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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 June 30, 2023

OR

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

For the transition period from _____ to _____

Commission file number: 001-38219

DECIPHERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(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 July 28, 2023, there were 78,821,161 shares of Common Stock, $0.01 par value per share, outstanding.

Deciphera Pharmaceuticals, Inc.

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SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

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

- There is no assurance that our commercialization efforts with respect to QINLOCK® (ripretinib), referred to as QINLOCK, including, without limitation, our launch of QINLOCK in the EU4 (Germany, France, Italy, and Spain) and the 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 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 European geographic expansion of QINLOCK, and our ability to generate revenue will be materially impaired.
- Our reliance on sole source third-party suppliers could harm our ability to commercialize QINLOCK or any drug candidates that may be approved in the future.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.
- Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and decrease the prices we may obtain for our approved drug.
- QINLOCK or any current drug candidates, such as vimseltinib and DCC-3116, or future drug candidates, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to drug candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- If the market opportunities for our approved drug or any potential expanded market for our approved drug or drug candidates are smaller than what we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.
- The commercial success of QINLOCK, and of any future approved drugs, such as vimseltinib or DCC-3116, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.
- Our failure to obtain additional marketing approvals in other foreign jurisdictions would prevent QINLOCK and our drug candidates from being marketed more extensively internationally, and any approval we are granted for QINLOCK or our drug candidates in the United States (U.S.) or key European markets would not assure approval of QINLOCK or our drug candidates in other foreign jurisdictions.
- QINLOCK and any drug candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of QINLOCK or any future approved product from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of QINLOCK, and any future approved products, and ongoing regulation of our products, may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug and drug candidates.

- If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our Phase 3 INSIGHT study, and our ongoing clinical trials of vimseltinib and 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, if granted, retain orphan drug exclusivity for our drug or drug candidates.
- The COVID-19 pandemic and the future outbreak of any other highly infectious or contagious diseases, could seriously harm our research, development, and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition, and results of operations.
- We have incurred significant operating losses since our inception and have not generated sufficient revenue to result in a profit from product sales. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than QINLOCK, and 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). The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

FORWARD-LOOKING STATEMENTS

This Form 10-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 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 and the Phase 3 MOTION study of vimseltinib for the potential treatment of tenosynovial giant cell tumor (TGCT) patients, 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 the INSIGHT study and our ongoing clinical trials of vimseltinib and 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 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 and Macau, 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 war in Ukraine, 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 81,394	$ 64,741
Short-term marketable securities	247,346	259,745
Accounts receivable, net	23,200	22,429
Inventory	25,343	20,561
Prepaid expenses and other current assets	27,767	25,482
Total current assets	405,050	392,958
Long-term marketable securities	60,683	14,550
Long-term investments—restricted and other long-term assets	3,339	3,277
Property and equipment, net	6,213	6,707
Operating lease assets	34,333	36,547
Total assets	$ 509,618	$ 454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,211	$ 18,612
Accrued expenses and other current liabilities	59,455	64,622
Operating lease liabilities	3,368	3,235
Total current liabilities	81,034	86,469
Operating lease liabilities, net of current portion	24,154	25,879
Total liabilities	105,188	112,348
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; 78,772,870 shares and 67,637,351 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	788	676
Additional paid-in capital	1,736,143	1,575,361
Accumulated other comprehensive income (loss)	(967)	(983)
Accumulated deficit	(1,331,534)	(1,233,363)
Total stockholders' equity	404,430	341,691
Total liabilities and stockholders' equity	$ 509,618	$ 454,039

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenues, net	$ 37,320	$ 31,497	$ 70,542	$ 60,306
Collaboration revenues	984	997	1,207	1,411
Total revenues	38,304	32,494	71,749	61,717
Cost and operating expenses:				
Cost of sales	173	1,799	661	2,181
Research and development	58,296	44,858	113,061	92,270
Selling, general, and administrative	32,610	29,625	64,059	57,946
Total cost and operating expenses	91,079	76,282	177,781	152,397
Loss from operations	(52,775)	(43,788)	(106,032)	(90,680)
Other income (expense):				
Interest and other income, net	4,213	727	7,861	727
Total other income (expense), net	4,213	727	7,861	727
Net loss	$ (48,562)	$ (43,061)	$ (98,171)	$ (89,953)
Net loss per share—basic and diluted	$ (0.57)	$ (0.60)	$ (1.17)	$ (1.31)
Weighted average common shares outstanding—basic and diluted	85,020,344	72,133,428	83,854,959	68,441,998
Comprehensive loss:				
Net loss	$ (48,562)	$ (43,061)	$ (98,171)	$ (89,953)
Other comprehensive income (loss):				
Unrealized losses on marketable securities	(894)	(657)	(185)	(1,197)
Currency translation adjustment	108	(48)	201	(122)
Total other comprehensive income (loss)	(786)	(705)	16	(1,319)
Total comprehensive loss	$ (49,348)	$ (43,766)	$ (98,155)	$ (91,272)

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, March 31, 2023	78,507,752	$ 785	$ 1,722,452	$ (181)	$ (1,282,972)	$ 440,084
Issuance of common stock under stock option and incentive and employee stock purchase plans	265,118	3	835	—	—	838
Stock-based compensation expense	—	—	12,856	—	—	12,856
Other comprehensive income (loss)	—	—	—	(786)	—	(786)
Net loss	—	—	—	—	(48,562)	(48,562)
Balance, June 30, 2023	78,772,870	$ 788	$ 1,736,143	$ (967)	$ (1,331,534)	$ 404,430

	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 and employee stock purchase plans	721,715	8	1,001	—	—	1,009
Stock-based compensation expense	—	—	25,370	—	—	25,370
Other comprehensive income (loss)	—	—	—	16	—	16
Net loss	—	—	—	—	(98,171)	(98,171)
Balance, June 30, 2023	78,772,870	$ 788	$ 1,736,143	$ (967)	$ (1,331,534)	$ 404,430

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, March 31, 2022	58,697,263	$ 586	$ 1,372,866	(563)	$ (1,101,324)	$ 271,565
Issuance of common stock, net of underwriting discounts, commissions and offering costs	7,501,239	75	163,278	—	—	163,353
Issuance of common stock upon pre-funded warrant exercise	317,316	3	—	—	—	3
Issuance of common stock under stock option and incentive and employee stock purchase plans	299,693	4	864	—	—	868
Stock-based compensation expense	—	—	12,988	—	—	12,988
Other comprehensive income (loss)	—	—	—	(705)	—	(705)
Net loss	—	—	—	—	(43,061)	(43,061)
Balance, June 30, 2022	66,815,511	$ 668	$ 1,549,996	$ (1,268)	$ (1,144,385)	$ 405,011

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2021	58,549,644	$ 585	$ 1,358,516	$ 51	$ (1,054,432)	$ 304,720
Issuance of common stock, net of underwriting discounts, commissions and offering costs	7,501,239	75	163,278	—	—	163,353
Issuance of common stock upon pre-funded warrant exercise	317,316	3	—	—	—	3
Issuance of common stock under stock option and incentive and employee stock purchase plans	447,312	5	946	—	—	951
Stock-based compensation expense	—	—	27,256	—	—	27,256
Other comprehensive income (loss)	—	—	—	(1,319)	—	(1,319)
Net loss	—	—	—	—	(89,953)	(89,953)
Balance, June 30, 2022	66,815,511	$ 668	$ 1,549,996	$ (1,268)	$ (1,144,385)	$ 405,011

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

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (98,171)	$ (89,953)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	25,370	27,256
Depreciation expense	1,179	1,603
Noncash lease expense	2,215	1,954
Net (accretion) amortization of (discounts) premium on marketable securities	(3,519)	222
Changes in operating assets and liabilities:		
Accounts receivable	(689)	(5,397)
Inventory	(4,889)	(6,911)
Prepaid expenses and other current assets	(2,264)	(1,992)
Other long-term assets	(61)	(160)
Accounts payable	(428)	3,136
Accrued expenses and other current liabilities	(5,230)	(25,212)
Operating lease liabilities	(1,594)	(1,422)
Net cash flows used in operating activities	(88,081)	(96,876)
Cash flows from investing activities:		
Purchases of marketable securities	(229,135)	(181,885)
Maturities of marketable securities	197,950	137,630
Sales of marketable securities	785	—
Purchases of property and equipment	(653)	(287)
Net cash flows used in investing activities	(31,053)	(44,542)
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of underwriting discounts and commissions	135,125	163,778
Proceeds from pre-funded warrant exercise	24	3
Payments of offering costs	(634)	(425)
Proceeds from stock option exercises and employee stock purchase plan	1,009	951
Net cash flows provided by financing activities	135,524	164,307
Net increase in cash and cash equivalents	16,390	22,889
Effect of exchange rate changes on cash and cash equivalents	263	(254)
Cash and cash equivalents at beginning of period	64,741	87,063
Cash and cash equivalents at end of period	$ 81,394	$ 109,698

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, Israel, Macau, New Zealand, Singapore, Switzerland, Taiwan, the United Kingdom (U.K.), and the United States (U.S.) for the treatment of fourth-line advanced GIST. The Company wholly owns QINLOCK and all of its drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. In addition to QINLOCK, the Company has developed a robust pipeline of novel drug candidates using its switch-control kinase inhibitor platform, including vimseltinib and DCC-3116.

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, market acceptance and the successful commercialization of QINLOCK or any of the Company's current or future drug candidates for which it receives marketing approval, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, compliance with government regulations, and the ability to secure additional capital to fund operations. QINLOCK and the Company's drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval. In addition to supporting its research and development efforts, the Company will be required to invest in the Company's commercial capabilities and infrastructure, to support its commercialization of QINLOCK, the Company's first approved drug, and any current or future drug candidate for which the Company obtains marketing approval. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's drug development and commercialization efforts are successful, it is uncertain when, if ever, the Company will realize sufficient revenue to result in a profit from product sales of QINLOCK or any current or future drug candidates for which it receives marketing approval.

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

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

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

During the six months ended June 30, 2023, 2,427,693 shares of pre-funded warrants were exercised resulting in net proceeds of less than $0.1 million. As of June 30, 2023, there were 6,428,270 pre-funded warrants outstanding. There were no shares of pre-funded warrants exercised in the three months ended June 30, 2023.

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

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℠ (the Sales Agreement) with Jefferies, pursuant to which the Company may issue and sell the Shares having aggregate offering proceeds of up to $200.0 million from time to time through Jefferies as its sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell the Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any Shares under the Sales Agreement. The Company or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions.

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 $98.2 million and $178.9 million for the six months ended June 30, 2023 and the year ended December 31, 2022, respectively. As of June 30, 2023, the Company had an accumulated deficit of $1.3 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 $389.4 million as of June 30, 2023, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under its collaboration or license agreements will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to fund its operations.

The Company will need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce, or further terminate its research or drug development programs or certain commercialization efforts. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

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

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, 2022 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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, 2022 included in the Company's Annual Report on Form 10-K (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 June 30, 2023, consolidated results of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022, and consolidated cash flows for the six months ended June 30, 2023 and 2022, have been made. The consolidated results of operations for the three and six months ended

June 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

The significant accounting policies used in preparation of these consolidated financial statements for the three and six months ended June 30, 2023 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, 2022.

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 for the period, including pre-funded warrants. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of common shares, including pre-funded warrants and potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock, as determined using the treasury stock method.

For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the three and six months ended June 30, 2023 and 2022.

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 June 30,	
	2023	2022
Options to purchase common stock	9,456,610	8,205,617
Unvested restricted common stock units	2,905,473	1,942,621
Unvested employee stock purchase plan shares	45,612	53,429
Total	12,407,695	10,201,667

2. Revenues

Net Product Revenues

To date, the Company's only source of product revenues has been from the sales of QINLOCK, which began in May 2020, following the approval of QINLOCK by the U.S. Food and Drug Administration (FDA) on May 15, 2020, and during the three and six months ended June 30, 2023 and 2022 in certain other jurisdictions following regulatory approval or on a named patient basis.

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

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 June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
U.S.	$ 28,916	$ 23,733	$ 53,540	$ 47,142
Rest of world	8,404	7,764	17,002	13,164
Total product revenues, net	$ 37,320	$ 31,497	$ 70,542	$ 60,306

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

(in thousands)	**Trade discounts and allowances**	**Chargebacks and administrative fees**	**Government rebates and other incentives**	**Returns**	**Total**
Balance as of December 31, 2022	$ 475	$ 656	$ 15,825	$ 1,375	$ 18,331
Provision related to sales in the current year	2,007	4,686	8,969	2,295	17,957
Adjustments related to prior period sales	(31)	—	145	—	114
Credits and payments made during the period	(1,792)	(4,556)	(2,484)	(2,848)	(11,680)
Balance as of June 30, 2023	$ 659	$ 786	$ 22,455	$ 822	$ 24,722

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

(in thousands)	**As of June 30, 2023**	**As of December 31, 2022**
Reduction of accounts receivable, net	$ 1,346	$ 1,082
Component of accrued expenses and other current liabilities	23,376	17,249
Total revenue-related reserves	$ 24,722	$ 18,331

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 June 30, 2023 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 and six months ended June 30, 2023 and 2022, 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, 2022 for further details on the Zai License Agreement.

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

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.

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 June 30, 2023 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	$ 75,101	$ —	$ (127)	$ 74,974
Corporate debt securities	63,016	1	(279)	62,738
U.S. government securities	97,907	4	(326)	97,585
Certificates of deposit	12,060	1	(12)	12,049
Due after one year through five years:				
Corporate debt securities	17,672	—	(177)	17,495
U.S. government securities	43,717	—	(529)	43,188
Total	$ 309,473	$ 6	$ (1,450)	$ 308,029

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

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 June 30, 2023 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 50,710	$ —	$ 50,710
U.S. government securities	—	2,985	—	2,985
Commercial paper	—	1,695	—	1,695
Marketable securities:				
Corporate debt securities	—	80,233	—	80,233
Commercial paper	—	74,974	—	74,974
U.S. government securities	—	140,773	—	140,773
Certificates of deposit	—	12,049	—	12,049
Total	$ —	$ 363,419	$ —	$ 363,419

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

The tables above exclude certificates of deposit totaling $3.1 million as of both June 30, 2023 and December 31, 2022 that the Company held to secure a letter of credit associated with its leases and to secure a credit card account. The certificates of deposit are measured at carrying value in the consolidated balance sheets in long-term investments—restricted and approximate fair value. For additional information on the letter of credit associated with the Company's leases, please read Note 7, *Leases*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2022.

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 June 30, 2023 and December 31, 2022.

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

4. Inventory

Capitalized inventory consisted of the following:

(in thousands)	As of June 30, 2023	As of December 31, 2022
Raw materials	$ 4,933	$ 6,844
Work in process	18,511	11,125
Finished goods	1,899	2,592
Total inventory	$ 25,343	$ 20,561

Inventory written down as a result of excess, obsolescence, unmarketability, or other reasons is charged to cost of sales. During the three and six months ended June 30, 2023, there was no inventory written down as a result of excess, obsolescence, unmarketability, or other reasons. During the three and six months ended June 30, 2022, $0.4 million in inventory was written down as a result of excess, obsolescence, unmarketability, or other reasons, respectively.

5. Other Consolidated Financial Statement Detail

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	As of June 30, 2023	As of December 31, 2022
External research and development expenses	$ 17,524	$ 17,411
Payroll and related expenses	11,140	21,971
Revenue-related reserves	23,376	17,249
Professional fees	4,016	4,275
Other	3,399	3,716
Total accrued expenses and other current liabilities	$ 59,455	$ 64,622

Interest Income

For the three and six months ended June 30, 2023, interest income was $4.4 million and $8.2 million, respectively. For the three and six months ended June 30, 2022, interest income was $0.6 million and $0.7 million, respectively.

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 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 and six months ended June 30, 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 June 30, 2023, 1,346,799 shares of common stock were available for issuance under the 2017 Plan. As of June 30, 2023, 2,266,771 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 2023, the Inducement Plan was amended and the number of shares reserved for issuance under the Inducement Plan was increased by 270,000. The Inducement Plan provides for the grant of equity-based awards in the form of nonstatutory stock options, stock

appreciation rights, restricted stock awards, restricted stock unit awards, unrestricted stock awards, and dividend equivalent rights. The Inducement Plan was adopted by the Company without stockholder approval pursuant to Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. As of June 30, 2023, 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 June 30,		Six Months Ended June 30,	
(in thousands)	2023	2022	2023	2022
Research and development	$ 5,737	$ 5,406	$ 11,192	$ 11,690
Selling, general, and administrative	7,119	7,582	14,178	15,566
Total stock-based compensation	$ 12,856	$ 12,988	$ 25,370	$ 27,256

As of June 30, 2023, total unrecognized compensation cost related to the unvested share-based awards was $72.7 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 June 30, 2023, the Company's contractual commitments for its commercial supply agreements were $10.7 million, of which $5.1 million is 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 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 June 30, 2023 or December 31, 2022.

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, 2022 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 kinase inhibitor platform and deep expertise in kinase biology, we design kinase inhibitors to target the switch pocket region of the kinase with the goal of developing potentially transformative medicines. Through our patient-inspired approach, we seek to develop a broad portfolio of innovative medicines to improve treatment outcomes. QINLOCK, our switch-control tyrosine kinase inhibitor, was discovered using our proprietary drug discovery platform and designed for the treatment of GIST. QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Israel, Macau, New Zealand, Singapore, Switzerland, Taiwan, the U.K., and the U.S. for the treatment of fourth-line advanced GIST. We wholly own QINLOCK and all of our drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. In addition to QINLOCK, we have developed a robust pipeline of novel drug candidates using our switch-control kinase inhibitor platform, including vimseltinib and DCC-3116.

Recent Developments

QINLOCK

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

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

Vimseltinib

Vimseltinib is an investigational, orally administered, potent, and highly-selective switch-control kinase inhibitor of the colony stimulating factor 1 receptor (CSF1R).

We are currently studying vimseltinib in the pivotal Phase 3 MOTION study in patients with TGCT (MOTION study). The MOTION study is a two-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of vimseltinib in patients with TGCT who are not amenable to surgery. In March 2023, we announced the completion of enrollment in the MOTION study. We expect to report top-line results in the fourth quarter of 2023.

We are also conducting an international, multicenter, ongoing open-label Phase 1/2 study designed to evaluate the safety, efficacy, pharmacokinetics (PK), and pharmacodynamics (PD) of vimseltinib in patients with solid tumors and TGCT. In the fourth quarter of 2023, we plan to provide updated data from our Phase 1/2 study of vimseltinib in TGCT patients.

DCC-3116

DCC-3116 is a potential first-in-class investigational, orally administered, potent, and highly selective switch-control inhibitor of the ULK kinase.

DCC-3116 is being studied in a Phase 1/2 study designed to evaluate the safety, tolerability, clinical activity, PK, and PD of DCC-3116 as a single agent and in combination with (i) trametinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; (ii) binimetinib in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations; (iii) sotorasib in patients with advanced or metastatic solid tumors with KRASG12C mutations; (iv) ripretinib in patients with GIST; and (v) encorafenib and cetuximab in patients with colorectal cancer.

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

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

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

In August 2023, we also announced that we opened the first site for enrollment in two new combinations evaluating DCC-3116 in combination cohorts with ripretinib in patients with GIST and in combination with encorafenib and cetuximab in patients with colorectal cancer. Under the terms of the clinical trial collaboration and supply agreement with Pfizer Inc. (Pfizer) announced in January 2023, we will sponsor the trial and Pfizer will supply encorafenib at no cost.

We currently expect to have sufficient data in the first half of 2024 to make decisions about whether to open expansion cohorts of DCC-3116 in combination with trametinib, binimetinib, and/or sotorasib. Subject to favorable data from the combination dose escalation portion of the study and selection of combination doses, we plan to invest in and prioritize the expansion combination(s) that we believe will have the best chance to demonstrate clinical proof-of-concept.

Platform Development and Preclinical Pipeline

We are also making a focused investment in our next generation of research programs, which are designed to provide first-in-class or best-in-class treatments using our proprietary switch-control inhibitor platform. We announced the nomination of DCC-3084 as our pan-RAF development candidate in November 2022 and DCC-3009 as our next generation KIT inhibitor in April 2023. We also plan to continue to develop our in-licensed research-stage program, which targets the VPS34 kinase, pursuant to our agreement with Sprint Biosciences AB (the Sprint Agreement).

DCC-3084

DCC-3084 is a potential best-in-class pan-RAF inhibitor that is designed to broadly inhibit Class I, II, and III BRAF mutations, BRAF fusions, and BRAF/CRAF heterodimers. In April 2023, we presented preclinical data for DCC-3084 at the AACR Annual Meeting 2023. We expect to submit an IND application to the FDA for DCC-3084 in the fourth quarter of 2023.

DCC-3009

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

Components of Our Results of Operations

Revenues

QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Israel, Macau, New Zealand, Singapore, Switzerland, Taiwan, the U.S. and the U.K. for the treatment of fourth-line advanced 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 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 and six months ended June 30, 2023 and 2022, 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 and six months ended June 30, 2023 and 2022, 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, as of June 30, 2023 we have received an upfront cash payment of $20.0 million and three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances. Additionally, certain costs we incur associated with the Zai License Agreement are reimbursed by Zai.

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

Zai Supply Agreement

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

Cost of Sales

Our cost of sales includes external costs of producing and distributing inventories that are related to product revenue during the respective period of the associated sales. In addition, shipping and handling costs for product shipments are recorded in cost of sales as incurred. Further, cost of sales includes the external costs of producing and distributing commercial inventories sold under the Zai Supply Agreement. Cost of sales also includes charges related to inventory written down as a result of excess, obsolescence, unmarketability, or other reasons.

Cost of sales for newly launched products will not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. The gross margin on sales of QINLOCK for the three and six months ended June 30, 2022 was enhanced by sales of the initial pre-launch inventory, and therefore, use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the

launch of QINLOCK, referred to as zero cost inventories. We began selling inventory with the full cost of manufacturing in the fourth quarter of 2022, and we do not expect that the cost of sales as a percentage of net sales of QINLOCK will increase significantly.

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;
- successful completion of our Phase 3 INSIGHT study of QINLOCK and our Phase 3 MOTION study for vimseltinib in TGCT patients, advancing our DCC-3116 program through clinical development, and nominating additional drug candidates from our switch control inhibitor platform;
- the rate and degree of market acceptance of QINLOCK or any current or future drug candidate for which we may receive marketing approval;
- 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 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 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 QINLOCK prior to FDA approval; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, supplies, and technology-related costs.

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

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

Research and development activities are central to our business model. Drugs and drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development expenses associated with our drug and drug candidate programs will increase in 2023 as these programs progress. 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 due to increased selling, general, and administrative expenses to be incurred related to the continued planned launches of QINLOCK in new jurisdictions in 2023. 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 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, 2022 on file with the SEC, as of June 30, 2023, 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, 2022 on file with the SEC. There have been no significant changes to our critical accounting policies since December 31, 2022.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Revenues:				
Product revenues, net	$ 37,320	$ 31,497	$ 70,542	$ 60,306
Collaboration revenues	984	997	1,207	1,411
Total revenues	38,304	32,494	71,749	61,717
Cost and operating expenses:				
Cost of sales	173	1,799	661	2,181
Research and development	58,296	44,858	113,061	92,270
Selling, general, and administrative	32,610	29,625	64,059	57,946
Total cost and operating expenses	91,079	76,282	177,781	152,397
Loss from operations	(52,775)	(43,788)	(106,032)	(90,680)
Other income (expense):				
Interest and other income, net	4,213	727	7,861	727
Total other income (expense), net	4,213	727	7,861	727
Net loss	$ (48,562)	$ (43,061)	$ (98,171)	$ (89,953)

Revenues

Product Revenues, Net

During the three and six months ended June 30, 2023 and 2022, our only source of product revenues was from the sales of QINLOCK. During the three and six months ended June 30, 2023 and 2022, net product revenues by geography consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
U.S.	$ 28,916	$ 23,733	$ 53,540	$ 47,142
Rest of world	8,404	7,764	17,002	13,164
Total product revenues, net	$ 37,320	$ 31,497	$ 70,542	$ 60,306

For the three and six months ended June 30, 2023 compared to the same periods in 2022, U.S. net product revenues increased $5.2 million and $6.4 million, respectively, primarily due to increased sales volume and an increase in net price.

For the three and six months ended June 30, 2023 compared to the same period in 2022, rest of world net product revenues increased $0.6 million and $3.8 million, respectively, primarily due to increased sales volume of QINLOCK in Germany, which launched in January 2022, partially offset by a decrease in net price in Germany as price negotiations were completed in 2023, France, where we have conducted a post-approval paid access program since April 2022, and other jurisdictions as we continued our commercialization efforts.

Collaboration Revenues

For the three months ended June 30, 2023 compared to the same period in 2022, collaboration revenues were consistent.

For the six months ended June 30, 2023 compared to the same period in 2022, collaboration revenues decreased $0.2 million, primarily due to a decrease in supply revenues under the Zai Supply Agreement, partially offset by an increase in royalty revenues under the Zai License Agreement.

Cost of Sales

During the three and six months ended June 30, 2023 and 2022, cost of sales by type consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Cost of product sales	$ 118	$ 975	$ 548	$ 1,341
Cost of collaboration sales	55	824	113	840
Total cost of sales	$ 173	$ 1,799	$ 661	$ 2,181

For the three and six months ended June 30, 2023 compared to the same periods in 2022, cost of sales decreased $1.6 million and $1.5 million, respectively, primarily due to a decrease in cost of sales recognized under the Zai Supply Agreement and a decrease in cost of sales in the U.S. due to the write down of inventory in the prior year period. The decrease in cost of sales for the six months ended June 30, 2023 also included a credit received during the first quarter of 2023 for inventory previously written down during the year ended December 31, 2022. During the three and six months ended June 30, 2023, there was no inventory written down as a result of excess, obsolescence, unmarketability, or other reasons. During the three and six months ended June 30, 2022, $0.4 million in inventory was written down as a result of excess, obsolescence, unmarketability, or other reasons, respectively.

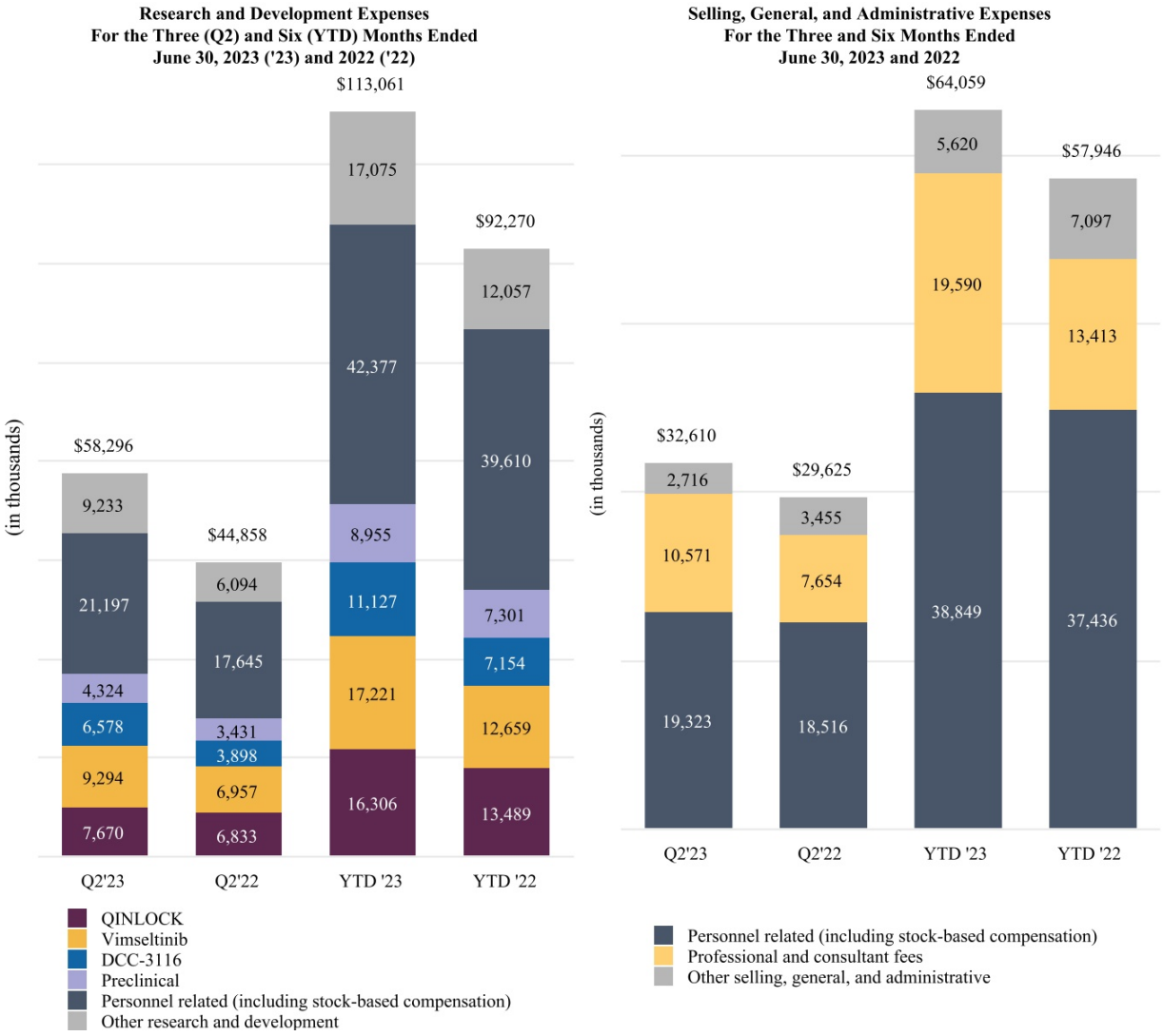
For the three and six months ended June 30, 2022, cost of sales associated with product sales of QINLOCK was primarily related to the sales of zero cost inventories, which consisted of packaging, labeling, shipping, and distribution costs.

Prior to receiving FDA approval for QINLOCK in May 2020, we manufactured inventory to be sold and recorded approximately $6.0 million related to this inventory build-up as research and development expense. We did not record any such costs related to the build-up of this inventory as research and development expense during the three and six months ended June 30, 2023 and 2022.

Utilizing the actual direct costs to manufacture QINLOCK prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the three and six months ended June 30, 2022 would have increased by approximately $0.7 million and $1.3 million, respectively. We began selling inventory with the full cost of manufacturing in the fourth quarter of 2022.

We do not expect our cost of sales for QINLOCK to increase significantly as a percentage of net sales in future periods as we continue to produce inventory for future sales, which will reflect the full cost of manufacturing, and then sell such inventory.

Operating Expenses



Research and Development Expenses

QINLOCK

For the three and six months ended June 30, 2023 compared to the same periods in 2022, research and development expenses related to QINLOCK increased primarily as a result of increased clinical trial expenses of $0.5 million and $2.0 million, respectively, and increased manufacturing expenses of $0.3 million and $1.0 million, respectively. Clinical trial expenses for QINLOCK increased primarily as a result of increased expenses associated with our Phase 3 INSIGHT study of QINLOCK versus sunitinib in patients with mutations in KIT exon 11 and 17/18 and our ongoing Phase 1 trial of QINLOCK, partially offset by a decrease in expenses associated with INVICTUS, our Phase 3 study of QINLOCK for the treatment of fourth-line GIST. Additionally, for the six months ended June 30, 2023, clinical trial expenses increased as a result of increased expenses associated with INTRIGUE, our Phase 3 study of QINLOCK for the treatment of second-line GIST. Manufacturing costs increased primarily due to timing of processing of inventory for clinical and commercial use.

Vimseltinib

For the three and six months ended June 30, 2023 compared to the same periods in 2022, research and development expenses related to our vimseltinib program increased primarily as a result of increased clinical trial expenses of $0.8 million and $1.7 million, respectively, increased manufacturing expenses of $1.0 million and $1.7 million, respectively, and increased

preclinical expenses of $0.6 million and $1.2 million, respectively. Clinical trial expenses increased primarily due to increased activities associated with our Phase 3 study of vimseltinib in patients with TGCT, MOTION, which was initiated in the fourth quarter of 2021 and clinical trial expenses associated with our Phase 1/2 study of vimseltinib to assess the safety, tolerability, PK, and PD in patients with TGCT, partially offset by a decrease in clinical pharmacology study activities. Manufacturing expenses increased primarily due to inventory manufacturing and process developments. Preclinical expenses increased primarily due to increased activities related to toxicology and biology studies.

DCC-3116

For the three and six months ended June 30, 2023 compared to the same periods in 2022, research and development expenses related to our DCC-3116 program increased primarily as a result of increased clinical trial expenses of $0.9 million and $2.6 million, respectively, increased manufacturing expenses of $1.2 million and $0.8 million, respectively, and increased preclinical expenses of $0.5 million and $0.6 million, respectively. Clinical trial expenses increased primarily due to increased activities associated with our Phase 1/2 study of DCC-3116, which we initiated in June 2021. Manufacturing expenses increased due to the timing of raw materials procurement and inventory production for product to be used in our Phase 1/2 study of DCC-3116. Preclinical expenses increased primarily due to increased activities related to toxicology and biology studies.

Preclinical

For the three and six months ended June 30, 2023 compared to the same periods in 2022, research and development expenses related to preclinical costs increased $0.9 million and $1.7 million, respectively, primarily due to increased activities related to toxicology and biology studies for our early-stage drug discovery programs.

Personnel-related and Other Research and Development Expenses

For the three months ended June 30, 2023 compared to the same period in 2022, the increase in personnel-related and other research and development expenses was primarily associated with increased personnel-related costs of $3.6 million, including an increase in stock-based compensation of $0.3 million, and increased other research and development of $3.1 million, primarily related to manufacturing expenses for DCC-3084, our pan-RAF inhibitor, and other manufacturing and development expenses not allocated to specific projects, partially offset by a reversal of certain accrued research and development expenses due to a change in estimate as certain of our clinical trials are closing.

For the six months ended June 30, 2023 compared to the same period in 2022, the increase in personnel-related and other research and development expenses were primarily associated with increased other research and development expenses of $5.0 million and increased personnel-related costs of $3.3 million, partially offset by a decrease in stock-based compensation expense of $0.5 million. The other research and development expenses increase primarily related to manufacturing and development expenses for DCC-3084 and DCC-3009 and temporary employment services, partially offset by a reversal of certain accrued research and development expenses due to a change in estimate as certain of our clinical trials are closing.

We expect research and development expenses associated with our drug and drug candidate programs will increase in 2023 as these programs progress.

Selling, General, and Administrative Expenses

For the three and six months ended June 30, 2023 compared to the same periods in 2022, the increase in selling, general, and administrative expenses was primarily associated with increased professional and consultant fees of $2.9 million and $6.2 million, respectively, and increased personnel-related costs of $1.3 million and $2.8 million, respectively, partially offset by a decrease in stock-based compensation expense of $0.5 million and $1.4 million, respectively, and a decrease in other selling, general, and administrative expenses of $0.7 million and $1.5 million, respectively, primarily due to an increase in sublease income, which began during the second quarter of 2022. The increase in professional and consultant fees is primarily due to an increase in professional, consulting, and other expenses related to the commercialization of QINLOCK and temporary employment services.

We anticipate that our selling, general, and administrative expenses will increase modestly overall due to increased selling, general, and administrative expenses to be incurred related to the continued launch of QINLOCK in additional jurisdictions in 2023.

Interest and Other Income, Net

For the three and six months ended June 30, 2023 compared to the same periods in 2022, the increase in interest and other income, net, was primarily due to increased interest income on our cash equivalents and marketable securities associated with an increase in our investment holdings and changes in interest rates.

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 thirteen territories for the treatment of fourth-line advanced GIST. During the three and six months ended June 30, 2023 and 2022, our product revenues were primarily derived from sales of QINLOCK in the U.S. Additionally, we launched QINLOCK in Germany in January 2022 and have conducted the post-approval paid access program in France since April 2022. 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 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, including our underwritten public offerings in April 2022 and January 2023, and the Sales Agreement and the Amended Sales Agreement with Jefferies. Through such issuances, we have issued and sold 45,156,736 shares of our common stock and pre-funded warrants to purchase 9,748,761 shares of our common stock resulting in net proceeds of $1.3 billion after deducting underwriting discounts and commissions and other offering expenses.

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

During the six months ended June 30, 2023, 2,427,693 shares of pre-funded warrants were exercised resulting in net proceeds of less than $0.1 million. As of June 30, 2023, there were 6,428,270 pre-funded warrants outstanding. There were no shares of pre-funded warrants exercised in the three months ended June 30, 2023 and 2022.

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, the Company entered into the Sales Agreement with Jefferies, pursuant to which the Company may issue and sell shares of its common stock having aggregate offering proceeds of up to $200.0 million from time to time through Jefferies as its sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell the Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any Shares under the Sales Agreement. The Company or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions.

Cash Flows

As of June 30, 2023, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $389.4 million, which consisted of cash, money market funds, U.S. government securities, commercial paper, corporate debt securities, and certificates of deposit. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. Given the nature of these investments, we believe that the market for these instruments is not illiquid.

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

	Six Months Ended June 30,	
(in thousands)	**2023**	**2022**
Net cash flows used in operating activities	$ (88,081)	$ (96,876)
Net cash flows used in investing activities	(31,053)	(44,542)
Net cash flows provided by financing activities	135,524	164,307
Net increase in cash and cash equivalents	$ 16,390	$ 22,889

Operating Activities

During the six months ended June 30, 2023 compared to the same period in 2022, net cash flows used in operating activities decreased $8.8 million, primarily resulting from a decrease in net cash flows related to changes in our operating assets and liabilities of $22.8 million, partially offset by an increase in our net loss of $8.2 million and a decrease in net non-cash charges of $5.8 million, including a decrease in share-based compensation of $1.9 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 and the completion of payments under our restructuring program initiated during the fourth quarter of 2021.

Investing Activities

During the six months ended June 30, 2023 compared to the same period in 2022, net cash flows used in investing activities decreased $13.5 million, primarily resulting from an increase in proceeds from maturities and sales of marketable securities of $61.1 million, partially offset by an increase in purchases of marketable securities of $47.2 million and an increase in purchases of property, plant, and equipment of $0.4 million.

Financing Activities

During the six months ended June 30, 2023 compared to the same period in 2022, net cash flows provided by financing activities decreased $28.8 million, primarily resulting from net proceeds from an offering of our common stock in a follow-on public offering in April 2022 for $163.4 million, partially offset by 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 $98.2 million for the six months ended June 30, 2023 and $178.9 million for the year ended December 31, 2022. As of June 30, 2023, we had an accumulated deficit of $1.3 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;
- continue with our ongoing and planned clinical programs for vimseltinib as a potential single agent 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, including those associated with the Sprint Agreement;
- 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 June 30, 2023 of $389.4 million, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under our collaboration or license agreements will enable us to fund our operating expenses and capital expenditure requirements into 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 June 30, 2023, 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, 2022.

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, 2022 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, 2022 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 June 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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 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 January 2022, and have conducted the post-approval paid access program in France since April 2022. We also plan to continue the European expansion of QINLOCK in 2023, with planned commercial launches following conclusion of pricing and reimbursement negotiations in other key European markets. 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 European 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 initiate and 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 European 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 reliance on sole source third-party suppliers could harm our ability to commercialize QINLOCK or any drug candidates that may be approved in the future.

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

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors 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, 2022.

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, 2022.

Our ability to successfully commercialize our drug and drug candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford 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, 2022.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The full effects of the IRA on our business and the healthcare industry in general is not yet known.

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

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

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 European Medicines Agency (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 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 international operations or international operations we may have in the future may preclude us from developing, manufacturing, and selling certain drug candidates and products outside of the U.S. and require us to develop and implement costly compliance programs.

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 the countries of Europe, 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.

In California, the California Consumer Privacy Act (CCPA), which became effective in 2020, broadly defines personal information, gives California residents expanded individual privacy rights and protections and provides for civil penalties for violations and a private right of action for data breaches. Further, the California Privacy Rights Act (CPRA), which became effective in 2023, and amends the CCPA, creates additional obligations with respect to processing and storing personal information. We will continue to monitor developments related to the CCPA and anticipate additional costs and expenses associated with CPRA compliance. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "Business" regulated by the CCPA. Unlike

other state privacy laws, the CCPA also regulates personal information collected in a business to business and in human resources contexts. Further, there continues to be some uncertainly about how certain provisions of the CCPA will be interpreted and how the law will be enforced.

In addition to the CCPA, broad consumer privacy laws recently went into effect in Virginia on January 1, 2023 and in Colorado and Connecticut on July 1, 2023 and new privacy laws will become effective in Utah on December 31, 2023, in Florida, Montana and Texas in 2024, in Tennessee and Iowa in 2025, and in Indiana in 2026 and numerous other states are considering new privacy laws. Furthermore, other U.S. states, such as New York, Massachusetts, and Utah have enacted stringent data security laws and numerous other states have proposed similar privacy laws.

New privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate 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 as it existed on December 31, 2020 but subject to certain U.K. specific amendments incorporated into U.K. law on January 1, 2021 under the U.K. GDPR, and other data protection requirements. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. We currently conduct clinical trials and engage in regulatory and commercial operations in the EEA and the U.K. As a result, we are subject to additional privacy laws, including the GDPR and U.K. GDPR (collectively referred to as “GDPR”). The GDPR imposes a broad range of data protection obligations on companies subject to the GDPR, including, for example, imposing obligations on companies around how they process personal data, stricter requirements relating to processing health and other sensitive data, ensuring there is a legal basis to justify the processing of personal data, stricter requirements relating to obtaining consent of individuals, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, implementing safeguards to protect the security and confidentiality of personal data, taking certain measures on engagement with third parties, restrictions on transfers outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and has created onerous new obligations and liabilities on services providers or data processors. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. Moreover, data subjects can claim damages resulting from infringement of the GDPR. The GDPR further grants non-profit organizations the right to bring claims on behalf of data subjects. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

In addition, further to the U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the U.K. GDPR into U.K. law. The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but, currently, aligned to the EU's data protection regime. Non-compliance with the U.K. GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In addition, on June 28, 2021, the EC adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EEA remain unaffected. The U.K. Government has also now introduced a Data Protection and Digital Information Bill (or the UK Bill) into the UK legislative process with the intention for this bill to reform the U.K.’s data protection regime following Brexit. If passed, the final version of the U.K. Bill may have the effect of further altering the similarities between the U.K. and EU data protection regime and threaten the U.K. Adequacy Decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk.

Over the past few years, the number of enforcement actions and the fines have both steadily increased. 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.

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

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with EEA and U.K. data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. In some cases, we rely upon the recently updated standard contractual clauses (new standard contractual clauses) to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the GDPR). Transition to the new standard contractual clauses requires significant effort and cost particularly given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. The U.K. is not subject to the EC's new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the U.K. On June 28, 2021, the EC announced a decision of “adequacy” concluding that the U.K. ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the U.K. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. The U.K. Government has confirmed that transfers from the U.K. to the EEA may currently continue to flow freely. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U.S. have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (“Framework”), which enters into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the US are carried out in line with GDPR. The Framework could be challenged like its predecessor frameworks.

If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

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

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

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

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

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.

In addition, regarding the war in Ukraine, while we do not have any clinical trial sites or operations in Ukraine or Russia, if the war expands into the surrounding region, resulting heightened economic sanctions from the U.S. and the international community could limit our ability to procure or use certain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and high inflation, as well as by the war in Ukraine and the possibility of a wider European or 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.

Actual 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. For example, in March 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, in March 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership; since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future. Although a statement by the Department of the Treasury, the Federal Reserve, and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit, and certain other

financial instruments with financial institutions that have been placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we do not have investments with any financial institution currently in receivership, 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. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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.

Any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by any parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a third party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. In addition, a third party with whom we conduct business could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to, delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any bankruptcy or insolvency by a third party with whom we conduct business, or the failure of such party to make

payments when due, or any breach or default by such party, or the loss of any significant relationships, could result in material losses to us and may have a material adverse impact on our business.

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

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

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

Risks Related to Sales, Marketing, and Competition

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new pharmaceutical and biotechnology products is highly competitive. We face competition with respect to our approved drug and current clinical-stage drug candidates and will face competition with respect to any drugs and drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our drug candidates and commercializing our approved drug. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Specifically, there are a large number of pharmaceutical and biotechnology companies developing or marketing treatments for cancer that would be competitive with QINLOCK and the drug candidates we are developing, if such drug candidates are approved. Many of these companies are developing cancer therapeutics that are also kinase inhibitors. Although there are currently marketed drugs that have activity in GIST through their targeting of primary and secondary KIT mutants, other than avapritinib for GIST PDGFRA exon 18 mutations only, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRA, and no currently marketed drug provides coverage of all KIT and PDGFRA mutants. With respect to QINLOCK, there are a number of large pharmaceutical companies and biotechnology companies marketing small molecule drugs or biologic drugs for the treatment of GIST, including Blueprint 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 (Taiho), Theseus Pharmaceuticals, Inc., 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, 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 Erasca, Inc. (Erasca), Txinno Bioscience Inc., and Ailon Pharma Oy. With respect to DCC-3084, we are also aware of pharmaceutical and biotechnology companies developing pan-RAF development candidates, including Day One Biopharmaceuticals, Inc. (Day One), Jazz Pharma Pharmaceuticals, Inc. (Jazz Pharma), F. Hoffmann-La Roche AG (Roche), Kinnate Biopharma Inc. (Kinnate), Erasca, Pfizer, Black Diamond Therapeutics, Inc. (Black Diamond), BeiGene, Inc. (BeiGene) Nested Therapeutics, METiS Therapeutics (METiS), and Verastem, Inc. (Verastem). Several of these programs are in clinical studies, including but not limited to Day One, Jazz Pharma, Roche, Kinnate, Black Diamond, BeiGene, and Verastem.

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 a New Drug Application (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 that indication depends on a number of additional factors, including the adoption of ctDNA testing for GIST patients. Any of these factors 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. or key European markets 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 Macau in 2023. Following EC approval in November 2021, we launched QINLOCK in Germany in January 2022 and have conducted the post-approval paid access program in France since April 2022. In addition, 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.

In order to market and sell QINLOCK, or any future products in other jurisdictions, we or our partners must obtain separate marketing approvals in applicable foreign jurisdictions and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing as well as additional information and filings. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not (and/or our partners, as applicable, may not) obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, or may not be successful in seeking and obtaining favorable local reimbursement and pricing approvals. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Except for QINLOCK in select countries where we have received approval, we, or our partners, may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market outside the U.S.

QINLOCK and any drug candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of QINLOCK or any future approved product from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of QINLOCK, and any future approved products, and ongoing regulation of our products, may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

QINLOCK and any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such products, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping. Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

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

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

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

In addition, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for QINLOCK or any future approved products withdrawn by regulatory authorities and our ability to market QINLOCK or any future approved products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

We currently have only limited experience in the sale, marketing, or distribution of biopharmaceutical products. To achieve commercial success for QINLOCK or any other product for which we obtain marketing approval, we will need to successfully maintain and expand our sales, marketing, and distribution capabilities, either ourselves or through collaboration, licensing, distribution, or other arrangements with third parties. In addition, our licensee for QINLOCK for Greater China is building a sales and marketing infrastructure but currently has limited experience in sales, marketing, and distribution of a commercial product.

We have built our own focused, specialized sales and marketing organization in the U.S. and commercial capabilities in key European markets. In addition to our existing QINLOCK license to Zai for Greater China, we have executed, and intend to seek additional, distribution arrangements in select geographies where we choose not to establish a sales presence to support the commercialization of QINLOCK or our drug candidates for which we obtain marketing approval and that can be commercialized through such arrangements.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting, training, and motivating a sales force is expensive and time-consuming and could delay any product launch. We will need to commit significant management and other resources to maintain our commercial organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train, and retain sales and marketing personnel. We cannot be sure that we will be able to recruit, hire, train, and retain a sufficient number of sales representatives or that they will be effective at promoting QINLOCK or any future approved drugs.

Factors that may inhibit our efforts to commercialize QINLOCK or any future approved products on our own include:

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

Our product revenues and profitability, if any, are likely to be lower as a result of any partnerships we choose to enter into in markets outside of the U.S. or key European markets than if we were to market and sell the products ourselves in those markets. In addition, we may not be successful in entering into arrangements with third parties to market and sell QINLOCK or any future approved products or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to develop (as necessary in the relevant jurisdiction), sell, and market QINLOCK or any future approved products effectively. If we do not maintain and expand our sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing QINLOCK or any of our drug candidates for which we may receive marketing approval. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of QINLOCK and our drug candidates, if approved, could be delayed which would negatively impact our ability to generate product revenues.

Other Risks Related to Our Business

Our business could be negatively affected by cyber security threats.

A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. We are dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers, and other business partners, may become the target of cyberattacks or information security 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. 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 technology (IT) 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 IT and business infrastructure to third-party providers, and we currently use these providers to perform business critical IT 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 IT service availability due to a variety of factors outside of our control, including technical failures, natural disasters, fraud, or security 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.

As a global pharmaceutical company, our systems are subject to frequent cyber-attacks. Due to the nature of some of these 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 breaches (e.g., ransomware or phishing). Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential 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 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, breaches, and/or attacks (e.g., ransomware, computer viruses, worms, and other destructive or disruptive software), unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents, or security attacks and/or breaches of our systems 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 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 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 confidential 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 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 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 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 of their systems 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 confidential 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 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 of our security measures by third-party actions, employee negligence 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 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 and/or breaches, such as investigative and remediation costs, the costs of providing individuals and/or data owners with notice of the breach, legal fees, the costs of any additional fraud or cyber detection activities, or the costs of prolonged system disruptions or shutdowns.

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

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

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

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

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

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

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, 2022, 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.

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

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus spread to the majority of countries around the world, including the U.S. The extent to which the COVID-19 pandemic, or the future outbreak of any other 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.

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. 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 17/18 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 announced plans to initiate 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 with a third-party provider to run ctDNA testing for our Phase 3 INSIGHT study in order to help identify eligible patients and 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 DCC-3116 in a Phase 1/2 study in patients with advanced or metastatic tumors with a RAS or RAF mutation and vimseltinib in a Phase 3 study in patients with TGCT, 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. In addition, although we observed encouraging preliminary efficacy results including ORR (best response) in our Phase 1/2 study of vimseltinib in TGCT, the assessments of efficacy from the Phase 1/2 study of vimseltinib were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of vimseltinib, including our ongoing Phase 3 MOTION study for vimseltinib. These factors also apply to the earlier-stage trials for our drug candidates, such as 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 will 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 Phase 3 INSIGHT study, and our ongoing clinical trials of vimseltinib and 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 will require 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 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 January 2023, we also announced plans to initiate 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 MOTION study of vimseltinib and our Phase 3 INSIGHT study of QINLOCK;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize any current or future drug candidates for which we obtain marketing approval;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug and drug candidates;
- making and maintaining timely and cost-effective arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;

- 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 plan to conduct only one pivotal Phase 3 trial of vimseltinib for patients with TGCT and one pivotal Phase 3 trial of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18, 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 ongoing Phase 1 study of QINLOCK, there were differences observed between imaging data assessed at the clinical sites in accordance with the Phase 1 protocol and by central review, including some instances where central review's findings regarding the number of objective responses were less favorable than those previously reported. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In addition, we, or our licensees, such as Zai in Greater China, may be required to conduct additional clinical trials in the local region or regions where the licensees seek to commercialize our drug or drug candidates before a local regulatory authority will approve any marketing application. These local studies may involve, among other things, exploration of the effect our drug or drug candidates may have on a local population, which could be different than our clinical trial results or experience to date and subject these trials and our development efforts to the risk that they do not support regional approval.

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

In addition, we may:

- be delayed in obtaining marketing approval for our drug or drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or

- have the product, including QINLOCK, removed from the market after obtaining marketing approval.

Risks Related to the Industry

With the exception of QINLOCK, we have not received approval or authorization to market any of our drug candidates from regulatory authorities in any jurisdiction. Even if we complete the necessary clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, which may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates or expand our marketing for QINLOCK in additional geographies. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug and drug candidates 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 European 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, if granted, retain orphan drug exclusivity for our drug or drug candidates.

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

ripretinib for the treatment of GIST 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.

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.

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.

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+17/17 mutations). We have in the past received and may in the future seek a BTD for some of our drug candidates.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

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

Risks Related to Drug Discovery

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 six months ended June 30, 2023 and the year ended December 31, 2022, we reported net losses of $98.2 million and $178.9 million, respectively. As of June 30, 2023, we had an accumulated deficit of $1.3 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 under the Sales Agreement, sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, upfront and milestone payments received under our license agreement with Zai, borrowings under a repaid construction loan, and research and development grants from the Kansas Bioscience Authority. Since our inception, we received an aggregate of $1.5 billion in net proceeds from such transactions. As of June 30, 2023, our cash, cash equivalents, and marketable securities were $389.4 million.

We expect to incur operating losses for the foreseeable future, particularly as we commercialize QINLOCK and advance development of our drug and drug candidates. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to incur significant research and development expenses in connection with our ongoing and 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 Europe in connection with the marketing approval for QINLOCK in select countries in Europe. We have and will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated 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;
- successfully complete our Phase 3 INSIGHT study of QINLOCK and our Phase 3 MOTION study for vimseltinib in patients with TGCT, 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 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 or the development of 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. 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 June 30, 2023, together with anticipated product, royalty, and supply revenues, and the net proceeds from our underwritten public offering completed in January 2023, but excluding any potential future milestone payments under our collaboration or license agreements will enable us to fund our operating expenses and capital expenditure requirements into 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;
- the cost of maintaining, expanding, or contracting out sales, marketing, and distribution capabilities in connection with commercialization of QINLOCK or any future drugs for which we may receive marketing approval;
- the success of our commercialization efforts and market acceptance for QINLOCK or any of our future approved drugs;
- the number and development requirements of drug candidates that we pursue, including ones we may acquire from third parties;
- the costs and timing of arrangements with third parties for the manufacture of clinical and commercial supplies of QINLOCK and our drug candidates;
- the costs, timing, and outcome of regulatory review of our drug candidates and for QINLOCK in additional geographies, including in key European markets;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK and any of our drug candidates for which we obtain marketing approval, as well as infrastructure costs in the U.S. and 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, your ownership interest will be diluted, and the terms of our securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, drug or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or commercialization efforts, or grant rights to develop and market drugs and drug candidates that we would otherwise prefer to develop and market ourselves.

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

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

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

As of June 30, 2023, our executive officers and directors, combined with our stockholders who own more than 10% of our outstanding capital stock, beneficially own shares, in the aggregate, representing approximately 33% 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, any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, these forum selection clauses in our amended and restated 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 ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is unenforceable, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders.

The market price of our common stock may be volatile and fluctuate substantially upon the occurrence of future events, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Our common stock is currently quoted on the Nasdaq Global Select Market under the symbol "DCPH." Since our common stock began trading on the Nasdaq Global Select Market on September 28, 2017, our stock has traded at prices as low as $6.51 per share and as high as $71.11 per share through June 30, 2023. 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. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.

We do not own any manufacturing facilities. We produce in our research laboratories very small quantities of drug substance for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical and clinical testing, and for the commercial manufacture of any of our current and future drugs. As a general matter, our manufacturers represent our sole source of supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality or in a timely manner, which could delay, prevent, or impair our development or commercialization efforts, or those of our partners. Although we actively manage these third-party relationships to ensure continuity, quality, and compliance with regulations, some events beyond our control, including global 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 acquire many key materials on a purchase order basis. As a result, while we have commercial supply arrangements for our drug substance and finished drug product for QINLOCK, we do not have long term supply arrangements with respect to our drug candidates and other materials. We do not currently have arrangements in place for redundant supply or a second source for drug substance or drug product. We rely on our sole source suppliers to manufacture all of our drug substance and finished drug product for commercialization of QINLOCK unless and until we add additional sources. 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 have not yet scaled up the commercial manufacturing process for any of our drug candidates, other than our approved drug, QINLOCK. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug or drug candidates or in the manufacturing facilities in which our drug or drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

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

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

We have in the past, currently have, and may in the future, seek third-party licensees and/or collaborators for the development and commercialization of certain approved drugs or drug candidates on a selective basis. Our likely licensees and/or collaborators for any arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. For example, in 2019, we licensed QINLOCK for development and commercialization in Greater China to Zai, a China and U.S.-based commercial stage biopharmaceutical company. Zai received regulatory approval to market QINLOCK in the PRC, Hong Kong, and Taiwan in 2021 and Macau 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 will initially focus 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 other developing countries, 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 is pending 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 U.S. Congress, the U.S. courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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 product candidates.

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

Under our current license agreements, 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 have decided to opt out of the UPC, we cannot guarantee that our 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 our 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 June 30, 2023, Steven L. Hoerter, our Chief Executive Officer and a section 16 officer, 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. Hoerter’s Rule 10b5-1 Trading Plan was adopted on June 13, 2023 and will continue until June 30, 2024 unless earlier terminated or modified. Under the Rule 10b5-1 Trading Plan, an aggregate number of 237,500 securities can be sold or purchased during the duration of the Rule 10b5-1 Trading Plan, which includes any shares sold to cover mandatory tax withholding obligations.

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).
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).
10.1*	Open Market Sale Agreement℠, dated May 3, 2023, by and between Deciphera Pharmaceuticals, LLC and Jefferies LLC
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 and exhibits have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon its request; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit 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: August 9, 2023

By: /s/ Thomas P. Kelly

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

OPEN MARKET SALE AGREEMENT[SM]

May 3, 2023

JEFFERIES LLC
520 Madison Avenue
New York, New York 10022
Ladies and Gentlemen:

Deciphera Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "**Agent**"), shares of the Company's common stock, par value $0.01 per share (the "**Common Shares**"), on the terms set forth in this agreement (this "**Agreement**").

Section 1. DEFINITIONS

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

"**Affiliate**" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first-mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agency Period**" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

"**Commission**" means the U.S. Securities and Exchange Commission.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

"**Floor Price**" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less than $1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

"**Issuance Amount**" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

[SM] "Open Market Sale Agreement" is a service mark of Jefferies LLC

"**Issuance Notice**" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President or Chief Financial Officer.

"**Issuance Notice Date**" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"**Issuance Price**" means the Sales Price less the Selling Commission.

"**Maximum Program Amount**" means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"**Principal Market**" means The Nasdaq Global Select Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

"**Sales Price**" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"**Selling Commission**" means up to three percent (3.0%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

"**Settlement Date**" means the second business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"**Shares**" shall mean the Company's Common Shares issued or issuable pursuant to this Agreement.

"**Trading Day**" means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, unless such representation, warranty or agreement specifies otherwise, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed or will file with the Commission an automatic shelf registration statement on Form S-3ASR that contains a base prospectus (the "**Base Prospectus**"). Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3ASR under the Securities Act as from time to time amended or supplemented, is herein referred to as the "**Registration Statement,**" and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3ASR under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "**Prospectus,**" except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "**Prospectus**" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "**Original Registration Statement.**" As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing

of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Original Registration Statement originally became effective and at the time the Company's most recent Annual Report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3ASR under the Securities Act. During the Agency Period, each time the Company files an Annual Report on Form 10-K, the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. The Original Registration Statement became automatically effective on filing with the Commission under Rule 462(e) of the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission. No notice of objection of the Commission to the use of such registration statement or any post-effective amendment thereto pursuant to Rule 401(g)(2) under the Securities Act has been received by the Company. The initial effective date of the Registration Statement was not earlier than the date three years before the date hereof.

The Prospectus when filed complied or will comply in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("**EDGAR**") (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus (as defined below) considered together (collectively, the "**Time of Sale Information**") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only

such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Issuer Status. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act and is a "well-known seasoned issuer," as defined in Rule 405 under the Securities Act (a "**WKSI**"). Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent's prior consent, prepare, use or refer to, any Free Writing Prospectus.

(d) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(e) Due Authorization. The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation by it of the transactions contemplated hereby has been duly and validly taken.

(f) This Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(g) Authorization of the Shares. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(h) Description of the Agreement. This Agreement conforms in all material respects to the description thereof contained in the Prospectus.

(i) No Material Adverse Change. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, (i) there has not been any material change in the capital stock (other than the issuance of equity interests or Common Shares upon exercise of options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement and the Prospectus), short-term debt or long-term debt of the Company, or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a prospective material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole (any such change being referred to herein as a "**Material Adverse Change**"); (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the business of the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement and the Prospectus.

(j) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries included or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly in all material respects the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles ("**GAAP**") in the United States applied on a consistent basis throughout the periods covered thereby, except in the case of unaudited financial statements, which are subject to normal year end adjustment and do not contain certain footnotes as permitted by the applicable rules of the Commission, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly in all material respects the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly in all material respects the information shown thereby.

(k) Organization and Good Standing. The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing (to the extent such concepts

are applicable under such laws) under the laws of their respective jurisdictions of organization, are duly qualified to do business and are in good standing (to the extent such concepts are applicable under such laws) in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a "**Material Adverse Effect**"). The Company does not have any significant subsidiary as defined in Rule 1-20(w) of Regulation S-X other than the subsidiaries listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the most recently ended fiscal year.

(l) Capitalization and Other Capital Stock Matters. The Company has an authorized capitalization as set forth in the Registration Statement and the Prospectus; all the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are not subject to any pre-emptive or similar rights; except as described in or expressly contemplated by the Registration Statement and the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company or any such subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options; the capital stock of the Company conforms in all material respects to the description thereof contained in the Registration Statement and the Prospectus; and except as otherwise disclosed in the Registration Statement and the Prospectus, all the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly and validly authorized and issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

(m) Stock Options. With respect to the stock options (the "**Stock Options**") granted pursuant to the stock-based compensation plans of the Company = (the "**Company Stock Plans**"), (i) each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**"), so qualifies, (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (iii) each such grant was made in all material respects in accordance with the terms of the Company Stock Plans, the Exchange Act and all

other applicable laws and regulatory rules or requirements including the rules of the Nasdaq Global Select Market and any other exchange on which Company securities are traded, and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company and disclosed in the Company's filings with the Commission in accordance with the Exchange Act. The Company has not knowingly granted, and there is no and has been no policy or practice of the Company of granting, Stock Options prior to, or otherwise coordinating the grant of Stock Options with, the release or other public announcement of material information regarding the Company or its subsidiaries or their results of operations or prospects.

(n) Stock Exchange Listing. The Common Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance in all material respects with all applicable listing requirements of the Principal Market.

(o) No Violation or Default. Neither the Company nor any of its significant subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its significant subsidiaries is a party or by which the Company or any of its significant subsidiaries is bound or to which any property or asset of the Company or any of its significant subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

(p) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by this Agreement or the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, result in the termination, modification or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of the Company or any of its significant subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its significant subsidiaries is a party or by which the Company or any of its significant subsidiaries is bound or to which any property, right or asset of the Company or any of its significant subsidiaries is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its significant subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (i) and (iii) above, for any such conflict, breach,

violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, have a Material Adverse Effect.

(q) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by this Agreement, except for the registration of the Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Financial Industry Regulatory Authority, Inc. ("**FINRA**") and under applicable state securities laws in connection with the purchase and distribution of the Shares by the Agent.

(r) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, and to its knowledge, by its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with FINRA rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct. The Company meets the definition of the term "experienced issuer" specified in FINRA Rule 5110(j)(6).

(s) Legal Proceedings. Except as described in the Registration Statement and the Prospectus, there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings ("**Actions**") pending to which the Company or any of its significant subsidiaries is a party or to which any property of the Company or any of its significant subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or any of its significant subsidiaries, would reasonably be expected to have a Material Adverse Effect; no such Actions are threatened or, to the knowledge of the Company, contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending Actions that are required under the Securities Act to be described in the Registration Statement or the Prospectus that are not so described in the Registration Statement and the Prospectus and (ii) there are no statutes, regulations or contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement or described in the Registration Statement or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement and the Prospectus.

(t) Independent Accountants. PricewaterhouseCoopers LLP, who have certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.

(u) Title to Real and Personal Property. The Company and its significant subsidiaries have good and marketable title in fee simple (in the case of real property) to, or have valid rights to lease or otherwise use, all items of real and personal property that are material to the respective businesses of the Company and its significant subsidiaries, in each case free and clear

of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its significant subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(v) Intellectual Property. Except as could not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, (i) the Company and its significant subsidiaries own or possess adequate rights to use all patents, trademarks, service marks, trade names, domain names and other source indicators, copyrights and copyrightable works, licenses and know-how, trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures, and all other worldwide intellectual property, industrial property and proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, the foregoing) (collectively, "**Intellectual Property**") used in or necessary for the conduct of their respective businesses as currently conducted and as proposed to be conducted in the Registration Statement and the Prospectus; (ii) to the knowledge of the Company and its significant subsidiaries, the Company and its significant subsidiaries' conduct of their respective businesses has not conflicted with, infringed, misappropriated or otherwise violated any Intellectual Property of any third party (it being understood that the foregoing representation and warranty is made without giving effect to any exemption under applicable law to which the Company or its significant subsidiaries may be entitled (*e.g.*, 35 U.S.C. Section 271(e)(1))); (iii) the Company and its significant subsidiaries have not received any written notice of any claim of infringement, misappropriation or other violation of, or conflict with, any Intellectual Property of any third party, or any written notice challenging the ownership, validity, enforceability or scope of any Intellectual Property of the Company or its significant subsidiaries; (iv) to the knowledge of the Company, the Intellectual Property of the Company and its significant subsidiaries has not been in conflict with, infringed, misappropriated or otherwise violated by any third party; and (v) to the knowledge of the Company and its significant subsidiaries, all Intellectual Property of the Company and its significant subsidiaries is valid and enforceable.

(w) No Undisclosed Relationships. No relationship, direct or indirect, exists between or among the Company or any of its significant subsidiaries, on the one hand, and the directors, officers, stockholders, customers, suppliers or other affiliates of the Company or any of its significant subsidiaries, on the other, that is required by the Securities Act to be described in each of the Registration Statement and the Prospectus and that is not so described in such documents.

(x) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Common Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(y) Investment Company Act. The Company is not nor after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Registration Statement and the Prospectus will be an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the "**Investment Company Act**").

(z) Taxes. The Company has paid all federal, state, local and foreign taxes and filed all tax returns required to be paid or filed through the date hereof, except where the failure to pay or file would not have a Material Adverse Effect; and except as otherwise disclosed in each of the Registration Statement and the Prospectus, there is no tax deficiency that has been, or would reasonably be expected to be, asserted against the Company or any of its significant subsidiaries or any of their respective properties or assets and which would have a Material Adverse Effect.

(aa) Licenses and Permits. The Company and its significant subsidiaries possess all licenses, sub-licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in each of the Registration Statement and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in each of the Registration Statement and the Prospectus, neither the Company nor any of its significant subsidiaries has received notice of any revocation or material modification of any such license, sub-license, certificate, permit or authorization or has any reason to believe that any such license, sub-license, certificate, permit or authorization will not be renewed in the ordinary course, except where such revocation, modification or nonrenewal would not have a Material Adverse Effect.

(bb) No Labor Disputes. No labor disturbance by or dispute with employees of the Company or Deciphera Pharmaceuticals, LLC (the "**LLC**") exists or, to the knowledge of the Company is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except as would not have a Material Adverse Effect. Neither the Company nor the LLC has received any notice of cancellation or termination with respect to any collective bargaining agreement to which it is a party.

(cc) Certain Environmental Matters. (i) The Company and its significant subsidiaries (x) are in compliance with all, and have not violated any, applicable federal, state, local and foreign laws (including common law), rules, regulations, requirements, decisions, judgments, decrees, orders and other legally enforceable requirements relating to pollution or the protection of human health or safety, the environment, natural resources, hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "**Environmental Laws**"); (y) have received and are in compliance with all, and have not violated any, permits, licenses, certificates or other authorizations or approvals required of them under any Environmental Laws to conduct their respective businesses; and (z) have not received notice of any actual or potential liability or obligation under or relating to, or any actual or potential violation of, any Environmental Laws,

including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its significant subsidiaries, except in the case of each of (i) and (ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in each of the Registration Statement and the Prospectus, (x) there is no proceeding that is pending, or to the Company's knowledge, contemplated, against the Company or any of its significant subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed, (y) the Company and its significant subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its significant subsidiaries, and (z) none of the Company or its significant subsidiaries anticipate material capital expenditures relating to any Environmental Laws.

(dd) Compliance with ERISA. (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), for which the Company or any member of its "Controlled Group" (defined as any entity, whether or not incorporated, that is under common control with the Company within the meaning of Section 4001(a)(14) of ERISA or any entity that would be regarded as a single employer with the Company under Section 414(b),(c),(m) or (o) of the Code) would have any liability (each, a "**Plan**") has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no Plan has failed (whether or not waived), or is reasonably expected to fail, to satisfy the minimum funding standards (within the meaning of Section 302 of ERISA or Section 412 of the Code) applicable to such Plan; (iv) no Plan is, or is reasonably expected to be, in "at risk status" (within the meaning of Section 303(i) of ERISA) and no Plan that is a "multiemployer plan" within the meaning of Section 4001(a)(3) of ERISA is in "endangered status" or "critical status" (within the meaning of Sections 304 and 305 of ERISA) (v) the fair market value of the assets of each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan); (vi) no "reportable event" (within the meaning of Section 4043(c) of ERISA and the regulations promulgated thereunder) has occurred or is reasonably expected to occur; (vii) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification; (viii) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guarantee Corporation, in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan" within the meaning

of Section 4001(a)(3) of ERISA); and (ix) none of the following events has occurred or is reasonably likely to occur: (A) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company or its Controlled Group affiliates in the current fiscal year of the Company and its Controlled Group affiliates compared to the amount of such contributions made in the Company's and its Controlled Group affiliates' most recently completed fiscal year; or (B) a material increase in the Company and its significant subsidiaries' "accumulated post-retirement benefit obligations" (within the meaning of Accounting Standards Codification Topic 715-60) compared to the amount of such obligations in the Company and its significant subsidiaries' most recently completed fiscal year, except in each case with respect to the events or conditions set forth in (i) through (ix) hereof, as would not, individually or in the aggregate, have a Material Adverse Effect.

(ee) Disclosure Controls. The Company and each of its significant subsidiaries maintain an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company has carried out evaluations of the effectiveness of its disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

(ff) Accounting Controls. The Company and the each of its significant subsidiaries maintain systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company maintains internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Based on the Company's most recent evaluation of its internal controls over financial reporting pursuant to Rule 13a-15(c) of the Exchange Act, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which have adversely affected or are

reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) to the knowledge of the Company, any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

(gg) eXtensible Business Reporting Language. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(hh) Insurance. The LLC has insurance covering its properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as are generally maintained by similarly situated companies and which the Company believes are reasonably adequate to protect the LLC and its business; and the LLC has not (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) knowledge of any events that have occurred, or circumstances that exist, with respect to the LLC that would cause it to be unable to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

(ii) Cybersecurity. (i)(x) Except as disclosed in the Registration Statement and the Prospectus, there has been no security breach, attack or other compromise of or relating to any of the Company's or any of its subsidiaries' information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, "**IT Systems and Data**") and (y) the Company and its subsidiaries have not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems and Data; (ii) the Company and its subsidiaries have been in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to (x) the privacy and security of IT Systems and Data, (y) the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification and (z) the collection, use, transfer, storage, disposal and disclosure by the Company and its subsidiaries of personally identifiable information and/or any other information collected from or provided by third parties, except as would not, in the case of this clause (ii), individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and its subsidiaries have implemented commercially reasonable backup and disaster recovery and security plans, procedures and facilities for their respective businesses consistent with industry standards and practices; and (iv) the Company and its subsidiaries have taken commercially reasonable steps to protect the IT Systems and Data.

(jj) No Unlawful Payments. Neither the Company nor any of its subsidiaries nor any director, officer or employee of the Company or any of its subsidiaries nor, to the knowledge of the Company, any agent, Affiliate or other person associated with or acting on behalf of the

Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(kk) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with financial recordkeeping and reporting requirements applicable to such entities, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines applicable to such entities issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(ll) No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries, directors, officers, or employees, nor, to the knowledge of the Company, any agent, Affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S. government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**") or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council ("**UNSC**"), the European Union, His Majesty's Treasury ("**HMT**") or other relevant sanctions authority (collectively, "**Sanctions**"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or target of Sanctions, including, without limitation, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, the so-called Luhansk People's Republic, Cuba, Iran, North Korea, and Syria (each, a "**Sanctioned Country**"); and the Company and its subsidiaries will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person

or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(mm) No Restrictions on Subsidiaries. No significant subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock or similar ownership interest, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary of the Company.

(nn) No Broker's Fees. Except as otherwise disclosed in the Prospectus, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(oo) No Registration Rights. No person has the right to require the Company to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Shares, other than rights that have been validly waived.

(pp) Margin Rules. Neither the issuance, sale and delivery of the Shares nor the application of the proceeds thereof by the Company as described in each of the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(qq) Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) included or incorporated by reference in any of the Registration Statement or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(rr) Statistical and Market Data. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included or incorporated by reference in each of the Registration Statement and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

(ss) Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002, as amended and the rules and regulations promulgated in connection therewith (the "**Sarbanes-Oxley Act**"), including Section 402 related to loans and Sections 302 and 906 related to certifications.

(tt) Status Under the Securities Act. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or any offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) under the Securities Act) of the Shares and at the date hereof, the Company is a "well-known seasoned issuer", in each case as defined in Rule 405 under the Securities Act. The Company has paid the registration fee for this offering pursuant to Rule 456(b)(1) under the Securities Act or will pay such fee within the time period required by such rule (without giving effect to the proviso therein) and in any event in connection with the filing of the Prospectus.

(uu) No Ratings. There are, and will be at each Time of Sale, no debt securities or preferred stock issued or guaranteed by the Company or any of its subsidiaries that are rated by a "nationally recognized statistical rating organization", as such term is defined under Section 3(a)(62) under the Exchange Act.

(vv) Preclinical and Clinical Studies. (i) Except as described in the Registration Statement and the Prospectus, the preclinical and clinical studies conducted by or, to the knowledge of the Company, on behalf of or sponsored by the Company, or in which the Company has participated, that are described in the Registration Statement and the Prospectus, or the results of which are referred to in the Registration Statement and the Prospectus, as applicable, were, and if still pending are, being conducted in all material respects in accordance with standard medical and scientific research standards and procedures for products or product candidates comparable to those being developed by the Company and all applicable statutes and all applicable rules and regulations of the U.S. Food and Drug Administration, any U.S. state departments of health and boards of pharmacy, and comparable regulatory agencies outside of the United States to which they are subject, including the European Medicines Agency (collectively, the "**Regulatory Authorities**") and Good Clinical Practice and Good Laboratory Practice requirements; (ii) the descriptions in the Registration Statement and the Prospectus of the results of such studies are accurate and complete descriptions in all material respects and fairly present the data derived therefrom; (iii) the Company does not have any knowledge of any other studies not described in the Registration Statement and the Prospectus, the results of which are inconsistent with or call into question the results described or referred to in the Registration Statement and the Prospectus; (iv) the Company has operated at all times and are currently in compliance in all material respects with all applicable statutes, rules and regulations of the Regulatory Authorities, except where such non-compliance would not, individually or in the aggregate, have a Material Adverse Effect; and (v) the Company, to the Company's knowledge, has not received any written notices, correspondence or other communications from the Regulatory Authorities or any other governmental agency requiring or threatening the termination, material modification or suspension of any preclinical or clinical studies that are described in the Registration Statement and the Prospectus or the results of which are referred to in the Registration Statement and the Prospectus, other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies, and to the Company's knowledge, there are no reasonable grounds for the same.

(ww) Regulatory Filings. The Company has not failed to file with the Regulatory Authorities any required filing, declaration, report or submission with respect to the Company's

product candidates that are described or referred to in the Registration Statement and the Prospectus; all such filings, declarations, reports or submissions were in material compliance with applicable laws when filed; and no deficiencies regarding compliance with applicable law have been asserted by any applicable regulatory authority with respect to any such filings, declarations, reports or submissions.

(xx) Duties, Transfer Taxes, Etc. No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by the Agent in the United States or any political subdivision or taxing authority thereof or therein in connection with the execution, delivery or performance of this Agreement by the Company or the sale and delivery by the Company of the Shares.

(yy) WKSI. (A) At the original effectiveness of the Registration Statement, (B) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Securities Act (whether such amendment was by post-effective amendment or incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or in the form of a prospectus), (C) at the time the Company or any person acting on its behalf (within the meaning, for this clause only, of Rule 163(c) under the Securities Act) made any offer relating to the Shares in reliance on the exemption of Rule 163 under the Securities Act, and (D) as of the Representation Date, the Company was and is a "well-known seasoned issuer" (as defined in Rule 405).

(zz) Regulatory Matters; Products and Product Candidates. Except as described in the Registration Statement and the Prospectus, the Company (collectively with its subsidiaries) and except, in each case, as would not, individually or in the aggregate, have a Material Adverse Effect: (i) has operated and currently operates its business in compliance with all Health Care Laws (as defined below) applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's product candidates and any product manufactured or distributed by the Company; (ii) has not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other written correspondence or notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Health Care Laws or (B) any licenses, certificates, approvals, clearances, exemptions, authorizations, permits and supplements or amendments thereto required by any such Health Care Laws ("Regulatory Authorizations"); (iii) possesses all Regulatory Authorizations required to conduct its business as currently conducted, and such Regulatory Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Regulatory Authorizations; (iv) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA, the Department of Health and Human Services or any comparable foreign or other regulatory authority to which they are subject (collectively, the "Applicable Regulatory Authorities") alleging that any product candidate or product of the Company is in violation of any Health Care Laws or Regulatory Authorizations and has no knowledge that the Applicable Regulatory Authorities or any other third party is threatening any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received written notice that any of the Applicable Regulatory Authorities

has taken, is taking or intends to take action to limit, suspend, or revoke any Regulatory Authorizations and has no knowledge that any of the Applicable Regulatory Authorities is considering such action; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Regulatory Authorizations and, to the knowledge of the Company, that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were materially corrected or supplemented by a subsequent submission); (vii) is not a party to and does not have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred or non-prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Applicable Regulatory Authority; and (viii) along with its employees, officers and directors, has not been excluded, suspended or debarred from participation in any government health care program or human clinical research and, to the knowledge of the Company, is not subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

The term "Health Care Laws" means Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute); the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act, 42 U.S.C. 1320a-7b(a); any criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1347 and 1349, and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq. ("HIPAA"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a and 1320a-7b; the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the Exclusion Statute, 42 U.S.C. § 1320a-7; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) and Section 1899 of the Social Security Act; the regulations promulgated pursuant to such laws; and any other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company and the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product candidate or product under development, manufactured or distributed by the Company.

(aaa) Privacy Laws. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have complied and are presently in compliance with all internal and external privacy policies, industry standards, all applicable statutes, judgments, orders, rules, regulations of any court or arbitrator or other governmental or regulatory entity, any other legal obligations, and applicable data privacy and security laws and regulations, including, without limitation, the California Consumer Privacy Act ("CCPA"), the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, "Privacy Laws") and any other applicable contractual obligation, in each case relating to the collection, use, transfer, import, export, storage, protection, disposal and disclosure by the Company or any of its subsidiaries of personal, personally identifiable,

household, sensitive, confidential or regulated data ("Data Security Obligations"). To ensure compliance with the Data Security Obligations, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling and analysis of Personal Data (the "Policies"). The Company provides accurate notice of its Policies to its employees, third party vendors and representatives as required by the applicable Privacy Laws. The Policies provide accurate and sufficient notice of the Company's then-current privacy practices relating to its subject matter and such Policies do not contain any material omissions of the Company's then-current privacy practices. "Personal Data" means (i) a natural persons' name, street address, telephone number, email address, photograph, social security number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR; and (iv) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. To the Company's knowledge, none of such disclosures made or contained in any of the Policies have been inaccurate, misleading, deceptive or in violation of any Privacy Laws or Policies, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries, (i) has received written notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Privacy Law; (iii) is a party to any order, decree, or agreement that imposed any obligation or liability under any Privacy Law or (iv) is a party to any action, suit or proceeding by or before any court or governmental agency, authority or body pending or, to the Company's knowledge, threatened alleging non-compliance with any Data Security Obligation.

(bbb) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(p) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent,

acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(bb) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; provided, however, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule 2 hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in negotiated transactions with the prior written consent of the Company or (B) by any other method permitted by law deemed to be an "**at the market offering**" as defined in Rule 415(a)(4) under the Securities Act, including block transactions, sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clause (A) above) the method of placement of any Shares by the Agent shall be at the Agent's discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable e-mail), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; provided, however, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "**Blue Sky Survey**" or memorandum and a "**Canadian wrapper**", and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; (ix) the costs and expenses of the Company relating to investor presentations on any "**road show**" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) $75,000 in connection with execution of this Agreement, (B) $25,000 in connection with each Triggering Event Date (as defined below) involving the filing of a Form 10-K on which the Company is required to provide a certificate pursuant to Section 4(o) and (C) $15,000 in connection with each other Triggering Event Date on which the Company is required to provide a certificate pursuant to Section 4(o).

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "**Interim Prospectus Supplement**"), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, any Free Writing Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes; and (v) of the Company losing its status as a WKSI as of the time the Company files with the Commission an annual report on Form 10-K. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and Section 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to

make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act (it being acknowledged that the Company may delay the filing of any amendment or supplement if, in the judgment of the Company, it is in the best interest of the Company). Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 4(d) and Section 4(f).

(d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Use of Free Writing Prospectus. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

(f) Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances

prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed.

(g) Filing of Agent Free Writing Prospectuses. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

(h) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance (it being acknowledged that the Company may delay the filing of any amendment or supplement if, in the judgment of the Company, it is in the best interest of the Company); provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from

the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its commercially reasonable efforts to obtain the withdrawal thereof as soon as practicable.

(j) Earnings Statement. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(k) Listing; Reservation of Shares. (a) The Company will maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(l) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an Annual Report on Form 10-K or a Quarterly Report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed Annual Report on Form 10-K or Quarterly Report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such Current Report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) confirming that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a

certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, a negative assurances letter and the written legal opinion of Goodwin Procter LLP, counsel to the Company, and Goodwin Procter LLP, intellectual property counsel to the Company, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided that the Company shall be required to furnish no more than one opinion and negative assurances letter per calendar quarter and the Company shall not be required to furnish any such opinion or letter if the Company does not intend to deliver an Issuance Notice in such calendar quarter until such time as the Company delivers the next Issuance Notice. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

(q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause PricewaterhouseCoopers LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. At any time when an Issuance Notice is outstanding, if requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent on the date of occurrence of any material transaction or event requiring the filing of a Current Report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter hereunder per each filing of an annual report on Form 10-K or a Quarterly Report on Form 10-Q.

(r) Secretary's Certificate. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such

certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company and (iii) containing any other certification that the Agent shall reasonably request.

(s) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(u) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its Affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall cause each of its Affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply. The Company shall promptly notify the Agent if it no longer meets the requirements set forth in Section (d) of Rule 102.

(v) Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, or effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Common Shares, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice; and will not directly or indirectly enter into any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be required in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under

Nasdaq rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities, settlement of restricted stock units or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement, and (iii) issuance or sale of Common Shares or securities convertible into or exchangeable for Common Shares as consideration for mergers, acquisitions, other business combinations, joint ventures or strategic alliances occurring after the date of this Agreement which are not used for capital raising purposes, *provided* that the aggregate number of Common Shares issued, or issuable pursuant to the conversion or exchange of securities convertible into or exchangeable for Common Shares, under this subsection (iii) does not exceed 5% of the aggregate number of Common Shares outstanding immediately prior to giving effect to such issuance or sale and (iv) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

(i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).

(ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(iii) Material Adverse Changes. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any

securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Principal Market, Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or the FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Agent Counsel Legal Opinion. Agent shall have received from Cooley LLP, counsel for Agent, such opinion or opinions, on or before the date on which the delivery of the Company counsel legal opinion is required pursuant to Section 4(p), with respect to such matters as Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and to reimburse the Agent and each such officer, employee and controlling person for any and all expenses (including the fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in subsection (b) below. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged

untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the first sentence of the ninth paragraph under the caption "Plan of Distribution" in the Prospectus, and to reimburse the Company and each such director, officer and controlling person for any and all expenses (including the fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the

preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section 6(b) above), (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall

be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(c) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this Section 6(e), the Agent shall not be required to contribute any amount in excess of the Selling Commission received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) Term. Subject to the provisions of this Section 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

(i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the

Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 3(d), Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement. Upon termination of this Agreement, the Company shall not have any liability to the Agent for any discount, commission or other compensation with respect to any Shares not otherwise sold by the Agent under this Agreement.

(ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8 K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules . If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm’s-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with

respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered, sent via electronic mail (if applicable) or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC
520 Madison Avenue
New York, NY 10022
Facsimile: (646) 786-57149
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Cooley LLP
55 Hudson Yards
New York, NY 10001
Attention: Daniel I. Goldberg, Esq.
E-mail: dgoldberg@cooley.com

If to the Company:

Deciphera Pharmaceuticals, Inc.
200 Smith Street
Waltham, MA 02451
Attention: Steven L. Hoerter
E-mail: shoerter@deciphera.com

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Richard Hoffman, Esq.
E-mail: rhoffman@goodwinlaw.com

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

(e) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "successors" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(f) Partial Unenforceability. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(g) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and terminates and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof, including that certain Open Market Sale Agreement dated August 4, 2020, as amended, between the Company and the Agent. This Agreement may be executed in two or

more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file(including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com). This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[*Signature Page Immediately Follows*]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Name: Steven L. Hoerter
Title: President and Chief Executive Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: /s/ Michael Magarro
Name: Michael Magarro
Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

[Date]

Jefferies LLC
520 Madison Avenue
New York, New York 10022
Attn: [_____]

Reference is made to the Open Market Sale Agreement℠ between Deciphera Pharmaceuticals, Inc. (the "**Company**") and Jefferies LLC (the "**Agent**") dated as of May 3, 2023. The Company

confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)):

_____

Issuance Amount (equal to the total Sales Price for such Shares):

$

Number of days in selling period:

First date of selling period:

Last date of selling period:

Settlement Date(s) if other than standard T+2 settlement:

Floor Price Limitation (in no event less than $1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent's sole discretion): $ ____ per share

Comments:

By:
Name:
Title:

Schedule 2

Notice Parties

The Company

Steven L. Hoerter

Thomas P. Kelly

Jennifer Larson

Jeffrey M. Held

Meghan McDevitt

The Agent

Dustin Tyner

Jesse Mark

Charlie Glazer

Michael Magarro

Donald Lynaugh

Jack Fabbri

Form of Officer's Certificate Pursuant to Section 4(o)

The undersigned, the duly qualified and elected [●] of Deciphera Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 4(o) of the Open Market Sale Agreement℠, dated May 3, 2023, between the Company and Jefferies LLC (the "**Sale Agreement**"), that to the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 2 of the Sale Agreement are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof; provided, however that such representations and warranties are qualified by the disclosure included or incorporated by reference in the Registration Statement and Prospectus (including any documents incorporated by reference therein and any supplements thereto); and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sale Agreement at or prior to the date hereof.

Goodwin Procter LLP and Cooley LLP are entitled to rely on this certificate in connection with the respective opinions such firms are rendering pursuant to the Sale Agreement. Capitalized terms used herein without definition shall have the meanings given to such terms in the Sale Agreement.

DECIPHERA PHARMACEUTICALS, INC.

By:

Name:

Title:

Date: [•]

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: August 9, 2023

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: August 9, 2023

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 June 30, 2023 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: August 9, 2023

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 June 30, 2023 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: August 9, 2023

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