, 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.

If the pending transaction (see Merger Agreement defined within Note 8, *Subsequent Events*) with Ono Pharmaceutical Co., Ltd., a Japanese company (*kabushiki kaisha*) (Parent or Ono), does not close, the future viability of the Company will be dependent on its ability to raise additional capital to fund its operations and 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.

Unaudited Interim Financial Information

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

The consolidated balance sheet as of December 31, 2023 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 and 2023 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2023 included in the Company's Form 10-K on file with the SEC.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's consolidated financial position as of March 31, 2024, consolidated results of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, and consolidated cash flows for the three months ended March 31, 2024 and 2023, have been made. The consolidated results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

The significant accounting policies used in preparation of these consolidated financial statements for the three months ended March 31, 2024 are consistent with those discussed in Note 2, *Summary of Significant Accounting Policies,* to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2023.

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

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.

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 and potential dilutive common shares assuming the dilutive effect as determined using the treasury stock method.

For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the three months ended March 31, 2024 and 2023.

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 March 31,	
	2024	2023
Options to purchase common stock	10,091,606	9,256,574
Unvested restricted stock units	3,122,494	2,930,554
Employee stock purchase plan shares	84,623	61,307
Total	13,298,723	12,248,435

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.

2. Revenues

Net Product Revenues

To date, the Company's only source of product revenues has been from the sales of QINLOCK.

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

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
U.S.	$ 31,836	$ 24,624
Rest of world	10,714	8,598
Total product revenues, net	$ 42,550	$ 33,222

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

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, 2023	$ 754	$ 880	$ 24,866	$ 1,095	$ 27,595
Provision related to sales in the current year	1,312	3,879	5,682	1,026	11,899
Adjustments related to prior period sales	—	—	—	(164)	(164)
Credits and payments made during the period	(1,097)	(3,654)	(2,787)	(521)	(8,059)
Balance as of March 31, 2024	$ 969	$ 1,105	$ 27,761	$ 1,436	$ 31,271

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

(in thousands)	As of March 31, 2024	As of December 31, 2023
Reduction of accounts receivable, net	$ 1,999	$ 1,528
Component of accrued expenses and other current liabilities	29,272	26,067
Total revenue-related reserves	$ 31,271	$ 27,595

Collaboration Revenues

Zai License Agreement

In June 2019, the Company entered into a license agreement (Zai License Agreement) with Zai Lab (Shanghai) Co., Ltd. (Zai), 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, as of March 31, 2024 the Company has 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 three months ended March 31, 2024 and 2023, 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).

Please read Note 3, *Revenues*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2023 for further details on the Zai License Agreement.

Zai Supply Agreement

In February 2020, the Company entered into a Supply Agreement (the Zai Supply Agreement) with Zai, 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 People's Republic of China (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.

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

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.

3. Marketable Securities and Fair Value Measurements

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

As of March 31, 2024 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
U.S. government securities	$ 80,831	$ 4	$ (176)	$ 80,659
Corporate debt securities	72,448	6	(94)	72,360
Commercial paper	28,294	3	(17)	28,280
Due after one year through five years:				
U.S. government securities	19,790	5	(156)	19,639
Corporate debt securities	7,134	11	(6)	7,139
Total	$ 208,497	$ 29	$ (449)	$ 208,077

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

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

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 March 31, 2024 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 43,773	$ —	$ 43,773
Commercial paper	—	1,996	—	1,996
Marketable securities:				
U.S. government securities	—	100,298	—	100,298
Corporate debt securities	—	79,499	—	79,499
Commercial paper	—	28,280	—	28,280
Total	$ —	$ 253,846	$ —	$ 253,846

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

The tables above exclude certificates of deposit totaling $3.1 million as of both March 31, 2024 and December 31, 2023 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 other long-term assets and 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 the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2023.

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 March 31, 2024 and December 31, 2023.

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

4. Inventory

Capitalized inventory consisted of the following:

(in thousands)	As of March 31, 2024	As of December 31, 2023
Raw materials	$ 4,934	$ 4,934
Work in process	16,968	18,253
Finished goods	4,130	2,957
Total inventory	$ 26,032	$ 26,144

Long-term inventory, which consists of raw materials, is included in other long-term assets and long-term investments—restricted in the consolidated balance sheets. As of both March 31, 2024 and 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. During the three months ended March 31, 2024 and 2023, there were no amounts in inventory written down as a result of excess, obsolescence, unmarketability, or other reasons.

5. Other Consolidated Financial Statement Detail

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

(in thousands)	As of March 31, 2024	As of December 31, 2023
Prepaid external research and development expenses	$ 12,767	$ 12,729
Prepaid selling, general, and administrative expenses	8,062	5,811
Short-term interest receivable	1,413	1,772
Other current assets	1,386	1,406
Total prepaid expenses and other current assets	$ 23,628	$ 21,718

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	As of March 31, 2024	As of December 31, 2023
Revenue-related reserves	$ 29,272	$ 26,067
External research and development expenses	16,236	16,095
Payroll and related expenses	7,918	20,519
Professional fees	6,013	5,669
Other	957	1,945
Total accrued expenses and other current liabilities	$ 60,396	$ 70,295

Interest Income

For the three months ended March 31, 2024 and 2023, interest income was $3.6 million and $3.9 million, respectively.

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

6. Stock-Based Awards

Equity Plans

The Company grants stock-based awards under its 2017 Stock Option and Incentive Plan (the 2017 Plan) and is authorized to issue common stock under its 2017 Employee Stock Purchase Plan (ESPP). In February 2024 and 2023, the Company granted performance-based restricted stock unit awards under the 2017 Plan. No performance-based restricted stock units vested, no performance-based restricted stock units were forfeited, and no stock-based compensation expense was recognized related to performance-based restricted stock units during the three months ended March 31, 2024 and 2023. The Company also has outstanding stock options under its 2015 Equity Incentive Plan but is no longer granting awards under this plan. As of March 31, 2024, 2,119,578 shares of common stock were available for issuance under the 2017 Plan. As of March 31, 2024, 2,619,550 shares of common stock were available for issuance to participating employees under the ESPP.

In January 2022, the Company adopted an inducement plan (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. In February 2024 and 2023, the Inducement Plan was amended and the number of shares reserved for issuance under the Inducement Plan was increased by 355,600 and 270,000, respectively. As of March 31, 2024, 800,000 shares of common stock were available for issuance under the Inducement Plan.

Stock-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
Research and development	$ 4,731	$ 5,455
Selling, general, and administrative	5,443	7,059
Total stock-based compensation	$ 10,174	$ 12,514

As of March 31, 2024, total unrecognized compensation cost related to the unvested share-based awards was $78.1 million, which is expected to be recognized over a weighted average of 2.3 years.

7. 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 March 31, 2024, the Company's contractual commitments for its commercial supply agreements were $9.0 million which are expected to be paid within one year.

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

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

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 March 31, 2024 or December 31, 2023.

8. Subsequent Events

On April 29, 2024, the Company, Ono, and Topaz Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent (Merger Sub), entered into an Agreement and Plan of Merger (the Merger Agreement). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions therein, Merger Sub will commence a cash tender offer (the Offer) to acquire all of the issued and outstanding shares of the Company's common stock, at a price per share of $25.60, net to the seller in cash, without interest and subject to any withholding of taxes required by applicable law. Following the consummation of the Offer, Merger Sub will merge with and into the Company, with the Company continuing as the surviving corporation. The merger is expected to close in the third quarter of 2024. If the Merger Agreement is terminated by the Company under certain circumstances specified in the Merger Agreement, the Company will be required to pay Parent a termination fee of $78.8 million.

Item 2. 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 elsewhere in this Form 10-Q and our Annual Report on Form 10-K (Form 10-K) for the year ended December 31, 2023 on file with the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, 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-Q, 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 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, 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.

Pending Transaction with Ono Pharmaceutical Co., Ltd.

On April 29, 2024, we, Ono Pharmaceutical Co., Ltd., a Japanese company (*kabushiki kaisha*) (Parent or Ono), and Topaz Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent (Merger Sub), entered into an Agreement and Plan of Merger (the Merger Agreement). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions therein, Merger Sub will commence a cash tender offer (the Offer) to acquire all the issued and outstanding shares of our common stock, at a price per share of $25.60, net to the seller in cash, without interest and subject to any withholding of taxes required by applicable law. Following the consummation of the Offer, Merger Sub will merge with and into our company, with our company continuing as the surviving corporation. The merger is expected to close in the third quarter of 2024. If the Merger Agreement is terminated by us under certain circumstances specified in the Merger Agreement, we will be required to pay Parent a termination fee of $78.8 million.

Components of Our Results of Operations

Revenues

QINLOCK is approved in Australia, Canada, China, the 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 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 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 three months ended March 31, 2024 and 2023, 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, *Revenues*, of these consolidated financial statements included in this Form 10-Q for further details of the reserves recorded for variable considerations.

Collaboration Revenues

For the three months ended March 31, 2024 and 2023, collaboration revenues were associated with the Zai License Agreement and Zai Supply Agreement, as applicable.

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.

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 contract research organizations (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. 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 during the remainder of 2024 as these programs continue to 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.

We anticipate that our selling, general, and administrative expenses will increase modestly overall during the remainder of 2024 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. 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.

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.

Consistent with our income tax disclosures described under the heading "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Components of Our Results of Operations*" in our Form 10-K for the year ended December 31, 2023 on file with the SEC, as of March 31, 2024, we have not recorded any U.S. federal or state income tax benefits for either the net losses we have incurred or our earned research and orphan drug credits, due to the uncertainty of realizing a benefit from those items in the future.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures in the consolidated financial statements. We believe that our critical accounting policies that involve the most judgment and complexity are those relating to:

- product revenue reserves;
- accrued research and development expenses; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments, and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

For a description of our critical accounting policies, please see "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates*" in our Form 10-K for the year ended December 31, 2023 on file with the SEC. There have been no significant changes to our critical accounting policies since December 31, 2023.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

(in thousands)	Three Months Ended March 31, 2024	2023
Revenues:		
Product revenues, net	$ 42,550	$ 33,222
Collaboration revenues	2,449	223
Total revenues	44,999	33,445
Cost and operating expenses:		
Cost of sales	2,088	488
Research and development	57,834	54,765
Selling, general, and administrative	33,924	31,449
Total cost and operating expenses	93,846	86,702
Loss from operations	(48,847)	(53,257)
Other income:		
Interest and other income, net	3,764	3,648
Total other income, net	3,764	3,648
Net loss	$ (45,083)	$ (49,609)

Revenues

Product Revenues, Net

During the three months ended March 31, 2024 and 2023, our only source of product revenues was from the sales of QINLOCK. During the three months ended March 31, 2024 and 2023, net product revenues by geography consisted of the following:

(in thousands)	Three Months Ended March 31, 2024	2023
U.S.	$ 31,836	$ 24,624
Rest of world	10,714	8,598
Total product revenues, net	$ 42,550	$ 33,222

For the three months ended March 31, 2024 compared to the same period in 2023, U.S. net product revenues increased $7.2 million primarily due to increased sales volume of $6.1 million and an increase in net price of $1.1 million. In the three months ended March 31, 2024 compared to the same period in 2023, increased sales volume for QINLOCK in the U.S. 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 three months ended March 31, 2024 compared to the same period in 2023, rest of world net product revenues increased $2.1 million, primarily due to increased sales volume of QINLOCK in Italy, which launched in the third quarter of 2023, and other jurisdictions as we continued our commercialization efforts.

Collaboration Revenues

For the three months ended March 31, 2024 and 2023 compared to the same period in 2023, collaboration revenues increased $2.2 million primarily due to an increase in supply revenues under the Zai Supply Agreement and an increase in royalties under the Zai License Agreement.

Cost of Sales

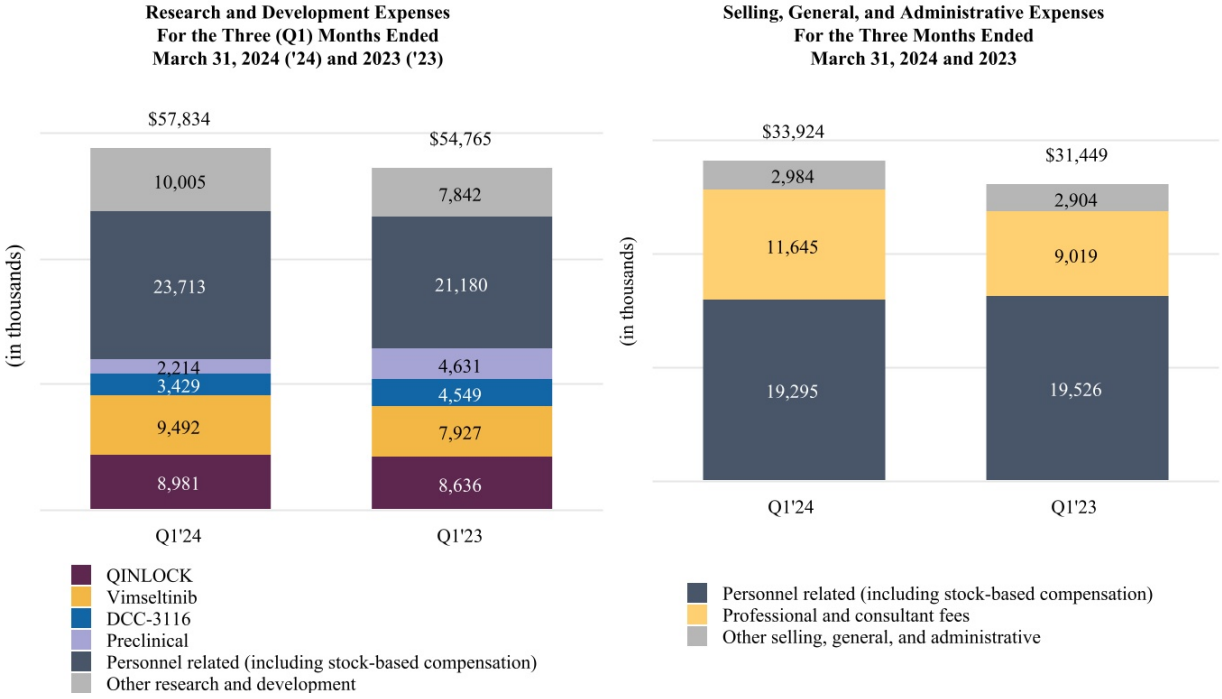
During the three months ended March 31, 2024 and 2023, cost of sales by type consisted of the following:

(in thousands)	Three Months Ended March 31, 2024	2023
Cost of product sales	$ 604	$ 430
Cost of collaboration sales	1,484	58
Total cost of sales	$ 2,088	$ 488

For the three months ended March 31, 2024 compared to the same period in 2023, cost of sales increased $1.6 million primarily due to an increase in cost of sales recognized under the Zai Supply Agreement and an increase in cost of sales in the U.S. due to a credit received during the first quarter of 2023 for inventory previously written down during the year ended December 31, 2022. During the three months ended March 31, 2024 and 2023, there was no inventory written down as a result of excess, obsolescence, unmarketability, or other reasons.

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, and then sell such inventory.

Operating Expenses



Research and Development Expenses

QINLOCK

For the three months ended March 31, 2024 compared to the same period in 2023, research and development expenses related to QINLOCK were relatively flat. Clinical trial expenses for QINLOCK increased less than $0.1 million 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, partially offset by a decrease in expenses associated with our Phase 3 INTRIGUE study of QINLOCK for the treatment of second-line GIST.

Vimseltinib

For the three months ended March 31, 2024 compared to the same period in 2023, research and development expenses related to our vimseltinib program increased primarily due to increased manufacturing expenses of $1.6 million. Manufacturing expenses increased primarily due to process development and validation activities and the timing of manufacturing and packaging and labeling activities.

DCC-3116

For the three months ended March 31, 2024 compared to the same period in 2023, research and development expenses related to our DCC-3116 program decreased primarily as a result of decreased manufacturing expenses of $1.7 million, partially offset by increased clinical trial expenses of $0.7 million. Manufacturing expenses decreased primarily due to the timing of inventory production and timing of raw materials procurement of product to be used in our Phase 1/2 study of DCC-3116. Clinical trial expenses increased primarily due to increased activities associated with our Phase 1/2 study evaluating DCC-3116 as a single agent and in combination cohorts and an increase in clinical pharmacology activities.

Preclinical

For the three months ended March 31, 2024 compared to the same period in 2023, research and development expenses related to preclinical costs decreased $2.4 million primarily due to decreased biology, pharmacokinetics, and toxicology activities for our early-stage drug discovery programs, including for DCC-3084. These decreases were partially offset by an increase in such preclinical activities for DCC-3009.

Personnel-related and Other Research and Development Expenses

For the three months ended March 31, 2024 compared to the same period in 2023, the increase in personnel-related and other research and development expenses was primarily associated with increased personnel-related costs of $2.5 million driven by headcount growth, partially offset by a decrease in stock-based compensation of $0.7 million primarily as a result of the completion of vesting during the second quarter of 2023 of grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. There was also an increase in other research and development expenses of $2.2 million, which was primarily related to an increase in manufacturing activities for DCC-3009 and our integrated stress response (ISR) program, our general control nonderepressible 2 (GCN2) activator program and an increase in clinical trial preparation activities for DCC-3084, partially offset by a decrease in manufacturing activities for DCC-3084.

We expect research and development expenses associated with our drug and drug candidate programs will increase during the remainder of 2024 as these programs continue to progress and as we support regulatory filing submissions for vimseltinib.

Selling, General, and Administrative Expenses

For the three months ended March 31, 2024 compared to the same period in 2023, the increase in selling, general, and administrative expenses was primarily associated with increased professional and consultant fees of $2.6 million, partially offset by decreased personnel-related costs of $0.2 million primarily due to a decrease in stock-based compensation expense of $1.6 million as a result of the completion of vesting during the second quarter of 2023 of grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. The decrease in personnel-related costs due to stock-based compensation was partially offset by an increase in headcount. The increase in professional and consultant fees was primarily due to an increase in third-party legal services and an increase in professional, consulting, and other expenses related to preparations for a potential commercial launch of vimseltinib.

We anticipate that our selling, general, and administrative expenses will increase modestly overall during the remainder of 2024 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 three months ended March 31, 2024 compared to the same period in 2023, interest and other income, net, was relatively flat, with increases being primarily due to foreign exchange rate differences, partially offset by a decrease in interest income.

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 three months ended March 31, 2024 and 2023, 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 post-approval paid access 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. Beginning in the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we 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, including vimseltinib, in the near future, if at all, unless and until we obtain marketing approval for, and begin to sell, such drug candidates. We may never generate revenues that are significant enough to achieve profitability.

On October 2, 2017, we completed our 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, and through at-the-market offerings. 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, 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, we issued and sold pre-funded warrants to purchase 9,748,761 shares of our 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.

During the three months ended March 31, 2024 and 2023, 914,001 and 2,427,693 shares of pre-funded warrants were exercised, respectively, resulting in net proceeds of less than $0.1 million during each period.

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 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 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 shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any shares under the Sales Agreement. We or Jefferies may suspend or terminate the offering of shares upon notice to the other party and subject to other conditions.

During the three months ended March 31, 2024, no shares were issued under the Sales Agreement. As of March 31, 2024, there was up to $185.0 million available for future issuance under the Sales Agreement.

Under the terms of the Merger Agreement, we have agreed to various covenants and agreements, including, among others, agreements to conduct our business in the ordinary course of business between the execution of the Merger Agreement and the closing of the merger. We do not believe these restrictions will prevent us from meeting our ongoing costs of operations, working capital needs or capital expenditure requirements. Under the terms of the Merger Agreement, we may be required to pay Ono a

termination fee of $78.8 million if the Merger Agreement is terminated under certain circumstances specified in the Merger Agreement. Moreover, we have incurred, and will continue to incur, significant costs and expenses in connection with the pending transaction. We must pay a material portion of these costs and expenses whether or not the transaction is completed. Payment of any such fees, costs or expenses may require us to use available cash that would have otherwise been available for general corporate purposes or other uses.

Cash Flows

As of March 31, 2024, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $299.3 million, which consisted of cash, money market funds, commercial paper, U.S. government securities, and corporate debt securities. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. Given the nature of these investments, we believe that the market for these instruments is not illiquid.

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

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
Net cash flows used in operating activities	$ (54,585)	$ (49,455)
Net cash flows provided by (used in) investing activities	62,631	(35,414)
Net cash flows provided by financing activities	522	134,686
Net increase in cash and cash equivalents	$ 8,568	$ 49,817

Operating Activities

During the three months ended March 31, 2024 compared to the same period in 2023, net cash flows used in operating activities increased $5.1 million, primarily resulting from a decrease in net cash flows related to changes in our operating assets and liabilities of $7.1 million and a decrease in net non-cash charges of $2.5 million, including a decrease in share-based compensation of $2.3 million, partially offset by a decrease in our net loss of $4.5 million. The decrease 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 three months ended March 31, 2024 compared to the same period in 2023, net cash flows provided by investing activities increased $98.0 million, primarily resulting from a decrease in purchases of marketable securities of $102.6 million, partially offset by a decrease in proceeds from maturities and sales of marketable securities of $4.8 million.

Financing Activities

During the three months ended March 31, 2024 compared to the same period in 2023, net cash flows provided by financing activities decreased $134.2 million, primarily resulting from net proceeds from an offering of our common stock in a follow-on public offering in January 2023 for $134.5 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 $45.1 million for the three months ended March 31, 2024 and $194.9 million for the year ended December 31, 2023. As of March 31, 2024, we had an accumulated deficit of $1.5 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 public health concerns, 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 March 31, 2024 of $299.3 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

As of March 31, 2024, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those that were presented in our Form 10-K for the year ended December 31, 2023.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

Based on our review of recently issued accounting pronouncements, we do not believe there are any such pronouncements that will have a material impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

For the Company's disclosures about market risk, please see "*Part II—Item 7A—Quantitative and Qualitative Disclosures About Market Risk*" in our Form 10-K for the year ended December 31, 2023 on file with the SEC. There have been no material changes to the Company's disclosures about market risk in Part II—Item 7A of our Form 10-K for the year ended December 31, 2023 on file with the SEC.

Item 4. 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 March 31, 2024. 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 March 31, 2024, 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.

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

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-Q, 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 the Pending Transaction with Ono

We may not complete the pending transaction with Ono within the time frame we anticipate, or at all, which could have an adverse effect on our business, financial results, and/or operations.

On April 29, 2024, we, Ono Pharmaceutical Co., Ltd., a Japanese company (*kabushiki kaisha*) (Parent or Ono), and Topaz Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent (Merger Sub), entered into an Agreement and Plan of Merger (the Merger Agreement). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions therein, Merger Sub will commence a cash tender offer (the Offer) to acquire all the issued and outstanding shares of our common stock, at a price per share of $25.60, net to the seller in cash, without interest and subject to applicable withholding tax required by applicable law. Following the consummation of the Offer, Merger Sub will merge with and into our company, with our company surviving as a wholly owned subsidiary of Ono, and each outstanding share of our common stock (other than shares of common stock held by us as treasury stock, owned by Ono or the Merger Sub or any of their direct or indirect subsidiaries at the commencement of the Offer, irrevocably accepted for payment by Merger Sub in the Offer or held by stockholders who are entitled to demand, and who properly demand, appraisal rights under Delaware law) will be converted into the right to receive $25.60 per share in cash, without interest, subject to any withholding of taxes required by applicable law.

The completion of the pending transaction is subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including that (i) there shall have been validly tendered and not validly withdrawn at or prior to the expiration of the Offer that number of shares of our common stock that, considered together with all other shares of our common stock (if any) beneficially owned by Parent and its controlled affiliates (excluding any shares of our common stock tendered pursuant to guaranteed delivery procedures that have not yet been "received" (as such term is defined in Section 251(h)(6)(f) of the General Corporation Law of the State of Delaware)), represent one more than 50% of the total number of shares of our common stock outstanding at the expiration of the Offer; (ii) the waiting period (and any extension thereof) applicable to consummation of the Offer and the merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, has expired or been terminated; (iii) no governmental entity of competent and applicable jurisdiction shall have enacted, issued, promulgated, enforced or entered any order or law that is in effect and restrains, enjoins or otherwise prohibits or makes illegal consummation of the Offer or the merger; (iv) our representations and warranties contained in the Merger Agreement shall be accurate, subject to customary materiality thresholds and exceptions; (v) we shall have performed or complied in all material respects with our covenants and agreements contained in the Merger Agreement; (vi) there shall not have occurred, and be continuing at the expiration time of the Offer, a Company Material Adverse Effect (as defined in the Merger Agreement); and (vii) other customary conditions as set forth in the Merger Agreement.

In addition, the Merger Agreement may be terminated under certain specified circumstances, including, but not limited to, a change in the recommendation of our board of directors or a termination of the Merger Agreement by us to enter into an agreement for a "Superior Proposal," as defined in the Merger Agreement. In addition, if the pending transaction is not completed by January 29, 2025 (or March 1, 2025 in certain circumstances), either we or Ono may terminate the Merger Agreement, subject to certain exceptions. As a result, we cannot assure you that the transaction with Ono will be completed, or that, if completed, it will be exactly on the terms set forth in the Merger Agreement or within the expected time frame.

If the pending transaction is not completed within the expected time frame or at all, we may be subject to a number of material risks. The price of our common stock may decline to the extent that current market prices reflect a market assumption that the transaction will be completed. We could be required to pay Ono a termination fee of $78.8 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement. The failure to complete the transaction also may result in negative publicity and negatively affect our relationship with our stockholders, employees, collaborators,

distributors, vendors, suppliers, regulators, and other business partners. We may also be required to devote significant time and resources to litigation related to any failure to complete the merger or related to any enforcement proceeding commenced against us to perform our obligations under the Merger Agreement.

The announcement and pendency of the transaction with Ono could adversely affect our business, financial results, and/or operations.

Our efforts to complete the transaction could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the transaction will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. A substantial amount of our management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from our day-to-day operations. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, distributors, vendors, suppliers, regulators and other business partners. For example, vendors, suppliers, collaborators, distributors, and other counterparties may react unfavorably, including by delaying or deferring decisions concerning their business relationships or transactions with us, or seek to change existing business relationships with us. Changes to or termination of existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities, generally requiring us to conduct our business in the ordinary course, and subjecting us to a variety of specified limitations absent Ono's prior consent. Outside certain limited exceptions, these limitations include, among other things, restrictions on our ability to acquire other businesses and assets in excess of a specified limit, dispose of our assets, make investments, enter into certain contracts, repurchase or issue securities, pay dividends, incur capital expenditures in excess of a specified limit, take certain actions relating to intellectual property, amend our organizational documents, and incur indebtedness. These restrictions could prevent us from pursuing strategic business opportunities, taking actions with respect to our business that we may consider advantageous and responding effectively and/or timely to competitive pressures and industry developments, and may as a result materially and adversely affect our business, results of operations, and financial condition.

In certain instances, the Merger Agreement requires us to pay a termination fee to Ono, which could require us to use available cash that would have otherwise been available for general corporate purposes.

Under the terms of the Merger Agreement, we may be required to pay Ono a termination fee of $78.8 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement. If the Merger Agreement is terminated under such circumstances, the termination fee we may be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business operations and financial condition, which in turn would materially and adversely affect the price of our common stock.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending transaction with Ono.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the pending transaction. We must pay a material portion of these costs and expenses whether or not the transaction is completed. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses, any of which could materially and adversely affect our business, prospects, financial condition, and results of operations.

Lawsuits may be filed against us and the members of our board of directors arising out of the proposed merger with Ono, which may delay or prevent the proposed merger.

Complaints may in the future be filed against us, our board of directors, Ono, Ono's board of directors and/or others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, including the amount of costs associated with defending these claims or any other liabilities that may be incurred in connection with the litigation of these claims, and we may not be successful in defending against any such future claims. Lawsuits that may be filed

against us, our board of directors, Ono, or Ono's board of directors could delay or prevent the consummation of the Offer and the merger, result in significant costs, and divert the attention of our management and employees from our day-to-day business which could affect our operations and otherwise adversely affect us financially.

The following risk factors assume that we remain a stand-alone company.

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 European Commission (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 our Form 10-K for the year ended December 31, 2023.

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 our Form 10-K for the year ended December 31, 2023.

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 our Form 10-K for the year ended December 31, 2023.

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. 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 our Form 10-K for the year ended December 31, 2023.

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 our Form 10-K for the year ended December 31, 2023.

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 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 Medicines Corporation, Novartis AG (Novartis), Pfizer, and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST including AB Sciences S.A., 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, 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. Further, there are numerous companies marketing or developing antibodies and small molecules targeting CSF1R for TGCT, including Abbisko Therapeutics Co., Ltd., AmMax Bio, Inc., Daiichi Sankyo Company, Limited, Dragonboat Biopharmaceutical Company Limited, HXPharma, SynOx Therapeutics Ltd, and HUTCHMED (China) Limited. 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 Ailon Pharma Oy, Galixir, and Txinno Bioscience Inc. With respect to DCC-3084, we are also aware of pharmaceutical and biotechnology companies developing pan-RAF development candidates, including BeiGene, Inc. (BeiGene), Black Diamond Therapeutics, Inc. (Black Diamond), Day One Biopharmaceuticals, Inc. (Day One), Erasca, Jazz Pharma Pharmaceuticals, Inc. (Jazz Pharma), F. Hoffmann-La Roche AG (Roche), METiS Therapeutics, Nested Therapeutics, Pfizer, Pierre Fabre S.A. (Pierre Fabre), and Verastem, Inc. (Verastem). Several of these programs are in clinical studies, including but not limited to BeiGene, Black Diamond, Day One, Jazz Pharma, Roche, Pierre Fabre, and Verastem. With respect to DCC-3009, we are aware of other pharmaceutical and biotechnology companies that are developing KIT inhibitors, including Cogent, IDRx, 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 Risk Evaluation and Mitigation Strategy (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 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.

Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act (AI Act), the world's first comprehensive AI law, is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems.

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 Breakthrough Therapy Designation (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 current or future 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 our Form 10-K for the year ended December 31, 2023.

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 our Form 10-K for the year ended December 31, 2023.

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 our Form 10-K for the year ended December 31, 2023.

A 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 our Form 10-K for the year ended December 31, 2023.

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 three months ended March 31, 2024 and the year ended December 31, 2023, we reported net losses of $45.1 million and $194.9 million, respectively. As of March 31, 2024, we had an accumulated deficit of $1.5 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 March 31, 2024, our cash, cash equivalents, and marketable securities were $299.3 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 March 31, 2024, 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 March 31, 2024, our executive officers and directors, and, combined with our stockholders who own more than 10% of our outstanding capital stock, beneficially own shares, in the aggregate, representing approximately 32% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may:

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

Provisions in our corporate charter, 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 March 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 currently rely on foreign CROs and CMOs, including WuXi, to manufacture our clinical materials, and will likely continue to rely on foreign CROs and CMOs in the future.

We currently rely on foreign CROs and CMOs, including WuXi, to manufacture our clinical materials, and will likely continue to rely on foreign CROs and CMOs in the future. Foreign CMOs may be subject to U.S. legislation or investigations, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our approved drug and drug candidates and could adversely affect our financial condition and business prospects. In addition, if we are required to change clinical material manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer, if we can identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the quarter ended March 31, 2024, Daniel Martin, our Chief Commercial Officer and an executive officer, and Jama Pitman, our Chief Development Officer and an executive officer, each adopted a trading arrangement for the sale of securities of the Company's common stock (Rule 10b5-1 Trading Plan) that is intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). Mr. Martin's Rule 10b5-1 Trading Plan was adopted on January 10, 2024 and will continue until December 31, 2024 unless earlier terminated or modified. Under Mr. Martin's Rule 10b5-1 Trading Plan, an aggregate number of 79,308 securities can be sold or purchased during the duration of the Rule 10b5-1 Trading Plan. Ms. Pitman's Rule 10b5-1 Trading Plan was adopted on February 8, 2024 and will continue until April 30, 2025 unless earlier terminated or modified. Under Ms. Pitman's Rule 10b5-1 Trading Plan, an aggregate number of 106,917 securities can be sold or purchased during the duration of the Rule 10b5-1 Trading Plan. In April 2024, Mr. Martin and Ms. Pitman terminated their Rule 10b5-1 Trading Plans adopted during the quarter ended March 31, 2024.

Item 6. Exhibits.

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).
2.2	Agreement and Plan of Merger, dated as of April 29, 2024, by and among Ono Pharmaceutical Co. Ltd., Topaz Merger Sub, Inc. and Deciphera Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on April 29, 2024 (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 By-laws 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).
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.

* Filed herewith.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

(1) Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934 for any schedules so furnished.

SIGNATURES

Pursuant to the requirements 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.

DECIPHERA PHARMACEUTICALS, INC.

Date: May 10, 2024

By: /s/ Thomas P. Kelly

Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Steven L. Hoerter, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2024

By: /s/ Steven L. Hoerter
Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Thomas P. Kelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2024

By: /s/ Thomas P. Kelly

Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven L. Hoerter, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 10, 2024

By: /s/ Steven L. Hoerter
Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas P. Kelly, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 10, 2024

By: /s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer
(Principal Financial and Accounting Officer)