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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 September 30, 2022

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 October 28, 2022, there were 67,576,051 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:

- Our corporate strategy and restructuring plan may not be successful.
- 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 Germany and a post-approval paid access program in France, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.
- We have limited experience as a commercial company and the marketing and sale of QINLOCK or any future approved drugs may be unsuccessful or less successful than anticipated.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug candidates, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.
- Our 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 drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.
- The commercial success of QINLOCK, and of any future approved drugs, 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 clinical trials of vimseltinib or 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 ongoing pandemic of the novel coronavirus (COVID-19), including the emergence of new variants and subvariants, recurring surges and waves of infection, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research, development, and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition, and results of operations.
- 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" in this Form 10-Q and include, among other things:

- our ability to successfully commercialize or otherwise provide access to QINLOCK for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib, in the U.S., 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, including the timing of our investigational new drug (IND) applications, and clearance thereof, for any other drug candidates;
- our ability to successfully complete the Phase 3 MOTION study for vimseltinib in 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;
- 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, and patient support activities, and our pricing of QINLOCK;
- the pricing and reimbursement of, and the extent to which patient assistance programs are utilized for, QINLOCK, or any current or future drug candidates for which we may receive marketing approval;
- our expectations regarding the size 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 operations;
- our ability to manufacture or obtain sufficient quantities of QINLOCK or our drug candidates, on a timely basis, to support our planned clinical trials and commercialization of QINLOCK or any of our current or future drug candidates for which we may receive marketing approval;
- the therapeutic benefit and effectiveness of QINLOCK and our drug candidates;
- the safety profile and related adverse events of QINLOCK and our drug candidates;
- our commercial preparedness efforts and our ability to 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, if approved, in 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;
- our ability to attract additional licensees and/or collaborators or distributors with development, regulatory, and commercialization expertise;

- our expectations regarding our ability to obtain, maintain, enforce, and defend our intellectual property protection for QINLOCK or our drug candidates;
- future agreements with third parties in connection with the commercialization of QINLOCK or any of our current or future drug candidates for which we may receive marketing approval;
- regulatory and legal developments in the U.S. and foreign countries;
- our ability to comply with healthcare laws and regulations in the U.S., key European markets, and any other foreign countries, including, without limitation, those applying to the marketing and sale of commercial drugs;
- the performance and experience of our third-party suppliers and manufacturers;
- the success and timing of competing therapies that are or may become available;
- our ability to attract and retain key scientific, medical, commercial, and management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- the success of the implementation of our corporate restructuring intended to prioritize clinical development of select programs, streamline commercial operations, maintain a focus on discovery research, and extend our cash runway;
- 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 continuing COVID-19 pandemic, which could harm our commercialization efforts for QINLOCK as well as the value of our common stock and our ability to access capital markets;
- natural and manmade disasters, including pandemics such as COVID-19, and other force majeures, which could impact our operations, and those of our partners and other participants in the health care industry, and which could adversely impact our clinical studies, preclinical research activities, and drug supply; and
- our use of the proceeds from our follow-on public offerings and any other financing transaction we may undertake.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere in this Form 10-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® word mark and logo and the QINLOCK® word mark and logo are registered trademarks 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 82,538	$ 87,063
Short-term marketable securities	282,039	198,571
Accounts receivable, net	23,278	20,595
Inventory	19,129	14,125
Prepaid expenses and other current assets	13,895	18,660
Total current assets	420,879	339,014
Long-term marketable securities	7,006	41,950
Long-term investments—restricted and other long-term assets	3,276	3,110
Property and equipment, net	7,152	8,610
Operating lease assets	37,639	36,800
Total assets	$ 475,952	$ 429,484
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,800	$ 13,130
Accrued expenses and other current liabilities	59,498	80,773
Operating lease liabilities	3,170	2,870
Total current liabilities	75,468	96,773
Operating lease liabilities, net of current portion	26,708	27,991
Total liabilities	102,176	124,764
Commitments and contingencies (Note 8)		
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; 67,429,720 shares and 58,549,644 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	674	585
Additional paid-in capital	1,562,572	1,358,516
Accumulated other comprehensive income (loss)	(2,042)	51
Accumulated deficit	(1,187,428)	(1,054,432)
Total stockholders' equity	373,776	304,720
Total liabilities and stockholders' equity	$ 475,952	$ 429,484

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenues, net	$ 32,318	$ 21,682	$ 92,624	$ 63,692
Collaboration revenues	3,656	1,538	5,067	8,257
Total revenues	35,974	23,220	97,691	71,949
Cost and operating expenses:				
Cost of sales	3,344	917	5,525	2,414
Research and development	47,485	66,444	139,755	182,109
Selling, general, and administrative	30,026	35,527	87,972	99,102
Total cost and operating expenses	80,855	102,888	233,252	283,625
Loss from operations	(44,881)	(79,668)	(135,561)	(211,676)
Other income (expense):				
Interest and other income, net	1,838	(170)	2,565	107
Total other income (expense), net	1,838	(170)	2,565	107
Net loss	$ (43,043)	$ (79,838)	$ (132,996)	$ (211,569)
Net loss per share—basic and diluted	$ (0.55)	$ (1.37)	$ (1.82)	$ (3.65)
Weighted average common shares outstanding—basic and diluted	78,206,647	58,107,611	73,129,804	57,948,612
Comprehensive loss:				
Net loss	$ (43,043)	$ (79,838)	$ (132,996)	$ (211,569)
Other comprehensive income (loss):				
Unrealized losses on marketable securities	(422)	(9)	(1,619)	(32)
Currency translation adjustment	(352)	148	(474)	186
Total other comprehensive income (loss)	(774)	139	(2,093)	154
Total comprehensive loss	$ (43,817)	$ (79,699)	$ (135,089)	$ (211,415)

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, June 30, 2022	66,815,511	$ 668	$ 1,549,996	$ (1,268)	$ (1,144,385)	$ 405,011
Issuance of common stock upon pre-funded warrant exercise	575,482	6	—	—	—	6
Issuance of common stock under stock option and incentive plans	38,727	—	203	—	—	203
Stock-based compensation expense	—	—	12,373	—	—	12,373
Other comprehensive income (loss)	—	—	—	(774)	—	(774)
Net loss	—	—	—	—	(43,043)	(43,043)
Balance, September 30, 2022	67,429,720	$ 674	$ 1,562,572	$ (2,042)	$ (1,187,428)	$ 373,776

	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 and pre-funded warrants, net of underwriting discounts, commissions and offering costs	7,501,239	75	163,278	—	—	163,353
Issuance of common stock upon pre-funded warrant exercise	892,798	9	—	—	—	9
Issuance of common stock under stock option and incentive and employee stock purchase plans	486,039	5	1,149	—	—	1,154
Stock-based compensation expense	—	—	39,629	—	—	39,629
Other comprehensive income (loss)	—	—	—	(2,093)	—	(2,093)
Net loss	—	—	—	—	(132,996)	(132,996)
Balance, September 30, 2022	67,429,720	$ 674	$ 1,562,572	$ (2,042)	$ (1,187,428)	$ 373,776

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, June 30, 2021	58,033,984	$ 580	$ 1,332,249	$ 26	$ (886,199)	$ 446,656
Issuance of common stock under stock option and incentive plans	293,905	3	1,703	—	—	1,706
Stock-based compensation expense	—	—	11,794	—	—	11,794
Other comprehensive income (loss)	—	—	—	139	—	139
Net loss	—	—	—	—	(79,838)	(79,838)
Balance, September 30, 2021	58,327,889	$ 583	$ 1,345,746	$ 165	$ (966,037)	$ 380,457

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2020	57,596,144	$ 576	$ 1,297,557	$ 11	$ (754,468)	$ 543,676
Issuance of common stock, net of underwriting discounts, commissions and offering costs	172,094	2	8,546	—	—	8,548
Issuance of common stock under stock option and incentive and employee stock purchase plans	559,651	5	4,359	—	—	4,364
Stock-based compensation expense	—	—	35,284	—	—	35,284
Other comprehensive income (loss)	—	—	—	154	—	154
Net loss	—	—	—	—	(211,569)	(211,569)
Balance, September 30, 2021	58,327,889	$ 583	$ 1,345,746	$ 165	$ (966,037)	$ 380,457

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (132,996)	$ (211,569)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	39,629	35,284
Depreciation expense	2,345	2,234
Noncash lease expense	3,035	2,527
Acquired in-process research and development	—	4,000
Net (accretion) amortization of (discounts) premium on marketable securities	(390)	1,392
Changes in operating assets and liabilities:		
Accounts receivable	(3,014)	(4,153)
Inventory	(3,746)	(3,275)
Prepaid expenses and other current assets	2,034	(5,240)
Other long-term assets	(167)	—
Accounts payable	(250)	1,178
Accrued expenses and other current liabilities	(22,013)	5,823
Operating lease liabilities	(2,171)	(1,849)
Net cash flows used in operating activities	(117,704)	(173,648)
Cash flows from investing activities:		
Purchases of marketable securities	(240,592)	(313,718)
Maturities of marketable securities	190,839	360,076
Sales of marketable securities	—	38,617
Purchases of property and equipment	(860)	(3,079)
Acquired in-process research and development	—	(4,000)
Net cash flows (used in) provided by investing activities	(50,613)	77,896
Cash flows from financing activities:		
Proceeds from offerings of common stock and pre-funded warrants, net of underwriting discounts and commissions	163,778	8,588
Proceeds from pre-funded warrant exercise	9	—
Payments of offering costs	(425)	(40)
Proceeds from stock option exercises and employee stock purchase plan	1,154	4,364
Net cash flows provided by financing activities	164,516	12,912
Net decrease in cash and cash equivalents	(3,801)	(82,840)
Effect of exchange rate changes on cash and cash equivalents	(724)	132
Cash and cash equivalents at beginning of period	87,063	135,897
Cash and cash equivalents at end of period	$ 82,538	$ 53,189

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 kinase inhibitor, was engineered using its proprietary drug discovery platform and developed for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is approved in Australia, Canada, China, the European Union (EU), Hong Kong, Switzerland, Taiwan, the United States (U.S.), and the United Kingdom (U.K.) for the treatment of fourth-line GIST. The Company wholly owns QINLOCK and all of its drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. In addition to QINLOCK, the Company has identified and advanced multiple drug candidates from its platform into clinical studies, 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, the impact of the novel coronavirus (COVID-19) pandemic on its operations, and the ability to secure additional capital to fund operations. QINLOCK and the Company's drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval. In addition to supporting its research and development efforts, the Company will be required to invest in the Company's commercial capabilities and infrastructure, to support its 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.

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

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

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

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 three and nine months ended September 30, 2022, 575,482 and 892,798 shares of pre-funded warrants were exercised resulting in net proceeds of less than $0.1 million and $0.1 million, respectively. As of September 30, 2022, there were 8,855,963 pre-funded warrants outstanding.

On August 4, 2022, the Company entered into an amendment to its existing Open Market Sale Agreement℠ (the Sales Agreement and as amended, the Amended Sales Agreement) with Jefferies LLC (Jefferies), pursuant to which the Company may issue and sell shares of its common stock having aggregate offering proceeds of up to $200.0 million from time to time through Jefferies as its sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Amended Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell the Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any Shares under the Amended Sales Agreement. The Company or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. During the nine months ended September 30, 2021, the Company issued 172,094 shares under the Sales Agreement resulting in net proceeds of $8.5 million after deducting discounts and commissions and other offering expenses. During the nine months ended, September 30, 2022, the Company did not issue any shares under the Sales Agreement or the Amended Sales Agreement.

Basis of Presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has incurred recurring losses including net losses of $133.0 million and $300.0 million for the nine months ended September 30, 2022 and the year ended December 31, 2021, respectively. As of September 30, 2022, the Company had an accumulated deficit of $1.2 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 $371.6 million as of September 30, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to fund its operations.

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

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

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, 2021 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 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

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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, 2021 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 September 30, 2022 and consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021 and consolidated cash flows for the nine months ended September 30, 2022 and 2021 have been made. The consolidated results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

The significant accounting policies used in preparation of these consolidated financial statements for the three and nine months ended September 30, 2022 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, 2021.

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.

Income Taxes

Effective for tax years beginning on or after January 1, 2022, research and experimental expenditures under Internal Revenue Code Section 174 must be capitalized over five years when performed in the U.S. and 15 years for research and experimental expenditures performed outside of the U.S. The modification is an accounting method change that will require the filing of Form 3115 with the Company's 2022 tax return. As of September 30, 2022, the Company has performed an assessment of the impact of this legislation enactment and determined that it will not result in income tax due to enough net operating losses available that are not subject to an 80% limitation. The Company maintains its full valuation allowance.

Leases - Sublease

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

In May 2022, the Company entered into a sublease agreement to sublease 44,343 square feet of space at 200 Smith Street, Waltham, MA, for a term of three years for $8.9 million over the term of the sublease. The Company determined the sublease to be an operating lease. Therefore the Company will recognize sublease income on a straight-line basis over the lease term in its consolidated statement of operations and comprehensive income. The Company will continue to account for the right-of-use asset and related liability of the original lease as it did prior to the commencement of the sublease. During the three and nine months ended September 30, 2022, the Company recognized $0.7 million and $1.0 million, respectively, of sublease income relating to lease payments within selling, general, and administrative expenses in the consolidated statement of operations and comprehensive loss.

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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 the pre-funded warrants given their nominal exercise price. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of common shares, including the pre-funded warrants and potential dilutive common shares assuming the dilutive effect as determined using the treasury stock method.

For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the three and nine months ended September 30, 2022 and 2021.

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 September 30,	
	2022	2021
Options to purchase common stock	8,316,531	6,405,542
Unvested restricted common stock units	2,106,283	839,407
Unvested employee stock purchase plan shares	53,429	34,183
Total	10,476,243	7,279,132

2. Revenues

Net Product Revenues

To date, the Company's only source of product revenues has been from the sales of QINLOCK, for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

Net product revenues by geography consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
U.S.	$ 24,478	$ 19,975	$ 71,621	$ 59,994
Rest of world	7,840	1,707	21,003	3,698
Total product revenues, net	$ 32,318	$ 21,682	$ 92,624	$ 63,692

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, 2021	$ 267	$ 494	$ 7,863	$ 817	$ 9,441
Provision related to sales in the current year	2,658	5,575	7,850	2,591	18,674
Adjustments related to prior period sales	—	(16)	(164)	(239)	(419)
Credits and payments made during the period	(2,378)	(5,496)	(3,938)	(2,432)	(14,244)
Balance as of September 30, 2022	$ 547	$ 557	$ 11,611	$ 737	$ 13,452

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

(in thousands)	As of September 30, 2022	As of December 31, 2021
Reduction of accounts receivable, net	$ 1,042	$ 719
Component of accrued expenses and other current liabilities	12,410	8,722
Total revenue-related reserves	$ 13,452	$ 9,441

Collaboration Revenues

Zai License Agreement

In June 2019, the Company entered into a License Agreement (the Zai License Agreement) with an affiliate of Zai Lab (Shanghai) Co., Ltd. (Zai), pursuant to which the Company granted Zai exclusive rights to develop and commercialize QINLOCK, including certain follow-on compounds (the Licensed Products), in Greater China (the Territory). The Company retains exclusive rights to, among other things, develop, manufacture, and commercialize the Licensed Products outside the Territory.

Pursuant to the terms of the Zai License Agreement, the Company received an upfront cash payment of $20.0 million and three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay the Company tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances. Additionally, certain costs incurred by the Company associated with the Zai License Agreement are reimbursed by Zai.

During the three and nine months ended September 30, 2022 and 2021, the Company recognized royalty revenues under the Zai License Agreement, which the Company began recognizing in the second quarter of 2021 following the approval from the China National Medical Products Administration (China NMPA).

During the nine months ended September 30, 2021, revenues recognized under the Zai License Agreement included the achievement of a $5.0 million development milestone associated with the approval of QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, by the China NMPA in March 2021.

Please read Note 3, *Revenues*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2021 for further details on the Zai License Agreement.

Zai Supply Agreement

In February 2020, the Company entered into a Supply Agreement (the Zai Supply Agreement) with Zai, as required by terms in the Zai License Agreement, pursuant to which the Company will supply the Licensed Products to Zai for use in the Territory for clinical trials as well as commercial inventory, if QINLOCK obtained regulatory approval in the Territory. In March 2021, QINLOCK was approved in the People's Republic of China (the PRC) and in Hong Kong. In September 2021, QINLOCK was approved in Taiwan. 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.

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3. Marketable Securities and Fair Value Measurements

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

As of September 30, 2022 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	$ 103,296	$ 1	$ (493)	$ 102,804
Corporate debt securities	120,626	1	(937)	119,690
Certificates of deposit	36,257	—	(187)	36,070
U.S. government securities	23,654	—	(179)	23,475
Due after one year through five years:				
Corporate debt securities	3,093	—	(26)	3,067
U.S. government securities	4,000	—	(61)	3,939
Total	$ 290,926	$ 2	$ (1,883)	$ 289,045

As of December 31, 2021 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	$ 105,433	$ 1	$ (44)	$ 105,390
Corporate debt securities	61,721	—	(70)	61,651
Certificates of deposit	23,528	1	(7)	23,522
U.S. government securities	8,008	—	—	8,008
Due after one year through five years:				
Corporate debt securities	37,003	—	(129)	36,874
U.S. government securities	5,094	—	(18)	5,076
Total	$ 240,787	$ 2	$ (268)	$ 240,521

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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 September 30, 2022 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 23,652	$ —	$ 23,652
Commercial paper	—	16,070	—	16,070
Marketable securities:				
Commercial paper	—	102,804	—	102,804
Corporate debt securities	—	122,757	—	122,757
Certificates of deposit	—	36,070	—	36,070
U.S. government securities	—	27,414	—	27,414
Total	$ —	$ 328,767	$ —	$ 328,767

As of December 31, 2021 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 47,800	$ —	$ 47,800
Marketable securities:				
U.S. government securities	—	13,084	—	13,084
Commercial paper	—	105,390	—	105,390
Corporate debt securities	—	98,525	—	98,525
Certificates of deposit	—	23,522	—	23,522
Total	$ —	$ 288,321	$ —	$ 288,321

The tables above exclude certificates of deposit totaling $3.1 million as of both September 30, 2022 and December 31, 2021 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 Annual Report on Form 10-K for the year ended December 31, 2021.

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 September 30, 2022 and December 31, 2021.

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4. Inventory

Capitalized inventory consisted of the following:

(in thousands)	As of September 30, 2022	As of December 31, 2021
Raw materials	$ 9,139	$ 4,721
Work in process	8,175	7,925
Finished goods	1,815	1,479
Total inventory	$ 19,129	$ 14,125

Inventory written down as a result of excess, obsolescence, unmarketability, or other reasons is charged to cost of sales. For the three and nine months ended September 30, 2022, there was $0.3 million and $0.7 million, respectively, in inventory written down and charged to cost of sales. For the three and nine months ended September 30, 2021, there were no amounts and less than $0.1 million, respectively, in inventory written down and charged to cost of sales.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	As of September 30, 2022	As of December 31, 2021
External research and development expenses	$ 25,955	$ 32,619
Restructuring reserve	79	20,790
Payroll and related expenses	15,639	11,945
Revenue-related reserves	12,410	8,722
Professional fees	3,761	5,626
Other	1,654	1,071
Total accrued expenses and other current liabilities	$ 59,498	$ 80,773

6. Stock-Based Awards

2017 Equity Incentive Plan

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). The Company also has outstanding stock options under its 2015 Equity Incentive Plan but is no longer granting awards under this plan. As of September 30, 2022, 1,393,769 shares of common stock were available for issuance under the 2017 Plan. As of September 30, 2022, 1,982,922 shares of common stock were available for issuance to participating employees under the ESPP.

2022 Inducement Plan

In January 2022, the Company adopted an inducement plan (the “Inducement Plan”) pursuant to which the Company reserved 800,000 shares of common stock to be used exclusively for grants of equity-based awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual’s entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. The Inducement Plan provides for the grant of equity-based awards in the form of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, unrestricted stock awards, and dividend equivalent rights. The Inducement Plan was adopted by the Company without stockholder approval pursuant to Rule 5635(c)(4) of the Marketplace Rules of the Nasdaq Stock Market, Inc. As of September 30, 2022, 530,000 shares of common stock were available for issuance under the Inducement Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2022	2021	2022	2021
Research and development	$ 5,305	$ 5,430	$ 16,995	$ 15,983
Selling, general, and administrative	7,068	6,364	22,634	19,301
Total stock-based compensation	$ 12,373	$ 11,794	$ 39,629	$ 35,284

As of September 30, 2022, total unrecognized compensation cost related to the unvested share-based awards was $76.9 million, which is expected to be recognized over a weighted average of 2.1 years.

7. Restructuring

In November 2021, the Company announced a corporate restructuring intended to prioritize clinical development of select programs, streamline commercial operations, maintain a focus on discovery research, and extend its cash runway. The corporate restructuring included a workforce reduction of approximately 35%, or approximately 140 positions, as well as discontinuation costs such as contract termination fees and non-cancellable commitments related to the rebastinib and ripretinib programs. These amounts will be substantially incurred and paid by the end of 2022.

The Company recognized a one-time charge in the fourth quarter of 2021 of approximately $26.2 million. This charge included approximately $9.8 million of employee-related termination costs and approximately $16.4 million of discontinuation costs such as contract termination fees and non-cancellable commitments related to the rebastinib and ripretinib programs. The restructuring reserve was included in accrued expenses and other in the Company's consolidated balance sheets.

The following table summarizes the charges and spending related to the Company's restructuring efforts during the nine months ended September 30, 2022:

(in thousands)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2021	$ 7,383	$ 13,408	$ 20,791
Adjustments to previous estimates, net	(374)	192	(182)
Payments	(6,930)	(13,600)	(20,530)
Restructuring reserve as of September 30, 2022	$ 79	$ —	$ 79

8. 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 September 30, 2022, the Company's contractual commitments for its commercial supply agreements were $12.3 million, which 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.

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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 September 30, 2022 or December 31, 2021.

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, 2021 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 kinase inhibitor, was engineered using our proprietary drug discovery platform and developed for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Switzerland, Taiwan, the U.S., and the U.K. 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 identified and advanced multiple drug candidates from our platform into clinical studies, 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 nine territories for the treatment of fourth-line advanced GIST. We launched QINLOCK in Germany in January 2022 and received approval by the French National Authority for Health (HAS) for a post-approval paid access program in France, which we launched in April 2022. In addition, in our effort to continue to pursue market access for QINLOCK in the EU and the U.K. on a country-by-country basis, we submitted for National Health Services (NHS) reimbursement to the National Institute for Health and Care Excellence (NICE) in the second quarter of 2022 and submitted for Agenzia Italiana Del Farmaco (AIFA) reimbursement in Italy and initiated the market access process in Spain with the Spanish Agency of Medicines and Medical Devices (AEMPS) in the third quarter of 2022.

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 a pivotal Phase 3 study in patients with TGCT (MOTION study). The MOTION study is a two-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of vimseltinib in patients with TGCT who are not amenable to surgery.

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 September 2022, we announced updated data from the Phase 1 dose escalation and Phase 2 expansion portions of the study in patients with TGCT in a poster presentation at the European Society For Medical Oncology (ESMO) Congress 2022. In the Phase 2 expansion portion of the study, Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is eligible) and Cohort B includes patients with prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is not eligible). As of the May 6, 2022 cutoff date, the objective response rate (ORR) was 69% in Phase 1 across all dose cohorts, 53% in Phase 2 Cohort A, and 46% in Phase 2 Cohort B. In addition, the ORR at week 25 in Phase 2 Cohort A was 38%. The median duration of treatment for patients in (i) Phase 1 across all dose cohorts was 17.5 months with 53% of patients remaining on treatment as of the data cutoff date, (ii) Phase 2 Cohort A was 9.8 months with 61% of patients remaining on treatment as of the cutoff date, and (iii) Phase 2 Cohort B was 5.9 months with 67% of patients remaining on treatment as of the cutoff date. In both Phase 1 and Phase 2, treatment with vimseltinib was generally well tolerated in patients with TGCT in Phase 1 across all cohorts and in Phase 2 at the recommended dose of 30 mg twice weekly. Most non-laboratory treatment-emergent

adverse events (TEAEs) were Grade 2 or lower and the only Grade 3/4 TEAE observed in >5% of patients was elevated creatine phosphokinase.

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 study designed to evaluate the safety, tolerability, clinical activity, PK, and PD of DCC-3116 as a single agent and in combination with trametinib, a U.S. Food and Drug Administration (FDA) approved MEK inhibitor, in patients with advanced or metastatic tumors with a RAS or RAF mutation.

We presented initial Phase 1 single agent dose escalation data on DCC-3116 in September 2022 in an oral presentation as a Proffered Paper at the ESMO Congress 2022. As of the June 9, 2022 cutoff date, 18 patients with locally advanced or metastatic cancer with a RAF or RAS mutation were enrolled across four dose cohorts treated with DCC-3116 twice daily (BID): 50 mg BID (n=3); 100 mg BID (n=4); 200 mg BID (n=7); and 300 mg BID (n=4). The median number of prior anti-cancer regimens was three (range 1-10). The most common cancer types were colorectal (56%) and pancreatic (28%) and patients had KRAS (83%) and BRAF (17%) mutations. DCC-3116 exposure appeared to increase dose-proportionally across the four dose levels tested from 50 mg BID to 300 mg BID; at all doses levels, the area under the curve (AUC) of DCC-3116 was at or above the AUC of the lowest tested dose that was active in preclinical studies. DCC-3116 demonstrated target inhibition with significant decreases in phosphorylation of ATG14, a direct ULK1/2 substrate, in peripheral blood mononuclear cells. At all dose levels, reductions in phosphorylated ATG14 were observed that were associated with anti-tumor activity in preclinical studies combining DCC-3116 and a MEK inhibitor as measured by reductions in phosphorylated ATG13 in tumors.

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

In the fourth quarter of 2022, we completed enrollment of the monotherapy dose escalation portion of the Phase 1 study of DCC-3116. Single-agent DCC-3116 did not reach a maximum tolerated dose, and we selected 50 mg BID as the starting dose of DCC-3116 for the combination dose escalation portion of the study. We also opened enrollment for our three combination dose escalation cohorts: (i) in combination with trametinib, an FDA-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations, (ii) in combination with binimetinib, an FDA-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations, and (iii) in combination with sotorasib, an FDA-approved $KRAS^{G12C}$ inhibitor, in patients with advanced or metastatic solid tumors with $KRAS^{G12C}$ mutations. In addition, in the fourth quarter of 2022, we treated the first patient in the combination dose escalation portion of the study.

DCC-3084

We are also making a focused investment in our next generation of research programs, which are designed to provide first-in-class or best-in-class treatments using our proprietary switch-control inhibitor platform. In November 2022, we announced the nomination of DCC-3084 for our pan-RAF development candidate. DCC-3084 is a selective inhibitor of BRAF/CRAF kinases that inhibits Class I, II, and III BRAF mutants, BRAF fusions, and NRAS mutant cell lines.

Coronavirus (COVID-19)

We continue to closely monitor the impact of the COVID-19 pandemic on our business operations in an effort to mitigate interruption to our clinical programs, research efforts, commercialization of QINLOCK, and other business activities and to ensure the safety and well-being of our employees, as well as the physicians and patients participating in our clinical trials. In addition, we actively monitor risks associated with potential interruptions to our clinical studies due to the impact of COVID-19 and are in frequent communication with clinical study sites and contract research organizations (CROs). While all of our studies remain open for enrollment, we have experienced some delays or disruptions in enrollment and enrollment may in the future be temporarily paused for new patients at some sites. We will continue to assess the duration, scope, and severity of the COVID-19 pandemic as it evolves and monitor local COVID-19 trends and government guidance for each of our site and office locations. However, in light of the changing circumstances surrounding the ongoing COVID-19 pandemic, the operating environment remains fluid and uncertain, and the full significance of the impact of COVID-19 on our business and the duration for which it

may have an impact cannot be determined at this time. For further information regarding the impact of the COVID-19 pandemic on us, see “Part II. Item 1A - Risk Factors” included in this Quarterly Report on Form 10-Q.

Components of Our Results of Operations

Revenues

QINLOCK is approved in Australia, Canada, China, the EU, Hong Kong, Switzerland, Taiwan, the U.S. and the U.K. for the treatment of fourth-line GIST. We may generate revenue in the future from a combination of product sales or payments from collaboration, distribution, or any potential additional license agreements that we may enter into with third parties. We expect that our revenue in the foreseeable future will be derived primarily from sales of QINLOCK and, payments owed to us under the license (the Zai License Agreement) and supply (the Zai Supply Agreement) agreements we entered into with Zai in June 2019 and February 2020, respectively, including royalty revenues under the Zai License Agreement following the approvals of QINLOCK in the PRC and Hong Kong in March 2021. We cannot provide assurance as to what extent we will generate revenue from the commercialization of QINLOCK or if, when, or to what extent we will generate revenue from the commercialization and sale of our drug candidates 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 nine months ended September 30, 2022 and 2021, our only source of product revenues was from the sales of QINLOCK. Product revenues are recorded net of estimates of variable consideration. Please read Note 2, *Revenues*, to the consolidated financial statements included in this Form 10-Q for further details of the reserves recorded for variable consideration.

Collaboration Revenues

For the three and nine months ended September 30, 2022 and 2021, collaboration revenues were associated with the Zai License Agreement and Zai Supply Agreement.

Zai License Agreement

Pursuant to the terms of the Zai License Agreement, we received an upfront cash payment of $20.0 million and three development milestone payments totaling $12.0 million and will be eligible to receive up to $173.0 million in potential development and commercial milestone payments, consisting of up to $38.0 million of development milestones and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances. Additionally, certain costs we incur associated with the Zai License Agreement are reimbursed by Zai.

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

Zai Supply Agreement

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

Cost of Sales

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

Cost of sales for newly launched products will not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. The gross margin on sales of QINLOCK for the three and nine months ended September 30, 2022 and 2021 was enhanced by sales of the initial pre-launch inventory, and therefore, use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the launch of QINLOCK, referred to as zero cost inventories. However, we do not expect that the cost of sales as a percentage of net sales of QINLOCK will increase significantly after we have sold all zero cost inventories and commenced the sales of inventories which will reflect the full cost of manufacturing. We will begin selling inventory with the full cost of manufacturing in the fourth quarter of 2022.

Operating Expenses

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

- continuing to establish sales, marketing, and distribution capabilities to support the commercialization of QINLOCK or our drug candidates, if and when approved, whether alone or in collaboration with others such as Zai, our licensee for QINLOCK in Greater China;
- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- acceptance of QINLOCK or our drug candidates, if and when approved, by patients, the medical community, and third-party payors;
- developing and implementing marketing and reimbursement strategies;
- raising additional funds necessary to fund ongoing operations and capital expenditure requirements, including to complete clinical development of and commercialize any current or future drug candidates for which we receive approval;
- making 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 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 vimseltinib and DCC-3116 will increase in 2022 as our drug and drug candidate development programs progress. However, we expect research and development expenses will decrease overall as compared to 2021 due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021. 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 decrease overall due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021, despite increased selling, general, and administrative expenses to be incurred related to the launch of QINLOCK in Germany and France in 2022. 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

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, 2021 on file with the SEC, as of September 30, 2022, 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 generally accepted accounting principles in the U.S. (GAAP). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and 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, 2021 on file with the SEC. There have been no significant changes to our critical accounting policies since December 31, 2021.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Revenues:				
Product revenues, net	$ 32,318	$ 21,682	$ 92,624	$ 63,692
Collaboration revenues	3,656	1,538	5,067	8,257
Total revenues	35,974	23,220	97,691	71,949
Cost and operating expenses:				
Cost of sales	3,344	917	5,525	2,414
Research and development	47,485	66,444	139,755	182,109
Selling, general, and administrative	30,026	35,527	87,972	99,102
Total cost and operating expenses	80,855	102,888	233,252	283,625
Loss from operations	(44,881)	(79,668)	(135,561)	(211,676)
Other income (expense):				
Interest and other income, net	1,838	(170)	2,565	107
Total other income (expense), net	1,838	(170)	2,565	107
Net loss	$ (43,043)	$ (79,838)	$ (132,996)	$ (211,569)

Revenues

Product Revenues, Net

During the three and nine months ended September 30, 2022 and 2021, our only source of product revenues was from the sales of QINLOCK. During the three and nine months ended September 30, 2022 and 2021, net product revenues by geography consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
U.S.	$ 24,478	$ 19,975	$ 71,621	$ 59,994
Rest of world	7,840	1,707	21,003	3,698
Total product revenues, net	$ 32,318	$ 21,682	$ 92,624	$ 63,692

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, U.S. net product revenues increased $4.5 million and $11.6 million, respectively, primarily due to increased sales volume and an increase in net price.

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, rest of world net product revenues increased $6.1 million and $17.3 million, respectively, primarily due to increased sales volume in Germany, which launched in January 2022, and France, which launched a post-approval paid access program in April 2022, as we continued our commercialization efforts.

Collaboration Revenues

For the three months ended September 30, 2022 compared to the same period in 2021, collaboration revenues increased $2.1 million, which was primarily due to an increase in revenues under the Zai Supply Agreement.

For the nine months ended September 30, 2022 compared to the same period in 2021, collaboration revenues decreased $3.2 million, which was primarily due to the recognition of a $5.0 million development milestone in the first quarter of 2021 associated with the approval of QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, by the China NMPA in March 2021. This decrease was partially offset by an increase in revenues under the Zai Supply Agreement.

Cost of Sales

During the three and nine months ended September 30, 2022 and 2021, cost of sales by type consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Cost of product sales	$ 672	$ 193	$ 2,013	$ 809
Cost of collaboration sales	2,672	724	3,512	1,605
Total cost of sales	$ 3,344	$ 917	$ 5,525	$ 2,414

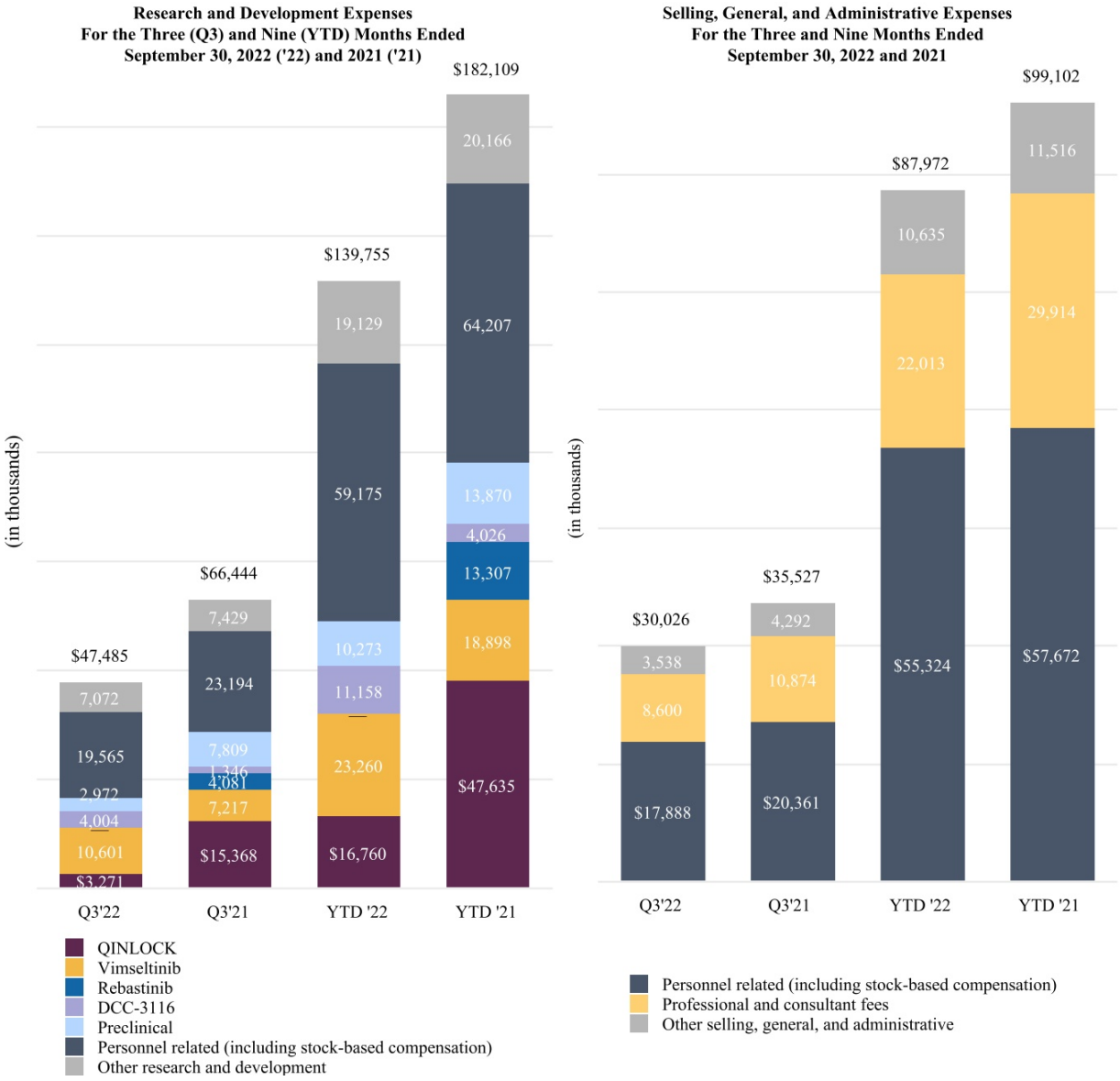
For the three and nine months ended September 30, 2022 compared to the same periods in 2021, cost of sales increased $2.4 million and $3.1 million, respectively, primarily due to costs associated with the commercial inventory of QINLOCK sold under the Zai Supply Agreement and increased product sales of QINLOCK in Germany and France. During the three and nine months ended September 30, 2022, cost of sales also included a $0.3 million and $0.7 million, respectively, of charges for inventory written down as a result of excess, obsolescence, unmarketability, or other reasons. During the nine months ended September 30, 2021, cost of sales also included a charge of less than $0.1 million for inventory written down as a result of excess, obsolescence, unmarketability, or other reasons. 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. As a result, the full costs of manufacturing QINLOCK inventory are not included in cost of sales during the three and nine months ended September 30, 2022 and 2021.

Prior to receiving FDA approval for QINLOCK in May 2020, we manufactured inventory to be sold and recorded approximately $6.0 million related to this inventory build-up as research and development expense. We did not record any such costs related to the build-up of this inventory as research and development expense during the three and nine months ended September 30, 2022 and 2021.

Utilizing the actual direct costs to manufacture QINLOCK prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the three and nine months ended September 30, 2022 would have increased by approximately $0.6 million and $1.9 million, respectively, and $0.3 million and $1.4 million, respectively, in the prior year comparative periods.

We do not expect our cost of sales for QINLOCK to increase significantly as a percentage of net sales in future periods as we continue to produce inventory for future sales, which will reflect the full cost of manufacturing, and then sell such inventory. We continued to sell the zero cost inventories of QINLOCK in the U.S. through the third quarter of 2022, and we will begin selling inventory with the full cost of manufacturing in the fourth quarter of 2022.

Operating Expenses



Research and Development Expenses

QINLOCK

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, research and development expenses related to QINLOCK decreased primarily as a result of decreases in clinical trial expenses of $10.1 million and $20.6 million and decreases in manufacturing costs of $1.4 million and $6.6 million, respectively. Clinical trial expenses for QINLOCK decreased primarily as a result of decreased expenses associated with INTRIGUE, our Phase 3 study of QINLOCK for the treatment of second-line GIST, which we initiated in December 2018 and for which enrollment was completed in December 2020 and our Phase 1 trial of QINLOCK. Manufacturing costs decreased primarily due to timing of processing of inventory for clinical and commercial use.

Vimseltinib

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, expenses related to our vimseltinib program increased primarily as a result of increases in clinical trial expenses of $2.7 million and $5.3 million,

respectively. Additionally, for the nine months ended September 30, 2022 clinical trial expenses were offset by decreases in manufacturing costs of $0.7 million. Clinical trial expenses increased primarily due to increased activities associated with our Phase 3 study of vimseltinib in patients with TGCT, MOTION, which was initiated in the fourth quarter of 2021 and increased clinical pharmacology study activities, partially offset by a decrease in clinical trial expense associated with our Phase 1/2 study of vimseltinib to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in patients with TGCT. Manufacturing costs for the vimseltinib program decreased for the nine months ended September 30, 2022 as a result of increased manufacturing in the prior year period to prepare for the initiation of the MOTION study.

Rebastinib

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, expenses related to our rebastinib program decreased primarily as a result of the discontinuation of our rebastinib program in the fourth quarter of 2021 following the corporate restructuring implemented in the fourth quarter of 2021.

DCC-3116

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, expenses related to our DCC-3116 program increased primarily as a result of increases in manufacturing costs of $2.1 million and $5.4 million and increases in clinical trial expenses of $0.7 million and $2.2 million, respectively, associated with our Phase 1 study of DCC-3116, which we initiated in June 2021, partially offset by a decrease in preclinical expense of $0.2 million and $0.4 million, respectively, due to the program moving from the preclinical to clinical stage in June 2021.

Preclinical

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, the decrease in preclinical costs of $4.8 million and $3.6 million, respectively, was primarily due to a $4.0 million upfront payment to Sprint Bioscience (Sprint) pursuant to the Sprint Agreement, an agreement to exclusively in-license worldwide rights to a research-stage program targeting VPS34, a key kinase in the autophagy pathway for the potential treatment of cancer, during the third quarter of 2021.

Unallocated Expenses

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, the decreases in unallocated research and development expenses were primarily associated with decreased personnel-related costs of $3.6 million and $5.0 million, respectively, primarily due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021, partially offset by an increase in employee expenses related to our international employees, who were primarily hired in the second half of 2021. Additionally, for the nine months ended September 30, 2022, the decrease was also partially offset by an increase in stock-based compensation expense of $1.0 million, primarily due to stock-based compensation grants issued in the fourth quarter of 2021 in connection with our corporate restructuring.

We expect research and development expenses associated with vimseltinib and DCC-3116 will increase in the fourth quarter of 2022 as we continue to invest in the development of these programs. However, we expect research and development expenses will decrease overall as compared to 2021 due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021.

Selling, General, and Administrative Expenses

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, the decrease in selling, general, and administrative expenses was primarily associated with a decreases in personnel-related costs of $2.5 million and $2.3 million, respectively, and professional and consultant fees of $2.3 million and $7.9 million, respectively. The decreases in personnel-related costs were primarily due to the cost reduction measures included in our corporate restructuring implemented in the fourth quarter of 2021, partially offset by an increase in employee expenses related to our international employees, who were primarily hired in the second half of 2021. Additionally, for the nine months ended September 30, 2022, the decrease in personnel-related costs was also partially offset by an increase in stock-based compensation expense of $3.3 million, primarily due to stock-based compensation grants issued in the fourth quarter of 2021 in connection with our corporate restructuring. The decreases in professional and consultant fees were primarily due to a decrease in various advisory fees related to establishing, in the prior year period, a targeted commercial infrastructure and commercialization preparedness in key European markets to support the launch of QINLOCK in Germany, which launched in January 2022, and a post-approval paid access program in France, which launched in April 2022.

We anticipate that our selling, general, and administrative expenses will decrease overall due to the cost reduction measures included in the corporate restructuring implemented in the fourth quarter of 2021, despite increased selling, general, and

administrative expenses to be incurred related to the launch of QINLOCK in Germany and a post-approval paid access program in France in 2022.

Interest and Other Income, Net

For the three and nine months ended September 30, 2022 compared to the same periods in 2021, the increases 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 foreign currency exchange differences.

Restructuring

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

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

The following table summarizes the charges and spending related to the Company's restructuring efforts during the nine months ended September 30, 2022:

(in thousands)	Workforce Reduction	Pipeline Programs	Total
Restructuring reserve as of December 31, 2021	$ 7,383	$ 13,408	$ 20,791
Adjustments to previous estimates, net	(374)	192	(182)
Payments	(6,930)	(13,600)	(20,530)
Restructuring reserve as of September 30, 2022	$ 79	$ —	$ 79

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 nine territories for the treatment of fourth-line GIST. During the three and nine months ended September 30, 2022 and 2021, our product revenues were primarily derived from sales of QINLOCK in the U.S. Additionally, we launched QINLOCK in Germany in January 2022 and launched a post-approval paid access program in France in 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. During the second quarter of 2021, following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we also began to recognize royalty revenues under the Zai License Agreement. However, we cannot provide assurance as to what extent we will generate revenue from the commercialization of QINLOCK by us or our partners. We do not expect to generate revenue from sales of any drug candidates in the near future, if at all, unless and until we obtain marketing approval for, and begin to sell, such drug candidates. We may never generate revenues that are significant enough to achieve profitability.

On October 2, 2017, we completed our initial public offering (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 offering announced in April 2022, and an Open Market Sale Agreement℠ (the Sales Agreement and as amended, the Amended Sales Agreement) with Jefferies LLC (Jefferies). Through such issuances, we have issued and sold 37,170,625 shares of our common stock and pre-funded warrants to purchase 9,748,761 shares of our common stock resulting in net proceeds of $1.1 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 of common stock to certain investors. In addition, we offered 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 three and nine months ended September 30, 2022, 575,482 and 892,798 shares of pre-funded warrants were exercised resulting in net proceeds of less than $0.1 million and $0.1 million, respectively. As of September 30, 2022, there were 8,855,963 pre-funded warrants outstanding.

On August 4, 2022, we entered into an amendment to our existing Sales Agreement with Jefferies, pursuant to which we may issue and sell shares of our common stock having aggregate offering proceeds of up to $200.0 million (the Shares) from time to time through Jefferies as our sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Amended Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. We may sell the Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any Shares under the Amended Sales Agreement. We or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. During the nine months ended September 30, 2021, we issued 172,094 shares under the Sales Agreement resulting in net proceeds of $8.5 million after deducting discounts and commissions and other offering expenses. During the nine months ended September 30, 2022, we did not issue any shares under the Sales Agreement of the Amended Sales Agreement.

Cash Flows

As of September 30, 2022, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $371.6 million.

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

	Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**
Net cash flows used in operating activities	$ (117,704)	$ (173,648)
Net cash flows (used in) provided by investing activities	(50,613)	77,896
Net cash flows provided by financing activities	164,516	12,912
Net increase (decrease) in cash and cash equivalents	$ (3,801)	$ (82,840)

Operating Activities

During the nine months ended September 30, 2022 compared to the same period in 2021, net cash flows used in operating activities decreased $55.9 million, primarily resulting from a decrease in our net loss of $78.6 million, partially offset by decreases in net non-cash charges of $0.8 million, including an increase in share-based compensation of $4.3 million, and increases in net cash flows related to changes in our operating assets and liabilities of $21.8 million. The increase in net cash flows related to changes in our operating assets and liabilities were generally due to the timing of vendor invoicing and payments.

Investing Activities

During the nine months ended September 30, 2022 compared to the same period in 2021, net cash flows used in investing activities increased $128.5 million, primarily resulting from a decrease in proceeds from maturities and sales of marketable securities of $207.8 million, partially offset by a decrease in purchases of marketable securities of $73.1 million, a decrease in purchases of property and equipment of $2.2 million and a $4.0 million upfront payment to Sprint pursuant to the Sprint Agreement during the third quarter of 2021.

Financing Activities

During the nine months ended September 30, 2022 compared to the same period in 2021, net cash flows provided by financing activities increased $151.6 million, primarily resulting from an increase in net proceeds from offerings of our common stock and pre-funded warrants of $154.8 million, partially offset by a decrease in proceeds from stock option exercises and

employee stock purchase plan activity of $3.2 million. Net of underwriting discounts and commissions and other offering costs, the increase in proceeds from offerings was due to our issuance of our common stock and pre-funded warrants in a follow-on public offering in April 2022 of $163.4 million as compared to our issuances of our common stock under the Sales Agreement during the nine months ended September 30, 2021 of $8.5 million.

Funding Requirements

Our ability to generate product revenues sufficient to achieve profitability will depend heavily on the successful commercialization of QINLOCK and eventual commercialization of one or more of our drug candidates. Our net loss was $133.0 million for the nine months ended September 30, 2022 and $300.0 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of $1.2 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 increase in connection with our ongoing activities, particularly as we:

- continue to commercialize QINLOCK in the U.S., and continue to build our global commercial capability as we actively prepare to bring QINLOCK to eligible patients around the world, including in key European markets;
- 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, 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, high inflation, the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or commercialization efforts or grant rights to develop and market drugs and drug candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing equity holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties (such as the Zai License Agreement), we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, drugs, or drug candidates, or grant licenses on terms that may not be favorable to us.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses and capital requirements or when or if we will be able to achieve or maintain profitability. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;
- the success of our commercialization efforts and market acceptance for QINLOCK or any of our future approved drugs;
- the timing and outcome of regulatory review of our drug and drug candidates;
- the cost to develop companion diagnostics as needed for each of our drug candidates;
- our ability to establish and manage agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- addition and retention of key research and development and commercial, including sales and marketing, personnel;
- 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 September 30, 2022 of $371.6 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 2025. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Contractual Obligations and Commitments

As of September 30, 2022, 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, 2021.

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 the Company's Form 10-K for the year ended December 31, 2021 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 the Company's Form 10-K for the year ended December 31, 2021 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 September 30, 2022. 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 September 30, 2022, 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 corporate strategy and restructuring plan may not be successful.

In November 2021, we announced a corporate restructuring to prioritize clinical development programs and streamline commercial operations. We are prioritizing the clinical development of our vimseltinib and DCC-3116 programs and continuing with a focused investment in our next generation of research programs, designed to provide first-in-class or best-in-class treatments for patients. There is no guarantee that the corporate restructuring plan will achieve its intended benefits or that our post-restructuring focus will be sufficient for us to achieve success. For example, our corporate restructuring may not result in anticipated savings or other economic benefits, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

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 Germany and a post-approval paid access program in France, 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, representing our first European launch of QINLOCK, and received approval by HAS for a post-approval paid access program in France, which we launched in April 2022. In addition, in our effort to continue to pursue market access for QINLOCK in the EU and the U.K on a country-by-country basis, we submitted for NHS reimbursement to NICE in the second quarter of 2022 and submitted for AIFA reimbursement in Italy and initiated the market access process in Spain with the AEMPS in the third quarter of 2022. 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 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 other European countries.

Our dependence on QINLOCK sales in fourth-line GIST in major geographies is even more important in light of the fact that our Phase 3 INTRIGUE study in second-line GIST did not meet its primary endpoint. We continue to evaluate results and data from INTRIGUE to inform future publications and/or further potential clinical development.

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, all of which risks are heightened following the reduction in the size of our U.S. commercial team in connection with the corporate restructuring described above. 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;
- 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 a profit or profits or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to QINLOCK in fourth-line 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. in fourth-line and fourth-line plus GIST, and initiating the launch of QINLOCK in Germany and a post-approval paid access program in France, 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. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act (FCA). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances;
- the federal False Claims laws which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- federal price reporting laws, which require drug manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Physician Payments Sunshine Act (Sunshine Act), created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services (HHS) under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also require the reporting of payments or other transfers of value. Many of these state laws differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are often not pre-empted by HIPAA, thus complicating compliance efforts.

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. On December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D (Part D), either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Further, on December 31, 2020, the Centers for Medicare & Medicaid Services (CMS) published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's (PhRMA) motion for summary judgement invalidating the accumulator adjustment rule. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to

the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General (OIG) of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management’s attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

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

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, including certain European countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country.

Adverse pricing limitations may hinder our ability to recoup our investment in QINLOCK or one or more of our drug candidates, even if such drug candidates obtain marketing approval.

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, including those in Europe, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our drug or drug candidates. Accordingly, in markets outside the U.S., including in Europe, the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits. The U.S. government and state legislatures have also shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. Certain states have enacted legislation with the goal of controlling prices on branded prescription drugs and placing restrictions on price increases or requiring companies to pay additional rebates in order to receive reimbursement from the state Medicaid programs, the effect of which is unknown. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products and could adversely affect our net revenues and operating results.

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

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

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

The ACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer is required to pay a prorated share of the branded prescription drug fee of $4.1 billion in 2018 and $2.8 billion in each year thereafter, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The ACA also expanded the Public Health Service's 340B Drug Pricing Program (340B program (described below)), to include additional types of covered entities. We will participate in the 340B program for QINLOCK and any of our drug candidates for which we receive approval. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid programs and purchased by certain federal grantees and agencies, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule (FSS) pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make products available for procurement on an FSS contract and charge a price to four federal agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard—that is at least 24% less than the Non-Federal Average Manufacturing Price (non-FAMP) for the prior fiscal year.

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

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

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

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell our approved drug and any drug candidates for which we obtain marketing approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the

elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

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

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

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to reform through legislation and Executive Orders by the previous U.S. presidential administration and to judicial challenges. In 2012, the U.S. Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the ACA. The Supreme Court's decision upheld most of the ACA and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation enacted into law in late December 2017, the individual mandate has been eliminated, effective January 1, 2019. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, the current U.S. president issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for the purpose of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the current U.S. presidential administration or other efforts, if any, to challenge, repeal, or replace the ACA will impact our business.

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

In December 2018, the CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method the CMS uses to determine this risk adjustment. In addition, the CMS has recently

published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have also been proposed and adopted since the ACA was enacted that, directly or indirectly, affect or are likely to affect, the pharmaceutical industry and the commercialization of our products, including the Budget Control Act of 2011 (BCA), the American Taxpayer Relief Act of 2012 (ATRA), and the Middle Class Tax Relief and Job Creation Act of 2012. In August 2011, the BCA, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the BCA will be suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction occurred beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022. The ATRA among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) was enacted in 2019 requiring sponsors of approved New Drug Applications (NDAs) and Biologics License Applications to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted.

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

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. At the federal level, the current U.S. president signed an Executive Order on July 9, 2021 (the July 9, 2021 Executive Order) affirming the administration's policy to (i) support legislative reforms that would lower the price of prescription drugs and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the July 9, 2021 Executive Order also directs the HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to continue to clarify and improve the approval framework for generic drugs, identify and address any efforts to impede generic drug competition, and work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the MMA and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. In response, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our drug candidates. Further, on November 20, 2020, the CMS issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model under which Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

On August 16, 2022 the Inflation Reduction Act of 2022 was passed, which among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

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

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

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

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

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

QINLOCK or any current 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.

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

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of QINLOCK or of our current drug candidates, such as vimseltinib and DCC-3116, or future drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug, and those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by QINLOCK or any future approved drug (or any other similar drugs), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;
- regulatory authorities may refuse to approve label expansion for additional indications for 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 in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, we may not promote QINLOCK in the U.S. or Europe 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. As we expand our presence outside of the U.S. in key European markets, we must dedicate additional resources to comply with these laws, and 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, 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 for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

The U.K.'s exit from the EU may have a negative effect on our business and increase our regulatory burden of conducting business in the U.K. and EU.

On June 23, 2016, the U.K. held a referendum in which voters approved an exit from the EU, commonly referred to as “Brexit.” During the Brexit transition period, which ended on December 31, 2020, the U.K. continued to follow all of the EU's rules and maintained its current trading relationship with the EU. In December 2020, the U.K. and EU signed the EU-U.K. Trade and Cooperation Agreement (TCA), which became provisionally applicable on January 1, 2021 and has been formally applicable since May 1, 2021. The TCA sets out the arrangements between the U.K. and EU on trade in certain areas (e.g. goods and some services, energy, fisheries, social security coordination), however there are still key aspects of the U.K.’s relationship with the EU which are not covered by the TCA, such as in respect of financial services. The withdrawal will, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe.

For example, the TCA includes limited specific provisions concerning medicinal products, primarily regarding the mutual recognition of good manufacturing practice (GMP) inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of U.K. and EU pharmaceutical regulations. Since the regulatory framework in the U.K. covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorizations, commercial sales and distribution of medicinal products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our current or future drug candidates in Great Britain (GB) now that the legislation has the potential to diverge from EU legislation. For instance, GB (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland and centralized EU authorizations will continue to be recognized) will now no longer be covered by the centralized procedure for obtaining marketing authorizations for medicinal products which are valid throughout the European Economic Area (EEA) (which comprises the 27 member states that comprise the EU (the Member States) plus Norway, Iceland, and Liechtenstein), and a separate process for authorization of drug products will be required in GB, resulting in an authorization covering the U.K. or GB only. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition, and cash flows. Likewise, similar actions taken by European and other countries in which we operate could have a similar or even more profound impact.

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

In California, the California Consumer Privacy Act (CCPA) was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, gives California residents expanded individual privacy rights and protections and provides for civil penalties for violations and a private right of action for data breaches. Further, a new California privacy law, the California Privacy Rights Act (CPRA) was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA and CPRA may impact our business activities if we become a "Business" regulated by the scope of the CCPA or are subject to CPRA and 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, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (CDPA). The CDPA will become effective January 1, 2023. The CDPA will regulate how businesses (which the CDPA refers to as “controllers”) collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

Also, on July 8, 2021, Colorado’s governor signed the Colorado Privacy Act (CPA), into law. The CPA is rather similar to the CPDA but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to its residents of the state that either: (1) control or process the personal data of at least 100,000 consumers during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25,000 consumers.

In addition, Utah recently, became the fourth state to enact a comprehensive privacy law when Governor Cox signed the Utah Consumer Privacy Act into law on March 24, 2022. In May 2022, Connecticut Governor Lamont signed the Connecticut Data Privacy Act (CTDPA) into law. The UCPA and CTDPA draw heavily upon their predecessors in Virginia and Colorado. With the CTDPA, Connecticut became the fifth state to enact a comprehensive privacy law.

With bills proposed in many other jurisdictions, it remains quite possible that other states will follow suit. 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 the new U.S. presidential administration. 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. The GDPR has enhanced data protection obligations for controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements, restrictions on transfers outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and has created onerous new obligations and liabilities on services providers or data processors. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. 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 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.

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. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA or the U.K., including to the U.S., providing details to those individuals regarding the processing of their personal information, where required obtaining consent from data subjects to process their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping.

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

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with European and U.K. data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. In some cases, we rely upon the standard contractual clauses to legitimize transfers of personal data out of Europe. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA (and not subject to the GDPR). The new forms of standard contractual clauses will replace the standard contractual clauses that were adopted previously under the Data Protection Directive. 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. We will be required to transition to the new forms of standard contractual clauses and doing so will require significant effort and cost. The new standard contractual clauses may also impact our business as companies based in Europe and the U.K. may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new standard contractual clauses impose upon exporters. 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. In addition, although EU and

U.S. negotiators have recently announced an agreement on a successor to the invalidated Privacy Shield, there remains much to be worked out before this program becomes a valid transfer mechanism.

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. On June 10, 2021, the Standing Committee of the PRC National People's Congress published the Data Security Law of the People's Republic of China (Data Security Law), which took effect on September 1, 2021. The Data Security Law 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, on August 20, 2021, the Standing Committee of the National People's Congress of the PRC promulgated the Personal Information Protection Law, which took effect on November 1, 2021. The Personal Information Protection Law raises the protection requirements for processing personal information, and many specific requirements of the Personal Information Protection Law remain to be clarified. 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, such as Russia, imposing data localization laws, which under Russian laws require personal information of Russian citizens to be, among other data processing operations, initially collected, stored, and modified in Russia. 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 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. 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 conflict 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.

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, Inc., and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST including AB Sciences S.A., Arog Pharmaceuticals, Inc. (Arog), Chia Tai Tianqing Pharmaceutical Group CO.(CTTPG), LTD, Cogent Biosciences, Inc. (Cogent), Immunicum AB (Immunicum), Jiangsu HengRui, Inc. (Jiangsu), Ningbo Tai

Kang Medical Technology Co. Ltd, (NTKMT), Novartis, Taiho Pharmaceutical Co. Ltd, Theseus Pharmaceuticals (Theseus), Xencor, Inc., and IDRx, Inc. (IDRx). Several of these programs are in clinical studies, including but not limited to Arog, CTTPG, Cogent, Immunicum, Jiangsu, NTKMT, Theseus, and IDRx. Further, there are numerous companies marketing or developing antibodies and small molecules targeting CSF1R inhibitors for TGCT that we are seeking to target with our vimseltinib program, including Abbisko Therapeutics Co., Ltd., AmMax Bio, Inc., 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 that entered a Phase 1 clinical study in the second quarter of 2021, we are aware of other companies that are advancing programs targeting ULK, including Endeavor Biomedicines, Inc., Erasca, Inc., Txinno Bioscience Inc. and Ailon Pharma Oy.

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

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

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

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

The precise incidence and prevalence for GIST, TGCT, 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.

The total addressable market opportunity for QINLOCK, 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 and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

The commercial success of QINLOCK, and of any future approved drugs, 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 following approval;
- 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. 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 and Hong Kong in March 2021 and Taiwan in September 2021. Following EC approval in November 2021, we launched QINLOCK in Germany and received approval from HAS for a post-approval paid access program in France. 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, particularly in light of the impact of COVID-19 on the global economy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other

countries or jurisdictions or by the FDA. 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.

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

We have built our own focused, specialized sales and marketing organization in the U.S. and 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, in particular in light of reduced in-person access to medical institutions and personnel in some areas and other significant disruptions to the healthcare system and community due to COVID-19;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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 increasingly 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 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. In the context of the COVID-19 pandemic, the risk of such threats and attacks increased, as virtual and remote working became more widely used, and sensitive data is accessed by employees working in less secure, home-based environments. The way we work continues to have and will likely continue 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 attacks). 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. 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 shareholder litigation.

Security incidents could also include supply chain attacks which, if successful, could cause a delay in the manufacturing 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.

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.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

In light of the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the Euro, may adversely affect us. Although we are based in the United States, we sell QINLOCK in the European Union 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. As a result, our business may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period and the price of our common stock. Currently, we do not have any exchange rate hedging arrangements in place.

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, 2021, we had U.S. federal net operating loss carryforwards and U.S. federal research and development tax credit carryforwards, which could be limited if we experience an "ownership change."

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous foreign, federal, state, and local environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous, or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development, or manufacturing efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

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

Natural disasters or global health crises, including the COVID-19 pandemic, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, global health crisis, power outage, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted our operations or the operations of our vendors, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster, health crisis, or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

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

Risks Related to Clinical Development

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

We currently have several drug candidates in varying stages of clinical development, including DCC-3116 in a Phase 1 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 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, particularly in light of the COVID-19 pandemic;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, due to interruptions to their business, including those impacts caused by the COVID-19 pandemic or global economic instability, or may fail to comply with regulatory requirements;

- we may have to suspend, change, or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks, including potential exposure to COVID-19 in their geography;
- our drug or drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs to suspend, change, or terminate the trials;
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as COVID-19, in or around the countries in which we conduct our clinical trials or where our third-party contractors operate, could delay the commencement or rate of completion of our clinical trials, or those 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, particularly in light of the uncertainties associated with global economic and political developments or the COVID-19 pandemic; and
- the supply or quality of our drug or drug candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials, including those caused by global economic instability, including historically high inflation, and the COVID-19 pandemic.

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

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. Furthermore, the FDA could place a clinical hold, either another partial clinical hold or a full clinical hold, on our trials if they are not satisfied with the information we provide to them, which could result in delays for the trial. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

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

If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our clinical trials of vimseltinib or 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 COVID-19, global economic and political developments, including historically high inflation and the conflict in Ukraine, or other factors.

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

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;

- the perceived risks and benefits of the drugs or drug candidates under study;
- the efforts to facilitate timely enrollment in clinical trials; 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 in slower than expected enrollment may include recruitment challenges for indications that are difficult to diagnose and/or treat where the population is small and dispersed or for a chronic non life-threatening condition, such as TGCT, and other competing trials are recruiting simultaneously. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause significant harm to our financial position, adversely impact our stock price, and impair our ability to raise capital.

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

If our drug or drug candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development, limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective or highlight these risks, side effects, or other characteristics in the approved product label. In pharmaceutical development, many drugs that initially show promise in early-stage testing for treating cancer and other diseases may later be found to cause side effects that prevent further development of the drug. Currently marketed therapies for the treatment of cancer are generally limited to some extent by their toxicity. In addition, some of our drug candidates would be chronic therapies or be used in pediatric populations, for which safety concerns may be particularly important. Use of our drug candidates as monotherapies may also result in adverse events consistent in nature with other marketed therapies. In addition, if used in combination with other therapies in the future, our drug or drug candidates 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. All of our drug candidates, including vimseltinib and DCC-3116, are still in varying stages of clinical development.

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

Our ability to generate continued product revenues will depend heavily on the successful development and commercialization of our approved drug and drug candidates, if approved. Our success in the development of our approved drug and drug candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including our ongoing Phase 3 study of vimseltinib;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize any current or future drug candidates for which we obtain marketing approval;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug and drug candidates;
- making and maintaining timely and cost-effective arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;

- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- 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 study of QINLOCK for second-line GIST, which failed to meet its primary endpoint.

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 MOTION study for vimseltinib in patients with TGCT, for a single randomized, placebo-controlled 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.

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 candidates, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S., the EMA and national competent authorities of the Member States in the EU, and the China NMPA and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. Our drug candidates are

in the 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, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates or 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.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017 (the FDARA). The FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in the FDARA would apply in cases where FDA issued an orphan designation before the enactment of the FDARA but where

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

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our drug candidates. Moreover, the commercial success of any of our drug candidates that

require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

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

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

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

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

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

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

Risks Related to Drug Discovery

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 study of DCC-3116 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 the COVID-19 Pandemic

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

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

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

- Our ability to successfully commercialize and generate revenue from QINLOCK may be adversely affected by the economic impact of the COVID-19 pandemic. For example, in the U.S. we plan to utilize various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and economic conditions caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and reimbursement of newly approved products as well as an increase in the numbers of uninsured patients or patients who may no longer be able to afford their co-insurance or co-pay obligations. These factors may lead to increased utilization of our patient assistance programs, which could reduce revenues.
- The COVID-19 pandemic may also negatively impact our commercialization strategy for QINLOCK. While restrictive safety measures are in place, limited hospital access for non-patients, which includes our sales personnel, social distancing requirements, proof of vaccination and/or negative COVID-19 test, and other precautionary measures due to COVID-19 may impact the ability of our sales personnel to interact in-person with customers in the same way as they did before the COVID-19 pandemic. As a result, in many circumstances we have needed to limit our interactions with physicians and payors and adapt our commercialization strategies and tactics to a virtual model, including developing and deploying various technology-enabled platforms for virtual engagement such as remote detailing, digital and non-personal marketing channels, and social media. Although some of these restrictions have been, and may continue to be lifted in certain healthcare institutions, the impact of prior and continued COVID-19 related safety measures, and the potential for reimposition of restrictions due to local surges and new waves of infection, including those caused by the spread of certain variants of the virus, may adversely affect the ability of our sales professionals to effectively market QINLOCK to physicians and the rate of uptake for QINLOCK, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians in specialties such as oncology have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume.
- We are currently conducting numerous clinical studies. We believe that the COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our ongoing clinical trials. For example, some clinical trial sites have imposed restrictions on site visits by sponsors and CROs, the initiation of new trials, and new patient enrollment to protect both site staff and patients from possible COVID-19 exposure and to focus medical resources on patients suffering from COVID-19. While all our studies remain open, enrollment of new patients at some sites may in

the future be temporarily paused. We have provided guidance to all of our clinical trial sites that new patient enrollment may occur at sites where resources allow these patients to be safely enrolled and closely monitored.

- Other potential impacts of the COVID-19 pandemic on our clinical trials include difficulties associated with study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local, or foreign laws, rules, and regulations, including closure of site access to outside monitors, quarantines, social distancing guidelines, or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of clinical trials, heightened exposure of patients, principal investigators, and site staff to COVID-19 if a surge occurs in their geography, or other reasons related to the COVID-19 pandemic. We are working closely with our study sites and CROs to allow for utilization of remote and local assessments, such as televisits, in accordance with FDA and EMA guidance, as well as to ensure availability of study drug for patients, but we cannot assure you these efforts will be successful or that our clinical trial activities will not be adversely affected, delayed, or interrupted by COVID-19. Despite our efforts to address these risks, some patients and clinical investigators may not be able to comply with clinical trial protocols if quarantines or social distancing guidelines impede movement or interrupt healthcare services or if medical resources are reallocated to focus on patients suffering from complications related to COVID-19. If patients choose to withdraw from our studies or we choose to or are required to pause enrollment and/or patient dosing or other clinical trial related activities in order to preserve healthcare resources, protect trial participants from being exposed to unacceptable health risks or comply with access restrictions resulting from COVID-19, our studies and related timelines may be adversely affected. It is unknown how long these pauses or disruptions could continue. In addition, other aspects of our clinical trials may be adversely affected, delayed, or interrupted while the COVID-19 pandemic continues or if future surges or waves of infection occur, including, for example, site initiation, patient recruitment, availability of clinical trial materials and data analysis.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our drug candidates for our clinical trials and our drug for commercial sales, ship investigational and commercial drug supply for use in clinical trials or by patients, as appropriate, perform quality testing, and supply other goods and services to run our business. Since the beginning of the COVID-19 pandemic, four vaccines for COVID-19 have received Emergency Use Authorization by the FDA and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. If any such third parties in our supply chain for materials are adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns, disruptions in delivery systems, or the resultant demand for vaccines and potential for their facilities to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation to produce supplies needed for COVID-19 remediation, our supply chain may be disrupted, limiting our ability to manufacture our drug candidates for our clinical trials, our research and development operations, or for commercial sale of QINLOCK. For example, the effect of recent restrictive quarantine measures imposed by the Chinese government and any restrictive measures that the Chinese government may impose in the future, which, when imposed, may continue for some indeterminate amount of time, may have a material adverse effect on the business and financial condition of third parties operating in, or doing business with, that region.
- We have implemented precautionary measures to protect the health and safety of our employees, partners, and patients during the COVID-19 pandemic, including instituting a vaccination requirement as part of our return-to-office plan for all of our U.S. employees as of December 1, 2021. Requests for accommodations for medical conditions and sincerely held religious beliefs have been granted to certain of our employees consistent with applicable law. In addition, our return-to-office plan requires adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines and allows our personnel, other than those engaged in laboratory research activities, to work remotely as part of a flexible hybrid work model. As a result, our personnel may choose to continue to work remotely, and this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, IRBs, and ethics committees, manufacturing sites, research or clinical trial sites, and other important agencies and contractors. Our business operations may be further disrupted if any of our employees, officers, or board of directors contract an illness related to COVID-19 and are unable to perform their duties.
- Our employees, and employees of third-party contractors responsible for conducting research activities may have limited or reduced access to laboratories for an extended period of time as a result of occupancy restrictions or the temporary closure of such workspaces and the possibility that governmental authorities impose or modify current restrictions. As a result, this could delay timely completion of ongoing preclinical activities, including completion of IND-enabling studies, our ability to select future development candidates, and initiation of additional clinical trials for our drug candidates.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the evolving COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and, as a result, review, inspection, and other timelines may be materially delayed. For example, as of May 26, 2021, the FDA noted that it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. However, it is possible that the FDA may not be able to continue its current pace and approval times could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring, and pre-approval. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review or inspection resulting from such disruptions could materially affect the development and study of our drug candidates.
- Health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we utilize in response to the COVID-19 pandemic and current regulatory guidance, which could delay, limit, or prevent marketing approval of our drug or drug candidates. For example, the FDA may find our actions, including the use of televisits and local laboratories and physicians to conduct clinical trial activities, fail to comply with evolving regulatory guidance and may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies.
- The trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression, inflation or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

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

Risks Related to Litigation

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

We face an inherent risk of product liability exposure related to the sale and use of our approved drug and the testing of drug candidates in human clinical trials and use of our drug candidates through compassionate use and expanded access programs, and an even greater risk in connection with our commercialization of our current and future drugs. If we cannot successfully defend ourselves against any claims that our approved drug or any of our drug candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our approved drug or any of our drug candidates or products that we may develop and commercialize;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;

- loss of revenue or royalties;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our approved drug or any of our drug candidates that we may develop.

We currently hold $20.0 million in product liability insurance coverage in the aggregate for the U.S. and certain other jurisdictions, with a per incident limit of $20.0 million, which may not be adequate to cover all liabilities that we may incur or may be responsible for with respect to indemnification obligations. We anticipate that we may need to further increase our insurance coverage as we expand our clinical trials or if we successfully commercialize additional drugs or drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We could be subject to securities class action litigation.

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

Risks Related to Intellectual Property Litigation

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

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and 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 nine months ended September 30, 2022 and the year ended December 31, 2021, we reported net losses of $133.0 million and $300.0 million, respectively. As of September 30, 2022, we had an accumulated deficit of $1.2 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 $1.4 billion in net proceeds from such transactions. As of September 30, 2022, our cash, cash equivalents, and marketable securities were $371.6 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 for 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 from sales of QINLOCK, and we do not know when, or if, we will generate profits or positive operating cash flows. We also have not obtained marketing approval for QINLOCK outside of the U.S. and other select jurisdictions, including in key European markets, or for any other indications, and we have not obtained marketing approval for any of our drug candidates. We do not expect to generate significant revenue from our drug candidates unless and until we obtain marketing approval for, and begin to sell, such drug candidates. Our ability to generate further revenue from sales of QINLOCK or revenue from sales of our drug candidates depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our Phase 3 MOTION study for vimseltinib in patients with TGCT;
- 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;
- commercialize QINLOCK by deploying a sales force and marketing QINLOCK in the U.S. and key European markets and, either ourselves or through third parties, in other jurisdictions where we receive approval including Canada and Australia, assisting our licensee, Zai, in its efforts to develop and commercialize QINLOCK in the PRC, Hong Kong, and Taiwan and, if approved, in Macau, and/or entering into additional license and/or collaboration agreements and/or distribution arrangements with third parties;
- obtain, maintain, protect, and defend our intellectual property portfolio; and
- achieve and maintain market acceptance of QINLOCK, or any current or future drug candidate for which we 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 only in early stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we are required by the FDA, the EMA, or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, or in completing our clinical trials for, the development of any of our drug candidates, or as a result of impacts from the COVID-19 pandemic, global economic instability or global political developments, our expenses could increase materially.

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

We have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than QINLOCK, and have not generated 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 and we have not generated sufficient revenue to result in a profit from product sales or profit from our operations. Consequently, we may never achieve or sustain profitability and any predictions you make about our future success or viability may not be as accurate as they could be if we had an operating history with these activities.

In addition, as a growing business entering into new stages of pharmaceutical development, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We are in the early stages of transitioning from a company with a research and development focus to a company supporting commercial activities and we have limited experience with activities designed to conduct large-scale sales, marketing, and distribution activities necessary for successful product commercialization. While these efforts are underway, some of the activities are in the early stages and all are subject to numerous risks and uncertainties; accordingly, there can be no assurance that we will be successful in such a transition.

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

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

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

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

Our management has broad discretion in the application of working capital, and stockholders do not have the opportunity to assess whether working capital is being used appropriately. Because of the number and variability of factors that will determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Management might not apply working capital in ways that ultimately increase stockholder value. Failure by us to apply working capital effectively could harm our business. Pending its use, we may invest our working capital in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. In addition, the fair value of such investments is subject to change as a result of potential market fluctuations, including resulting from global economic and political developments, including historically high inflation, rising interest rates and political unrest, and the impact of the COVID-19 pandemic. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Risks Related to Our Capital Needs

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

We expect to incur significant expenses in connection with our ongoing activities, particularly as we commercialize QINLOCK, and advance 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 the initiation of 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 September 30, 2022, 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 2025. 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 anticipated cost savings of our corporate restructuring;
- the cost of maintaining, expanding, or contracting our 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 any of our drug candidates that receive marketing approval, including for QINLOCK. In addition, QINLOCK and any of our drug candidates that receive marketing approval may not achieve commercial success. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. Adequate additional funds may not be available to us on acceptable terms, or at all.

Risks Related to Ownership of Our Common Stock

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

Until at least such time, if ever, as we can generate 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 September 30, 2022, 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 30% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may:

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

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

Provisions in our amended and restated certificate of incorporation and our amended and restated 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 September 30, 2022. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- the success of commercialization of our drug and drug candidates, if approved;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures, or capital commitments;
- variations in quarterly operating results or those of companies that are perceived to be similar to us;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally;
- the degree of success of competitive products or technologies;
- results of clinical trials and preclinical studies, of our drug or drug candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- receipt of, or failure to obtain, regulatory approvals;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our drug or any of our drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in-license additional technologies or drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- rumors or announcements regarding transactions involving our company or our drug or drug candidates;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions and other national 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 or political developments, including historically high inflation and the conflict in Ukraine, or the COVID-19 pandemic, 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 instability due to political unrest or from an outbreak of pandemic or contagious disease, such as COVID-19, and 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 manufacturer's ability to make changes or respond to address any FDA concerns. The facility that our supplier of QINLOCK will initially use to manufacture commercial supply has limited experience manufacturing commercial finished drug product.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), drafted in response to the U.S. COVID-19 pandemic, became law. Throughout the COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhanced 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 potential products, 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 and Hong Kong in March 2021 and Taiwan in September 2021. 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.

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

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

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

- the design or results of clinical trials;
- the likelihood of approval by the FDA or similar regulatory authorities outside of the U.S.;
- the potential market for the subject drug or drug candidate;
- the costs and complexities of manufacturing and delivering such drug or drug candidate to patients;
- the potential of competing products;
- the ability of our intellectual property portfolio to exclude others from marketing competing products that could read on our rights, including, without limitation, generic products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally, including due to the impact of global economic instability and of COVID-19.

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

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

Risks Related to Our Intellectual Property

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

Filing, prosecuting, and defending patents with respect to our drug and drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, our intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China 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. We have applied for patent term extension in the U.S. on patents covering QINLOCK and we expect to seek extensions of patent terms in the U.S. for other drug candidates and, if available, in other countries where we are prosecuting patents. In the U.S., the Hatch-Waxman Act permits a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during the regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment, and other requirements during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to our licensed patents and patent applications. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to file non-provisional applications claiming priority to our provisional applications by the statutory deadlines, failure to timely file national and regional stage patent applications based on an international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

Item 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.

None.

Item 6. Exhibits.

Exhibit Number	Description
1.1	Amendment No. 1 to Open Market Sale Agreement℠, dated August 4, 2022, by and between the Registrant Pharmaceuticals, Inc. and Jefferies LLC (Incorporated by reference to Exhibit 1.3 to the Registrant's Form S-3 filed on August 4, 2022).
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).
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: November 3, 2022

By: /s/ Thomas P. Kelly

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

Exhibit 31.1

CERTIFICATIONS

I, Steven L. Hoerter, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

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: November 3, 2022

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 September 30, 2022 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: November 3, 2022

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 September 30, 2022 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: November 3, 2022

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