

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, 2021

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

(State or other jurisdiction of incorporation or organization)

200 Smith Street, Waltham, MA

(Address of principal executive offices)

30-1003521

(I.R.S. Employer Identification Number)

02451

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 29, 2021, there were 58,480,837 shares of Common Stock, \$0.01 par value per share, outstanding.

Deciphera Pharmaceuticals, Inc.

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SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

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

- There is no assurance that our commercialization efforts with respect to QINLOCK® (ripretinib), referred to as QINLOCK, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.
- We have limited experience as a commercial company and the marketing and sale of QINLOCK or any future approved drugs may be unsuccessful or less successful than anticipated.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug and drug candidates, including regulatory approval of QINLOCK for second-line gastrointestinal stromal tumor (GIST), or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates or expand our marketing for QINLOCK in additional indications or geographies, and our ability to generate revenue will be materially impaired.
- Our reliance on sole source third-party suppliers could harm our ability to commercialize QINLOCK or any drug candidates that may be approved in the future.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.
- Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and decrease the prices we may obtain for our approved drug.
- QINLOCK or any current or future drug candidates, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to drug candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- If the market opportunities for our approved drug or drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.
- The commercial success of QINLOCK, and of any future approved drugs, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.
- Our failure to obtain additional marketing approvals in foreign jurisdictions, including Europe, would prevent QINLOCK and our drug candidates from being marketed more extensively internationally, and any approval we are granted for QINLOCK or our drug candidates in the United States (U.S.) would not assure approval of QINLOCK or our drug candidates in foreign jurisdictions.
- QINLOCK and any drug candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of QINLOCK or any future approved product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with QINLOCK or any future approved products, when and if any of them are approved. In addition, the terms of the marketing approval of QINLOCK, and any future approved products, and ongoing regulation of our products, may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug and drug candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our clinical trials of vimseltinib, rebastinib, 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 current pandemic of the novel coronavirus (COVID-19) may have a material adverse effect on our business, financial condition, and results of operations.
- We have incurred significant operating losses since our inception and have not generated 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.
- Our reliance on third parties for the manufacture of our drug candidates for preclinical testing and clinical trials, and for the manufacture of QINLOCK for commercialization and clinical trials, increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.
- We may not be able to enforce our intellectual property rights throughout the world.
- If we are unable to obtain and maintain sufficient patent protection for our approved drug or drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our approved drug or drug candidates successfully may be adversely affected.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled "Risk Factors" and the other information set forth in this 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 QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, in the U.S., and any other jurisdictions where we may receive marketing approval in the future;
- our plans to research, develop, and commercialize our drug candidates, including the timing of our ongoing Phase 3 study of QINLOCK for the treatment of patients with second-line GIST, and the timing of investigational new drug (IND) applications, and clearance thereof, for any other product candidates;
- 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 and build out our commercial infrastructure and successfully marketing and selling QINLOCK and any current or future drug candidate for which we may receive marketing approval, including our plans with respect to the focus and activities of our sales force, the nature of our marketing, market access, patient support activities, and our pricing of QINLOCK;
- the pricing and reimbursement of, and the extent to which patient assistance programs are utilized for, QINLOCK, or any current or future drug candidates for which we may receive marketing approval;
- our expectations regarding the size and growth potential of the markets for QINLOCK or any of our current or future drug candidates for which we may receive marketing approval and our ability to serve those markets;
- our ability to obtain funding for our 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 commercially launch our drug or drug candidates, if and when they are approved, including, without limitation, QINLOCK in Europe;
- 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, and 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. and any foreign countries, including, without limitation, those applying to the marketing and sale of commercial drugs;
- the performance and experience of our third-party suppliers and manufacturers;
- the success and timing of competing therapies that are or may become available;
- our ability to attract and retain key scientific, medical, commercial, and management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing;
- the impact of global economic and political developments on our business, including economic slowdowns or recessions that may result from the 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 majeure, 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,189	\$ 135,897
Short-term marketable securities	289,081	416,033
Accounts receivable, net	18,049	13,896
Inventory	7,253	5,716
Prepaid expenses and other current assets	17,722	12,489
Total current assets	385,294	584,031
Long-term marketable securities	49,926	9,375
Long-term investments—restricted	3,102	3,102
Property and equipment, net	10,820	9,583
Operating lease assets	34,276	36,341
Total assets	\$ 483,418	\$ 642,432
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 13,502	\$ 12,308
Accrued expenses and other current liabilities	59,625	55,227
Operating lease liabilities	2,662	2,457
Total current liabilities	75,789	69,992
Operating lease liabilities, net of current portion	27,172	28,764
Total liabilities	102,961	98,756
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized; 58,327,889 shares and 57,596,144 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	583	576
Additional paid-in capital	1,345,746	1,297,557
Accumulated other comprehensive income (loss)	165	11
Accumulated deficit	(966,037)	(754,468)
Total stockholders' equity	380,457	543,676
Total liabilities and stockholders' equity	\$ 483,418	\$ 642,432

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,	
	2021	2020	2021	2020
Revenues:				
Product revenues, net	\$ 21,682	\$ 15,164	\$ 63,692	\$ 19,989
Collaboration revenues	1,538	285	8,257	2,612
Total revenues	<u>23,220</u>	<u>15,449</u>	<u>71,949</u>	<u>22,601</u>
Cost and operating expenses:				
Cost of sales	917	90	2,414	98
Research and development	66,444	49,213	182,109	146,682
Selling, general, and administrative	35,527	30,143	99,102	84,012
Total cost and operating expenses	<u>102,888</u>	<u>79,446</u>	<u>283,625</u>	<u>230,792</u>
Loss from operations	<u>(79,668)</u>	<u>(63,997)</u>	<u>(211,676)</u>	<u>(208,191)</u>
Other income (expense):				
Interest and other income, net	(170)	296	107	4,442
Total other income (expense), net	<u>(170)</u>	<u>296</u>	<u>107</u>	<u>4,442</u>
Net loss	<u>\$ (79,838)</u>	<u>\$ (63,701)</u>	<u>\$ (211,569)</u>	<u>\$ (203,749)</u>
Net loss per share—basic and diluted	<u>\$ (1.37)</u>	<u>\$ (1.13)</u>	<u>\$ (3.65)</u>	<u>\$ (3.68)</u>
Weighted average common shares outstanding—basic and diluted	<u>58,107,611</u>	<u>56,390,748</u>	<u>57,948,612</u>	<u>55,296,775</u>
Comprehensive loss:				
Net loss	\$ (79,838)	\$ (63,701)	\$ (211,569)	\$ (203,749)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	(9)	47	(32)	(72)
Currency translation adjustment	148	—	186	—
Total other comprehensive income (loss)	<u>139</u>	<u>47</u>	<u>154</u>	<u>(72)</u>
Total comprehensive loss	<u>\$ (79,699)</u>	<u>\$ (63,654)</u>	<u>\$ (211,415)</u>	<u>\$ (203,821)</u>

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, 2021	58,033,984	\$ 580	\$ 1,332,249	\$ 26	\$ (886,199)	\$ 446,656
Issuance of common stock under stock option and incentive plan	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	<u>58,327,889</u>	<u>\$ 583</u>	<u>\$ 1,345,746</u>	<u>\$ 165</u>	<u>\$ (966,037)</u>	<u>\$ 380,457</u>

	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 sold, 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	<u>58,327,889</u>	<u>\$ 583</u>	<u>\$ 1,345,746</u>	<u>\$ 165</u>	<u>\$ (966,037)</u>	<u>\$ 380,457</u>

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

Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity (continued)
(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, 2020	56,081,993	\$ 561	\$ 1,247,158	\$ (8)	\$ (628,027)	\$ 619,684
Issuance of common stock under stock option and incentive plan	559,072	5	3,223	—	—	3,228
Stock-based compensation expense	—	—	9,828	—	—	9,828
Other comprehensive income (loss)	—	—	—	47	—	47
Net loss	—	—	—	—	(63,701)	(63,701)
Balance, September 30, 2020	<u>56,641,065</u>	<u>\$ 566</u>	<u>\$ 1,260,209</u>	<u>\$ 39</u>	<u>\$ (691,728)</u>	<u>\$ 569,086</u>

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2019	51,617,639	\$ 516	\$ 1,033,819	\$ 111	\$ (487,979)	\$ 546,467
Issuance of common stock sold in public offering, net of underwriting discounts, commissions and offering costs	3,659,090	37	188,348	—	—	188,385
Issuance of common stock under stock option and incentive plan	1,364,336	13	10,611	—	—	10,624
Stock-based compensation expense	—	—	27,431	—	—	27,431
Other comprehensive income (loss)	—	—	—	(72)	—	(72)
Net loss	—	—	—	—	(203,749)	(203,749)
Balance, September 30, 2020	<u>56,641,065</u>	<u>\$ 566</u>	<u>\$ 1,260,209</u>	<u>\$ 39</u>	<u>\$ (691,728)</u>	<u>\$ 569,086</u>

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (211,569)	\$ (203,749)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	35,284	27,431
Depreciation expense	2,234	1,610
Noncash lease expense	2,527	1,948
Acquired in-process research and development	4,000	—
(Gain) loss on disposal of equipment	—	(7)
Net amortization (accretion) of premium (discounts) on marketable securities	1,392	(1,850)
Changes in operating assets and liabilities:		
Accounts receivable	(4,153)	(11,814)
Inventory	(3,275)	(2,455)
Prepaid expenses and other current assets	(5,240)	1,030
Accounts payable	1,178	(9,908)
Accrued expenses and other current liabilities	5,823	8,339
Operating lease liabilities	(1,849)	(1,130)
Net cash flows used in operating activities	<u>(173,648)</u>	<u>(190,555)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(313,718)	(969,005)
Maturities of marketable securities	360,076	452,663
Sales of marketable securities	38,617	504,216
Purchases of property and equipment	(3,079)	(4,886)
Proceeds from sale of equipment	—	7
Acquired in-process research and development	(4,000)	—
Increase in restricted investments	—	(615)
Net cash flows provided by (used in) investing activities	<u>77,896</u>	<u>(17,620)</u>
Cash flows from financing activities:		
Proceeds from offerings of common stock, net of underwriting discounts and commissions	8,588	189,037
Payments of offering costs	(40)	(652)
Proceeds from stock option exercises and employee stock purchase plan	4,364	10,624
Net cash flows provided by financing activities	<u>12,912</u>	<u>199,009</u>
Net decrease in cash and cash equivalents	(82,840)	(9,166)
Effect of exchange rate changes on cash and cash equivalents	132	—
Cash and cash equivalents at beginning of period	135,897	120,320
Cash and cash equivalents at end of period	<u>\$ 53,189</u>	<u>\$ 111,154</u>
Supplemental disclosure of cash flow information:		
Operating lease liabilities arising from obtaining operating lease assets	\$ 462	\$ 14,883

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. The Company is leveraging its proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. The Company has one approved drug, QINLOCK® (ripretinib), referred to as QINLOCK, which is a switch control inhibitor developed through the Company's proprietary platform. Beyond QINLOCK, the Company is developing three clinical stage drug candidates and advancing its research-stage programs. The Company wholly owns QINLOCK and all of its drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in the People's Republic of China (the PRC), Hong Kong, Macau, and Taiwan, referred to as Greater China. The Company is preparing for a potential launch of QINLOCK in Europe and the Company has entered, and intends in the future to enter, into select distributor arrangements to offer QINLOCK in geographies where the Company does not intend to distribute QINLOCK on its own, such as Australia and Canada.

On May 15, 2020, QINLOCK was approved by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. Following the FDA approval of QINLOCK, in May 2020, the Company commenced commercial sales of QINLOCK in the U.S. In June 2020, QINLOCK was authorized for sale in Canada by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In July 2020, the Australian Therapeutic Goods Administration approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In March 2021, the China National Medical Products Administration (NMPA) approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In March 2021, the Hong Kong Department of Health approved QINLOCK in Hong Kong for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In September 2021, the Taiwan Food and Drug Administration approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. In September 2021, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of QINLOCK for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The CHMP opinion is a scientific recommendation for marketing authorization for the use of QINLOCK and is now being reviewed by the European Commission (EC), which has the authority to grant marketing authorization for medicinal products in the European Union. A final approval decision from the EC is expected in the fourth quarter of 2021. In October 2021, the Swiss Agency for Therapeutic Products granted approval for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, market acceptance and the successful commercialization of QINLOCK or any of the Company's current or future drug candidates for which it receives marketing approval, competition for QINLOCK or any of the Company's current or future drug candidates for which it receives marketing approval, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, compliance with government regulations, the impact of the novel coronavirus (COVID-19) pandemic on its operations, and the ability to secure additional capital to fund operations. QINLOCK and the Company's drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval. In addition to supporting its research and development efforts, the Company will be required to invest in the Company's commercial capabilities and infrastructure, to support its 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.

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Notes to the Consolidated Financial Statements
(Unaudited)

The full extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact the Company's business, including its preclinical studies, clinical trial operations, or commercialization efforts will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted at this time, such as the duration of such pandemic including future waves of infection, new strains of the virus that causes COVID-19, or the 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 February 2020, the Company issued and sold 3,659,090 shares of its common stock in a follow-on public offering at a public offering price of \$55.00 per share, resulting in net proceeds of \$188.4 million after deducting underwriting discounts and commissions and other offering expenses.

In August 2020, the Company entered into an Open Market Sale AgreementSM (the Sales Agreement) with Jefferies LLC (Jefferies), pursuant to which the Company may issue and sell shares of its common stock having aggregate offering proceeds of up to \$200.0 million (the Shares) from time to time through Jefferies as its sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell the Shares in amounts and at times to be determined by the Company from time to time subject to the terms and conditions of the Sales Agreement, but it has no obligation to sell any Shares under the Sales Agreement. The Company or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. During the nine months ended September 30, 2021, the Company issued 172,094 shares resulting in net proceeds of \$8.5 million after deducting underwriting discounts and commissions and other offering expenses under the Sales Agreement. As of September 30, 2021, there was up to \$172.5 million available for future issuance under the Sales Agreement.

Basis of Presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has incurred recurring losses including net losses of \$211.6 million and \$266.5 million for the nine months ended September 30, 2021 and the year ended December 31, 2020, respectively. As of September 30, 2021, the Company had an accumulated deficit of \$966.0 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents, and marketable securities of \$392.2 million as of September 30, 2021 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).

Deciphera Pharmaceuticals, Inc.
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The consolidated balance sheet as of December 31, 2020 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, 2021 and for the three and nine months ended September 30, 2021 and 2020 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2020 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, 2021 and consolidated results of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020 and consolidated cash flows for the nine months ended September 30, 2021 and 2020 have been made. The consolidated results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

The significant accounting policies used in preparation of these consolidated financial statements for the three and nine months ended September 30, 2021 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, 2020, except as noted within the section "Significant Accounting Policies" with respect to the Company's accounting policies for in-process research and development and comprehensive income and accumulated other comprehensive income (loss).

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, product revenue reserves, the accrual for research and development expenses, and the valuation of stock-based option awards. Estimates are periodically reviewed in light of changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Net Loss per Share

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

For periods in which the Company has reported net losses, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for the three and nine months ended September 30, 2021 and 2020.

Deciphera Pharmaceuticals, Inc.
Notes to the Consolidated Financial Statements
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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,	
	2021	2020
Options to purchase common stock	6,405,542	6,351,397
Unvested restricted common stock units	839,407	474,435
Unvested employee stock purchase plan shares	34,183	39,600
Total	<u>7,279,132</u>	<u>6,865,432</u>

Significant Accounting Policies

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

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

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

Comprehensive Loss and Accumulated Other Comprehensive Income (Loss)

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with shareholders. For the three and nine months ended September 30, 2021, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities and foreign currency translation adjustments. For the three and nine months ended September 30, 2020, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities.

As of September 30, 2021, accumulated other comprehensive income (loss) primarily consisted of currency translation adjustments. As of December 31, 2020, accumulated other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities.

2. Revenues

Net Product Revenues

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

Net product revenues by geography consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
U.S.	\$ 19,975	\$ 14,647	\$ 59,994	\$ 19,472
Rest of world	1,707	517	3,698	517
Total product revenues, net	<u>\$ 21,682</u>	<u>\$ 15,164</u>	<u>\$ 63,692</u>	<u>\$ 19,989</u>

Deciphera Pharmaceuticals, Inc.
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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, 2020	\$ 152	\$ 264	\$ 2,433	\$ 532	\$ 3,381
Provision related to sales in the current year	1,815	3,024	5,542	1,306	11,687
Adjustments related to prior period sales	85	57	(194)	(395)	(447)
Credits and payments made during the period for current year sales	(1,647)	(2,776)	(1,373)	(665)	(6,461)
Credits and payments made during the period for prior period sales	(207)	(97)	(645)	(95)	(1,044)
Balance as of September 30, 2021	\$ 198	\$ 472	\$ 5,763	\$ 683	\$ 7,116

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

(in thousands)	As of September 30, 2021	As of December 31, 2020
Reduction of accounts receivable, net	\$ 630	\$ 363
Component of accrued expenses and other current liabilities	6,486	3,018
Total revenue-related reserves	\$ 7,116	\$ 3,381

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 became eligible to receive up to \$185.0 million in potential development and commercial milestone payments, consisting of up to \$50.0 million of development milestones and up to \$135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay the Company tiered percentage royalties ranging from low to high teens on 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 nine months ended September 30, 2020, revenues recognized under the Zai License Agreement included the achievement of a \$2.0 million development milestone in the second quarter of 2020.

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

Please read Note 3, *Revenues*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2020 for further details on the Zai License Agreement.

Deciphera Pharmaceuticals, Inc.
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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 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.

3. Marketable Securities and Fair Value Measurements

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

As of September 30, 2021 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	\$ 152,641	\$ 10	\$ (17)	\$ 152,634
Corporate debt securities	55,810	1	(17)	55,794
Certificates of deposit	45,040	6	—	45,046
U.S. government securities	35,604	3	—	35,607
Due after one year through five years:				
Corporate debt securities	49,933	20	(27)	49,926
Total	<u>\$ 339,028</u>	<u>\$ 40</u>	<u>\$ (61)</u>	<u>\$ 339,007</u>
As of December 31, 2020 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
U.S. government securities	\$ 298,335	\$ 49	\$ (1)	\$ 298,383
Commercial paper	62,037	9	(15)	62,031
Corporate debt securities	38,309	—	(34)	38,275
Certificates of deposit	17,344	1	(1)	17,344
Due after one year through five years:				
U.S. government securities	9,370	5	—	9,375
Total	<u>\$ 425,395</u>	<u>\$ 64</u>	<u>\$ (51)</u>	<u>\$ 425,408</u>

Deciphera Pharmaceuticals, Inc.
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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, 2021 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ —	\$ 31,199	\$ —	\$ 31,199
Commercial paper	—	2,000	—	2,000
Marketable securities:				
Commercial paper	—	152,634	—	152,634
Corporate debt securities	—	105,720	—	105,720
Certificates of deposit	—	45,046	—	45,046
U.S. government securities	—	35,607	—	35,607
Total	\$ —	\$ 372,206	\$ —	\$ 372,206

As of December 31, 2020 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ —	\$ 46,676	\$ —	\$ 46,676
U.S. government securities	—	30,000	—	30,000
Marketable securities:				
U.S. government securities	—	307,758	—	307,758
Commercial paper	—	62,031	—	62,031
Corporate debt securities	—	38,275	—	38,275
Certificates of deposit	—	17,344	—	17,344
Total	\$ —	\$ 502,084	\$ —	\$ 502,084

The table above excludes certificates of deposit totaling \$3.1 million as of both September 30, 2021 and December 31, 2020 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, 2020.

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.

4. Inventory

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

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Notes to the Consolidated Financial Statements
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Capitalized inventory consisted of the following:

(in thousands)	As of September 30, 2021	As of December 31, 2020
Raw materials	\$ 1,352	\$ 1,352
Work in process	4,443	4,142
Finished goods	1,458	222
Total inventory	<u>\$ 7,253</u>	<u>\$ 5,716</u>

Inventory written down as a result of excess, obsolescence, unmarketability, or other reasons is charged to cost of sales, and totaled less than \$0.1 million during the nine months ended September 30, 2021. There were no inventory amounts written down and charged to cost of sales during the three months ended September 30, 2021 or during the three and nine months ended September 30, 2020.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	As of September 30, 2021	As of December 31, 2020
Accrued research and development	\$ 30,553	\$ 31,259
Payroll and related expenses	16,091	17,255
Professional fees	6,121	3,306
Revenue-related reserves	6,486	3,018
Other	374	389
Total accrued expenses and other current liabilities	<u>\$ 59,625</u>	<u>\$ 55,227</u>

6. Stock-Based Awards

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, 2021, 2,520,511 shares of common stock were available for issuance under the 2017 Plan. As of September 30, 2021, 1,729,854 shares of common stock were available for issuance to participating employees under the ESPP. Employees began participating in the ESPP program during the second quarter of 2020.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expenses	\$ 5,430	\$ 4,518	\$ 15,983	\$ 13,082
Selling, general, and administrative expenses	6,364	5,310	19,301	14,349
Total stock-based compensation	<u>\$ 11,794</u>	<u>\$ 9,828</u>	<u>\$ 35,284</u>	<u>\$ 27,431</u>

As of September 30, 2021, total unrecognized compensation cost related to the unvested share-based awards was \$106.8 million, which is expected to be recognized over a weighted average of 2.6 years.

During the three and nine months ended September 30, 2020, the Company recorded \$0.4 million and \$1.7 million of stock-based compensation expense related to vesting events associated with performance-based restricted stock units that became probable and were achieved during the second quarter of 2020. These expenses were classified as research and development expenses within the consolidated statements of operations and comprehensive loss.

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7. In-License Agreement

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

The Company accounted for this transaction as an asset acquisition as the value being acquired primarily relates to a single IPR&D asset. Pursuant to the terms of the Sprint Agreement, the Company made an upfront payment of \$4.0 million during the third quarter of 2021, which was recorded as research and development expense within the consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2021 as the acquired asset had not yet reached technological feasibility. Sprint is also eligible to receive up to an additional \$273.0 million in potential development and commercial milestone payments from the Company as well as tiered percentage royalties ranging from the mid-single-digits to the low-double-digits on the sales of a potential product from the program, if approved.

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, 2021, the Company's contractual commitments for its commercial supply agreements were \$12.6 million, which are expected to be paid within one year.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the 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, 2021 or December 31, 2020.

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, 2020 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. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. We have one approved drug, QINLOCK, for the treatment of adults with fourth-line or fourth-line plus GIST, which is a switch control inhibitor developed through our proprietary platform. Beyond QINLOCK, we are developing three clinical-stage drug candidates and advancing our research-stage programs. We wholly own QINLOCK and all of our drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China. We are preparing for a potential launch of QINLOCK in Europe and we have entered, and intend in the future to enter, into select distributor arrangements to offer QINLOCK in geographies where we do not intend to distribute QINLOCK on our own, such as Australia and Canada.

Recent Developments

QINLOCK

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

In September 2021, we announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of QINLOCK for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The CHMP opinion is a scientific recommendation for marketing authorization for the use of QINLOCK and is now being reviewed by the European Commission (EC), which has the authority to grant marketing authorization for medicinal products in the European Union (EU). A final approval decision from the EC is expected in the fourth quarter of 2021. In October 2021, we also announced that the Swiss Agency for Therapeutic Products (Swissmedic) granted approval for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

We expect to announce top-line results from our pivotal Phase 3 study in second-line GIST, INTRIGUE, in the fourth quarter of 2021. We are planning to initiate a Phase 1b/2 study of QINLOCK in combination with binimetinib, a commercially available MEK inhibitor, in patients with post-imatinib GIST, in the fourth quarter of 2021.

Vimseltinib

In September 2021, we announced plans to advance vimseltinib, our investigational, orally administered, potent, and highly-selective inhibitor of the colony stimulating factor 1 receptor (CSF1R), into a pivotal Phase 3 study in patients with tenosynovial giant cell tumor (TGCT), MOTION, at the European Society for Medical Oncology Congress (ESMO 2021). We expect to initiate the MOTION study in the fourth quarter of 2021. The MOTION study is two-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of vimseltinib in patients with symptomatic TGCT who are not amenable to surgery. In Part 1 of the MOTION study, eligible study participants will be assigned to receive either 30 mg twice weekly vimseltinib (n=80) or matching placebo (n=40) for 24 weeks. Participants assigned to placebo in Part 1 will have the option to receive vimseltinib for Part 2 of the MOTION study. Part 2 is a long-term treatment phase in which all participants will receive open-label vimseltinib. The primary endpoint of the study is objective response rate at week 25 as measured by RECIST v1.1 by blinded independent central review.

In September 2021, we also presented updated preliminary data from the ongoing Phase 1/2 study of vimseltinib to assess the safety, efficacy, pharmacokinetics, and pharmacodynamics in patients with TGCT at ESMO 2021.

In November 2021, we announced that vimseltinib had been granted fast track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with symptomatic TGCT who are not amenable to surgery.

Rebastinib

Rebastinib is currently in clinical development for the treatment of multiple solid tumors in combination with chemotherapy in two Phase 1b/2 trials, one with paclitaxel and one with carboplatin. The Phase 1b/2 trial of rebastinib in combination with paclitaxel is a two-part, open-label, multicenter study assessing the safety, tolerability, anti-tumor activity, and pharmacokinetics of rebastinib in patients with advanced or metastatic solid tumors. As previously announced, in Part 2 of the trial of rebastinib in combination with paclitaxel, designed as a Simon 2-stage design, we observed the required number of responses in Part 2, Stage 1 in both the endometrial and platinum-resistant ovarian cancer (PROC) cohorts, triggering the expansion of enrollment in these cohorts.

Rebastinib in Combination with Paclitaxel

In August 2021, we announced that the inflammatory breast cancer and gynecological carcinosarcoma cohorts in Part 2, Stage 1 of the trial of rebastinib in combination with paclitaxel, did not advance to Part 2, Stage 2. Enrollment in these cohorts has been closed.

In September 2021, we presented updated preliminary data from the ongoing Phase 1b/2 trial of rebastinib in combination with paclitaxel in patients with PROC at ESMO 2021. In September 2021, we also announced that we expect to finalize pivotal study plans and initiate a study of rebastinib in combination with paclitaxel in patients with PROC in 2022, subject to feedback from regulators. We have prioritized a pivotal study of rebastinib in combination with paclitaxel in patients with PROC, subject to feedback from regulators, and have not advanced the endometrial cancer cohort to a pivotal study at this time.

In November 2021, we announced that rebastinib received Orphan Drug Designation in the EU for the treatment of ovarian cancer based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products.

Rebastinib in Combination with Carboplatin

In August 2021, we announced that the platinum-sensitive ovarian cancer cohort in Part 2, Stage 1 of the trial of rebastinib in combination with carboplatin, designed as a Simon 2-stage design, did not advance to Part 2, Stage 2. Enrollment in the trial has been closed as no cohorts have advanced to the next stage of the study.

DCC-3116

In June 2021, we announced dosing of the first patient in the Phase 1, multicenter, open-label, first-in-human study of DCC-3116. DCC-3116 is an investigational ULK kinase inhibitor designed to inhibit autophagy and is being studied as a single agent and in combination with trametinib, a commercially available MEK inhibitor, in patients with advanced or metastatic tumors with a documented RAS or RAF mutation who have progressed despite standard therapies, or for whom conventional therapy is not considered effective or tolerable, as judged by the investigator.

In October 2021, we presented preclinical data on DCC-3116 in combination with EGFR inhibitors in non-small cell lung cancer models at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. In October 2021, we also announced that we expect to present initial data from the dose escalation phase of the Phase 1 study in 2022.

Business Development

In August 2021, we entered into an agreement with Sprint Bioscience (Sprint) to exclusively in-license worldwide rights to a research-stage program targeting VPS34, a key kinase in the autophagy pathway for the potential treatment of cancer (the Sprint Agreement). VPS34 is involved in the endosomal trafficking of cellular cargo targeted for lysosomal degradation in cancer cells. Targeting VPS34 may provide an additional approach to regulating autophagy that is complementary to inhibition of ULK kinase by blocking VPS34-mediated immunosuppression in tumors. For further details on the Sprint Agreement, please read Note 7, *In-License Agreement*, to the consolidated financial statements included in this Form 10-Q.

Coronavirus (COVID-19)

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

We are continuing to assess the long-term impact of COVID-19 on our business operations in an effort to mitigate interruption to our clinical programs, research efforts, 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 studies. COVID-19 infections continue to fluctuate in the U.S. and in many countries worldwide as local surges and new waves of infection continue to be reported, in particular as caused by new variants of the virus that causes COVID-19 and the lack of availability of effective vaccines in certain countries or regions, or failure to utilize available vaccines in other geographies. Although some of the 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 from the height of the pandemic, in response to local surges and waves of infection, including those caused by the Delta variant, some countries, states, and local governments have maintained or reinstated these restrictions, or may reinstate these restrictions from time to time, in response to rising rates of infection. In response to the COVID-19 pandemic, we have implemented precautionary measures to protect the health and safety of our employees, partners, and patients, including encouraging all employees, other than those engaged in laboratory research activities, to work-from-home, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines. These safety measures may be eased, lifted, or reinstated in accordance with updates to such guidelines.

Our ability to successfully commercialize and generate revenue from QINLOCK may be adversely affected by the impact of the COVID-19 pandemic. While restrictive safety measures are in place, limited hospital access for non-patients, including our sales personnel, social distancing requirements, and precautionary measures due to COVID-19 may impact the ability of our sales personnel to interact in-person with customers in the same manner as they did before the COVID-19 pandemic. In response, we have implemented a virtual sales model to supplement traditional means of customer engagement. 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 Delta variant, may adversely affect the ability of our sales professionals to effectively market QINLOCK to physicians, which may have a negative impact on our sales and our market penetration. The persistence of the COVID-19 pandemic could also impact the patient treatment paradigm and how patients are diagnosed and monitored. In addition, in the U.S. we are utilizing various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and higher levels of unemployment caused by the COVID-19 pandemic may lead to increased utilization of our patient assistance programs, which could reduce revenues.

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

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

Components of Our Results of Operations

Revenues

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following the FDA approval of QINLOCK, in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. We may generate revenue in the future from a combination of product sales or payments from collaboration, distribution, or any potential additional license agreements that we may enter into with third parties. We expect that our revenue in the foreseeable future will be derived primarily from sales of QINLOCK and, payments 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

Following the FDA approval of QINLOCK in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. During the three and nine months ended September 30, 2021 and 2020, 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 considerations.

Collaboration Revenues

For the three and nine months ended September 30, 2021 and 2020, 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 became eligible to receive up to \$185.0 million in potential development and commercial milestone payments, consisting of up to \$50.0 million of development milestones and up to \$135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on annual net sales of QINLOCK, including certain follow-on compounds (the Licensed Products), in Greater China, 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 we incur for external manufacturing services 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, 2021 and 2020 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.

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 complete clinical development of and commercialize QINLOCK and 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
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all.

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 costs to increase as our drug and drug candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of our drug and any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, legal, finance, commercial, human resources, and administrative functions. Selling, general, and administrative expenses also include direct and allocated facility- and technology-related costs as well as professional fees for legal, patent, consulting, accounting, and audit services.

We anticipate that our selling, general, and administrative expenses will increase as we continue to support the commercialization of QINLOCK in the U.S., the potential launch of QINLOCK in Europe, if approved, and the establishment of a targeted commercial infrastructure in key European markets. We also anticipate that we will continue to incur accounting, audit, legal, regulatory, compliance, and investor and public relations expenses associated with growth of the business and continued operations as a public company.

Other Income (Expense)

Interest and Other Income, net

Interest income consists of interest earned on our cash, cash equivalents, and marketable securities balances. Other income, net, consists of insignificant amounts of miscellaneous income and expenses unrelated to our core operations, including the impacts of foreign currency exchange differences.

Income Taxes

On October 2, 2017, immediately prior to the completion of our initial public offering (IPO), we engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation (the Conversion). Prior to the Conversion, we were treated as a partnership for tax purposes and had not been subject to U.S. federal or state income taxation. Upon the Conversion, we became subject to typical corporate U.S. federal and state income taxation; however, we do not have net operating loss carryforwards from periods prior to October 2, 2017 available to offset taxable income earned in future periods in which we will be treated as a corporation.

Consistent with our income tax disclosures described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Components of Our Results of Operations" in our Form 10-K for the year ended December 31, 2020 on file with the SEC, as of September 30, 2021, 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, 2020 on file with the SEC. There have been no significant changes to our critical accounting policies since December 31, 2020.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three and nine months ended September 30, 2021 and 2020:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product revenues, net	\$ 21,682	\$ 15,164	\$ 63,692	\$ 19,989
Collaboration revenues	1,538	285	8,257	2,612
Total revenues	23,220	15,449	71,949	22,601
Cost and operating expenses:				
Cost of sales	917	90	2,414	98
Research and development	66,444	49,213	182,109	146,682
Selling, general, and administrative	35,527	30,143	99,102	84,012
Total cost and operating expenses	102,888	79,446	283,625	230,792
Loss from operations	(79,668)	(63,997)	(211,676)	(208,191)
Other income (expense):				
Interest and other income, net	(170)	296	107	4,442
Total other income (expense), net	(170)	296	107	4,442
Net loss	\$ (79,838)	\$ (63,701)	\$ (211,569)	\$ (203,749)

Revenues**Product Revenues, Net**

During the three and nine months ended September 30, 2021 and 2020, our only source of product revenues was from the sales of QINLOCK, which commenced in the U.S. in May 2020 following the FDA approval of QINLOCK on May 15, 2020. During the three and nine months ended September 30, 2021 and 2020, net product revenues by geography consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
U.S.	\$ 19,975	\$ 14,647	\$ 59,994	\$ 19,472
Rest of world	1,707	517	3,698	517
Total product revenues, net	\$ 21,682	\$ 15,164	\$ 63,692	\$ 19,989

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, net product revenues increased \$6.5 million and \$43.7 million, respectively, primarily due to increased sales volume in the U.S. as we continued our commercialization efforts. For the nine months ended September 30, 2021 compared to the same period in 2020, the increase in net product revenues was also due to full quarters of sales in U.S. in the first and second quarters of 2021 compared to a partial quarter of sales in the U.S. in the second quarter of 2020.

Collaboration Revenues

For the three months ended September 30, 2021 compared to the same period in 2020, collaboration revenues increased \$1.3 million primarily due to an increase in revenues under the Zai Supply Agreement and an increase from royalty revenues. Following the approvals of QINLOCK in the PRC and Hong Kong in March 2021, we began recognizing revenues associated with the sales of commercial inventory of QINLOCK under the Zai Supply Agreement and began recognizing royalty revenues under the Zai License Agreement. The first sales of commercial inventory under the Zai Supply Agreement and first royalty revenues under the Zai License Agreement were recognized during the second quarter of 2021.

For the nine months ended September 30, 2021 compared to the same period in 2020, collaboration revenues increased \$5.6 million primarily due to an increase in milestone revenues of \$3.0 million under the Zai License Agreement. The increase in milestone revenues was due to the recognition of a \$5.0 million development milestone in the first quarter of 2021 associated with the approval of QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, by the China NMPA in March 2021, partially offset by the recognition of a \$2.0 million development milestone in the second quarter of 2020. There were also increased revenues from the Zai Supply Agreement and an increase from royalty revenues beginning in the second quarter of 2021 following the approvals of QINLOCK in the PRC and Hong Kong.

Cost of Sales

During the three and nine months ended September 30, 2021 and 2020, cost of sales by type consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of product sales	\$ 193	\$ 90	\$ 809	\$ 98
Cost of collaboration sales	724	—	1,605	—
Total cost of sales	\$ 917	\$ 90	\$ 2,414	\$ 98

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, cost of sales increased \$0.8 million and \$2.3 million, respectively, primarily associated with the costs of commercial inventory of QINLOCK sold under the Zai Supply Agreement beginning in the second quarter of 2021 as well as increased product sales of QINLOCK in the U.S. For the nine months ended September 30, 2021 compared to the same period in 2020, the increase in cost of product sales was also due to full quarters of sales in U.S. in the first and second quarters of 2021 compared to a partial quarter of sales in the U.S. in the second quarter of 2020. 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

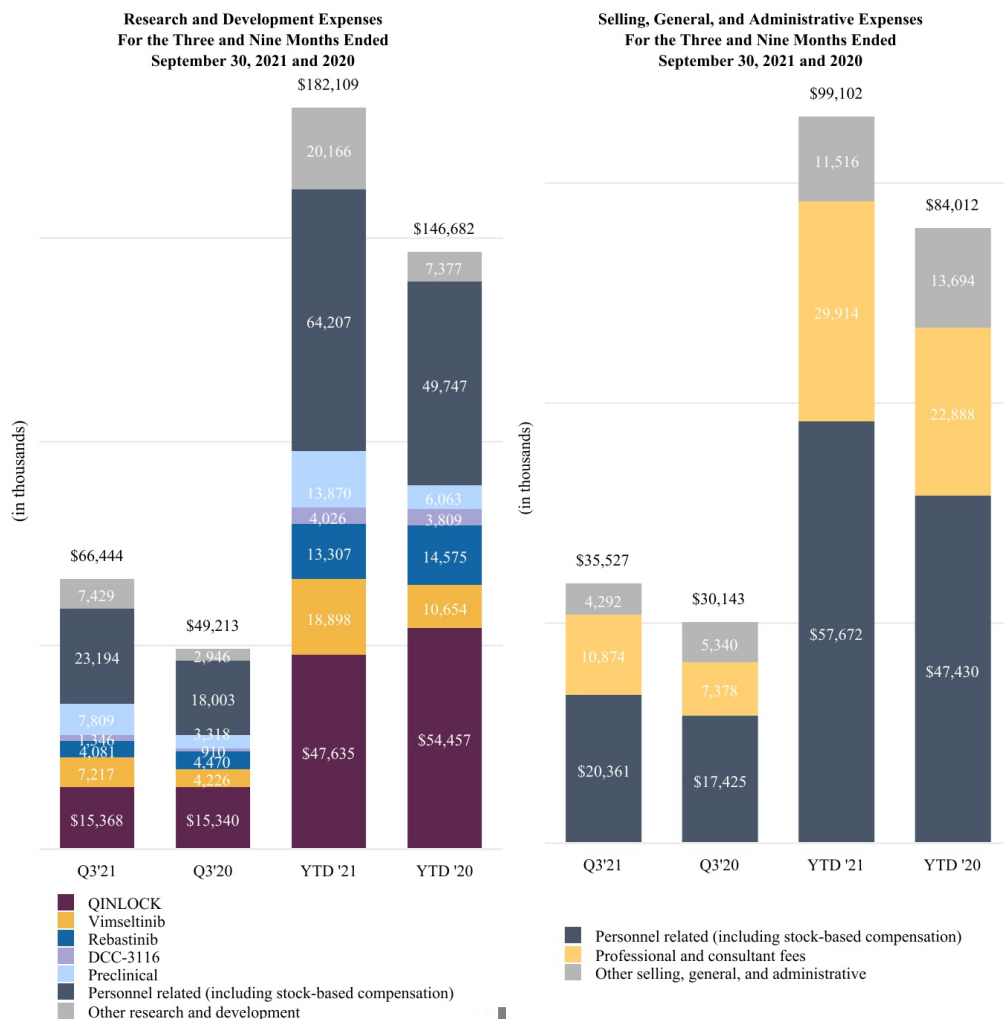
associated with product sales of QINLOCK was primarily related to the sales of zero cost inventories, which consisted of packaging, labeling, shipping, and distribution costs. As a result, the full costs of manufacturing QINLOCK inventory are not included in cost of sales during the three and nine months ended September 30, 2021 and 2020.

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. During the nine months ended September 30, 2020, we recorded approximately \$1.0 million of such costs related to the build-up of this inventory 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 months ended September 30, 2020 or during the three and nine months ended September 30, 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 ended September 30, 2021 would have increased by approximately \$0.3 million and \$1.4 million, respectively, and \$0.2 million and \$0.3 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 expect to continue to sell the zero cost inventories of QINLOCK in the U.S. during 2021 and into 2022.

Operating Expenses



Research and Development Expenses

QINLOCK

For the nine months ended September 30, 2021 compared to the same period in 2020, research and development expenses related to QINLOCK decreased primarily as a result of decreased clinical trial expenses of \$6.8 million. Clinical trial expenses for QINLOCK decreased primarily as a result of decreased expenses associated with INTRIGUE, which we initiated in December 2018 and for which enrollment was completed in December 2020, and INVICTUS, which we initiated in January 2018 and announced top-line results from in August 2019. In addition, clinical trial expenses decreased due to decreased expenses associated with our ongoing Phase 1 trial of QINLOCK. These decreases were partially offset by increased expenses associated with start-up activities for our planned Phase 1b/2 trial of QINLOCK in combination with binimetinib, which we expect to initiate in the fourth quarter of 2021.

Vimseltinib

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, expenses related to our vimseltinib program increased primarily as a result of increases in clinical trial expenses of \$2.0 million and \$6.4 million and increases in manufacturing costs of \$1.5 million and \$3.3 million, respectively. Clinical trial expenses increased primarily due to start-up activities associated with our Phase 3 study of vimseltinib in patients with TGCT, MOTION, which we expect to initiate in the fourth quarter of 2021, increased activities associated with our ongoing Phase 1/2 study of vimseltinib to assess the safety, efficacy, pharmacokinetics, and pharmacodynamics in patients with TGCT, and increased clinical pharmacology study activities. Manufacturing costs for the vimseltinib program increased as a result of increased activities to support clinical trials.

Rebastinib

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, expenses related to our rebastinib program decreased primarily as a result of decreases in clinical trial expenses of \$1.0 million and \$2.9 million, respectively. The decrease in clinical trial expenses was primarily associated with our Phase 1b/2 trial of rebastinib in combination with paclitaxel due to the completion of enrollment of multiple cohorts in the trial, including completion of enrollment in Part 2, Stage 2 of both the endometrial and platinum-resistant ovarian cancer cohorts, as announced in February 2021.

DCC-3116

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, expenses related to our DCC-3116 program changed as we completed preclinical studies, submitted our IND, and initiated our first clinical trial for DCC-3116. For the three months ended September 30, 2021 compared to the same period in 2020, expenses increased primarily as a result of increased clinical trial expenses of \$0.4 million associated with our Phase 1 study of DCC-3116, which we initiated in June 2021. For the nine months ended September 30, 2021 compared to the same period in 2020, the changes in expenses consisted of increased clinical trial and manufacturing expenses of \$1.3 million and \$0.5 million, respectively, associated with our Phase 1 study of DCC-3116, partially offset by decreased preclinical activities, including IND-enabling studies, of \$1.7 million.

Preclinical

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, the increases in preclinical costs of \$4.5 million and \$7.8 million, respectively, were primarily due to a \$4.0 million upfront payment to Sprint pursuant to the Sprint Agreement during the third quarter of 2021 in addition to increased activities for our early-stage drug discovery programs. For further details on the Sprint Agreement, please read Note 7, *In-License Agreement*, to the consolidated financial statements included in this Form 10-Q.

Unallocated Expenses

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, the increases in unallocated research and development expenses were associated with personnel-related and other research and development costs. For the three and nine months ended September 30, 2021 compared to the same periods in 2020, the increases in personnel-related costs, including increases in stock-based compensation expense of \$0.9 million and \$2.9 million, respectively, were primarily due to an increase in headcount in our research and development functions. The increases in stock-based compensation expense were partially offset by \$0.4 million and \$1.7 million of expenses incurred during the three and nine months ended September 30, 2020, respectively, related to the achievement of the vesting event associated with performance-based restricted stock units during the second quarter of 2020. For the three and nine months ended September 30, 2021 compared to the same periods in 2020, increases in other research and development costs were primarily due to increased costs for temporary staffing of \$0.8 million and \$3.0 million, respectively, and increased technology-related and facility-related expenses to support growth in our research and development functions associated with the increase in headcount.

We expect research and development expenses will increase in the fourth quarter of 2021 as compared to the first nine months of 2021 as we continue to invest in the development of our clinical pipeline.

Selling, General, and Administrative Expenses

For the three and nine months ended September 30, 2021 compared to the same periods in 2020, the increases in selling, general, and administrative expenses were primarily associated with personnel-related costs and professional and consultant fees. For the three and nine months ended September 30, 2021 compared to the same periods in 2020, the increases in personnel-related costs, including increases in stock-based compensation of \$1.1 million and \$5.0 million, respectively, were primarily a result of increases in headcount in our selling, general, and administrative functions. The increases in professional and consultant fees were

primarily due to an increase in various advisory and temporary staffing fees, including those related to establishing a targeted commercial infrastructure and commercialization preparedness in key European markets to support a potential launch of QINLOCK in Europe, if approved.

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

Interest and Other Income, Net

For the three months ended September 30, 2021 compared to the same period in 2020, the decrease in interest and other income, net, was primarily due to foreign currency exchange differences.

For the nine months ended September 30, 2021 compared to the same period in 2020, the decrease in interest and other income, net, was primarily due to decreased interest income earned on our cash equivalents and marketable securities associated with a decreased balance of our investment holdings and holding higher yield investments during the first half of 2020.

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. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following the FDA approval of QINLOCK, in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. During the three and nine months ended September 30, 2021 and 2020, our product revenues were primarily derived from sales of QINLOCK in the U.S. In addition to U.S. sales, we generate product revenue in select geographies where we do not currently intend to distribute QINLOCK on our own through exclusive distributor arrangements. 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 an 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, and an Open Market Sale AgreementSM (the Sales Agreement) with Jefferies LLC (Jefferies). Through such issuances, we have issued and sold 29,669,386 shares of our common stock resulting in net proceeds of \$956.5 million after deducting underwriting discounts and commissions and other offering expenses.

In August 2020, we entered into the Sales Agreement with Jefferies, pursuant to which we may issue and sell shares of our common stock having aggregate offering proceeds of up to \$200.0 million (the Shares) from time to time through Jefferies as our sales agent. Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. We may sell the Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the Sales Agreement, but we have no obligation to sell any Shares under the Sales Agreement. We or Jefferies may suspend or terminate the offering of Shares upon notice to the other party and subject to other conditions. As of September 30, 2021, there was \$172.5 million available for future issuance under the Sales Agreement.

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

(in millions, except share and per share amounts)	Shares Issued in Offering of Common Stock				Shares Issued Pursuant to The Underwriters' Exercise of Options to Purchase Additional Shares of Common Stock (if applicable)				Total	
	Price per Share ¹	Date	Shares Issued	Net Proceeds ²	Date	Shares Issued	Net Proceeds ²	Shares Issued	Net Proceeds ²	
IPO	\$ 17.00	October 2, 2017	7,500,000	\$ 114.1	October 4, 2017	666,496	\$ 10.5	8,166,496	\$ 124.6	
June 2018 Follow-on Public Offering	40.00	June 11, 2018	4,300,000	161.0	June 20, 2018	645,000	24.3	4,945,000	185.3	
Third Quarter of 2019 Follow-on Public Offering	37.00	August 19, 2019	10,810,810	375.4	September 3, 2019	1,621,621	56.4	12,432,431	431.8	
February 2020 Follow-on Public Offering	55.00	February 19, 2020	3,181,818	163.7	February 25, 2020	477,272	24.7	3,659,090	188.4	
Issuances Pursuant to the Sales Agreement ³	Various ³	Various ³	466,369	26.4	Not applicable			466,369	26.4	
								Total	29,669,386	\$ 956.5

- The price per share presented above represents the price per share at which shares were sold for both the public offering of shares and the underwriters' exercise of options to purchase additional shares, if applicable.
- Proceeds are presented net of underwriting discounts and commissions and other offering expenses.
- Information presented above represents the total number of shares of our common stock issued, and total net proceeds from issuances of shares of our common stock, pursuant to the Sales Agreement through September 30, 2021. Shares issued pursuant to the Sales Agreement were sold on multiple days at varying prices.

Cash Flows

As of September 30, 2021, our principal sources of liquidity were cash, cash equivalents, and marketable securities of \$392.2 million.

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

(in thousands)	Nine Months Ended September 30,	
	2021	2020
Net cash flows used in operating activities	\$ (173,648)	\$ (190,555)
Net cash flows provided by (used in) investing activities	77,896	(17,620)
Net cash flows provided by financing activities	12,912	199,009
Net decrease in cash and cash equivalents	\$ (82,840)	\$ (9,166)

Operating Activities

During the nine months ended September 30, 2021 compared to the same period in 2020, net cash flows used in operating activities decreased \$16.9 million, primarily resulting from increases in net non-cash charges of \$12.3 million and increases in net cash flows related to changes in our operating assets and liabilities of \$8.4 million, partially offset by an increase in our net loss of \$7.8 million. Net non-cash charges increased primarily due to an increase in share-based compensation of \$7.9 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 and settlement of accounts receivable.

Investing Activities

During the nine months ended September 30, 2021 compared to the same period in 2020, net cash flows from investing activities increased \$95.5 million, primarily resulting from a decrease in purchases of marketable securities, partially offset by a decrease in proceeds from sales and maturities of marketable securities and a \$4.0 million upfront payment to Sprint pursuant to the Sprint Agreement during the third quarter of 2021. For further details on the Sprint Agreement, please read Note 7, *In-License Agreement*, to the consolidated financial statements included in this Form 10-Q.

Financing Activities

During the nine months ended September 30, 2021 compared to the same period in 2020, net cash flows provided by financing activities decreased \$186.1 million, primarily resulting from a decrease in net proceeds from offerings of our common stock of \$180.4 million and a decrease in proceeds from stock option exercises and employee stock purchase plan activity of \$6.3 million. Net of underwriting discounts and commissions and other offering costs, the decrease in proceeds from our offerings was due to our issuance in February 2020 of \$188.4 million as compared to our issuances 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 the development and eventual commercialization of one or more of our drug candidates. Our net loss was \$211.6 million for the nine months ended September 30, 2021 and \$266.5 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of \$966.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses and capital requirements will increase in connection with our ongoing activities, particularly as we:

- continue to commercialize QINLOCK in the U.S., and continue to build our global commercial capability as we actively prepare to bring QINLOCK to eligible patients around the world, including in Europe, if approved;
- continue with our ongoing pivotal Phase 3 study of QINLOCK in second-line GIST and potentially other areas of GIST treatment;
- continue with our ongoing and planned clinical programs for vimseltinib as a potential single agent therapy for the treatment of TGCT, rebastinib as a combination therapy in PROC, and DCC-3116, our ULK kinase inhibitor, for the potential treatment of RAS or RAF mutant cancers;
- continue research and development and drug discovery activities and initiate additional clinical trials;
- seek marketing approval for our drug or any of our drug candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our drug candidates and commercialization of any of our drug candidates for which we obtain marketing approval;
- 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
- expand our operational, financial, and management systems and increase personnel, including to support our clinical development and commercialization efforts and our operations as a public company, including international operations in Europe and other potential geographies.

As we continue to seek regulatory approval for our drug and drug candidates, we expect to incur significant expenses related to our ongoing clinical development efforts and activities related to maintaining and expanding our internal commercialization capability to support product sales, marketing, and distribution except to the extent we enter into a commercialization partnership that covers such expenses. Further, we expect to continue to incur costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. We may not be successful in our commercialization of QINLOCK. Even if we are able to generate substantial product sales of QINLOCK, we may not become profitable. Until we become profitable, if ever, we expect to finance our operations primarily through a combination of equity, debt, or other financings, collaborations, strategic alliances, and marketing, distribution, or additional licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financings or other arrangements as, and when, needed, we may be required to significantly delay, limit, reduce, or discontinue our research, product development, or commercialization efforts of our drug or one or more of our drug candidates, or grant rights to develop and market our drug or 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 reduce or terminate our operations. The timing and amount of our operating expenditures will depend largely on:

- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK, including our planned commercial launch of QINLOCK in Europe, if approved, and any of our drug candidates for which we obtain marketing approval;
- the timing and progress of preclinical and clinical development activities;
- successful enrollment in and completion of clinical trials;
- the timing and outcome of regulatory review of our drug and drug candidates;
- the success of our commercialization efforts and market acceptance for QINLOCK or any of our future approved drugs;
- our ability to establish and manage agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- 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;
- the legal and patent costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- the cost to develop companion diagnostics as needed for each of our drug candidates;
- addition and retention of key research and development and commercial, including sales and marketing, personnel; and
- our efforts to enhance operational, financial, and information management systems and hire additional personnel to support the business.

We believe that our cash, cash equivalents, and marketable securities as of September 30, 2021 of \$392.2 million, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under the Zai License Agreement, if any, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2023. 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

In August 2021, we entered into the Sprint Agreement pursuant to which we are obligated to pay up to \$273.0 million in potential development and commercial milestone payments as well as tiered percentage royalties ranging from the mid-single-digits to the low-double-digits on the sales of a potential product from the program, if approved. Milestone payments under the Sprint Agreement are due and payable upon achievement of specified development or commercial milestones. We have not recorded any of these potential payments in our financial statements as of September 30, 2021 because the achievement and timing of these milestones and royalties is uncertain.

As of September 30, 2021, there have been no other 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, 2020.

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.

Our cash, cash equivalents, and marketable securities as of September 30, 2021 consisted of cash, money market funds, commercial paper, corporate debt securities, certificates of deposit, and U.S. government securities. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the general short-term nature of the instruments in our portfolio, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations. A potential change in fair value for interest rate sensitive instruments, which include marketable securities, has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of September 30, 2021 and December 31, 2020, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately \$3.4 million and \$4.3 million, respectively, to our interest rate sensitive instruments.

We do not believe that our cash, cash equivalents, and marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value, including changes resulting from the impact of the COVID-19 pandemic. In addition, we maintain significant amounts of cash, cash equivalents, and marketable securities at multiple financial institutions that are in excess of federally insured limits.

We contract with vendors in foreign countries. As such, we have exposure to adverse changes in exchange rates of foreign currencies associated with our foreign transactions. We believe this exposure to be immaterial. We do not hedge against this exposure to fluctuations in exchange rates.

Inflation generally affects us by increasing our cost of labor, clinical trial, and manufacturing costs. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three and nine months ended September 30, 2021 and 2020.

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, 2021. 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, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Our business is subject to numerous material and other risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Form 10-Q, including our consolidated financial statements and the related notes, and in our other filings with the SEC. If any of the following risks actually occur, our business, prospects, operating results, and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Business and Commercialization

Risks Related to Business Development and Commercialization

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

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

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

- the acceptance of QINLOCK by patients and the medical community;
- 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-mandated package insert requirements and successful completion of any related FDA post-marketing requirements;
- the actual market size for QINLOCK, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- our ability to obtain marketing approval for QINLOCK in Europe;
- our ability to successfully complete our Phase 3 study of QINLOCK for second-line GIST and obtain marketing approval and acceptance in such indication and potentially other areas of GIST treatment;
- the sufficiency of our drug supply to meet commercial and clinical demands which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory

requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;

- our ability to effectively compete with other therapies; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to QINLOCK.

Any of these issues could impair our ability to successfully commercialize our product or to generate 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 or other indications. We may also experience significant fluctuations in sales of QINLOCK from period to period and, ultimately, we may never generate sufficient revenues from QINLOCK to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize QINLOCK in the U.S., and any other international markets where it may subsequently be approved, including Europe, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

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

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

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

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

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

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

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

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of QINLOCK and any drug candidates for which we obtain marketing approval. Our arrangements with third-party payors, customers, and other third parties may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute

QINLOCK and any other products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances;
- the federal False Claims laws which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- 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 will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also require the reporting of payments or other transfers of value. Many of these state laws differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are often not pre-empted by HIPAA, thus complicating compliance efforts.

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the Centers for Medicare & Medicaid Services (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 Medicare Part D (Part D) beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

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

On December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers (PBMs), unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-

sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. 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.

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 (the 340B program (described below)), to include additional types of covered entities. We will participate in the 340B program for QINLOCK and any of our drug candidates for which we receive approval. Federal law requires that any company that participates in the Medicaid rebate program also participate in the 340B program in order for federal funds to be available for the

manufacturer's drugs under Medicaid. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid programs and purchased by certain federal grantees and agencies, a manufacturer also must participate in the 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, 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 December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Reform Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. 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.

The previous U.S. presidential administration signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, the previous U.S. President signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty, or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. In April 2020, the U.S. Supreme Court issued an opinion in *Moda Health Plan, Inc. v. United States* which held that the ACA requires the federal government to compensate insurers for significant losses their health plans incurred during the first three years of the ACA's marketplaces, and that insurers can sue for nonpayment in the Court of Federal Claims. The effects of this decision on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

On January 22, 2018, the previous U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. However, on December 20, 2019, the previous U.S. President signed into law the Further Consolidated Appropriations Act, 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 December 31, 2021 due to the COVID-19 pandemic. The ATRA among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. 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 will be calculated for certain drugs and biologics based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The MFN is currently subject to ongoing litigation. Further, 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 product candidates. Additionally, on December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through PBMs, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. 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.

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

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

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

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

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

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

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

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

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

- regulatory authorities may withdraw or limit their approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;

- regulatory authorities may refuse to approve label expansion for additional indications for QINLOCK or any future approved drugs;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drugs;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drugs from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking such drugs; and
- our reputation may suffer.

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

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

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

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

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing, and selling certain drug candidates and products outside of the U.S. and require us to develop and implement costly compliance programs.

To the extent we expand our operations outside of the U.S., including in Europe, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Similar laws in other countries, such as the United Kingdom's (U.K.) Bribery Act 2010, may apply to our operations.

Various laws, regulations, and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. To the extent we expand our presence outside of the U.S., including in Europe, it will require us to

dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drug candidates and products outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Governments outside of the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

The U.K.'s exit from the EU may have a negative effect on global economic conditions, financial markets, and our business.

In June 2016, the U.K. held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." This withdrawal has created political and economic uncertainty, particularly in the U.K. and the EU, where we currently conduct clinical trials and intend to seek marketing approvals in the future. During the Brexit transition period, which ended on December 31, 2020, the U.K. continued to follow all of the EU's rules and maintained its current trading relationship with the EU. In December 2020, the U.K. and EU signed an EU-U.K. Trade and Cooperation Agreement (the 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 is still uncertainty over how its terms will take effect in practice and there are still key aspects of the U.K.'s relationship with the EU which are not covered by the TCA, such as in respect of financial services. We expect that uncertainty over the terms of the TCA and other future agreements between the U.K. and EU will continue to cause political and economic uncertainty, which could harm our business and financial results. The withdrawal will, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Until there is greater understanding on how the terms of the TCA will take effect in the long-term, and until the terms of other potential agreements that the U.K. may eventually enter into with the EU are known, it is not possible to determine the extent of the impact that the U.K.'s departure from the EU and/or any related matters may have on us; however, any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition, and cash flows. Likewise, similar actions taken by European and other countries in which we operate could have a similar or even more profound impact.

For example, 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 product candidates in the U.K., now that the U.K. legislation has the potential to diverge from EU legislation. For instance, Great Britain (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. In addition, the withdrawal of the U.K. from the EU has had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity, and financial condition.

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

In California, the 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 uncertainty 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.

With the CPA, Colorado became the third state to enact a comprehensive privacy law but it is 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.'s European Union (Withdrawal) Act 2018 (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. Notably, on January 21, 2019, Google was fined almost \$57 million by French regulators for violating the GDPR. 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 in the EEA and the U.K. and intend to engage in regulatory and commercial operations there in the future. As a result, we are subject to additional privacy laws, including the GDPR and U.K. GDPR. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA or the U.K., including to the U.S., providing details to those individuals regarding the processing of their personal information, 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. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

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

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with European and U.K. data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. 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 EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/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. 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 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. 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.

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., Chia Tai Tianqing Pharmaceutical Group CO., LTD, Cogent Biosciences, Inc., Daiichi Sankyo Company, Limited (Daiichi), Exelixis, Inc., Immunicum AB, Jiangsu HengRui, Inc., Merck KGaA, Ningbo Tai Kang Medical Technology Co. Ltd., Novartis, Taiho Pharmaceutical Co. Ltd, Theseus Pharmaceuticals, and Xencor, Inc. Further, there are numerous companies marketing or developing antibodies and small molecules targeting CSF1R inhibitors that we are seeking to target with our vimseltinib program, including Abbisko Therapeutics Co., Ltd., AmMax Bio, Inc., Daiichi, and SynOx Therapeutics Ltd. In addition, while we believe that rebastinib, a TEK tyrosine kinase (TIE2) inhibitor, is a novel molecule, we believe we may face competition from drug candidates in clinical trials that are not TIE2 inhibitors, including small molecule drug candidates in clinical trials from Clovis Oncology, Inc., Eisai Co., Ltd., and Novartis, and antibody therapeutics from AstraZeneca PLC, ImmunoGen, Inc., Mersana Therapeutics, Inc., Roche Holding Ltd., Merck & Co., Inc., and Tesaro, a GlaxoSmithKline PLC company. 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 also seeking to address these types of cancers through similar targets.

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

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

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

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

The precise incidence and prevalence for GIST, TGCT, and other indications we are exploring, are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug or drug candidates, are based on estimates, which are inherently uncertain.

The total addressable market opportunity for QINLOCK, vimseltinib, rebastinib, and DCC-3116, and any other drug candidates we may produce will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our current and future drugs for sale for these indications, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

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

The commercial success of QINLOCK, and of any future approved drugs, will depend in part on market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current cancer treatments, such as surgery, existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If QINLOCK and any future approved drugs do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of QINLOCK and of any current or future drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the availability, perceived advantages, and relative cost, safety, and efficacy of alternative and competing treatments;
- the prevalence and severity of any side effects, adverse reactions, misuse, or any unfavorable publicity in these areas, in particular compared to alternative treatments;
- our ability (and the ability of our partners) to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength and effectiveness of our marketing, sales, and distribution strategy and efforts, including, without limitation, our own and that of our licensees and distributors, and the degree to which the approved labeling supports promotional initiatives for commercial success;
- the existence of distribution and/or use restrictions, such as through a 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; and
- any restrictions on the use of our products together with other medications.

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

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

In order to market and sell QINLOCK, or any future products, if approved, in Europe and many other jurisdictions, we or our partners must obtain separate marketing approvals in applicable foreign jurisdictions and comply with numerous and varying regulatory requirements. In October 2020, a marketing authorisation application (EU MAA) was accepted for review by the EMA for QINLOCK in fourth-line GIST. In September 2021, the CHMP adopted a positive opinion recommending the approval of QINLOCK for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The CHMP opinion is now being reviewed by the EC and we are planning for a potential approval in the fourth quarter of 2021. In October 2021, we also announced that the Swissmedic granted approval for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Our partner, Zai, obtained regulatory approval to market QINLOCK in the PRC and Hong Kong in March 2021 and Taiwan in September 2021. The approval procedure varies among countries and can involve additional testing as well as additional information and filings. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not (and/or our partners, as applicable, may not) obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, or may not be successful in seeking and obtaining favorable local reimbursement and pricing approvals, particularly in light of the impact of COVID-19 on the global economy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. 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 (the FDCA) and other statutes, including the False Claims Act (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 are in the early stages of building our commercial capabilities in Europe, and currently have only limited experience in the sale, marketing, or distribution of biopharmaceutical products. To achieve commercial success for QINLOCK or any other product for which we obtain marketing approval, we will need to successfully maintain and expand our sales, marketing, and distribution capabilities, either ourselves or through collaboration, licensing, distribution, or other arrangements with third parties. In addition, our licensee for QINLOCK for Greater China is building a sales and marketing infrastructure but currently has limited experience in sales, marketing, and distribution of a commercial product.

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

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of QINLOCK in Europe is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We will need to commit significant management and other resources to maintain and grow our commercial organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train, and retain sales and marketing personnel. We cannot be sure that we will be able to recruit, hire, train, and retain a sufficient number of sales representatives or that they will be effective at promoting QINLOCK or any future approved drugs.

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

- our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to maintain and grow our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate physicians about the benefits, safety, and effectiveness of QINLOCK or any future approved products or indications, 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

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

We have expanded and expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs, and sales, marketing, and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with expanding sales, marketing, and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay or prevent the execution of our business plans or disrupt our operations.

We 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 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 has increased, as virtual and remote working has become more widely used, and sensitive data is accessed by employees working in less secure, home-based environments. 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.

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 in order to gain access to our data. Like other companies, we have on occasion, and will continue to experience, threats to our data and systems, including malicious codes and viruses, and other 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 products. 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.

In addition, as we increase our commercial activities and our brand becomes more widely known and recognized, we may become a more attractive target for malicious third parties. If a material breach of our security or that of our third-party providers occur, 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 as a result of third-party action, employee negligence and/or error, malfeasance, defects, or otherwise that compromises the confidentiality, integrity, or availability of our data could result in:

- severe harm to our reputation or brand, or a material and adverse effect on the overall market perception of our technical and organizational measures to protect the confidentiality, integrity, and availability of our information;
- individual and/or class action lawsuits, which could result in financial judgments against us and which would cause us to incur legal fees and costs;
- legal or regulatory enforcement action, which could result in fines and/or penalties and which would cause us to incur legal fees and costs; and/or
- additional costs associated with responding to 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 blinded clinical study or to report an alleged adverse event (AE). When such disclosures occur, there is a risk that we fail to monitor and comply with applicable AE reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

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

It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations, and rulings may be enacted, promulgated, or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2020, we had U.S. federal net operating loss carryforwards and U.S. federal research and development tax credit carryforwards, which could be limited if we experience an "ownership change."

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

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

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

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

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

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

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

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

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

Risks Related to Clinical Development

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

We currently have several drug candidates in clinical development, as well as a Phase 3 study to expand the label of our approved drug, QINLOCK, and their risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim or preliminary results of a clinical trial do not necessarily predict final results, and results for one

indication may not be predictive of the success in additional indications. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we observed encouraging preliminary efficacy results including disease control rates, objective response rates (best response), and progression free survival in our Phase 1 study of QINLOCK, the primary objectives were to determine the safety, tolerability, and maximum tolerated dose of QINLOCK and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from the Phase 1 study of QINLOCK were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of QINLOCK, including our ongoing Phase 3 study for QINLOCK in second-line GIST. These factors also apply to the trials for our drug candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug or drug candidates, including:

- regulators may not authorize us to commence or continue a clinical trial or may impose a clinical hold or may limit the conduct of a clinical trial through the imposition of a partial clinical hold;
- 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 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 the outbreak of COVID-19; and
- the supply or quality of our drug or drug candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate and result in delays or suspension of our clinical trials, including those caused by the COVID-19 pandemic.

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

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured, or will be completed on schedule, or at all. Our ongoing trials continue to generate additional

data that may be requested by the FDA or other regulatory agencies. The FDA may request additional information or data 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, rebastinib, 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 or other factors.

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

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the drugs or drug candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the burden on patients due to inconvenient procedures and visits, in particular in light of considerations surrounding COVID-19;
- diversion of healthcare resources as a result of COVID-19, and the availability of qualified investigators to conduct clinical trials during the COVID-19 pandemic;
- the ability to monitor patients adequately during and after treatment, in particular in light of travel restrictions, access restrictions to medical institutions, and the impact of social distancing and quarantine guidelines as a result of COVID-19; and
- the proximity and availability of clinical trial sites for prospective patients, and the ability of patients to travel to study sites during the COVID-19 pandemic.

If we experience higher than expected drop-out rates for an event-driven study, as we previously experienced with our INTRIGUE study, we may choose to increase the total number of patients in the study to strengthen the ability to achieve the pre-specified number of events. Other factors in slower than expected enrollment may include recruitment challenges for indications that are difficult to diagnose and/or treat where the population is small and dispersed and other competing trials are recruiting simultaneously. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause significant harm to our financial position, adversely impact our stock price, and impair our ability to raise capital.

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

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

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

We currently have no products that are approved for sale with the exception of QINLOCK. All of our drug candidates, including vimseltinib, rebastinib, and DCC-3116, are still in early to mid-stages of 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 QINLOCK for second-line GIST;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize any current or future drug candidates for which we obtain marketing approval;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug and drug candidates;
- making and maintaining timely and cost-effective arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- protecting and enforcing our rights in our intellectual property portfolio.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize QINLOCK or any current or future drug candidates for which we receive approval, which would materially harm our business. For example, our business could be harmed if updated preliminary or final results of our ongoing Phase 3 study of QINLOCK for second-line GIST vary meaningfully from our expectations.

We may ultimately be unable to complete the development and commercialization of our drug candidates.

We may be required to conduct additional clinical trials or other testing of our drug 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. For

example, in GIST, we have completed a pivotal Phase 3 study of QINLOCK in fourth-line and fourth-line plus GIST, INVICTUS, and received FDA approval for QINLOCK on May 15, 2020 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, and have an ongoing second Phase 3 clinical study in second-line GIST, INTRIGUE. While we plan to conduct only one pivotal Phase 3 study for second-line GIST, for a single randomized trial to support submission to the FDA of a supplemental NDA, the trial must be well-designed, well-conducted, with a favorable risk/benefit ratio, and provide statistically persuasive efficacy findings so compelling that a second trial would be unethical or practically impossible to repeat. In addition, certain data that we have presented to date have been generated and reviewed at the clinical sites and are preliminary. The data may be subject to subsequent central review, and based on that review, there may be changes to these data which may not be favorable. For example, in our ongoing Phase 1 study of QINLOCK, there were differences observed between imaging data assessed at the clinical sites in accordance with the Phase 1 protocol and by central review, including some instances where central review's findings regarding the number of objective responses were less favorable than those previously reported. In addition to certain imaging results from our Phase 1 study, we also plan to have all of the data from our ongoing Phase 3 study of QINLOCK for second-line GIST centrally reviewed. The results from our ongoing Phase 3 study of QINLOCK in which all data will be subject to central review may be less favorable than the results of our Phase 1 study of QINLOCK that were based on data that has not been subject to central review. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In addition, we, or our licensees, such as Zai in Greater China, may be required to conduct additional clinical trials in the local region or regions where the licensees seek to commercialize our drug or drug candidates before a local regulatory authority will approve any marketing application. These local studies may involve, among other things, exploration of the effect our drug or drug candidates may have on a local population, which could be different than our clinical trial results or experience to date, and subject these trials and our development efforts to the risk that they do not support regional approval.

In addition, we may:

- be delayed in obtaining marketing approval for our drug or drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product, including QINLOCK, removed from the market after obtaining marketing approval.

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

Risks Related to the Industry

With the exception of QINLOCK, we have not received approval or authorization to market any of our drug candidates from regulatory authorities in any jurisdiction. Even if we complete the necessary clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, which may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or if we experience a delay in drug supply, we will not be able to commercialize our drug candidates or expand our marketing for QINLOCK in additional indications or geographies, and our ability to generate revenue will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S., the EMA and national competent authorities of the Member States in the EU, and China's NMPA and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. Our drug candidates are in the early to mid-stages of 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., 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 expanded approval for QINLOCK in additional indications or geographies, the commercial prospects for our drug or drug candidates may be harmed and our ability to generate further revenues will be materially impaired.

We may not be able to obtain or, if granted, retain orphan drug exclusivity for our drug or drug candidates.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may in response to a request from the sponsor designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. For example, we have received orphan drug designation for ripretinib for the treatment of GIST and glioblastoma multiforme in the U.S. 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 (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) 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.

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 the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Even if we obtain orphan drug exclusivity for a product's use in a specific indication, that exclusivity may not effectively protect the product from competition.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which may be based on a preliminary analysis of then-available data in a summary or "top-line" format, and the results and related findings may change as more patient data become available, may be interpreted differently if additional data are disclosed at a later time and are subject to audit and verification procedures that could result in material changes in the final data. If additional results from our clinical trials are not viewed favorably, our ability to obtain approval for and commercialize our approved drug and drug candidates, our business, operating results, prospects, or financial condition may be harmed and our stock price may decrease.

We also make assumptions, estimates, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or "top-line" results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been disclosed and/or are received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and "top-line" data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product, and our business in general. In addition, in regards to the information we publicly disclose regarding a particular study or clinical trial, such as "top-line" data, you or others may not agree with what we determine is the material or otherwise appropriate information to include in such disclosure, and any information we determine not to disclose – or to disclose at a later date, such as at a medical meeting—may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular drug, drug candidate, or our business. If the "top-line" data that we report differ from actual results or are interpreted differently once additional data are disclosed at a later date, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects, or financial condition may be harmed or our stock price may decline.

If we are unable to successfully develop companion diagnostic tests for our drug candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

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

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our drug candidates. Moreover, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify appropriate patients for our drug candidates. We may rely on third parties for the development, testing, and manufacturing of these companion diagnostics, the application for and

receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. Our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our drug candidates. In addition, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies.

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

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

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

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

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

Risks Related to Drug Discovery

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any other commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, distributor, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We may not be successful in our efforts to discover additional potential drug candidates.

A key element of our strategy is to apply our proprietary knowledge and our understanding of the structure, biology, and activity of kinase inhibitors that target the switch control mechanism to develop drug candidates. The therapeutic discovery

activities that we are conducting may not be successful in identifying additional drug candidates that are useful in treating cancer or other diseases. Our research programs may initially show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential drug candidates;
- potential drug candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or
- potential drug candidates may not be effective in treating their targeted diseases.

Research programs to identify new drug candidates require substantial technical, financial, and human resources. We may choose to focus our efforts and resources on a potential drug candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable drug candidates for preclinical and clinical development, we will not be able to obtain revenues from 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 current pandemic of COVID-19, including recurring surges and waves of infection, and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition, and results of operations.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus spread to the majority of countries around the world, including the U.S. To date, the COVID-19 pandemic has caused significant disruptions to the U.S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the 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, and mandatory closures of and/or occupancy limits for businesses to mitigate the spread of the virus. Although some 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 the Delta variant, some countries, states, and local governments have maintained or reinstated these restrictions, or may reinstate 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 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 caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and reimbursement of newly approved products as well as an increase in the numbers of uninsured patients and patients who may no longer be able to afford their co-insurance or co-pay obligations. These factors may lead to increased utilization of our patient assistance programs, which could reduce revenues.
- The 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, and 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 the Delta variant, may adversely affect the ability of our sales professionals to effectively market QINLOCK to physicians and the rate of uptake for QINLOCK, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians in specialties such as oncology have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume.

- We are currently conducting numerous clinical studies. We believe that the COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our ongoing clinical trials. For example, some clinical trial sites have imposed restrictions on site visits by sponsors and CROs, the initiation of new trials, and new patient enrollment to protect both site staff and patients from possible COVID-19 exposure and to focus medical resources on patients suffering from COVID-19. While all our studies remain open, enrollment has slowed at some sites, some sites have, or may in the future, temporarily pause enrollment of new patients, and we have provided guidance to all of our clinical trial sites that new patient enrollment may occur at sites where resources allow these patients to be safely enrolled and closely monitored.
- Other potential impacts of the COVID-19 pandemic on our clinical trials include difficulties associated with patient visits for screening enrollment and study conduct, and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local, or foreign laws, rules, and regulations, including closure of site access to outside monitors, quarantines, social distancing guidelines, or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of clinical trials, heightened exposure of patients, principal investigators, and site staff to COVID-19 if 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 guidance, as well as to ensure availability of study drug for patients, but we cannot assure you these efforts will be successful or that our clinical trial activities will not be adversely affected, delayed, or interrupted by COVID-19. Despite our efforts to address these risks, some patients and clinical investigators may not be able to comply with clinical trial protocols if quarantines or social distancing guidelines impede movement or interrupt healthcare services or if medical resources are reallocated to focus on patients suffering from complications related to COVID-19. If patients choose to withdraw from our studies or we choose to or are required to pause enrollment and/or patient dosing or other clinical trial related activities in order to preserve healthcare resources, protect trial participants from being exposed to unacceptable health risks or comply with access restrictions resulting from COVID-19, our studies and related timelines may be adversely affected. It is unknown how long these pauses or disruptions could continue. In addition, other aspects of our clinical trials may be adversely affected, delayed, or interrupted while the COVID-19 pandemic continues or if future surges or waves of infection occur, including, for example, site initiation, patient recruitment, availability of clinical trial materials and data analysis.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials and our drug for commercial sales, ship investigational and commercial drug supply for use in clinical trials or by patients, as appropriate, perform quality testing, and supply other goods and services to run our business. If any such third parties in our supply chain for materials are adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns, disruptions in delivery systems, or repurposing of their facilities to produce supplies needed for COVID-19 remediation, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, our research and development operations, or for commercial sale of QINLOCK.
- We have implemented precautionary measures to protect the health and safety of our employees, partners, and patients during the COVID-19 pandemic, including encouraging our personnel, other than those engaged in laboratory research activities, to work remotely, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines. These safety measures may be eased, lifted, or reinstated in accordance with updates to such guidelines. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, IRBs, and ethics committees, manufacturing sites, research or clinical trial sites, and other

important agencies and contractors. Our business operations may be further disrupted if any of our employees, officers, or board of directors contract an illness related to COVID-19 and are unable to perform their duties.

- Our employees, and employees of third-party contractors responsible for conducting research activities may have limited or reduced access to laboratories for an extended period of time as a result of occupancy restrictions or the temporary closure of such workspaces and the possibility that governmental authorities impose or modify current restrictions. As a result, this could delay timely completion of ongoing preclinical activities, including completion of IND-enabling studies, our ability to select future development candidates, and initiation of additional clinical trials for our drug candidates.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the 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. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring, and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safe to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for the industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and, in May 2021, announced plans to continue progress towards resuming standard operational levels. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions related to COVID-19, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, 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, or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

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

Risks Related to Litigation

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

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

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

- decreased demand for our approved drug or any of our drug candidates or products that we may develop and commercialize;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue or royalties;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our approved drug or any of our drug candidates that we may develop.

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

We could be subject to securities class action litigation.

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

Risks Related to Intellectual Property Litigation

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

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates, as well as successfully defending these rights against third-party challenges. Competitors may infringe our patents, trademarks, copyrights, trade secrets, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or their intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects, and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance

that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the U.S. or comparable foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation, or amendment to our patents in such a way that they no longer cover and protect our drug or drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our drug or drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our drug and drug candidates, and an unfavorable outcome could harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our drug and drug candidates without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our drug or drug candidates or their methods of use, or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our drug or drug candidates without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our drug or drug candidates, including interference proceedings before the 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, 2021 and the year ended December 31, 2020, we reported a net loss of \$211.6 million and \$266.5 million, respectively. As of September 30, 2021, we had an accumulated deficit of \$966.0 million.

Since our inception, we have focused substantially all of our efforts and financial resources on developing our proprietary compound library, including, without limitation, the preclinical and clinical development of QINLOCK and our drug candidates and, more recently, establishing a commercial infrastructure. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We are also developing QINLOCK for the treatment of second-line GIST. Except for QINLOCK, all of our drug candidates, including vimseltinib, rebastinib, and DCC-3116, are still in early to mid-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 \$1.3 billion in net proceeds from such transactions. As of September 30, 2021, our cash, cash equivalents, and marketable securities were \$392.2 million.

We expect to incur operating losses for the foreseeable future, particularly as we commercialize QINLOCK and advance development of our drug and drug candidates. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to incur significant research and

development expenses in connection with our ongoing and additional clinical trials for QINLOCK, vimseltinib, rebastinib, and DCC-3116, and development of any other future drug candidates we may choose to pursue. In addition, we will incur significant sales, marketing, and outsourced manufacturing costs and expenses in connection with the commercialization of QINLOCK and any other approved drugs in the future. We expect to incur costs associated with preparations for commercial activities in Europe in connection with potential marketing approval for QINLOCK in Europe. We have and will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated 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, or for any other indications, and we have not obtained marketing approval for any of our drug candidates. We do not expect to generate significant revenue from our drug candidates unless and until we obtain marketing approval for, and begin to sell, such drug candidates. Our ability to generate further revenue from sales of QINLOCK or revenue from sales of our drug candidates depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our second Phase 3 study of QINLOCK for the treatment of second-line GIST;
- initiate and successfully complete other later-stage clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety studies and related reports required to obtain U.S. and foreign marketing approval for our drug candidates;
- subject to obtaining favorable results from our Phase 3 study for QINLOCK for the treatment of second-line GIST, complete all requirements for the submission of a supplemental NDA, and apply for and obtain marketing approval;
- obtain approval of the EU MAA submitted to the EMA for QINLOCK;
- continue to maintain and expand commercial manufacturing capabilities or make further arrangements with third-party manufacturers for clinical supply and commercial manufacturing of QINLOCK and our drug candidates;
- commercialize QINLOCK by deploying a sales force and marketing QINLOCK in the U.S. and, if approved, in Europe and, either ourselves or through third parties, in other jurisdictions where we receive approval including Canada and Australia, assisting our licensee, Zai, in its efforts to develop and 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, 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 Europe. On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We are also developing QINLOCK for the treatment of second-line GIST. Except for QINLOCK, all of our drug candidates, including vimseltinib, rebastinib, and DCC-3116, are still in early to mid-stages of development.

We have not yet demonstrated our ability to successfully complete Phase 3 clinical trials other than for QINLOCK in fourth- and fourth-line plus GIST 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 the impact of the COVID-19 pandemic. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Risks Related to Our Capital Needs

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

We expect to incur significant expenses in connection with our ongoing activities, particularly as we commercialize QINLOCK and advance additional indications for QINLOCK, and our drug candidates, vimseltinib, rebastinib, and DCC-3116, and seek to identify lead drug candidates in our discovery programs. We expect increased expenses as we continue our research and development and initiate additional clinical trials and establish arrangements with third parties for the manufacture of clinical supplies of and seek marketing approval for our drug candidates. In addition, we expect to incur significant commercialization costs and expenses related to product manufacturing, marketing, sales, and distribution of QINLOCK, including preparations for a commercial launch in Europe, if approved, and any current or future drug candidate for which we 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, 2021, together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under the Zai License Agreement, if any, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the scope, progress, costs, and results of our clinical trial of QINLOCK for the treatment of second-line GIST;
- the scope, progress, costs, and results of drug discovery, preclinical development, and clinical trials for our drug candidates;
- the cost of maintaining, expanding, or contracting for sales, marketing, and distribution capabilities in connection with commercialization of QINLOCK or any future drugs for which we 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 for additional indications or in additional geographies, including Europe;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales, and distribution, for QINLOCK and any of our drug candidates for which we obtain marketing approval, as well as infrastructure costs in the U.S. and Europe, and in other jurisdictions where we may seek marketing approval and choose to sell or enter into distribution arrangements;
- the revenue received from commercial sales of QINLOCK and our drug candidates for which we obtain marketing approval, if any;

- the achievement of milestones or occurrence of other developments that trigger payments, including, without limitation, milestone or royalty payments, to us under our license agreement with Zai or any collaboration, distribution, or other license agreements that we have entered into or may enter into in the future, if any;
- the costs and timing of preparing, filing, and prosecuting any patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- our ability to establish additional license, distributor, and/or collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our drug candidates; and
- the extent to which we acquire or in-license drug candidates, technologies, and associated intellectual property rights.

Identifying potential drug candidates and conducting preclinical testing and clinical trials and, for any drug candidates that receive marketing approval, establishing and maintaining a commercial infrastructure, is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain additional marketing approvals, including for QINLOCK in additional indications or geographies, and achieve 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, 2021, 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 31% 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 \$15.15 per share and as high as \$71.11 per share through September 30, 2021. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- the success of commercialization of our drug and drug candidates, if approved;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures, or capital commitments;
- variations in quarterly operating results or those of companies that are perceived to be similar to us;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally;
- the degree of success of competitive products or technologies;
- results of clinical trials and preclinical studies, of our drug or drug candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- receipt of, or failure to obtain, regulatory approvals;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our drug or any of our drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in-license additional technologies or drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- rumors or announcements regarding transactions involving our company or our drug or drug candidates;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions and other national conditions; and
- the other factors described in this "Risk Factors" section.

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

As a result of our public float (the market value of our common stock held by non-affiliates) as of June 30, 2020, we became a large accelerated filer as of December 31, 2020 and therefore no longer qualify as an "emerging growth company," as defined in the JOBS Act. Additionally, due to our public float as of June 30, 2020, we no longer qualify as a "smaller reporting company" as defined in the Exchange Act.

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

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- the requirement that we provide full and more detailed disclosures regarding executive compensation; and
- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

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

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

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

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

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

which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. Further, any delay in compliance with the auditor attestation provisions of Section 404 could subject us to a variety of administrative sanctions, including ineligibility for short-form resale registration, action by the SEC and the suspension or delisting of our common stock, which could reduce the trading price of our common stock and could harm our business.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and as a large accelerated filer, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements we may enter into may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Risks Related to Our Dependence on Third Parties

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

We currently rely on various third-party CROs to conduct our ongoing clinical trials for QINLOCK, vimseltinib, rebastinib, 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 COVID-19, that could hinder their ability to meet their contractual obligations to us or may delay their performance of the services they conduct for us. If these third parties do not successfully carry out their

contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements, applicable laws, rules and regulations, and our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our approved drug for additional indications or our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our approved drug for additional indications or our drug candidates, if approved.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our drug candidates for preclinical testing, clinical trials, and for the manufacture of QINLOCK for commercialization and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.

We do not own any manufacturing facilities. We produce in our research laboratories very small quantities of drug substance for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical and clinical testing, and for the commercial manufacture of any of our current and future drugs. As a general matter, our manufacturers represent our sole source of supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug or drug candidates or such quantities at an acceptable cost or quality or in a timely manner, which could delay, prevent, or impair our development or commercialization efforts, or those of our partners. Although we actively manage these third-party relationships to ensure continuity, quality, and compliance with regulations, some events beyond our control, including global instability due to political unrest or from an outbreak of pandemic or contagious disease, such as COVID-19, could result in supply chain disruptions or the complete or partial failure of these manufacturing services. Any such failure or disruptions could materially adversely affect our business, financial condition, cash flows, and results of operations.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance, and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- if the third party 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. If we obtain marketing approval for any of our drug candidates, we will need to establish an agreement for commercial manufacture with a third party. Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval, or commercial supply, including with respect to QINLOCK. If our current sole source suppliers, 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.

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 enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or 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 COVID-19.

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

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

Risks Related to Our Intellectual Property

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

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

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China, and other developing countries, do not favor the enforcement of patents and other

intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation, or other violation of our patents or other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the U.S. and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

While we have obtained composition of matter patents with respect to our drug and certain of our drug candidates, we also rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. For example, we have elected to not patent our proprietary switch-control kinase inhibitor platform and therefore rely on protecting the proprietary aspects of our platform as a trade secret. We seek to protect our trade secrets and proprietary know-how in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers, collaborators, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement, or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets, including with respect to our proprietary switch-control kinase inhibitor platform, were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations, and our business prospects and competitive position could be materially harmed.

If we fail to comply with our obligations under any license, collaboration, or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our drug or drug candidates.

We rely, in part, on license, collaboration, and other agreements. We may need to obtain additional licenses from others to advance our research or allow commercialization of our drug and drug candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to use. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

In addition, our present and future licenses, collaborations, and other intellectual property related agreements, are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate

the license. If our license or other intellectual property related agreements are terminated, we may be required to cease developing and commercializing drugs or drug candidates that are covered by the licensed intellectual property. Disputes may arise regarding intellectual property subject to a licensing, collaboration, or other agreement, including:

- the scope of rights granted under the agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug or drug candidates.

In some circumstances, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained, and enforced in a manner consistent with the best interests of our business. If our licensors fail to obtain or maintain such intellectual property, or lose rights to such intellectual property, the rights we have licensed and our exclusivity may be reduced or eliminated and our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected.

Moreover, our rights to our in-licensed patents and patent applications may depend, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon commercialization of the relevant drug, or development of the relevant program or drug candidate, and our business, financial condition, results of operations, and prospects could suffer.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products similar to our approved drug or any of our drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Patents

If we are unable to obtain and maintain sufficient patent protection for our approved drug or drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our approved drug or drug candidates successfully may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our approved drug and drug candidates, for example, QINLOCK, vimseltinib, rebastinib, and DCC-3116, their methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary switch-control kinase inhibitor platform. If we do not adequately obtain, maintain, protect, or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have and market competition may increase, which could harm our business, reduce our potential revenues, and adversely affect our ability to achieve profitability.

The patent application and approval process is expensive, time-consuming, and complex. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the U.S. or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and drug candidates.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U.S, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our approved drug or drug candidates. In addition, we enter into non-disclosure and confidentiality

agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, consultants, advisors, and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our approved drug, drug candidates, or technology, an interference proceeding in the U.S. can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the U.S. and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge validity of our patents, to prevent a patent from issuing from a pending patent application. For example, we may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, *inter partes* review, or interference proceedings, in the U.S. or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing, and regulatory review of new drug candidates, our patents protecting such drugs or drug candidates might expire before or shortly after such drugs or drug candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, including generic versions of such products. Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our pending and future patent applications may not result in patents being issued that protect our approved drug or drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U.S. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned or licensed by us are invalid, unenforceable, or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Furthermore, our patents may be subject to a reservation of rights by one or more third parties. For example, if any of our technologies are developed in the future with government funding, the government may obtain certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties

and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Moreover, the failure of any patents that may issue to us or our licensors to adequately protect our drug, drug candidates, or technology could have an adverse impact on our business.

The term of our patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration, and other factors relating to any FDA marketing approval we receive for our approved drug or any of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. We have applied for patent term extension in the U.S. on patents covering QINLOCK and we expect to seek extensions of patent terms in the U.S. for other drug candidates and, if available, in other countries where we are prosecuting patents. In the U.S., the Hatch-Waxman Act permits a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during the regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

Item 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
	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).
	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).
	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).
	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.
	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.
	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.
	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.
	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.
	Inline XBRL Taxonomy Extension Schema Document.
	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
	Inline XBRL Taxonomy Extension Labels Linkbase Document.
	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
	Inline XBRL Taxonomy Extension Definition Linkbase Document.
	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 2, 2021

By: /s/ Thomas P. Kelly

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

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 2, 2021

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

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 2, 2021

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

**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, 2021 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 2, 2021

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

**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, 2021 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 2, 2021

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