Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____

Commission file number: 001-38219

decīphera™

DECIPHERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(781) 209-6400
Registrant's telephone number, including area code

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of July 31, 2020 there were 56,376,754 shares of Common Stock, $0.01 par value per share, outstanding.

Deciphera Pharmaceuticals, Inc.

INDEX

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Form 10-Q) contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates," or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under "Risk Factors" and include, among other things:

- our ability to successfully launch and commercialize QINLOCK™ (ripretinib), referred to as QINLOCK, for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib, in the United States (U.S.), and our readiness for commercial launch of QINLOCK in Canada and Australia, and any other jurisdictions where we may receive marketing approval in the future;
- the success, cost, and timing of our product development activities and clinical trials, including the timing of our ongoing Phase 3 trial of QINLOCK for the treatment of second line GIST patients and results therefrom;
- our ability to maintain and receive additional 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 build out our commercial infrastructure and successfully launching, marketing, and selling QINLOCK and any current or future drug candidate for which we may receive marketing approval, including our plans with respect to the focus and activities of our sales force, the nature of our marketing, market access, and patient support activities, and our pricing of QINLOCK and related assumptions;
- 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 of target patient populations for QINLOCK, or any of our current or future drug candidates for which we receive marketing approval;
- 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 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 plans to research, develop, and commercialize our drug candidates, including the timing of our ongoing Phase 3 trial of QINLOCK for the treatment of second line GIST patients, and the timing of investigational new drug (IND) applications, including, without limitation, the success of IND-enabling studies for, and the expected timing of, an IND application for our DCC-3116 program;
- the performance and experience of our licensee, Zai Lab (Shanghai) Co., Ltd. (Zai), to successfully develop and commercialize QINLOCK, if approved, in Mainland China, Hong Kong, Macau, and Taiwan, also referred to as Greater China or the Greater China region, under the terms and conditions of our license agreement;
- 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;
- 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;
- 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 or 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 outbreak of the novel coronavirus (COVID-19), which could harm our commercialization efforts for QINLOCK as well as the value of our common stock and our ability to access capital markets;
- natural and manmade disasters, including pandemics such as COVID-19, and other force majeures, which could impact our operations, and those of our partners and other participants in the health care industry, and which could adversely impact our clinical studies, preclinical research activities, and drug supply; and
- our use of the proceeds from our follow-on public offerings and any other financing transaction we may undertake.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere in this Form 10-Q and our prior filings with the Securities and Exchange Commission (SEC). 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 155,446	$ 120,320
Short-term marketable securities	454,890	459,256
Accounts receivable, net	7,384	—
Inventory	1,389	—
Prepaid expenses and other current assets	13,977	13,832
Total current assets	633,086	593,408
Long-term marketable securities	21,431	—
Long-term investments—restricted	2,125	1,510
Property and equipment, net	9,567	6,333
Operating lease assets	20,096	21,158
Total assets	$ 686,305	$ 622,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,582	$ 19,575
Accrued expenses and other current liabilities	37,333	38,716
Operating lease liabilities	1,424	1,747
Total current liabilities	51,339	60,038
Operating lease liabilities, net of current portion	15,282	15,904
Total liabilities	66,621	75,942
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 56,081,993 shares and 51,617,639 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	561	516
Additional paid-in capital	1,247,158	1,033,819
Accumulated other comprehensive income (loss)	(8)	111
Accumulated deficit	(628,027)	(487,979)
Total stockholders' equity	619,684	546,467
Total liabilities and stockholders' equity	$ 686,305	$ 622,409

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product revenues, net	$ 4,825	$ —	$ 4,825	$ —
Collaboration revenues	2,265	25,000	2,327	25,000
Total revenues	7,090	25,000	7,152	25,000
Cost and operating expenses:				
Cost of sales	8	—	8	—
Research and development	46,081	34,811	97,469	70,600
Selling, general, and administrative	29,933	13,164	53,869	26,400
Total cost and operating expenses	76,022	47,975	151,346	97,000
Loss from operations	(68,932)	(22,975)	(144,194)	(72,000)
Other income (expense):				
Interest and other income, net	1,691	1,540	4,146	3,194
Interest expense	—	(25)	—	(38)
Total other income (expense), net	1,691	1,515	4,146	3,156
Net loss	$ (67,241)	$ (21,460)	$ (140,048)	$ (68,844)
Net loss per share—basic and diluted	$ (1.20)	$ (0.56)	$ (2.56)	$ (1.81)
Weighted average common shares outstanding—basic and diluted	55,920,122	38,200,288	54,743,778	38,129,049
Comprehensive loss:				
Net loss	$ (67,241)	$ (21,460)	$ (140,048)	$ (68,844)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	(771)	154	(119)	175
Total other comprehensive income (loss)	(771)	154	(119)	175
Total comprehensive loss	$ (68,012)	$ (21,306)	$ (140,167)	$ (68,669)

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)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, March 31, 2020	—	$ —	55,681,027	$ 557	$ 1,231,726	$ 763	$ (560,786)	$ 672,260
Issuance of common stock upon exercise of stock options	—	—	400,966	4	4,823	—	—	4,827
Stock-based compensation expense	—	—	—	—	10,609	—	—	10,609
Unrealized gains (losses) on marketable securities	—	—	—	—	—	(771)	—	(771)
Net loss	—	—	—	—	—	—	(67,241)	(67,241)
Balance, June 30, 2020	—	$ —	56,081,993	$ 561	$ 1,247,158	$ (8)	$ (628,027)	$ 619,684

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	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 upon exercise of stock options	—	—	805,264	8	7,388	—	—	7,396
Stock-based compensation expense	—	—	—	—	17,603	—	—	17,603
Unrealized gains (losses) on marketable securities	—	—	—	—	—	(119)	—	(119)
Net loss	—	—	—	—	—	—	(140,048)	(140,048)
Balance, June 30, 2020	—	$ —	56,081,993	$ 561	$ 1,247,158	$ (8)	$ (628,027)	$ 619,684

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)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, March 31, 2019	—	$ —	38,189,052	$ 382	$ 582,700	$ 21	$ (343,107)	$ 239,996
Issuance of common stock upon exercise of stock options	—	—	26,056	—	81	—	—	81
Stock-based compensation expense	—	—	—	—	4,107	—	—	4,107
Unrealized gains (losses) on marketable securities	—	—	—	—	—	154	—	154
Net loss	—	—	—	—	—	—	(21,460)	(21,460)
Balance, June 30, 2019	—	$ —	38,215,108	$ 382	$ 586,888	$ 175	$ (364,567)	$ 222,878

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2018	—	$ —	37,676,760	$ 377	$ 575,327	$ —	$ (295,723)	$ 279,981
Issuance of common stock upon exercise of stock options	—	—	538,348	5	1,225	—	—	1,230
Stock-based compensation expense	—	—	—	—	10,336	—	—	10,336
Unrealized gains (losses) on marketable securities	—	—	—	—	—	175	—	175
Net loss	—	—	—	—	—	—	(68,844)	(68,844)
Balance, June 30, 2019	—	$ —	38,215,108	$ 382	$ 586,888	$ 175	$ (364,567)	$ 222,878

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

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (140,048)	$ (68,844)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	17,603	10,336
Depreciation expense	944	216
Noncash lease expense	1,062	337
Net accretion of discounts on marketable securities	(2,010)	(1,297)
Changes in operating assets and liabilities:		
Accounts Receivable	(7,384)	(20,000)
Unbilled Receivables	—	(5,000)
Inventory	(798)	—
Prepaid expenses and other current assets	(146)	1,263
Accounts payable	(7,056)	5,592
Accrued expenses and other current liabilities	(2,436)	7,239
Operating lease liabilities	(945)	(349)
Other long-term liabilities	—	235
Net cash flows used in operating activities	(141,214)	(70,272)
Cash flows from investing activities:		
Purchases of marketable securities	(818,182)	(253,759)
Maturities of marketable securities	323,263	68,364
Sales of marketable securities	479,746	18,688
Purchases of property and equipment	(3,653)	(244)
Increase in restricted investments	(615)	(441)
Net cash flows used in investing activities	(19,441)	(167,392)
Cash flows from financing activities:		
Proceeds from public offerings, net of underwriting discounts and commissions	189,037	—
Repayment of notes payable to related party	—	(93)
Payments of public offering costs	(652)	—
Proceeds from exercise of stock options	7,396	1,230
Net cash flows provided by financing activities	195,781	1,137
Net increase (decrease) in cash and cash equivalents	35,126	(236,527)
Cash and cash equivalents at beginning of period	120,320	293,764
Cash and cash equivalents at end of period	$ 155,446	$ 57,237
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 38
Inventory purchases included in accrued expenses and other current liabilities	$ 591	$ —
Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities	$ 525	$ —

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. On May 15, 2020, QINLOCK™ (ripretinib), referred to as 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. QINLOCK is currently being investigated in a Phase 3 study for the treatment of patients with second-line GIST. In addition to QINLOCK, the Company is advancing multiple drug candidates from its platform in various stages of clinical development. The Company wholly owns its drug and all of its drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Mainland China, Hong Kong, Macau, and Taiwan, also referred to as Greater China or the Greater China region.

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 launch and commercialization of QINLOCK, the Company's first and recently approved drug in the U.S., Canada, and Australia, 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 significant revenue from product sales of QINLOCK or any current or future drug candidates for which it receives marketing approval.

The full extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact the Company's business, including its preclinical studies, clinical trial operations, or commercialization efforts, will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted at this time, such as the duration of such pandemic including future waves of infection, 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 launch, commercialize, and generate revenue from sales of QINLOCK.

In June 2018, the Company issued and sold 4,945,000 shares of its common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $185.3 million after deducting underwriting discounts and commissions and other offering expenses. In the third quarter of 2019, the Company issued and sold 12,432,431 shares of its common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $431.8 million after deducting underwriting discounts and commissions and other offering expenses. 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.

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

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 $140.0 million and $192.3 million for the six months ended June 30, 2020 and the year ended December 31, 2019, respectively. As of June 30, 2020, the Company had an accumulated deficit of $628.0 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 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 may need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce, or eliminate its research or drug development programs or certain commercialization efforts. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

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

Unaudited Interim Financial Information

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

The consolidated balance sheet at December 31, 2019 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019 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, 2019 included in the Company's Annual Report on Form 10-K (Form 10-K) on file with the SEC.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's consolidated financial position as of June 30, 2020 and consolidated results of operations and comprehensive loss for the three and six months ended June 30, 2020 and 2019 and consolidated cash flows for the six months ended June 30, 2020 and 2019 have been made. The consolidated results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

Certain prior year amounts have been reclassified to conform to current year presentation.

The significant accounting policies used in preparation of these consolidated financial statements for the three and six months ended June 30, 2020 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, 2019, except as noted within the section "Significant Accounting Policies" with respect to the Company's accounting policies for product revenue, accounts receivable, and inventory and within the section "Recently Issued Accounting Pronouncements."

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, revenue recognition, the accrual for research and development expenses, and the valuation of stock-based 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 six months ended June 30, 2020 and 2019.

The following potential dilutive securities, presented based on amounts outstanding at the end of each reporting period, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	As of June 30,	
	2020	2019
Options to purchase common stock	7,073,775	6,891,799
Unvested time-based restricted common stock units	409,955	77,000
Unvested performance-based restricted common stock units	57,000	—
Unvested employee stock purchase plan shares	39,600	—
Total	7,580,330	6,968,799

Significant Accounting Policies

Product Revenues

In May 2020, the Company began generating product revenue from sales of QINLOCK to specialty distributors and specialty pharmacies in the U.S. 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.

The Company recognizes product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. The Company records product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, trade discounts and allowances, product returns, and other incentives, which are described below.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Company's customer) or a liability (if the amount is payable to a party other than the Company's customer). The Company's estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying, and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

Chargebacks and Administrative Fees: Chargebacks for discounts represent the Company's estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the

list prices charged to the customers who directly purchase the product from the Company. The customers charge the Company for the difference between what the customers pay the Company for the product and the customer's ultimate contractually committed or government required lower selling price to the qualified healthcare providers. As part of the Company's contractual commitments to sell product to qualified healthcare providers, the Company pays fees for administrative services, such as account management and data reporting.

Government rebates: Government rebates consist of Medicare, Tricare, and Medicaid rebates. These reserves are recorded in the same period the related revenue is recognized. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom it will owe a rebate under the Medicare Part D program.

Trade discounts and allowances: The Company provides the customers with discounts that are explicitly stated in the contracts and recorded in the period the related product revenue is recognized. In addition, the Company also receives sales order management, inventory management, and data services from the customers in exchange for certain fees.

Product returns: The Company estimates the amount of its product sales that may be returned by its customers and records this estimate in the period the related product revenue is recognized. The Company currently estimates product return liabilities based on available industry data and its visibility into the inventory remaining in the distribution channel.

Other incentives: Other incentives include co-payment assistance provided to qualified patients, whereby the Company may provide financial assistance to patients with prescription drug co-payments required by the patient's insurance provider. Reserves for co-payment assistance are recorded in the same period the related revenue is recognized.

Accounts Receivable

Accounts receivable arise from product sales and amounts due from the Company's collaboration partners and have standard payment terms that generally require payment within 30 to 90 days. The amount from product sales represents amounts due from specialty distributors and specialty pharmacies in the U.S., which are recorded net of reserves for customer chargebacks, trade discounts and allowances, and other incentives to the extent such amounts are payable to the customer by the Company. The Company monitors economic conditions to identify facts or circumstances that may indicate that its receivables are at risk of collection. The Company provides reserves against accounts receivable for estimated losses, if any, that may result from a customer's inability to pay based on the composition of its accounts receivable, current economic conditions, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve. During the three and six months ended June 30, 2020, the Company did not record any expected credit losses related to outstanding accounts receivable.

Inventory

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the regulatory approval of its drug candidates, the Company incurs expenses for the manufacture of drug product supplies to support clinical development that could potentially be available to support the commercial launch of those drugs. Until the date at which regulatory approval has been received or is otherwise considered probable, the Company records all such costs as research and development expenses.

The Company performs an assessment of the recoverability of capitalized inventories during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of sales in the Company's consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required.

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

The Company commenced the capitalization of QINLOCK inventory in May 2020 upon receiving FDA approval of QINLOCK. Capitalized inventory consisted of the following:

(in thousands)	As of June 30, 2020
Raw materials	$ 765
Work in process	624
Total inventory	$ 1,389

There were no inventory amounts written down as a result of excess, obsolescence, unmarketability, or other reasons charged to cost of sales during the three and six months ended June 30, 2020.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its consolidated financial statements or disclosures.

Credit Losses

In June 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13). The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date of January 1, 2020. This standard requires entities to estimate an expected lifetime credit loss on financial assets and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases.

This standard became effective for the Company on January 1, 2020, and adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

2. Revenues

Net Product 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.

As of June 30, 2020, the Company's only source of product revenues were from the U.S. sales of QINLOCK, with total net product revenues of $4.8 million for the three and six months ended June 30, 2020.

The Company primarily sells QINLOCK through specialty distributors and specialty pharmacies. The Company recognized revenues from two customers accounting for 50% and 33% of gross product revenues for the three and six months ended June 30, 2020. As of June 30, 2020, two customers individually accounted for approximately 51% and 32% of accounts receivable associated with the Company's product sales.

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

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

(in thousands)	Trade discounts and allowances	Chargebacks and administrative fees	Government rebates and other incentives	Returns	Total
Balance at December 31, 2019	$ —	$ —	$ —	$ —	$ —
Provision related to sales in the current year	165	142	221	119	647
Adjustments related to prior period sales	—	—	—	—	—
Credits and payments made	(58)	(52)	(28)	—	(138)
Balance at June 30, 2020	$ 107	$ 90	$ 193	$ 119	$ 509

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

(in thousands)	As of June 30, 2020
Reduction of accounts receivable, net	$ 305
Component of accrued expenses and other current liabilities	204
Total revenue-related reserves	$ 509

As of June 30, 2020, net receivables related to the Company's net product revenue were $5.1 million, which were included in accounts receivable, net within the consolidated balance sheet.

Collaboration Revenues

In June 2019, the Company entered into a License Agreement (the Zai License Agreement) with 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 potential annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

Under the Zai License Agreement, the Company recognized revenue of $25.0 million during the second quarter of 2019, which consisted of the $20.0 million upfront payment and a $5.0 million INTRIGUE study-related development milestone payment, which the Company believed to be probable of achievement in the second quarter of 2019 and was achieved in July 2019.

Under the Zai License Agreement, during the three and six months ended June 30, 2020, the Company recognized revenues of $2.1 million, which consisted of the achievement of a $2.0 million development milestone in the second quarter of 2020 and $0.1 million in reimbursable costs.

Subject to the terms and conditions of the Zai License Agreement, Zai will be responsible for conducting the development and commercialization activities in the Territory related to the Licensed Products. Please read Note 3, *License Agreement*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2019 for further details on the Zai License 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 obtains regulatory approval in the Territory. Subject to the Zai Supply Agreement, costs incurred by the Company for external manufacturing services are reimbursed by Zai.

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

Under the Zai Supply Agreement, the Company recognized revenues of $0.1 million and $0.2 million associated with the reimbursement of costs incurred for external manufacturing services provided during the three and six months ended June 30, 2020, respectively.

The Company's receivables related to its agreements with Zai included in accounts receivable, net within the consolidated balance sheets were $2.3 million as of June 30, 2020. There were no receivables related to the Company's agreements with Zai as of December 31, 2019.

3. Marketable Securities and Fair Value Measurements

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

As of June 30, 2020 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
U.S. government securities	$ 454,878	$ 75	$ (63)	$ 454,890
Due after one year through five years:				
U.S. government securities	21,451	—	(20)	21,431
Total	$ 476,329	$ 75	$ (83)	$ 476,321

As of December 31, 2019 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Due within one year:				
Commercial paper	$ 314,292	$ 74	$ (23)	$ 314,343
U.S. government securities	78,612	48	(3)	78,657
Certificates of deposit	66,241	17	(2)	66,256
Total	$ 459,145	$ 139	$ (28)	$ 459,256

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

As of June 30, 2020 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 120,776	$ —	$ 120,776
U.S. government securities	—	20,600	—	20,600
Marketable securities:				
U.S. government securities	—	476,321	—	476,321
Total	$ —	$ 617,697	$ —	$ 617,697

As of December 31, 2019 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 28,192	$ —	$ 28,192
Certificates of deposit	—	20,500	—	20,500
Marketable securities:				
Commercial paper	—	314,343	—	314,343
U.S. government securities	—	78,657	—	78,657
Certificates of deposit	—	66,256	—	66,256
Total	$ —	$ 507,948	$ —	$ 507,948

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

The table above excludes certificates of deposit totaling $2.1 million and $1.5 million as of June 30, 2020 and December 31, 2019, respectively, that the Company held to secure a letter of credit associated with a lease and to secure a credit card account. The Company increased its credit card limit and corresponding certificate of deposit in the first quarter of 2020. The certificates of deposit are Level 2 instruments and 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 a lease, please read Note 6, *Leases*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2019.

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. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	As of June 30, 2020	As of December 31, 2019
External research and development expenses	$ 26,076	$ 20,462
Payroll and related expenses	7,849	12,902
Professional fees	2,381	3,810
Revenue-related reserves	204	—
Other	823	1,542
Total accrued expenses and other current liabilities	$ 37,333	$ 38,716

5. 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 June 30, 2020, 1,608,183 shares of common stock were available for issuance under the 2017 Plan. As of June 30, 2020, 1,409,433 shares of common stock were available for issuance to participating employees under the ESPP. The purchase price of common stock under the Company's 2017 ESPP, is equal to 85% of the lesser of (i) the fair market value per share of the common stock on the first business day of an offering period and (ii) the fair market value per share of the common stock on the purchase date. The fair value of the discounted purchases made under the Company's 2017 ESPP is calculated using the Black-Scholes valuation model. The fair value of the look-back provision plus the 15% discount is recognized as stock-based compensation expense in the consolidated statements of operations and comprehensive loss over the 6-month purchase period. Employees began participating in the ESPP program during the second quarter of 2020.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2020	2019	2020	2019
Research and development expenses	$ 5,293	$ 1,790	$ 8,564	$ 3,482
Selling, general, and administrative expenses	5,316	2,317	9,039	6,854
Total stock-based compensation	$ 10,609	$ 4,107	$ 17,603	$ 10,336

As of June 30, 2020, total unrecognized compensation cost related to the unvested share-based awards was $105.0 million, which is expected to be recognized over a weighted average of 2.8 years.

During the six months ended June 30, 2019, the Company recorded $2.4 million of stock-based compensation expense related to the modification of stock options pursuant to the transition agreement with its former President and Chief Executive

Officer. These expenses were classified as selling, general, and administrative expenses within the consolidated statements of operations and comprehensive loss.

During the three and six months ended June 30, 2020, the Company recorded $1.3 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.

6. Commitments and Contingencies

KBA Grants

Prior to 2014, the Company received funding from two research and development grants from the Kansas Bioscience Authority (KBA), totaling $2.0 million and no further amounts will be received under these grants. Pursuant to Kansas law, the Company may be required to repay some or all of the financial assistance received from the KBA, subject to the discretion of the KBA, if the Company relocates the operations in which the KBA invested outside of the State of Kansas, if the Company initiates procedures to dissolve and wind up or cease operations within ten years after receiving such financial assistance or upon certain significant changes to ownership of the Company. The Company will only account for the repayment of the grants if it becomes probable that the Company will be required to repay any funds previously received.

Purchase Commitments Associated with Commercial Supply Agreements

The Company has entered into commercial supply agreements related to the supply of QINLOCK that require the Company to make binding forecasts for a certain amount of purchases. The related cancellation clauses would as a general matter require the Company to pay the full amount of these binding forecasts. As of June 30, 2020, the Company's contractual commitments for such obligations were $5.0 million, which are expected to be paid within one year.

Legal Proceedings

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of June 30, 2020 or December 31, 2019.

7. Subsequent Event

In April 2019, the Company amended its lease for office space at 200 Smith Street in Waltham, Massachusetts (the Premises), to add an additional 38,003 square feet of space (the Additional Space). The initial term of the lease for the Additional Space will expire in November 2029 unless terminated earlier in accordance with the terms of the lease and the Company is entitled to two five-year options to extend the lease. The initial annual base rent for the Additional Space is approximately $1.9 million and will increase annually for a total of $18.2 million over the lease term. The Company will be required to pay its share of operating expenses, taxes, and other expenses related to the additional leased premises.

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

In July 2020, the lease commencement date was met for the Additional Space under Accounting Standards Codification Topic 842, *Leases*, and will result in the addition of an operating lease asset and corresponding lease liability in the third quarter of 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, 2019 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. 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. QINLOCK is currently being investigated in a Phase 3 study for the treatment of patients with second-line GIST. In addition to QINLOCK, we are advancing multiple drug candidates from our platform in various stages of clinical development. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate, and/or durability of their responses to treatment that includes our approved drug, QINLOCK, and two clinical-stage, one preclinical-stage, and ongoing research-stage programs. We wholly own QINLOCK and our drug candidates with the exception of a development and commercialization out-license agreement for QINLOCK in Greater China.

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, and building a commercial and marketing organization. Our only product approved for sale is QINLOCK, which only recently received approval, and we have not generated substantial revenue from product sales.

On October 2, 2017, we completed an initial public offering (IPO), of our common stock, pursuant to which we issued and sold 7,500,000 shares of common stock at a public offering price of $17.00 per share, resulting in net proceeds of $114.1 million after deducting underwriting discounts and commissions and other offering expenses. On October 4, 2017, we issued and sold an additional 666,496 shares of our common stock at the IPO price of $17.00 per share, pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $10.5 million after deducting discounts and commissions.

On June 11, 2018, we issued and sold 4,300,000 shares of our common stock in a follow-on public offering at a public offering price of $40.00 per share, resulting in net proceeds of $161.0 million after deducting underwriting discounts and commissions and other offering expenses. On June 20, 2018, we issued and sold an additional 645,000 shares of our common stock at the public offering price of $40.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.3 million after deducting underwriting discounts and commissions.

On August 19, 2019, we issued and sold 10,810,810 shares of our common stock in a follow-on public offering at a public offering price of $37.00 per share, resulting in net proceeds of $375.4 million after deducting underwriting discounts and commissions and other offering expenses. On September 3, 2019, we issued and sold an additional 1,621,621 shares of our common stock at the public offering price of $37.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $56.4 million after deducting underwriting discounts and commissions.

On February 19, 2020, we issued and sold 3,181,818 shares of our common stock in a follow-on public offering at a public offering price of $55.00 per share, resulting in net proceeds of $163.7 million after deducting underwriting discounts and commissions and other offering expenses. On February 25, 2020, we issued and sold an additional 477,272 shares of our common stock at the public offering price of $55.00 per share, pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $24.7 million after deducting underwriting discounts and commissions.

Prior to our IPO, we had funded our operations primarily with proceeds from the sales of preferred shares, proceeds from the issuance of convertible notes, payments received under a concluded collaboration agreement, borrowings under a repaid construction loan, and research and development grants from the Kansas Bioscience Authority (KBA).

Since our inception, we have incurred significant operating losses. 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 $140.0 million for the six months ended June 30, 2020 and $192.3 million for the year ended December 31, 2019. As of June 30, 2020 we had an accumulated deficit of $628.0 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 our commercial activities in support of the launch of 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.;
- continue enrollment in and proceed with the expansion cohorts of our Phase 1 clinical trial for QINLOCK;
- continue with our ongoing pivotal Phase 3 clinical trial of QINLOCK in second-line GIST;
- continue with our ongoing and planned clinical programs for DCC-3014 and rebastinib;
- conduct IND-enabling studies and potential development of DCC-3116;
- develop any other future drug candidates we may choose to pursue;
- 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, including without limitation, our efforts to scale up drug substance and drug product manufacturing capabilities for commercial-grade product;
- maintain, expand, protect, and enforce our intellectual property portfolio;
- develop and expand our sales, marketing, and distribution capabilities for QINLOCK and any current or future drug candidates for which we obtain marketing approval, if any, including potential international capabilities; 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 potential international operations.

As we continue to seek regulatory approval for our drug and drug candidates, including QINLOCK for the treatment of second-line GIST patients, 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 incur additional costs associated with continuing to operate 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. Until at least such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operations primarily through a combination of equity offerings, debt 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. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our drug candidates.

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 or when or if we will be able to achieve or maintain profitability. Even if we are able to generate substantial product sales of QINLOCK, we may not become profitable. 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.

As of June 30, 2020, we had cash, cash equivalents, and marketable securities of $631.8 million. We believe that our cash, cash equivalents, and marketable securities as of June 30, 2020, together with anticipated product revenues, but excluding any

potential future milestone payments or other payments under our collaboration or license agreements, if any, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. For additional information, please read the "Liquidity and Capital Resources" section included below.

Recent Developments

QINLOCK

On May 15, 2020, QINLOCK was approved by the FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Following the FDA approval of QINLOCK, in May 2020, we commenced U.S. commercial sales of QINLOCK and began generating product revenue. 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 (TGA) approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. Additionally, in July 2020, our licensee, Zai, announced that the China National Medical Products Administration (NMPA) accepted the NDA submission 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 continue to study QINLOCK in INTRIGUE, our ongoing Phase 3 study, to evaluate QINLOCK compared to sunitinib in 426 patients in second-line GIST, and in an ongoing Phase 1 trial studying QINLOCK in patients with multiple advanced malignancies, including GIST. We currently expect to achieve our previously stated QINLOCK clinical milestone of full target enrollment in INTRIGUE in the second half of 2020.

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, 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 launch, 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, commercial launch 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. Because COVID-19 infections have been reported throughout the U.S. and worldwide, certain national, state, and local governmental authorities have issued orders, proclamations, and/or directives aimed at minimizing the spread of COVID-19. Although some of these restrictions have been eased or lifted, additional, more restrictive orders, proclamations, and/or directives may be issued in the future. 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.

Our ability to successfully launch, commercialize, and generate revenue from QINLOCK may be adversely affected by the impact of the COVID-19 pandemic. For example, limited hospital access for non-patients, social distancing requirements, and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. In response, we have implemented a virtual launch model, which 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. In addition, in the U.S. we plan to utilize various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and rising 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 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 some sites have temporarily paused enrollment of new patients. 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 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.

DCC-3014

We continue to study DCC-3014 in an ongoing dose escalation portion of the study in patients with tenosynovial giant cell tumor (TGCT). We currently expect to achieve our previously stated DCC-3014 clinical milestones in the second half of 2020, including that we expect updated clinical data for DCC-3014 from the dose escalation portion of the study in patients with TGCT and the selection of a Phase 2 dose for DCC-3014 and opening the expansion portion of the study in TGCT patients.

Rebastinib Development Update

Rebastinib is an investigational, orally administered, potent, and selective inhibitor of TIE2 kinase, which plays an important role in regulating tumor angiogenesis, invasiveness, metastasis, and immunotolerance. We are currently studying rebastinib in two Phase 1b/2 studies in combination with chemotherapy, one with paclitaxel and one with carboplatin. Both studies are divided into two parts. Part 1 of each study was designed to select a combination dose of rebastinib with each chemotherapy agent. Part 2 of each study is designed as a Simon 2-stage design; in the first stage, the combinations are being evaluated in multiple solid tumor cohorts in up to 18 patients each. If there are more than four responses in a given cohort, that cohort is expanded to up to a total of 33 patients.

In May 2020, we announced that we have observed in the paclitaxel combination study the required number of responses in the first stage in both the endometrial and ovarian cancer cohorts, two of the cohorts in Part 2 of this study, triggering the expansion of enrollment in these cohorts. In addition, based on the clinical activity observed in Part 1, we have added a cohort for patients with carcinosarcoma in Part 2 of the study.

Components of Our Results of Operations

Revenues

To date, we have not generated substantial revenue from product sales. 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. If we enter into collaboration agreements, distributor arrangements, or additional license agreements with third parties, 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 near future will be derived primarily from the product sales of QINLOCK in the U.S. and, payments, if any, made 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, as well as any collaborations, distributor arrangements, or additional license agreements that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all. We cannot provide assurance as to when or 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 receive marketing approval, if any. We may never succeed in obtaining regulatory approval for any of our drug candidates other than QINLOCK.

Net Product Revenues

Following the FDA approval of QINLOCK in May 2020, we commenced commercial sales of QINLOCK in the U.S. and began generating product revenue. Product revenues are recorded net of estimates of variable consideration. Please read Note 1, *Nature of the Business and Summary of Significant Accounting Policies*, of these consolidated financial statements for further details of the reserves recorded for variable considerations.

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 potential annual net sales of QINLOCK, including certain follow-on compounds (the Licensed Products), if approved, in the Greater China region (the Territory), subject to adjustments in specified circumstances.

Under the Zai License Agreement, we recognized revenues of $25.0 million during the second quarter of 2019, which consisted of the $20.0 million upfront payment and a $5.0 million INTRIGUE study-related development milestone payment, which we believed to be probable of achievement in the second quarter of 2019 and was achieved in July 2019.

Under the Zai License Agreement, we recognized revenues of $2.1 million during the second quarter of 2020, which consisted of the achievement of a $2.0 million development milestone in the second quarter of 2020 and $0.1 million in reimbursable costs.

As of June 30, 2020, QINLOCK had not received regulatory approval in the Territory, and it is not possible to estimate when, or if, we may receive royalty payments or commercial milestones under the Zai License Agreement.

Zai Supply Agreement

Pursuant to the terms of the Zai Supply Agreement, costs incurred by the Company for external manufacturing services are reimbursed by Zai.

Under the Zai Supply Agreement, the Company recognized revenues of $0.1 million and $0.2 million associated with the reimbursement of costs incurred for external manufacturing services provided during the three and six months ended June 30, 2020, respectively.

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.

Cost of sales for newly launched products, such as QINLOCK, will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. As a result, the gross margin on sales of QINLOCK for the three and six months ended June 30, 2020 was enhanced by the use of active pharmaceutical ingredients and components that were previously expensed as research and development expenses prior to the launch of QINLOCK.

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:

- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize QINLOCK and any current or future drug candidates for which we receive approval;
- obtaining and maintaining patent, trade secret and other intellectual property protection, and regulatory exclusivity for our drug and drug candidates;

- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;
- developing and implementing marketing and reimbursement strategies;
- continuing to establish sales, marketing, and distribution capabilities to support the commercial launch 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 the Greater China region;
- acceptance of QINLOCK or our drug candidates, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of our products following approval.

A change in the outcome of any of these variables with respect to the commercialization of QINLOCK or the development of any of our drug candidates would significantly change the costs and timing associated with the commercialization of QINLOCK or development of 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 for QINLOCK prior to FDA approval; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and supplies.

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 kinase switch control inhibitor platform technology, or facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product 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, and administrative functions. Selling, general, and administrative expenses also include direct and allocated facility-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 commercial launch of QINLOCK as well as our continued research activities and development of our drug and drug candidates. We also anticipate that we will continue to incur increased 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.

Interest Expense

Interest expense for the three and six months ended June 30, 2019 consisted of interest expense associated with a previously outstanding construction loan from a related party. We anticipate that we will not have interest expense in 2020 as the outstanding balance of notes payable to a related party was repaid in December 2019.

Income Taxes

We are 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 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, 2019 on file with the SEC, as of June 30, 2020, 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, assumptions, 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:

- revenue recognition;
- 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.

Except for product revenue, which is described below, 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, 2019 on file with the SEC. Other than for product revenue, there have been no significant changes to our critical accounting policies since December 31, 2019.

Product Revenues

We recognize product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. We record product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, trade discounts and allowances, product returns, and other incentives, which are described below.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying, and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Chargebacks and Administrative Fees: Chargebacks for discounts represent our estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list prices charged to the customers who directly purchase the product from us. The customers charge us for the difference between what the customers pay us for the product and the customer's ultimate contractually committed or government required lower selling price to the qualified healthcare providers. As part of our contractual commitments to sell product to qualified healthcare providers, we pay fees for administrative services, such as account management and data reporting.

Government rebates: Government rebates consist of Medicare, Tricare, and Medicaid rebates. These reserves are recorded in the same period the related revenue is recognized. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe a rebate under the Medicare Part D program.

Trade discounts and allowances: We provide customers with discounts that are explicitly stated in contracts and recorded in the period the related product revenue is recognized. In addition, we also receive sales order management, inventory management, and data services from customers in exchange for certain fees.

Product returns: We estimate the amount of our product sales that may be returned by our customers and record this estimate in the period the related product revenue is recognized. We currently estimate product return liabilities based on available industry data and our visibility into the inventory remaining in the distribution channel.

Other incentives: Other incentives include co-payment assistance provided to qualified patients, whereby we may provide financial assistance to patients with prescription drug co-payments required by the patient's insurance provider. Reserves for co-payment assistance are recorded in the same period the related revenue is recognized.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Revenues:				
Product revenues, net	$ 4,825	$ —	$ 4,825	$ —
Collaboration revenues	2,265	25,000	2,327	25,000
Total revenues	7,090	25,000	7,152	25,000
Cost and operating expenses:				
Cost of sales	8	—	8	—
Research and development	46,081	34,811	97,469	70,600
Selling, general, and administrative	29,933	13,164	53,869	26,400
Total cost and operating expenses	76,022	47,975	151,346	97,000
Loss from operations	(68,932)	(22,975)	(144,194)	(72,000)
Other income (expense):				
Interest and other income, net	1,691	1,540	4,146	3,194
Interest expense	—	(25)	—	(38)
Total other income (expense), net	1,691	1,515	4,146	3,156
Net loss	$ (67,241)	$ (21,460)	$ (140,048)	$ (68,844)

Revenues

Net Product 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.

As of June 30, 2020, our only source of product revenues were from the sales of QINLOCK in the U.S., and total net product revenues were $4.8 million for the three and six months ended June 30, 2020.

Collaboration Revenues

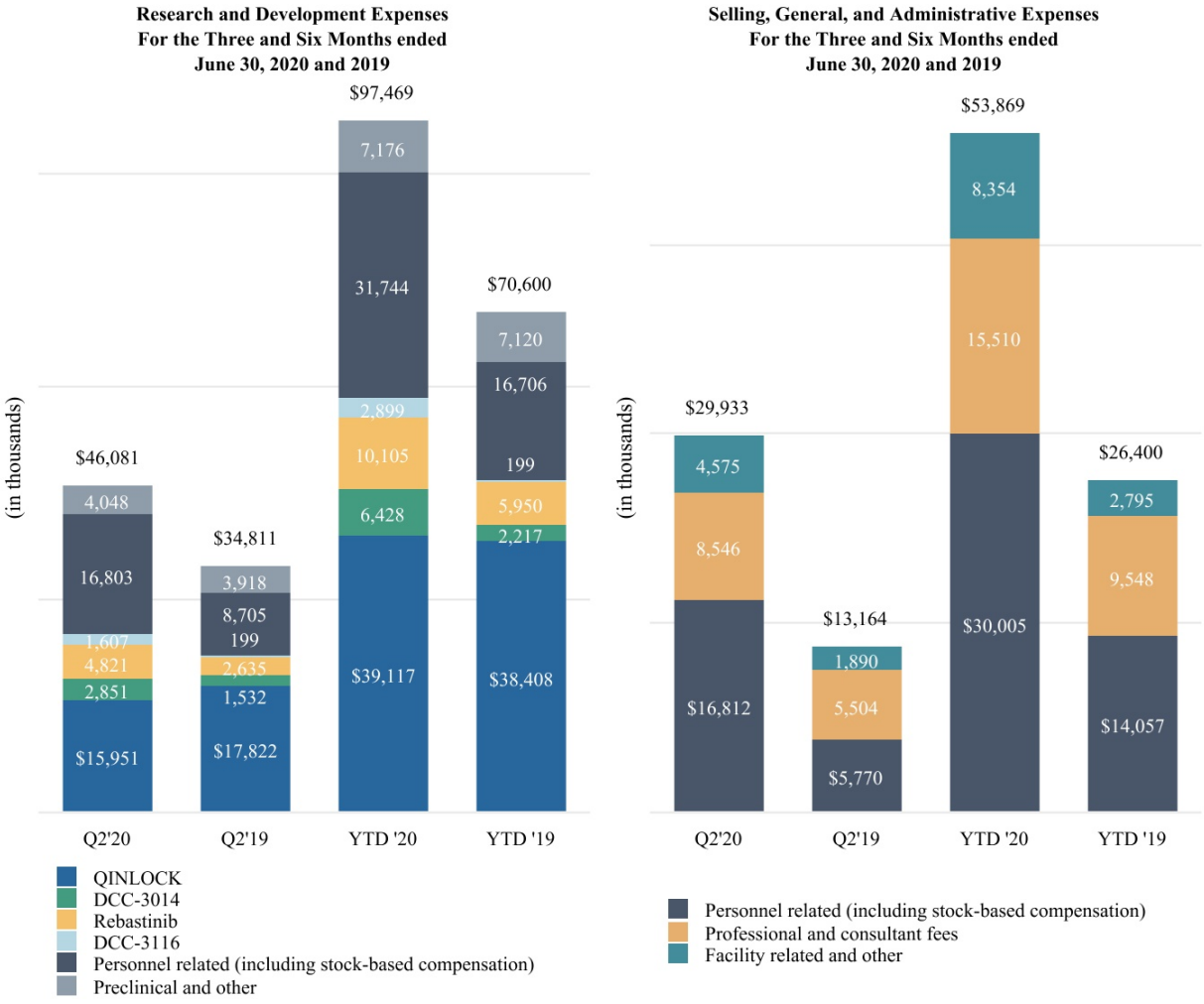
For the three and six months ended June 30, 2020 compared to the same periods in 2019, collaboration revenues decreased $22.8 million and $22.7 million, respectively, primarily driven by the recognition of up-front and development milestone payments of $20.0 million and $5.0 million, respectively, associated with the Zai License Agreement in the second quarter of 2019 as compared to the recognition of a $2.0 million development milestone payment associated with the Zai License Agreement in the second quarter of 2020. The decrease in upfront and milestone payments were partially offset by revenue increases during the three and six months ended June 30, 2020 compared to the same periods in 2019 for reimbursable costs under the Zai License Agreement, which were $0.1 million during the three and six months ended June 30, 2020, and for the reimbursement of costs incurred for external manufacturing services provided under the Zai Supply Agreement, which were $0.1 million and $0.2 million during the three and six months ended June 30, 2020, respectively.

Cost of Sales

Cost of sales were less than $0.1 million for the three and six months ended June 30, 2020 and were primarily related to packaging, labeling, shipping, and distribution costs associated with sales of QINLOCK. External manufacturing costs associated with QINLOCK inventory prior to FDA approval were previously expensed as research and development expenses and, therefore, are not included in cost of sales during the three and six months ended June 30, 2020.

We expect our cost of sales for QINLOCK to increase as a percentage of net sales in future periods as we continue to produce inventory for future sales, which will reflect the full cost of manufacturing, and then sell such inventory.

Operating Expenses



Research and Development Expenses

QINLOCK

For the three months ended June 30, 2020 compared to the same period in 2019, research and development expenses related to QINLOCK decreased primarily as a result of decreases in manufacturing costs of $0.9 million and clinical trial expenses of $0.7 million. Manufacturing costs for QINLOCK decreased primarily due to the commencement of capitalization of inventory following FDA approval of QINLOCK on May 15, 2020. Clinical trial expenses for QINLOCK decreased primarily as a result of decreased costs associated with our pivotal Phase 3 trial in fourth-line and fourth-line plus GIST, 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 costs associated with our ongoing Phase 1 trial of QINLOCK. These decreases were partially offset by increased costs related to our pivotal Phase 3 trial in second-line GIST, INTRIGUE, which we initiated in December 2018.

For the six months ended June 30, 2020 compared to the same period in 2019, research and development expenses related to QINLOCK increased primarily as a result of an increase in manufacturing costs of $1.7 million. Manufacturing costs for QINLOCK increased primarily as a result of increased activities to support anticipated drug requirements for commercialization prior to the FDA approval of QINLOCK on May 15, 2020. Clinical trial expenses for QINLOCK decreased $0.5 million during the six months ended June 30, 2020 compared to the same period in 2019. The decrease in clinical trial expenses was primarily related to decreased costs associated with our pivotal Phase 3 trial in fourth-line and fourth-line plus GIST, 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 costs associated with our ongoing Phase 1 trial of QINLOCK. These decreases were partially offset by increased costs related to our pivotal Phase 3 trial in second-line GIST, INTRIGUE, which we initiated in December 2018.

DCC-3014

For the three and six months ended June 30, 2020 compared to the same periods in 2019, expenses related to our DCC-3014 program increased primarily as a result of increases in clinical trial expenses of $0.5 million and $1.5 million, increases in manufacturing costs of $0.4 million and $1.4 million, and increases in preclinical costs of $0.3 million and $1.1 million, respectively. The increases in clinical trial expenses were primarily due to our ongoing dose escalation Phase 1 trial of DCC-3014 to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in patients with advanced malignancies and TGCT. Manufacturing costs for the DCC-3014 program increased as a result of increased activities to support clinical trials. The increases in preclinical costs were primarily due to ongoing studies.

Rebastinib

For the three and six months ended June 30, 2020 compared to the same periods in 2019, expenses related to our rebastinib program increased primarily as a result of increases in clinical trial expenses of $1.2 million and $2.4 million and manufacturing costs of $0.9 million and $1.7 million, respectively. The increases in clinical trial expenses were primarily due to our Phase 1b/2 trial of rebastinib in combination with paclitaxel, which we initiated in October 2018 and moved to Part 2 of the Phase 1b/2 trial in the second quarter of 2019, and our second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which we initiated in January 2019 and moved to Part 2 of the Phase 1b/2 trial in January 2020. Manufacturing costs for the rebastinib program increased as a result of increased activities to support clinical trials.

DCC-3116

For the three and six months ended June 30, 2020 compared to the same periods in 2019, expenses related to our DCC-3116 program increased primarily as a result of increased preclinical activities, including IND-enabling studies, related to this drug candidate, which we announced as an addition to our pipeline in June 2019.

Unallocated Expenses

For the three and six months ended June 30, 2020 compared to the same periods in 2019, the increase in personnel-related costs included in unallocated expenses was primarily due to an increase in headcount and stock-based compensation expense in our research and development functions. Personnel-related costs included stock-based compensation expense of $5.3 million and $1.8 million during the three months ended June 30, 2020 and 2019, respectively, and $8.6 million and $3.5 million during the six months ended June 30, 2020 and 2019, respectively. The increase in stock-based compensation expense was primarily related to headcount increases and increased valuations of share-based awards granted to our employees as well as $1.3 million of expenses incurred during the three and six months ended June 30, 2020 related to the achievement of vesting events associated with performance-based restricted stock units during the second quarter of 2020.

We expect research and development expenses will increase in the second half of 2020 compared to the first half of 2020 as we continue to support clinical and development activities.

Selling, General, and Administrative Expenses

For the three and six months ended June 30, 2020 compared to the same periods in 2019, the increase in selling, general, and administrative expenses was related to personnel-related costs, professional and consultant fees, and facility related and other costs. For the three and six months ended June 30, 2020 compared to the same periods in 2019, the increase in personnel-related costs was primarily a result of increases in headcount in our selling, general, and administrative functions. Personnel-related costs included stock-based compensation expense of $5.3 million and $2.3 million during the three months ended June 30, 2020 and 2019, respectively, and $9.0 million and $6.9 million during the six months ended June 30, 2020 and 2019, respectively. The increase in stock-based compensation expense was primarily related to increased headcount and increased valuations of share-based awards granted to our employees. These increases in stock-based compensation were partially offset by the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer during the six months ended June 30, 2019 resulting in expense of $2.4 million. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness and launch of QINLOCK. The increase in facility related and other costs was primarily due to increased technology related costs to support the growth of the business and expenses associated with our new headquarters that commenced in October 2019.

We expect selling, general, and administrative expenses will increase in the second half of 2020 compared to the first half of 2020 as we continue to support the commercial launch of QINLOCK.

Interest and Other Income, Net

For the three and six months ended June 30, 2020 compared to the same periods in 2019, the increases in interest and other income, net, was primarily due to increases in interest income earned on our cash equivalents and marketable securities associated with higher investment balances as a result of our follow-on public offerings in the third quarter of 2019 and February 2020.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from our product sales, license and supply agreements with Zai, a concluded collaboration agreement, and research and development grants from the KBA. 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. 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 TGA approved QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. We have not obtained marketing approval for QINLOCK in any other jurisdictions or for any additional indications. As of June 30, 2020, our only source of product revenues were from the sales of QINLOCK in the U.S. 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.

Since October 2017, when we completed the IPO of our common stock, we have issued and sold 29,203,017 shares of common stock through our initial public offering and subsequent follow-on offerings, resulting in net proceeds of $930.1 million after deducting underwriting discounts and commissions and other offering expenses.

For further details on our recent follow-on offering in February 2020, please read the "Overview" section included above.

Cash Flows

As of June 30, 2020, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $631.8 million.

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

	Six Months Ended June 30,	
(in thousands)	**2020**	**2019**
Cash flows used in operating activities	$ (141,214)	$ (70,272)
Cash flows used in investing activities	(19,441)	(167,392)
Cash flows provided by financing activities	195,781	1,137
Net increase (decrease) in cash and cash equivalents	$ 35,126	$ (236,527)

Operating Activities

During the six months ended June 30, 2020, operating activities used $141.2 million of cash, primarily resulting from our net loss of $140.0 million and cash used in changes in our operating assets and liabilities of $18.8 million, partially offset by net non-cash charges of $17.6 million, primarily resulting from share-based compensation expense of $17.6 million. Net cash used in changes in our operating assets and liabilities for the six months ended June 30, 2020 consisted of an $9.5 million decrease in accounts payable and accrued expenses and other current liabilities, a $7.4 million increase in accounts receivable, a $0.9 million decrease in operating lease liabilities associated with lease payments, a $0.8 million increase in inventory, and an increase in prepaid expenses and other current assets of $0.1 million. Changes in accounts payable, accrued expenses and other current liabilities, and prepaid expenses were generally due to the timing of vendor invoicing and payments. Increases in accounts receivable were primarily associated with product sales of QINLOCK beginning in May 2020 and with revenues recognized in the second quarter of 2020 under the Zai License and Supply Agreements. Inventory increases were associated with the build-up and commencement of capitalization of inventory to support commercial sales of QINLOCK following the FDA approval of QINLOCK in the second quarter of 2020.

During the six months ended June 30, 2019, operating activities used $70.3 million of cash, primarily resulting from our net loss of $68.8 million and cash used by changes in our operating assets and liabilities of $11.0 million, partially offset by non-cash charges of $9.6 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2019 consisted primarily of a $20.0 million increase in accounts receivable and a $5.0 million increase in unbilled receivable, partially offset by a $12.8 million increase in accounts payable and accrued expenses and other liabilities and a decrease in prepaid expenses and other current assets of $1.3 million. Increases in accounts receivable and unbilled receivables were associated with an up-front payment and development milestone payment, respectively, under the Zai License Agreement, which was entered into in June 2019. Changes in accounts payable, accrued expenses, and prepaid expenses were generally due to growth in our business.

Investing Activities

During the six months ended June 30, 2020, investing activities used $19.4 million of cash, consisting of $15.2 million for the net purchases of marketable securities, $3.7 million to purchase property and equipment, and an increase in our restricted investments by $0.6 million to increase our Company credit card limit to support the growth of the business in the first quarter of 2020.

During the six months ended June 30, 2019, investing activities used $167.4 million of cash, primarily consisting of $166.7 million for the net purchases of marketable securities and an increase in our restricted investments by $0.4 million to secure a Company credit card.

Financing Activities

During the six months ended June 30, 2020, net cash provided by financing activities was $195.8 million, consisting of proceeds from our follow-on public offering in February 2020, net of underwriting discounts and commissions, of $189.0 million and the exercise of stock options of $7.4 million, partially offset by $0.7 million of payments of offering costs.

During the six months ended June 30, 2019, net cash provided by financing activities was $1.1 million, primarily consisting of proceeds from the exercise of stock options of $1.2 million.

Funding Requirements

We expect that our expenses and capital requirements will increase in connection with our ongoing activities. The timing and amount of our operating expenditures will depend largely on:

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

As of June 30, 2020, we had cash, cash equivalents, and marketable securities of $631.8 million. We believe that our cash, cash equivalents, and marketable securities as of June 30, 2020, together with anticipated product revenues, but excluding any potential future milestone payments or other payments under our collaboration or license agreements, if any, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. 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.

Until at least such time, if ever, as we can generate substantial product revenues, we expect to finance our operations primarily through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or additional licensing arrangements. 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 our license agreement with Zai), 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. 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 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.

Contractual Obligations and Commitments

We have entered into commercial supply agreements related to the supply of QINLOCK that require us to make binding forecasts for a certain amount of purchases. The related cancellation clauses would as a general matter require us to pay the full amount of these binding forecasts. As of June 30, 2020, our contractual commitments for such obligations were $5.0 million, which are expected to be paid within one year.

As of June 30, 2020, 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, 2019, which primarily consisted of our obligations under non-cancellable operating leases.

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

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1, *Nature of the Business and Summary of Significant Accounting Policies*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Our cash, cash equivalents, and marketable securities as of June 30, 2020 consisted of cash, money market funds, 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 June 30, 2020, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $4.8 million to our interest rate sensitive instruments.

We do not believe that our cash, cash equivalents, and marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and marketable securities do not contain excessive risk, we cannot provide absolute

assurance that in the future our investments will not be subject to adverse changes in market value, including changes resulting from the impact of the COVID-19 pandemic. In addition, we maintain significant amounts of cash, cash equivalents, and marketable securities at 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 six months ended June 30, 2020 and 2019.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, 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 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 Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and have not generated substantial revenue 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 substantial revenue from product sales. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and have incurred losses in each year since inception. For the six months ended June 30, 2020 and the year ended December 31, 2019, we reported a net loss of $140.0 million and $192.3 million, respectively. As of June 30, 2020, we had an accumulated deficit of $628.0 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 DCC-3014, rebastinib, and DCC-3116 are still in preclinical and clinical development. To date, we have not generated substantial revenue from the product sales of QINLOCK and have funded our operations primarily with proceeds from the sales of our common stock in public offerings, 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 KBA. Since our inception, we received an aggregate of $1.2 billion in net proceeds from such transactions. As of June 30, 2020, our cash, cash equivalents, and marketable securities were $631.8 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, DCC-3014, and rebastinib, our preclinical studies for 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 have and will 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 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 substantial revenue 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., Canada, and Australia 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 clinical trial 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 trial for QINLOCK for the treatment of second-line GIST, completing all requirements for the submission of a supplemental NDA, and applying for and obtaining marketing approval;
- complete all requirements for the submission of a marketing authorisation application (EU MAA) to the European Medicines Agency (EMA) and obtain marketing approval for QINLOCK in the European Union (EU);
- 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, 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, if approved, commercialize QINLOCK in Greater China, 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 market acceptance of QINLOCK, or any current or future drug candidate for which we 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 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.

We may 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, DCC-3014, 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 and any current or future drug candidate for which we receive marketing approval. Furthermore, we expect to continue to incur costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce, or eliminate our research or drug development programs or our commercialization efforts.

We believe that our cash, cash equivalents, and marketable securities as of June 30, 2020, together with anticipated product revenues, but excluding any potential future milestone payments or other payments under our collaboration or license agreements, if any, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. 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 trials 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 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;
- 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 in other jurisdictions where we may seek marketing approval and choose to sell or enter into distribution arrangements;
- the revenue, if any, 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 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 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 substantial revenues 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.

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 substantial product revenue, we expect to finance our cash needs primarily through a combination of equity offerings, debt 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, drugs 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 have a limited operating history, have not successfully completed late-stage clinical trials for any drug candidate other than QINLOCK, and have not generated substantial revenue from product sales or profits. 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 initial quantities of our drug candidates, and 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. All of our drug candidates are still in clinical trials or preclinical development.

We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials other than for QINLOCK in fourth- and fourth-line plus GIST and we have not generated substantial revenue 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 capable of supporting commercial activities and we have not yet demonstrated our ability 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.

Risks Related to 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. 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 substantial revenues 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. We may never be able to successfully commercialize the 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, 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 in anticipation of the launch and commercialization of QINLOCK in the U.S. in GIST will be sufficient for us to achieve success at the levels we expect.

We may encounter issues and challenges in commercializing QINLOCK and generating substantial revenues. 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 substantial revenues, 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 develop, validate, and 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 successfully complete our Phase 3 clinical trial of QINLOCK for second-line GIST and obtain marketing approval in such indication;
- 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; 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 the product or to generate substantial revenues 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 launch or commercialization efforts with respect to QINLOCK. 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, 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 initiating the commercial launch of QINLOCK in the U.S., 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;
- gain 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 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 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.

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, SM, and other solid tumors driven by KIT or PDGFRα, and TGCT, 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, DCC-3014, 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 licensees) 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;
- 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.

If we and/or our licensees are unable to maintain and further develop sales and marketing capabilities, we or our licensees 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 substantial revenue.

We have only recently established our sales and marketing infrastructure 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. In addition to our existing QINLOCK license to Zai for Greater China, we are currently exploring selectively establishing partnerships in markets outside the U.S. to support the commercialization of QINLOCK or our drug candidates for which we obtain marketing approval and that can be commercialized with such capabilities, and we are currently exploring the possibility of building our own sales capabilities in Europe as an alternative to partnering.

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. 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 our 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, in particular in light of current reduced in-person access to medical institutions and personnel 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.

As a result of any potential partnerships in markets outside of the U.S., or if we are unable to successfully establish our own sales and marketing capabilities in the U.S. and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug 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 our 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 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.

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 and drug candidates. 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 PDGFRα exon 18 mutations only, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRα, and no currently marketed drug provides coverage of all KIT and PDGFRα 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 (BPMC), Novartis AG (Novartis), Pfizer, Inc. (Pfizer), and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST and/or SM including AB Sciences S.A., Arog Pharmaceuticals, Inc., BPMC, Chia Tai Tianqing Pharmaceutical Group CO., LTD, Daiichi Sankyo Company, Limited, Exelixis, Inc., Immunicum AB, Jiangsu HengRui, Inc., Ningbo Tai Kang Medical Technology Co. Ltd., Novartis, Taiho Pharmaceutical Co. Ltd, Unum Therapeutics, and Xencor, Inc. Some of these competitors are further along in their clinical development programs than we are in ours. Further, there are numerous companies marketing or developing antibodies and small molecules targeting colony stimulating factor receptor 1 (CSF1R), inhibitors that we are seeking to target with our DCC-3014 program, including Abbisko Therapeutics Co., Ltd., Five Prime Therapeutics, Inc., and LifeMax Laboratories, Inc. In addition, while we believe that rebastinib, a TIE2 inhibitor, is a novel molecule, we believe we may face competition from drug candidates in clinical trials that are not TIE2 inhibitors, but aim to achieve similar effects on the immune system. These include small molecule drug candidates in clinical trials from Bristol-Myers Squibb Company and Novartis, and antibody therapeutics from AstraZeneca PLC, Eisai Co., Ltd., Roche Holding Ltd., Merck & Co., Inc., Pfizer, and Tesaro, a GlaxoSmithKline PLC company.

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 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.

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 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 our drug candidates; 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.

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.

Risks Related to the Discovery and Development of Our Drug Candidates

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 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. We are early in our development efforts for all of our other drug candidates. Two of our drug candidates are only in Phase 1 or Phase 1b/2 clinical trials.

Our drug and drug candidates target key interactions with kinase switch regions to inhibit kinase activity. Other than QINLOCK, there are no currently approved switch-control kinase inhibitors. 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 drug and drug candidates, if approved. The success 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 clinical trial of QINLOCK for second-line GIST;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to commercialize QINLOCK and complete clinical development of and commercialize any current or future drug candidates for which we obtain marketing approval;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our drug and drug candidates;
- making and maintaining timely and cost-effective arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug and drug candidates;
- successful commercialization of our approved drug and drug candidates, if and when approved;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of QINLOCK and our drug candidates, if and when approved, whether alone and/or in collaboration with others, such as Zai, our licensee for QINLOCK in Greater China, and building infrastructure to support such sales;
- acceptance of QINLOCK and any future drug products, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and

- maintaining a continued acceptable safety profile of our approved drug and drug candidates following approval.

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 clinical trial of QINLOCK for second-line GIST or our ongoing Phase 1 clinical trial of QINLOCK vary meaningfully from our expectations.

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, estimations, 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. For example, in 2019, we announced preliminary results from the initial three diffuse-type TGCT patients enrolled in the dose-escalation portion of our Phase 1 study of DCC-3014. 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.

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 our drug or 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 trial 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 clinical trial 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 clinical trial for QINLOCK in second-line GIST. These factors also apply to the Phase 1 and Phase 1b/2 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 outbreak of COVID-19, 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 expected to be conducted in China under our collaboration with Zai;
- the cost of clinical trials for our 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 PDGFRα 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 PDGFRα, 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 PDGFRα or mutations in KIT that are resistant to QINLOCK. If patients have or develop resistance to treatment with our 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. The FDA may request additional information or data and any such requests could result in clinical trial 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.

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 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 outbreak continues to evolve as additional cases of the virus are identified and public health officials learn more about the spread of the virus and the efficacy of containment measures. Many countries, including the U.S., have reacted by instituting varying levels of quarantines, restrictions on travel and mandatory closures of businesses. Certain states and cities, including where we or the third parties with whom we engage operate, have also engaged in efforts to mitigate the impact of the COVID-19 pandemic by instituting restrictions on types of business that may continue to operate, and/or restrictions on the types of construction projects that may continue. Although some of these restrictions have been eased or lifted in a phased approach over time, additional, more restrictive orders, proclamations, and/or directives may be issued in the future.

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, 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 launch, commercialize, and generate revenue from QINLOCK may be adversely affected by the economic impact of the COVID-19 pandemic. For example, in the U.S. we plan to utilize various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and rising unemployment 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 recent outbreak of COVID-19 may also negatively impact our commercialization strategy for QINLOCK. Some hospitals and other medical institutions continue to have limited hospital access for non-patients, which includes our sales personnel. In addition, social distancing requirements and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. As a result, in many circumstances we have needed to limit our interactions with physicians and patients and adapt our launch 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, telemedicine, and social media. These circumstances 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 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 for enrollment, some sites in each of our studies

have temporarily paused 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 an outbreak 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 health resources, protect trial participants from being exposed to unacceptable health risks or comply with other 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 if 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 commercial launch, ship investigational drug supply for use in clinical trials or by patients, 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 and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and conduct 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. 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 not be able to access laboratories for an extended period of time as a result of 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 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, in April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. 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 resulting from such disruptions could materially affect the development and study of our drug or 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.

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 candidates beyond those that we currently contemplate if we are unable to successfully complete clinical trials for our 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 trial 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 trial in second-line GIST, INTRIGUE. While we plan to conduct only one pivotal Phase 3 trial 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 clinical trial 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 trial, we also plan to have all of the data from our ongoing Phase 3 trial of QINLOCK for second-line GIST centrally reviewed. The results from our Phase 3 trial of QINLOCK in which all data will be subject to central review may be less favorable than the results of our Phase 1 trial 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, our licensees, such as Zai in Greater China, may be required to conduct additional clinical trials in the local region or regions where the licensees seek to commercialize our drug or drug candidates before a local regulatory authority will approve any marketing application. These local studies may involve, among other things, exploration of the effect our drug or drug candidates may have on a local population, which could be different than our clinical trial results or experience to date, and subject these trials and our development efforts to the risk that they do not support regional approval.

We have scaled up our manufacturing process for QINLOCK in anticipation of greater drug requirements for commercialization. If we are unable to manufacture sufficient quantities of QINLOCK in a timely and cost-efficient manner to meet commercial demand, our business and results of operations will be harmed.

In addition, we may:

- be delayed in obtaining marketing approval for our drug or drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product, including QINLOCK, removed from the market after obtaining marketing approval.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including in our Phase 3 clinical trial of QINLOCK in second-line GIST, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or 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 or access restrictions resulting from COVID-19 or other factors. In particular, the majority of the GIST patients we have enrolled in our Phase 1 trial of QINLOCK have been fourth-line or later GIST patients. However, we have enrolled a limited number of second-line GIST patients in our Phase 1 trial and are now enrolling second-line GIST patients in our Phase 3 trial, INTRIGUE. We cannot predict how difficult it will be to enroll and retain GIST patients for current and future trials in earlier lines of therapy such as second-line GIST where alternative therapies already are approved.

Therefore, our ability to identify and enroll eligible patients for these clinical trials and possibly other clinical trials may be limited or may result in slower enrollment than we anticipate. 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 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 have recently 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. For example, we have experienced these challenges in our Phase 1 QINLOCK expansion cohort for systemic mastocytosis, other than indolent systemic mastocytosis (such subgroups of systemic mastocytosis are herein referred to as SM). 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 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 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 products.

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.

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. For example, we are in the early preclinical development stage with DCC-3116 and if IND-enabling studies for DCC-3116 do not produce favorable results, we may discontinue further development of DCC-3116. If we are unable to identify suitable drug candidates for preclinical and clinical development, we will not be able to obtain revenues from 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 Our Dependence on Third Parties

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. We will not derive revenue from Zai's sales of QINLOCK in Greater China, if any, 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, if approved, 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 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 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 the applicable approved drug or drug candidates;
- license and/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 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 license 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 may also 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 or collaborators. 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.

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, DCC-3014, and rebastinib, and do not plan to independently conduct any clinical trials for our other drug candidates, such as DCC-3116. 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.

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 licensees. 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 ceased 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 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.

We depend on the proprietary technology of our third-party manufacturers for certain of our drug and drug candidates, including QINLOCK. 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.

For our other potential products, if we are not able to negotiate commercial supply terms with any such third-party manufacturers, we may be unable to commercialize our products 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. 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 products. 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.

Risks Related to Our Intellectual Property

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, DCC-3014, 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 kinase switch control 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 U.S. Patent and Trademark Office (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. 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.

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.

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.

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 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 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, products, 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 product. 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 products 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.

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 any of our approved drug or 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 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 noncompliance 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 of technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 certain of our drugs and 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 kinase switch control 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 kinase switch control 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 any of our approved drug or 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 Regulatory Approval and Marketing of Our Drug and Drug Candidates and Other Legal Compliance Matters

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 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. Some of our drug candidates are in the early stages of development and are subject to the risks of failure inherent in drug development. With the exception of QINLOCK in the U.S., Canada, and Australia, we have not received approval or authorization to market QINLOCK or any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting and managing the 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 abroad, 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. For example, while we conducted only one pivotal Phase 3 trial for our NDA filing in fourth-line and fourth-line plus GIST, and we plan to conduct only one pivotal Phase 3 trial for second-line GIST, for a single randomized trial to support a 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. 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 label for our approved drug, 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.

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 Europe. 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. The FDA also can approve a different drug for the same orphan indication, or the same drug for a different indication, during the orphan exclusivity period.

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.

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.

Our failure to obtain marketing approval in foreign jurisdictions would prevent QINLOCK and our drug candidates from being marketed abroad, 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 our products in the EU and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. In Greater China, our licensee will be responsible for obtaining marketing approval for QINLOCK. 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 licensees, as applicable, may not) obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. 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. We 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., Canada, and Australia.

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.

Even after marketing approval of a drug candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for QINLOCK and any of our drug candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote QINLOCK or any future approved products for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, 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. 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.

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, and 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.

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.

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.

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 (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.

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 will play a primary role in the recommendation and prescription of QINLOCK and any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers 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.

California recently enacted the California Consumer Privacy Act (CCPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities if we become covered by the scope of the statute. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the EU adopted a new regulation governing data practices and privacy called the General Data Protection Regulation (GDPR) which became effective on May 25, 2018. 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 enhances data protection obligations for processors and 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, and onerous new obligations on services providers. 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 GDPR. 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. Further, the United Kingdom's (U.K.) decision to leave the EU, often referred to as

Brexit, has created uncertainty with regard to data protection regulation in the U.K. In particular, it is unclear how data transfers to and from the U.K. will be regulated now that the U.K. has left the EU.

In the U.S., to help patients afford our products, if approved, we plan to have various programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In 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 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.

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 newly-approved products 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, 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, 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., 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, 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 products 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 products 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 Part A, 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 noncompliance;
- 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 of the current 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 (the Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017 (TCJA), 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, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Since January 2017, the current U.S. presidential administration has 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 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. On October 13, 2017, the U.S. President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The current U.S. presidential administration has concluded that cost-sharing reduction (CSR) payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. 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. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

On January 22, 2018, the 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 U.S. President signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. The Bipartisan Budget Act of 2018 (the BBA) 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, 2020 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.

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. presidential administration's budget for fiscal year 2020

contains further drug price control measures that could be enacted during the 2020 legislative session or in other future legislation, including, for example, measures to permit Part D plans to negotiate the price of certain drugs under Medicare Part B (Part B), to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the current U.S. presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In May 2019, the CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified the CMS's policy change that was effective January 1, 2019. The U.S. Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require HHS to directly negotiate drug prices with manufacturers. The Lower Drug Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. 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.

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.

On December 22, 2017, the U.S. President signed into law the TCJA. The TCJA made major changes to the taxation of corporations, including reduction of the corporate tax rate from 35% to 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Further, on March 27, 2020, the U.S. President signed into law the Coronavirus Aid, Relief, and Economic Security Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. 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, 2019, 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." The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating losses generated after December 31, 2017 will not be subject to expiration.

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 the EU, 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," The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our operating results. 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. While the U.K.'s withdrawal from the EU was completed on January 31, 2020, there remains considerable uncertainty about the terms of the U.K.'s trade agreements and other relationships with the EU following the transition period which ends December 31, 2020. During the transition period, the U.K. will continue to follow all of the EU's rules and will maintain its current trading relationship with the EU. We expect that uncertainty over the terms of the trade and other 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 could, 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 the terms of the free trade and other agreements that the U.K. will eventually enter into with the EU are known, it is not possible to determine 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, Brexit could result in the U.K. or the EU significantly altering its regulations affecting the clearance or approval of our product or drug candidates as the U.K. determines which EU laws to replace or replicate. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the U.K., the EU, and elsewhere. In addition, the announcement of Brexit and the withdrawal of the U.K. from the EU have 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 European and other privacy laws, which could adversely affect our business, results of operations and financial condition.

We currently conduct clinical trials in the European Economic Area (EEA). As a result, we are subject to additional privacy laws. The GDPR became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. 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, including to the U.S., providing details to those individuals regarding the processing of 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. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. 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 27 member states that comprise the EU (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, in particular to the U.S., in compliance with European 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. 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.

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.

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

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

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

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.

Risks Related to Employee Matters and Managing Growth

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 kinase switch control 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.

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 rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, 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 breaches could cause interruptions in our operations, and could result in 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 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 disruption or security breach were to result in a loss of, or damage to, 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 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 release 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 cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our security or that of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business, and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. 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.

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.

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 will have 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 Common Stock

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

As of June 30, 2020, our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares, in the aggregate, representing approximately 40% 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 bylaws 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 bylaws.

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 bylaws 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 bylaws 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 bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, or 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 bylaws 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 bylaws 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.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the Nasdaq Global Select Market on September 28, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

Future sales of common stock by stockholders may have an adverse effect on the then prevailing market price of our common stock.

In the event a public market for our common stock is sustained in the future, sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933. In general, under Rule 144, a non-affiliated person who has satisfied a six-month holding period in a company registered under the Exchange Act, as amended, may, sell their restricted common stock without volume limitation, so long as the issuer is current with all reports under the Exchange Act in order for there to be adequate common public information. Affiliated persons may also sell their common shares held for at least six months, but affiliated persons will be required to meet certain other requirements, including manner of sale, notice requirements, and volume limitations. Non-affiliated persons who hold their common shares for at least one year will be able to sell their common stock without the need for there to be current public information in the hands of the public. Future sales of shares of our public float or by restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock.

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 June 30, 2020. 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 any of our drug or 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.

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.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. 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. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including "emerging growth companies" such as, but not limited to, potentially not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Our status as a smaller reporting company is determined on an annual basis. We cannot predict if investors will find our common stock less attractive or our company less comparable to certain other public companies because we will rely on these exemptions. For example, if we do not adopt a new or revised accounting standard, our future financial results may not be as comparable to the financial results of certain other companies in our industry that adopted such standards. 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.

Effective as of December 31, 2020, we will be 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 shares held by non-affiliates) as of June 30, 2020, we will be a large accelerated filer as of December 31, 2020 and will 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 will no longer qualify as a "smaller reporting company" as defined in the Exchange Act. However, we are not required to reflect the change in our smaller reporting company status, and comply with the associated increased disclosure obligations, until our first quarterly report in our next fiscal year (i.e., the quarterly report for the three-month period ended March 31, 2021).

As a large accelerated filer, we will be 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 will be 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 have not previously implemented will 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.

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.

The exhibits filed as part of this Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DECIPHERA PHARMACEUTICALS, INC.

Date: August 4, 2020

By: /s/ Thomas P. Kelly

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

EXHIBIT INDEX

Exhibit Number	Description
2.1	Reorganization Agreement and Plan of Merger by and among the Registrant, Deciphera Pharmaceuticals, LLC and the other parties named therein, dated October 2, 2017. (Incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2017) (1)
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 5, 2017).
3.2	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 12, 2020)
10.1*	Commercial Manufacturing Services and Supply Agreement, made as of April 3, 2019, by and between Deciphera Pharmaceuticals, LLC and Lonza (2)
10.2*	Supply Agreement, made as of February 28, 2020, by and between Deciphera Pharmaceuticals, LLC and Cambrex (2)
10.3#*	Amendment No. 1 to Employment Agreement, between Deciphera Pharmaceuticals, LLC and Thomas P. Kelly
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.

# Indicates management contract or compensation plan.

† 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.

(2) Portions of this exhibit (indicated by asterisk) have been omitted in accordance with the rules of the Securities and Exchange Commission.

Exhibit 10.1

Execution version

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

COMMERCIAL MANUFACTURING SERVICES AND SUPPLY AGREEMENT

This Commercial Manufacturing Services and Supply Agreement (the "Agreement") is made and entered into as of April 3rd, 2019 ("Effective Date"), by and between Deciphera Pharmaceuticals, LLC, having an address at 500 Totten Pond Road, 6th Floor, Waltham, Massachusetts 02451 ("Customer"), and [***] ("Lonza"). Each of Lonza and Customer may be referred to individually as a "Party," and Lonza and Customer may be referred to collectively as the "Parties."

WHEREAS, Customer is engaged in research and development of pharmaceutical products; and

WHEREAS, Lonza can manufacture commercial pharmaceutical products; and

WHEREAS, Customer wishes to engage Lonza, and Lonza wishes to be engaged by Customer, to manufacture quantities of Product (defined below), pursuant to the terms and subject to the conditions of this Agreement for human pharmaceutical use in the Territory produced in accordance with cGMPs.

NOW THEREFORE, in consideration of the representations, covenants and warranties set forth herein, and for other good and valuable consideration, the Parties agree as follows:

1. DEFINITIONS AND GENERAL MATTERS

1.1 **Defined Terms.** As used in this Agreement, the following words and phrases shall have the meanings set forth below.

- "Adjustment Index" has the meaning set forth in Section 4.5.
- "Adverse Experience" has the meaning set forth in Section 6.5.
- "Affiliate" means any Person who, directly or indirectly through one or more intermediaries, Controls, is Controlled by, or is under common Control with any other Person. "Control" means (a) the direct or indirect legal or beneficial ownership of more than fifty percent (50%) of (i) the ownership interests in a Person or (ii) the outstanding voting rights in a Person or (b) the power to otherwise direct the business activities of a Person.
- "Agents" has the meaning set forth in Section 10.1.
- "API" means Customer's DCC-2618 compound (ripretinib).
- "Approval" means the approval by FDA or EMA to market and sell Product in the United States or the European Union, respectively, that is manufactured at the Facility.
- "Background Intellectual Property" means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party independently from the performance of the Services hereunder. For clarity, Lonza's Background Intellectual Property includes, but is not limited to, the Lonza Patents.
- "Batch" means the quantity of Product derived from a single run of the Manufacturing Process.
- [***]

- “Calendar Year One” has the meaning set forth in Section 12.5.4(c).
- “Calendar Year Two” has the meaning set forth in Section 12.5.4(c).
- “Campaign” has the meaning set forth in Section 2.7.
- “Cancellation Fee” has the meaning set forth in Section 3.6.
- “Certificate of Analysis” means a document prepared by Lonza listing tests performed by Lonza or an approved contract laboratory organization, the Specifications and test results with respect to a Batch and such other information and certifications as are required to be in such document pursuant to the Quality Agreement.
- “Claim or Proceeding” means any third party claim, action, suit, proceeding or arbitration, including any governmental authority action or investigation for death, bodily injury or property damage.
- “Commencement Date” means the [***] Product Commencement Date or Drug Product Commencement Date, as applicable.
- “Confidential Information” has the meaning set forth in Section 10.1.
- “Current Good Manufacturing Practices” or “cGMPs” mean all applicable laws and regulations in the Territory relating to manufacturing practices of medicinal products for human use promulgated by any relevant governmental authority, as may be updated, supplemented or amended from time to time, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210 and 211) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC.
- “Customer Indemnified Party” has the meaning set forth in Section 9.1.
- “Customer Withdrawal” means a good faith determination by Customer’s board of directors, as a result of regulatory, safety and/or efficacy concerns regarding the Product, to cease and refrain from development and promotion of the Product and not seek marketing approvals therefor.
- “Disclosing Party” has the meaning set forth in Section 10.1.
- “DP Estimated Schedule” has the meaning set forth in Section 3.1.2.
- “DP Expect Yield” has the meaning set forth in Section 2.7.
- “DP Firm Order” has the meaning set forth in Section 3.1.2.
- “DP Forecast” has the meaning set forth in Section 3.1.2.
- “DP Minimum Yield” has the meaning set forth in Exhibit A.
- “Drug Product” means the bulk finished tablet product manufactured by Lonza for Customer in accordance with cGMPs and the Specifications hereunder, containing the API and other Raw Materials identified in the Master Batch Record.
- “Drug Product Commencement Date” means, with respect to a Batch of Drug Product, the date of commencement of manufacturing activities for such Drug Product hereunder.
- “EMA” means the European Medicines Agency or any successor agency thereto.
- “European Union” means the organization of member states of the European Union as it may be constituted from time to time.

- "Facility" means Lonza's manufacturing facility located at [***], or such other Lonza facility as may be agreed upon by the Parties in writing.
- [***]
- "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- "Hidden Defect" means any defect in a Product that is not visible or readily identifiable at the time of delivery to Customer and that is the result of the Product failing to comply with the Product Warranty.
- "Initial Term" has the meaning set forth in Section 12.1.
- "Indemnified Party" has the meaning set forth in Section 9.3.
- "Indemnifying Party" has the meaning set forth in Section 9.3.
- "Intellectual Property" means any and all inventions, whether or not patentable, worldwide patents, copyrights, trade secrets, know-how and all other intellectual property rights, including all applications and registrations with respect thereto, but excluding all trademarks, trade names, service marks, logos and other corporate identifiers.
- "KPIs" has the meaning set forth in Section 2.6 below.
- "Law" means all applicable treaties, laws, and regulations in the Territory, including all cGMPs together with amendments thereto.
- "License Agreement" means the License Agreement entered into by and between the Parties, dated effective as of April 3rd, 2019, that is attached hereto in Exhibit E.
- "Lonza Indemnified Party" has the meaning set forth in Section 9.2.
- "Lonza Patents" means the patents listed in the License Agreement.
- "Loss Allowance" has the meaning set forth in Section 5.1.
- "Losses" means any and all losses, fines, fees, settlements, payments, obligations, penalties, deficiencies, liabilities, damages, costs and expenses (including reasonable attorneys' fees).
- "Manufacturing Process" means the production process for the manufacture of Product that is mutually agreed to by the Parties in writing, as such process may be improved or modified from time to time by agreement of the Parties in writing.
- "Master Batch Record" means the document approved by Lonza and Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product, including the starting Batch size (in units or kilograms, as applicable) and the Raw Materials required.
- "Minimum Quantities" has the meaning set forth in Section 3.5.
- "MSA" means the Master Services and Clinical Manufacture Agreement entered into between the Parties, dated effective February 18, 2013, as amended.
- "New Customer Intellectual Property" has the meaning set forth in Section 11.2.
- "New General Application Intellectual Property" has the meaning set forth in Section 11.3.
- "Non-Complying Product" has the meaning set forth in Section 4.8(a).
- "Person" means an individual, partnership, corporation, association, trust, joint venture, unincorporated organization.

- "PDUFA" has the meaning set forth in Section 3.1.1.
- "Price" has the meaning set forth in Section 4.1.
- "Process Validation Batch" means a Batch that is produced according to Master Batch Record and approved validation protocol(s) with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.
- "Product" means each of the [***] Product and Drug Product, individually or collectively, as context requires.
- "Product Non-Approval Notice" has the meaning set forth in Section 12.2(b).
- "Product Warranty" has the meaning set forth in Section 7.3.6.
- "Purchase Order" means with respect to a Batch of [***] Product or Drug Product, a document submitted by Customer to Lonza which must include the quantity and estimated Release date, Customer's purchase order number, the invoice address, the shipping address and any further information necessary or reasonably requested by Lonza to facilitate the shipment of such Product.
- "Quality Agreement" has the meaning set forth in Section 8.1.
- "Raw Materials" means the materials as specified in the Master Batch Record.
- "Receiving Party" has the meaning set forth in Section 10.1.
- "Regulatory Withdrawal Notice" has the meaning set forth in Section 12.2(b).
- "Release" has the meaning set forth in Section 4.6.
- "Rescheduling Fee" has the meaning set forth in Section 3.4.2.
- "[***] Firm Order" has the meaning set forth in Section 3.1.1.
- "[***] Forecast" has the meaning set forth in Section 3.1.1.
- "[***] Product" means bulk finished drug product intermediate manufactured by Lonza in accordance with cGMPs and the Specifications hereunder, containing the API and other Raw Materials identified in the Master Batch Record.
- "[***] Product Commencement Date" means, with respect to a Batch of [***] Product, the date of commencement of manufacturing activities for such [***] Product hereunder.
- "[***] Product Expected Yield" has the meaning set forth in Section 2.7.
- "[***] Product Estimated Schedule" has the meaning set forth in Section 3.1.1.
- "[***] Product Minimum Yield" has the meaning set forth in Exhibit A.
- "Services" means the commercial manufacturing services and related services (including, without limitation, process and analytical method transfer, process validation, process optimization, validation, quality control and quality assurance activities, and storage services), to be performed by Lonza under this Agreement, particulars of which are set out in a Purchase Order.
- "Specifications" means the release specifications for the manufacture, processing, bulk packaging, testing and testing procedures, shipping, storage and supply of the Product, any Raw Material requirements, analytical procedures and standards of quality control and quality assurance, in each case, as established by the Parties for the Product. The initial Specifications are attached as Exhibit B, which shall be updated as mutually agreed to by the Parties in writing in accordance with the

requirements of any Approval of the Product, and which may be amended from time to time as mutually agreed to by the Parties in writing in accordance with this Agreement.

- "Steering Committee" has the meaning set forth in Section 2.6.
- "Term" has the meaning set forth in Section 12.1.
- "Territory" means the United States of America, the European Union, and any other countries or jurisdictions that are mutually agreed to by the Parties in writing.

1.2 **Exhibits.** The attached Exhibits are incorporated in and form part of this Agreement:

EXHIBIT A	COMMERCIAL TERMS
EXHIBIT B	SPECIFICATIONS
EXHIBIT C	ENVIRONMENTAL AND HEALTH AND SAFETY INFORMATION
EXHIBIT D	SDS OF MATERIALS PROVIDED BY CUSTOMER
EXHIBIT E	LICENSE AGREEMENT

2. **SERVICES; FACILITY; AFFILIATES**

2.1 **Services.** Subject to the terms and conditions of this Agreement, Lonza shall perform the Services and supply the Product as provided in Purchase Order(s) and use commercially reasonable efforts to perform the Services and supply the Product according to the [***] Product Estimated Schedule or DP Estimated Schedule, as applicable. Lonza agrees that, during the Term, it shall manufacture and supply products containing the APIs to Customer only and it shall not market or sell any product containing the API for and to any other third parties. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement.

2.1.1 In the event that Customer requests that one or more of its licensees or third party collaborators be able to purchase Services and obtain supply of the Product under this Agreement, Lonza will reasonably consider such request. If Lonza agrees to such request in its sole discretion, then Lonza will negotiate in good faith an amendment to this Agreement to facilitate such request.

2.2 **Process Validation Batches**. Lonza shall manufacture and deliver and Customer shall purchase Process Validation Batches as mutually agreed by the Parties sufficient to document the operability and reproducibility of the Manufacturing Process at the Facility and permit the Parties to complete and file the necessary regulatory documents. Prior to commencement of Process Validation Batches, Lonza and Customer shall agree on a process validation plan identifying the validation requirements of the Manufacturing Process. Any regulatory support activities (including pre-Approval inspection) required by Customer and agreed to by Lonza to support the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer.

2.3 **Facility.**

2.3.1 Lonza shall perform all Services at the Facility. Without limiting the foregoing, Lonza shall tablet all [***] Product manufactured by Lonza at the Facility. Lonza may use other facilities for the Services provided that (i) such facilities have been approved for such Services by all applicable

governmental authorities and (ii) Customer written approval is obtained prior to the use of such facilities, such approval not to be unreasonably withheld by Customer.

2.3.2 [***]

2.4 **[Intentionally omitted.]**

2.5 **Subcontractors.** Lonza may subcontract Services to third parties with Customer's prior written consent, such consent not to be unreasonably withheld. Without limiting the generality of the foregoing, any agreement entered into by Lonza with a third party subcontractor shall, at a minimum, provide for ownership and allocation of Intellectual Property rights and for obligations of confidentiality of information, record-keeping, access, and rights to data that are consistent with the intent and terms of this Agreement. Lonza shall remain liable for the performance of any of its obligations hereunder that it delegates to a subcontractor, and for the acts and omissions of such subcontractors under this Agreement with respect to such delegated obligations.

2.6 **Steering Committee**. Each Party shall mutually agree upon an equal number of management representatives for a joint steering committee (the "**Steering Committee**"), which shall meet at least quarterly during the first two (2) years of the Term and two (2) times per calendar year thereafter or for additional times as mutually agreed to by the Parties. The location of the Steering Committee meetings shall be mutually agreed to by the Parties. In the event that Customer grants to a third party marketing partner of Customer any license or rights to Product in the U.S. or the European Union, then subject to execution of an appropriate confidentiality agreement between such third party marketing partner and Lonza, Customer may, but need not, permit such third party marketing partner to be represented on the Steering Committee or to participate in Steering Committee meetings as a non-voting participant, at Customer's sole discretion. The primary function of the Steering Committee is to (i) ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement; (ii) agree to and monitor deadlines for the Services, including the [***] Product Commencement Date, Drug Product Commencement Date, [***] Product Estimated Schedule and DP Estimated Schedule; and (iii) develop key performance indicators ("**KPIs**"), including expected yields for the Services and monitor such KPIs. The Steering Committee shall make all decisions by consensus, with the representatives of each Party having a single vote in the aggregate. In the event that the Steering Committee is unable to resolve any dispute within thirty (30) days of written notification of such dispute, then such dispute shall be escalated to a senior executive of each of Customer and Lonza for attempted resolution. If such senior executives are unable to resolve such dispute within thirty (30) days of such escalation, then either Party may pursue any and all remedies available at law or in equity. The Steering Committee may not amend or modify the terms of this Agreement.

2.7 **Yields; Yield Adjustments.** Lonza acknowledges that forecasts and orders of [***] Product and Drug Product by Customer will be denominated in numbers of Batches, with Customer making a determination of the number of Batches based on the total quantity, by weight or units, as applicable, of Product forecast or needed by Customer and an expected yield per Batch. The number of Batches set forth in a single Purchase Order from Customer for Product shall be referred to herein as a "Campaign." The expected yield of a Batch of [***] Product as of the Effective Date is set forth on Exhibit A (as such expected yield may be adjusted from time to time in accordance with the terms of this Section 2.7, the "[***] Product Expected Yield"). The expected yield of a Batch of Drug Product as of the Effective Date is set forth on Exhibit A (as such expected yield may be adjusted from time to time in accordance with the terms of this Section 2.7, the "DP Expected Yield"). From time to time during the Term, and no less frequently than once per calendar year, the Steering Committee shall review the Batch

records and other actual [***] Product and Drug Product production information of Lonza during the period since the last adjustment to an expected yield hereunder. The Steering Committee shall make a good faith determination based on such records and other information of reasonably expected yields of a Batch of [***] Product and of a Batch of Drug Product. Such determination of the Steering Committee with respect to the expected yield of a Batch of [***] Product shall from and after the date of such determination be deemed the [***] Product Expected Yield hereunder and shall supersede any previously determined or agreed [***] Product Expected Yield. Such determination of the Steering Committee with respect to the expected yield of a Batch of Drug Product shall from and after the date of such determination be deemed the DP Expected Yield hereunder and shall supersede any previously determined or agreed DP Expected Yield.

3. FORECASTS AND ORDERS; CAPACITY

3.1 **Forecasts.**

3.1.1 [***] Forecasts. Within [***] of the beginning of each calendar quarter, commencing with the calendar quarter starting on [***], Customer shall submit to Lonza a good faith, estimated [***] rolling forecast of the number of Batches of [***] Product that Customer expects to order for production commencing with the month following the month in which such forecast is provided ("[***] Forecast"). No later than [***] following Lonza's receipt of a [***] Forecast, and subject to Section 3.9, Lonza shall provide written notice to Customer of whether it has (as of the date of receipt of the [***] Forecast) capacity available to manufacture the number of Batches of [***] Product forecasted therein and shall provide Customer with an estimated production schedule showing the estimated [***] Product Commencement Date and Release date of each applicable Batch of [***] Product (the "[***] Product Estimated Schedule"). Lonza shall use commercially reasonable efforts to meet the [***] Product Commencement Date and [***] Product Estimated Schedule. Each [***] Forecast shall be non-binding, with the exception of the [***] Forecast for the nearest [***] of the [***] Forecast, which shall be considered a firm order for [***] Product ("[***] Firm Order"); [***]. Lonza shall notify Customer immediately in writing if at any time Lonza has reason to believe that it will not be able to fill a [***] Firm Order. If the [***] Product Estimated Schedule varies from the [***] Forecast, the [***] Forecast for the nearest [***] shall not be considered a [***] Firm Order, and Customer shall not be required to submit a Purchase Order for a [***] Firm Order until the Parties mutually agree on the [***] Product Estimated Schedule. No [***] Forecast shall amend any previous [***] Firm Order unless otherwise agreed to by the Parties in writing.

3.1.2 DP Forecasts. Within [***] of the beginning of each calendar quarter, commencing with the calendar quarter starting on [***], Customer shall submit to Lonza a good faith, estimated [***] rolling forecast of the number of Drug Product Batches that Customer expects to order for production commencing with the month following the month in which such forecast is provided ("DP Forecast"). No later than [***] following Lonza's receipt of a DP Forecast, Lonza shall provide written notice to Customer of whether it has (as of the date of receipt of the DP Forecast) capacity available to manufacture the number of Batches of Drug Product forecasted therein and shall provide Customer with an estimated production schedule showing the estimated Drug Product Commencement Date and Release date of each applicable Batch of Drug Product (the "DP Estimated Schedule"). Lonza shall use commercially reasonable efforts to meet the Drug Product Commencement Date and DP Estimated Schedule. Each DP Forecast shall be non-binding, provided that, for the nearest [***] of the DP Forecast, all Drug Product Batches forecasted and actually manufactured based on the [***] Firm Order for such [***] period will be considered a firm order for Drug Product ("DP Firm Order"); [***]. Lonza shall notify Customer immediately in writing if at any time Lonza has reason to believe that it will not be able to fill a DP Firm

Order. If the DP Estimated Schedule varies from the DP Forecast, the DP Forecast for the nearest [***] shall not be considered a DP Firm Order and Customer shall not be required to submit a Purchase Order for a DP Firm Order until the Parties mutually agree on the DP Estimated Schedule. No DP Forecast shall amend any previous DP Firm Order.

3.2 **Purchase Orders.** For [***] Product, Customer shall submit a Purchase Order corresponding to the [***] Firm Order within [***] of the later of: (a) Customer's receipt of the applicable [***] Product Estimated Schedule if such [***] Product Estimated Schedule first provided by Lonza does not vary from the [***] Forecast for the [***], or (b) the date the Parties mutually agree on the applicable [***] Product Estimated Schedule if the [***] Product Estimated Schedule first provided by Lonza varies from the [***] Forecast. For Drug Product, Customer shall submit Purchase Orders corresponding to the DP Firm Order within [***] of the later of: (x) Customer's receipt of the applicable DP Product Estimated Schedule if such DP Product Estimated Schedule first provided by Lonza does not vary from the DP Forecast for the nearest [***], or (y) the date the Parties mutually agree on the applicable DP Product Estimated Schedule if the DP Product Estimated Schedule first provided by Lonza varies from the DP Forecast. Lonza shall confirm acceptance of Purchase Orders within [***] of receipt and shall confirm the estimated Commencement Date; provided that Release dates set forth in any Purchase Order shall be deemed to be estimated only subject to Lonza's obligation to use commercially reasonable efforts to meet such Release dates. Upon confirmation by Lonza, each Purchase Order will be regarded as a binding commitment by Lonza to manufacture and deliver to Customer the relevant quantity of Product according to the requirements set forth in such Purchase Order.

3.3 **Forms and Inconsistencies.** Any term or condition of a Purchase Order, acceptance form used by Lonza, or any other correspondence between the Parties that is different from, inconsistent with or contrary to the terms and condition of this Agreement shall be void. All Purchase Orders submitted by Customer shall be deemed to incorporate and be subject to the terms and conditions of this Agreement. Lonza's failure to object to any provisions contained in any communication from Customer shall not be deemed a waiver of the provisions herein.

3.4 **Rescheduling**.

3.4.1 Reschedule by Lonza. Lonza shall have the right to reschedule a Commencement Date of manufacturing of any Product upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is: (a) no later than (i) [***] after the Commencement Date originally estimated at the time of Lonza's acceptance of the binding Purchase Order for Purchase Orders submitted by Customer during the [***] or (ii) [***] after the Commencement Date originally estimated at the time of Lonza's acceptance of the binding Purchase Order for Purchase Orders submitted [***]; and (b) no earlier than (i) [***] prior to the Commencement Date originally estimated at the time of Lonza's acceptance of the binding Purchase Order for Purchase Orders submitted by Customer during the [***], or (ii) [***] prior to the Commencement Date originally estimated at the time of Lonza's acceptance of the binding Purchase Order for Purchase Orders submitted [***].

3.4.2 Reschedule by Customer. If the Customer requests to change the Commencement Date, Lonza will make commercially reasonable efforts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Product may be delayed until an adequate time period is available

in the Facility schedule. Any such change requested by Customer may result in a rescheduling fee as calculated below (the "Rescheduling Fee"), subject to Section 3.8:

Number of days in advance of the Commencement Date that the rescheduling notice is received	% of Purchase Order that is payable
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

3.5 **Minimum Quantity**. Customer undertakes to purchase from Lonza and Lonza undertakes to supply to Customer certain minimum quantity of Product as set forth in Exhibit A (the "Minimum Quantities"). [***].

3.6 **Cancellation of a Binding Purchase Order**. Customer may cancel a binding Purchase Order upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"), subject to Section 3.8:

[***]

3.7 **Payment of Rescheduling Fee and Cancellation Fee**.

3.7.1 Any Rescheduling Fee or Cancellation Fee, as applicable, shall be payable within [***] following the written notice of the rescheduling or cancellation associated with the rescheduled or cancelled Batch, in each case, as applicable.

3.7.2 The Cancellation Fee shall include all Lonza's costs associated with the cancelled Batch, including the costs of any Raw Materials. The Cancellation Fee shall be Lonza's sole remedy for Customer's cancellation of a binding Purchase Order. Notwithstanding anything herein to the contrary, no Cancellation Fee shall be applicable in the event Customer cancels a Purchase Order solely due to Lonza's inability to manufacture Minimum Quantities pursuant to Section 3.5.

3.8 **Replacement Project**. Notwithstanding the foregoing, and in order to mitigate the Rescheduling Fee or Cancellation Fee, as applicable, Lonza will use commercially reasonable efforts to secure a new project for the manufacturing space, and for the same dates and duration that would have been occupied by Customer, and then, in such case, the Rescheduling Fee or Cancellation Fee, as applicable, for each Purchase Order rescheduled or cancelled that is replaced by a new project shall be reduced by an amount equal to one hundred percent (100%) of the production fees associated with such replacement project.

3.9 **Reservation of Capacity**. Lonza shall reserve manufacturing capacity at the Facility as set forth on Exhibit A hereto.

4. PRICE; PAYMENT TERMS; DELIVERY; ACCEPTANCE AND REJECTION

4.1 **Price.** Customer agrees to pay Lonza for the [***] Product and Drug Product provided hereunder at the price set forth on Exhibit A hereto (the "Price").

4.2 **Taxes**. The Price is exclusive of taxes, which taxes shall be for the account of Customer. Taxes that Lonza is required by Law to collect from Customer, e.g., V.A.T., will be separately stated in Lonza's invoice and will be paid by Customer to Lonza.

4.3 **Payment Terms.** Lonza shall invoice Customer at the time Product is Released. Each shipment shall constitute an independent transaction, and Customer shall pay for the same in accordance with the specified payment terms. All undisputed invoices shall be paid within [***] of receipt, and without deduction, deferment, lien, counterclaim, or set-off. All payments shall be in United States Dollars (USD).

4.4 **Late Payment Interest.** If Customer is in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) [***] per month, or (ii) the maximum rate allowable by applicable Law, interest to accrue on a day to day basis until full payment. If any undisputed invoice is unpaid for more than [***] following the due date, then Lonza shall, at its sole discretion and without prejudice to any other of its accrued rights, and upon prior written notice to Customer, be entitled to suspend the provision of the Services and or delivery of Product until all such overdue amounts have been paid in full including interest for late payments.

4.5 **Price adjustments.** Lonza may adjust the Price in accordance with changes in the US Department of Labor's Bureau of Labor Statistics Pharmaceutical Preparations Index, ethical PCU SI07003 (https://www.bls.gov/ppi) or any successor index (the "Adjustment Index") [***]. The Price shall be adjusted based on the change in the Adjustment Index from January 1 of the prior calendar year to January 1 of the current calendar year. The new Price reflecting such adjustment shall be effective for any manufacture of Product for which the Commencement Date is on or after the date of Lonza's written notice to Customer of the Price adjustment.

In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect (i) an increase in variable costs (such as energy) by more than [***] (based on the initial Price or any previously amended Price), or for a process adjustment, and (ii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and ability to perform the Services.

4.6 **Delivery; Title.** All Product shall be delivered ExWorks (as defined by Incoterms® 2010) the Facility. Title and risk of loss or damage to the Product shall pass to Customer at the time Product is released by Lonza's QA department and Lonza delivers to Customer the Certificate of Analysis and such other release documentation as is reasonably required to meet all applicable regulatory requirements of the applicable governmental authorities in the Territory (the "Release"). Lonza shall provide necessary documentation to allow shipment from Lonza's premises to those detailed in the Purchase Order. Customer shall arrange for shipment and take delivery of such Product from the Facility, at Customer's expense, within [***] after Release of the Product by Lonza or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***]; provided that any additional storage beyond [***] will be subject to availability and, if available, will be charged to Customer and will be subject to a separate bill and hold agreement. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

4.7 **Credit.** Customer agrees to make available to Lonza such statements of Customer's financial condition as Lonza may, from time to time, reasonably request; provided, however, that for so long as Customer is, or it is part of a consolidated group that is, a public reporting company under

applicable securities laws, Customer shall not be required to provide any statements of Customer's financial condition other than Customer's, or its consolidate group's, as applicable, most recent publicly available financial statements.

4.8 **Acceptance and Rejection of Product; Disposal of Rejected Shipments**.

(a) Customer may reject any Product that does not meet the Product Warranty ("Non-Complying Product") by providing written notice of rejection to Lonza within [***] following Lonza's Release of the Product for delivery hereunder; provided that such period for rejection shall in the case of Hidden Defects in the Product be [***] following Lonza's Release of the Product for delivery hereunder. Failure by Customer to provide notice of rejections within the applicable timeframe shall constitute irrevocable acceptance of the Product by Customer.

(b) Lonza shall have the right to examine and test any Product that Customer claims to be a Non-Complying Product and shall notify Customer in writing of the results of such examination.

(c) In the event the Parties cannot agree as to whether or not any shipment of Product is a Non- Complying Product, the Parties shall appoint a third party, which shall be a mutually acceptable independent reputable laboratory, to review records, test data and perform comparative tests and/or analyses on samples of Products. Such analytical procedures performed by the independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory shall complete and report its findings in writing within [***], the findings of which shall be binding on the Parties, absent manifest error. The Parties shall ensure that such independent laboratory is bound to the Parties by obligations of confidentiality no less exacting than those applying between the Parties. Expenses of such laboratory testing shall be borne by the Party whose position is determined to have been in error or, if the laboratory cannot place the fault noticed and complained about, then the Parties shall share equally the expenses of the laboratory.

(d) Notwithstanding anything else in this Agreement, [***].

4.9 **Remedy for Non-Complying Product and Non-Complying Services**. Customer shall return any shipments of Non-Complying Product (or portions thereof) rejected pursuant to Section 4.8 to Lonza at Lonza's expense. As Lonza's sole liability and Customer' sole remedy with respect to such Non-Complying Product, [***], Lonza shall [***]. The provisions of this Section 4.9 shall survive termination or expiration of this Agreement, provided that, subsequent to the termination or expiration of this Agreement, Lonza may, in lieu of [***].

4.10 **Minimum Yield**. For each Batch of Product ordered pursuant to a Purchase Order, Lonza shall manufacture the Product in accordance with the terms of this Agreement and the Quality Agreement using commercially reasonable efforts to deliver the applicable expected yield per Batch. If the actual yield of any Campaign for [***] Product is less than the product of the number of Batches in such Campaign multiplied by the [***] Product Minimum Yield, then Lonza shall promptly notify Customer of such shortfall, and except if such shortfall is solely due to the failure of the API provided by Customer for use in the manufacture of a Batch within such Campaign to conform to the applicable specifications for such materials, then, within [***] of such notice, Customer may elect to either: [***].

5. OBLIGATIONS OF THE CUSTOMER

5.1 **Manufacture and Supply of API.** Customer shall comply with all applicable Laws related to the manufacture of API and the delivery of API to Lonza. Customer shall identify, qualify, purchase and deliver the API to the Facility. Customer shall be responsible for the quality of the API, Quality Assurance and management of API vendor relationship. Customer shall supply Lonza with the quantity of API required to manufacture the [***] Product in the amount specified in Customer's Purchase Order, [***] (excluding material for lab testing and retain) ("Loss Allowance") to allow for normal waste and breakage, not less than: (a) [***] prior to the Commencement Date for such [***] Product for Purchase Orders submitted [***] following the Effective Date; and (b) [***] prior to the Commencement Date for such [***] Product for Purchase Orders submitted [***] following the Effective Date. Delivery shall take place DDP Facility Incoterms 2010. Title to the API shall remain with the Customer and shall not transfer to Lonza. Lonza shall not be responsible for any failure to deliver or any delivery delay of [***] Product due to the failure of Customer to deliver or cause delivery of API in the time specified in this Section and Customer shall be responsible for the Rescheduling Fees in Section 3.4 or the Cancellation Fees in Section 3.6, as applicable, in each case, subject to Section 3.8. In the event of any loss or damage to API while in the possession of Lonza in excess of the Loss Allowance [***].

5.2 **Health & Safety Data.** (a) Customer has provided to Lonza certain information relating to the API, attached hereto as Exhibit D. To the extent Customer has not provided the information in Exhibit D and to the extent it possesses the information, Customer shall provide to Lonza, prior to the shipment of any API to Lonza hereunder, the environmental, health and safety information described in Exhibit C as it relates to the API. To the extent the information contained in paragraphs 2 and 3 of Exhibit C has not yet been generated by Customer, tests, analyses and/or research necessary to collect such information and data shall be conducted, at the expense of Customer, by Customer internally or by an outside laboratory retained by Customer. Customer shall properly document all such test results and shall provide such documentation to Lonza prior to the delivery of any API to Lonza. If the data indicates that Lonza cannot safely manage the API without the addition of certain engineering controls or other changes to its facilities and/or equipment, the Parties will [***].

(b) Customer shall provide to Lonza promptly upon receipt by Customer (i) any information needed to clarify, correct, supplement or amend any of the information described in Exhibit C or provided in Exhibit D and (ii) any other information reasonably related to the environmental, health and safety implications, including employee health and safety, of the handling, manufacture, distribution, use and disposal of the API. Lonza shall not be responsible for any failure to deliver or delivery delay due to Customer's failure to deliver such results or documentation.

5.3 **Compliance with Law; Use and Disposal of Product.** Customer is responsible for (a) the formulation, use, packaging, labeling (including developing all Product labeling, printing the labels, and for labeling content), distribution, marketing, promotion, sale and disposal of Product, including compliance with all Laws related to the same; (b) communicating with any governmental authority concerning the Product, including without limitation with respect to the registration, classification or notification of a new Product or substance, or the use, packaging, labeling, distribution, marketing, promotion, sale or disposal of the same or any adverse events related to the Product (for the avoidance of doubt, Lonza may interact with governmental authorities for the purpose of fulfilling its obligations hereunder); (c) storing and handling Product in appropriate conditions following its delivery by Lonza; (d) determining that the Specifications for the Product permit its sale in each country in the world in which Customer intends to sell the Product; and (e) determining that the Product is permitted for human use. Customer shall conduct all such activities at all times in compliance with applicable Laws. The

Parties acknowledge and agree that Lonza has no control, role, or other form of influence in Customer's use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product, nor does it control or influence over any payments or transfers of value that may be made by Customer to health care professionals, health care institutions, or any other customer or third party. Customer is responsible for participation and compliance in all government health care programs such as Medicare and Medicaid, and any rebate liability, mandatory pricing, or reporting obligations resulting therefrom.

5.4 **Customs License.** To the extent applicable, Customer shall provide Lonza with a copy of any customs license relating to API supplied by Customer to Lonza hereunder and that is required to be available in accordance with the applicable laws, as well as other documentation and information reasonably requested by Lonza relating to the same. In the event Lonza requests or seeks an amendment to such license, Customer agrees to cooperate reasonably with Lonza in obtaining the same.

5.5 **Additional Obligations.** Customer acknowledges and agrees that Lonza is not responsible for any intellectual property decisions, and is not responsible for any litigation costs, which result solely from the filing of the Products for regulatory approval. Customer acknowledges and agrees that Lonza is not responsible for maintaining pharmacovigilance infrastructure as would be required of a distributor of Product.

5.6 **Regulatory Approvals.** Customer will own and control all regulatory approvals in the Territory (including all associated contents and correspondences) and applications therefore related to the Product and any other marketing authorizations within the Territory. Customer is responsible for compiling the registration dossiers (with reasonable and necessary assistance from Lonza), filing the marketing applications with the regulatory authorities in the Territory, and maintaining marketing authorizations for the Product and the costs associated with the same.

6. OBLIGATIONS OF LONZA

6.1 **Materials.** Lonza shall be responsible for procuring Raw Materials identified in the Master Batch Record other than the API. Upon cancellation of any Batch or termination of the Agreement, (a) all unused Raw Materials shall be paid for by Customer within [***] of invoice and at Customer's option such Raw Materials and API will either be (i) [***].

6.2 **Lonza Regulatory Obligations**. Lonza is responsible for (a) manufacturing and supplying the Product in compliance with all applicable Laws, including but not limited to environmental health and safety laws and cGMPs, and (b) storing and handling Product in appropriate conditions before its delivery to Customer in accordance with Section 4.6. Lonza shall obtain and maintain during the Term all regulatory approvals necessary in the jurisdiction in which the Facility is located for Lonza to operate the Facility.

6.3 **Inspections and Audits**. Subject to the terms of the Quality Agreement, Customer and its representatives shall have the right to visit or audit, or request a reputable third party to visit or audit, the Facility to verify that the documentation, equipment and material relating to the Product is maintained in accordance with applicable Laws and that Lonza is performing its obligations hereunder. Customer shall bear all its costs related to any such audit, visit or inspection. This Section 6.3 is subject in all cases to any such party executing a confidentiality agreement with Lonza, in form and substance reasonably acceptable to Lonza.

Subject to the terms of the Quality Agreement, Lonza will: (a) allow full access to any governmental regulatory inspection; (b) allow Customer's representatives or agents to be on-site at any inspection by any regulatory authority to the extent such inspection relates to the Product or the Services; (c) give Customer reasonable advance notice of any such inspection; (d) promptly inform Customer of the results of such inspections to the extent such inspection directly relates to the Product, the Services or that affects Lonza's performance under this Agreement; (e) comply with all reasonable requests and comments by Customer with respect to all contacts and communications with any regulatory authority relating in any way to the Products or Services; (f) immediately inform Customer in the event any regulatory authority takes regulatory action against Lonza that could have an effect on Lonza's performance of the Services; and (g) take such actions that are commercially reasonable to correct any deficiencies identified by any inspection or audit conducted by such regulatory authority.

6.4 **Marketing Authorizations.** Subject to Customer's obligations in Section 5.6, Lonza shall reasonably assist Customer in obtaining and maintaining marketing authorizations for the Product.

6.5 **Adverse Events.** Lonza shall promptly notify and forward to Customer any information concerning any potentially serious or unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or other adverse experience related to the Product (an "Adverse Experience") reported to it. Customer agrees that it shall be solely responsible to review, analyze and respond to any Adverse Experience. Lonza shall provide all reasonable support as requested by Customer in connection with such Adverse Experience.

7. REPRESENTATIONS AND WARRANTIES

7.1 **Disclaimer of Other Warranties.** EXCEPT AS STATED IN THIS ARTICLE 7 NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, AND TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW EACH PARTY SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7.2 Lonza advises, and Customer acknowledges that, the Products resulting from the Services performed under this Agreement may not be used in the production, encapsulation, packaging or marketing of any product which is in violation of any applicable Laws or with any person or entity on any applicable government sanction, restricted party or denial list without a license or otherwise in violation of applicable Laws.

7.3 **Lonza Representations and Warranties**. Lonza represents and warrants that:

7.3.1 as of the Effective Date it is duly organized, validly existing, and in good standing under the laws of the jurisdiction of establishment or organization;

7.3.2 it is authorized to enter into this Agreement and perform its obligations under this Agreement;

7.3.3 this Agreement has been duly executed and delivered on behalf of Lonza and constitutes a legal, valid and binding obligation of Lonza;

7.3.4 its performance of this Agreement will not breach any agreement to which Lonza is bound;

7.3.5 it will comply with all Laws that affect its performance and activities under this Agreement;

7.3.6 all Product delivered by Lonza hereunder shall on the date of delivery to Customer: (a) conform to the Specifications; (b) be manufactured and delivered in accordance with the Quality Agreement and cGMPs; and (c) not be adulterated within the meaning of the United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder (collectively the "Product Warranty");

7.3.7 all Product delivered by Lonza hereunder shall on the date of delivery to Customer be free and clear of any lien or encumbrance;

7.3.8 as of the Effective Date it holds all necessary permits, approvals, consents and licenses necessary to enable the performance of the Services at the Facility;

7.3.9 as of the Effective Date neither it nor any of its employees or subcontractors that are performing Services under this Agreement are debarred or, to Lonza's knowledge, threatened to be debarred by the FDA; and

7.3.10 to its knowledge as of the Effective Date, Lonza has all the rights necessary to permit Lonza to use the Manufacturing Process and manufacture Products without infringing or misappropriating the Intellectual Property of any third party, and to its knowledge no claims are pending or threatened against Lonza by any third party with respect to any such infringement or misappropriation (each an "Infringement Claim").

7.4 **Customer Representations and Warranties**. Customer represents and warrants that:

7.4.1 as of the Effective Date it is duly organized, validly existing, and in good standing under the laws of the jurisdiction of establishment or organization;

7.4.2 it is authorized to enter into this Agreement and perform its obligations under this Agreement;

7.4.3 this Agreement has been duly executed and delivered on behalf of Customer and constitutes a legal, valid and binding obligation of Customer;

7.4.4 neither it nor any of its Affiliates' performance of this Agreement will breach any agreement to which Customer is bound;

7.4.5 the Products will not be made available to any person or entity on any sanction, restricted party or denied party list of the United States of America, Switzerland, the European Union or United Nations without a license or otherwise in violation of Laws; and

7.4.6 it will comply with all Laws that affect its performance and activities under this Agreement.

7.5 **Other Obligations.**

7.5.1 Lonza shall hold and maintain all necessary permits, approvals, consents and licenses necessary to enable the performance of the Services.

7.5.2 Lonza shall not engage any employees or knowingly engage any subcontractors to perform Services under this Agreement that are debarred, or to Lonza's knowledge, threatened to the debarred, by the FDA (or subject to any similar sanction of the EMA or any other applicable foreign equivalent of which Customer provides notice to Lonza). Lonza shall notify Customer immediately if Lonza becomes aware that it, or any of its employees or subcontractors that are performing Services, become debarred.

7.5.3 Lonza shall not knowingly incorporate any third party Intellectual Property into the Manufacturing Process or Product resulting from the Services performed under this Agreement.

7.5.4 Lonza shall notify Company promptly in writing if it becomes aware of any Infringement Claim.

8. MANUFACTURING STANDARDS

8.1 **Quality Agreement.** The Parties agree to negotiate in good faith and enter into a mutually acceptable quality agreement prior to the manufacture of the Product, and that will set out the responsibilities of the Parties in relation to quality assurance and quality control of Product as required for compliance with cGMPs ("**Quality Agreement**"). Lonza shall manufacture and supply the Product in accordance with the Quality Agreement as reasonably updated by the Parties from time to time, notably to take into consideration any marketing authorization(s) for Product. If there are any conflicts between the Quality Agreement and the Agreement, the provisions of the Agreement shall govern and control, with the exception that the Quality Agreement shall control for matters relating to the quality and disposition of the Product.

8.2 **Modifications in Specifications.** Any changes to the Specifications shall be agreed between the Parties in writing. Costs for amendments to the Specifications (including without limitation any additional Product or procurement costs) [***].

8.3 **Modifications in Materials.** Customer shall notify Lonza of any change related to the API that may affect the validated process including but not limited to supplier changes, process change, regulatory change, and environment health safety characteristics. Customer should provide to Lonza a written notification of such change at least [***] before implementation of the change. In the case the change warrants validation batches, the costs associated [***].

9. INDEMNIFICATION

9.1 **Indemnification of Customer**. Lonza shall indemnify, defend and hold Customer, its Affiliates and their respective officers, directors, employees and agents (each, a "Customer Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Customer Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from: (i) Lonza's breach of a representation or warranty of Lonza in this Agreement; (ii) Lonza's breach of a material obligation of Lonza in this Agreement; or (iii) Lonza's gross negligence or willful misconduct in connection with this Agreement; provided however, that Lonza shall have no obligation of indemnity hereunder with respect to any Losses suffered, incurred or sustained by any Customer Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from an act or omission described in clause (i), (ii), (iii), or (iv) of Section 9.2.

9.2 **Indemnification of Lonza**. Customer shall indemnify, defend and hold Lonza, its Affiliates and their respective officers, directors, employees and agents (each, a "Lonza Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Lonza Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from (i) Customer's breach of a representation, warranty or material obligation of Customer in this Agreement; (ii) Customer's gross negligence or willful misconduct in connection with this Agreement; (iii) the use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product or API by or under the authority of Customer; or (iv) a claim or allegation that the Product, or any part thereof, or the API infringes, misappropriates, or otherwise violates a patent, copyright, trade secret, trademark or other intellectual property right of any third party; provided however, that Customer shall have no obligation of indemnity hereunder with respect to any Losses suffered, incurred or sustained by any Lonza Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from an act or omission described in clause (i), (ii), or (iii) of Section 9.1.

9.3 **Indemnification Procedures**. In the event that any Claim or Proceeding is asserted or imposed against any Party, and such Claim or Proceeding involves a matter which is subject to a claim for indemnification under this Article 9, then such Party (an "Indemnified Party") shall promptly give written notice to the other Party (the "Indemnifying Party") of such Claim or Proceeding and provide the Indemnifying Party with a copy of any complaint, summons or other written notice that the Indemnified Party receives in connection with such Claim or Proceeding. An Indemnified Party's failure to so notify the Indemnifying Party promptly will relieve the Indemnifying Party's obligation set forth in Section 9.1 or Section 9.2, as applicable, only to the extent such failure is materially prejudicial to the Indemnifying Party's ability to defend the Claim or Proceeding. Provided that the Indemnifying Party is not contesting its indemnity obligation, the Indemnifying Party shall assume, at its cost and expense, the defense of such Claim or Proceeding through its legal counsel selected and reasonably acceptable to the Indemnified Party. Notwithstanding the foregoing, the Indemnified Party may, at its option and expense, select and be represented by separate counsel. The Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the Claim or Proceeding and (b) have control over the Claim or Proceeding, including the right to settle; provided, however, that the Indemnifying Party shall not, absent the prior written consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement that (1) provides for any relief other than the payment of monetary damages for which the Indemnifying Party shall be solely liable and (2) where the claimant or plaintiff does not release the Indemnified Party, its Affiliates and their respective directors, officers, employees, agents and representatives, as the case may be, from all liability in respect thereof. In no event shall the Indemnified Party be liable for any claims that are compromised or settled in violation of this Section 9.3.

9.4 **Waiver of Certain Losses.** EXCEPT FOR [***] IN NO EVENT SHALL EITHER PARTY OR SUCH PARTY'S AFFILIATES BE LIABLE TO THE OTHER PARTY OR SUCH OTHER PARTY'S AFFILIATES FOR ANY LOSS OF OPPORTUNITY, LOSS OF PROFITS, LOSS OF ANTICIPATED SALES, OR FOR ANY PUNITIVE, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR SPECIAL LOSSES OR DAMAGES WHETHER OR NOT FORESEEABLE, OR WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OF ANY KIND HOWEVER CAUSED, WHETHER BASED ON CONTRACT, TORT, NEGLIGENCE, INDEMNITY OR OTHER THEORY OF LAW, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PURCHASE ORDER, AS APPLICABLE.

9.5 **Limitation of Liability**.

9.5.1 NOTWITHSTANDING ANY OTHER PROVISION IN THIS AGREEMENT OR A PURCHASE ORDER, AS APPLICABLE, THE TOTAL LIABILITY, IN THE AGGREGATE, OF EITHER PARTY AND ITS AFFILIATES, TO THE OTHER PARTY AND ANYONE CLAIMING BY OR THROUGH THE OTHER PARTY, FOR ANY AND ALL CLAIMS, LOSSES, COSTS, DAMAGES OR FEES, INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES RESULTING FROM OR IN ANY WAY RELATED TO THIS AGREEMENT OR A PURCHASE ORDER FROM ANY CAUSE OR CAUSES SHALL IN NO EVENT EXCEED, IN THE AGGREGATE, THE GREATER OF [***].

9.5.2 [***]

9.6 **Insurance.** Each Party shall, during the Term and for [***] after termination or expiration of the Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance, which is reasonable and customary in the United States of America, and product liability coverage in the amount of at least [***] per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

10. CONFIDENTIALITY

10.1 **Non-disclosure and Non-use.** Neither Party shall disclose to any third party nor use for its own purposes (other than those contemplated by this Agreement) any Confidential Information of the other Party. For purposes of this Agreement, "Confidential Information" shall mean all proprietary information, including know-how, trade secrets, business plans, pharmaceuticals, materials, operations, equipment, processes, methods, strategies and systems, and financial information, prices, materials, building techniques and any drawings, specifications, designs and other information or data, or any fact with respect to any of the foregoing relating to the Services performed under this Agreement, that is disclosed in any manner by or on behalf of a Party (the "Disclosing Party") to the other Party (the "Receiving Party") or its permitted recipients pursuant to this Agreement or prior to entry into this Agreement in connection with the Parties' discussions to enter into this Agreement commencing on [***]. This Agreement will be deemed to be the Confidential Information of both Parties. Notwithstanding the above, either Party may disclose Confidential Information to those of its and its Affiliates' directors, officers, employees, agents, consultants, representatives and advisors (collectively, "Agents") and to those approved subcontractors who have a need to know for the purposes of this Agreement. Each Party shall ensure that all of its Agents and subcontractors are bound by confidentiality obligations no less stringent than those stated herein. The Receiving Party shall be liable for any failure of any of its Agents to (a) maintain the confidentiality of the Disclosing Party's Confidential Information, or (b) otherwise comply with the terms of this Article 10 to the same extent as the Receiving Party is obligated to do so. Additionally, each Receiving Party shall have the right to disclose Confidential Information of the Disclosing Party (including the Agreement) to the Receiving Party's actual or potential third party investors or actual or potential third party acquirers, licensees or collaborative or other partners, and to the Receiving Party's bankers, auditors, lawyers, accountants, and agents, provided, in each case that each such third party needs to know such Confidential Information and is bound to confidentiality and non-use obligations no less stringent than those set forth herein.

10.2 **Exclusion of Confidential Information.** The obligations of confidentiality and non-use set forth in Section 10.1 shall not apply for Confidential Information that: (a) is or becomes part of the public domain without a violation of this Agreement; (b) was already in possession of the Receiving Party or its Affiliates (other than under an obligation of confidentiality) at the time of receipt from the Disclosing Party, as shown by documentary evidence, without violating an obligation of confidentiality to the Disclosing Party; (c) is received (other than under an obligation of confidentiality) from a third party who had no obligation to the Disclosing Party not to disclose such Confidential Information to the Receiving Party; or (d) the Receiving Party can demonstrate was independently developed by or for the Receiving Party or its Affiliates without use of the Disclosing Party's Confidential Information or otherwise violating the terms of this Agreement.

10.3 **Information Required by Law.**

(a) If the Receiving Party is requested to disclose the Confidential Information of the Disclosing Party or any terms of this Agreement in connection with a lawful order of a government agency or court of competent jurisdiction or disclosure is required by operation of Law, including a legal or administrative proceeding, the Receiving Party will, to the extent legally permissible, give the Disclosing Party prompt written notice of such request so that the Disclosing Party may seek an appropriate protective order, confidential treatment of such information, or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protective order, confidential treatment, or other remedy, the Receiving Party, at the Disclosing Party's request and expense, will reasonably cooperate with and assist the Disclosing Party in such efforts. If the Disclosing Party fails to obtain the requested remedy or waives compliance with the relevant provisions of this Agreement, the Receiving Party will disclose only that portion of the Confidential Information which its legal counsel determines is required by Law to be disclosed. Confidential Information that is disclosed pursuant to this Section 10.3(a) shall remain otherwise subject to the confidentiality and non-use provisions set forth in this Article 10.

(b) Notwithstanding anything to the contrary in Section 10.3(a), the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is reasonably necessary in order to comply with Law, including securities Laws and the rules of any securities exchange or market on which a Receiving Party's securities are listed or traded, including the filing of this Agreement as an exhibit to any filing or other communication; provided that the Receiving Party provides the Disclosing Party with prior written notice of any such disclosure (to the extent reasonably practicable and legally permissible), and, (i) in the case of disclosures other than those required by securities Laws or the rules of any securities exchange or market on which a Receiving Party's securities are, or are to be, listed or traded, the Receiving Party provides reasonable assistance to the Disclosing Party to limit disclosure of or seek confidential treatment for such Confidential Information, and (ii) in the case of disclosures required by securities Laws or the rules of any securities exchange or market on which a Receiving Party's securities are, or are to be, listed or traded, the Receiving Party takes reasonable steps, upon the advice of securities counsel, to limit disclosure of or seek confidential treatment for such Confidential Information.

10.4 **Confidentiality Period.** All obligations of confidentiality under this Article 10 will remain in effect during the Term and until [***] after the expiration or termination of the Agreement; provided however that the obligations of confidentiality for Confidential Information identified as a trade secret will survive indefinitely until such trade secret information no longer qualifies as a trade secret.

10.5 **Publicity.** Neither Party shall refer to, display or use or reference in any advertising, sales promotion, press release or other communication, any endorsement, direct or indirect quote, code, drawing, logo, name, trademark, specification, or picture of the other Party or the other Party's Affiliates without the prior written consent of the other Party. In the event the Parties' mutually agree to any external communications (e.g., joint press release) regarding the Parties' collaboration, Customer and Lonza agree to coordinate such external communications.

10.6 **Return of Customer Confidential Information.** Upon termination of the Agreement, at Customer's written request and election, all tangible forms of Customer Confidential Information shall be destroyed or returned to Customer without retaining any copies except for such copies necessary for Lonza to exercise its surviving rights or obligations under the Agreement. Notwithstanding the foregoing, (a) Lonza will be permitted to retain one copy of such Confidential Information of Customer for archival and legal compliance purposes (including all executed documents of exhibit and commercial batches as per regulatory requirements; provided that such documents shall be destroyed after such time period without retaining any copies) and (b) Lonza will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by Lonza's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its standard archiving and back-up procedures.

10.7 **Reservation of Rights**. Except as specifically set forth herein, this Agreement does not (i) give any Party any license, right, title, interest in or ownership to any Confidential Information of the other Party; or (ii) grant any license or right under any intellectual property rights.

11. INTELLECTUAL PROPERTY

11.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party.

11.2 Subject to Section 11.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and/or its Affiliates, or contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with Customer or others, in the course of performance of the Services that is a derivative of or improvement to the Product (including any composition of matter or method of use), or that uses or incorporates, Customer's Confidential Information and/or Customer's Background Intellectual Property (collectively, the "New Customer Intellectual Property"). For avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes or other items that solely embody, or that solely are claimed or covered by, any of the foregoing Intellectual Property, but shall exclude any New General Application Intellectual Property. New Customer Intellectual Property is deemed the Confidential Information of Customer.

11.3 Notwithstanding Section 11.2, and subject to the licenses granted in Section 11.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, or contractors or agents of Lonza, solely or jointly with Customer, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services that (i) is generally applicable to the development or manufacture of chemical or biological products or product components or (ii) is an

improvement of, or direct derivative of, any of Lonza' Background Intellectual Property and, in each case, does not require the use of, or incorporate any Customer's Confidential Information and/or Customer's Background Intellectual Property ("New General Application Intellectual Property"). For avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property. New General Application Intellectual Property is deemed the Confidential Information of Lonza.

11.4 (a) Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, or contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.

(b) Customer hereby assigns to Lonza all of its right, title and interest in any New General Application Property. Customer shall execute, and shall require its personnel as well as its Affiliates, or contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Lonza's ownership of the New General Application Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New General Application Intellectual Property.

(c) Lonza and Customer agree to cooperate in the filing of any patent application relating to New Customer Intellectual Property and New General Application Intellectual Property.

11.5 **License to Lonza Intellectual Property.**

11.5.1 **New General Application Intellectual Property.** Subject to the terms and conditions set forth herein, Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, irrevocable, perpetual, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property to the extent necessary to develop, make, have made, use, sell, have sold, offer for sale and import the Product (as defined without giving regard to Lonza as the manufacturer).

11.5.2 **Lonza Patents.** The License Agreement governs licenses to the Lonza Patents.

11.6 Customer acknowledges that it shall be solely and fully responsible for doing any and all freedom to operate assessments regarding possible infringement of third party intellectual property rights for any and all products and processes for any Product which it makes, has made, uses, sells, offers for sale or imports, other than with respect to Lonza's Background Intellectual Property, the Lonza Patents and any other intellectual property rights licensed by Lonza to Customer under the License Agreement.

11.7 The marketing of Products shall be carried out by Customer under its own trademark. A Party shall acquire no rights or license on the other Party's trademarks, unless such other Party provides prior written consent.

12. **TERM; TERMINATION**

12.1 **Term.** The term of this Agreement shall commence on the Effective Date and, subject to the rights of earlier termination contained in this Agreement, shall remain in effect until [***] ("Initial Term"). The Initial Term may thereafter be extended for subsequent years upon the mutual written agreement of the Parties (the Initial Term, together with such subsequent periods, the "Term").

12.2 [***]

12.3 **Breach; Insolvency.** If either Party is in material breach of any of its obligations, including its representations, warranties or covenants, under this Agreement, and fails to remedy such breach within [***] for non-payment of undisputed invoices) of receipt of written notice from the other Party, the non-breaching Party may terminate this Agreement with immediate effect with written notice of termination to the breaching Party, without liability to the other Party and without prejudice of any other rights or remedies; provided however, that if such breach is capable of being cured and the breaching party is diligently pursuing in good faith the remedy of the breach at the expiration of such [***] cure period, then the breaching Party shall have an additional period of time, not to exceed [***] or such other time period as mutually agreed to by the Parties, within which to complete such cure. Subject to any limitations under Law, either Party shall have the right to terminate this Agreement by giving notice to the other Party in the event that the other Party becomes insolvent or goes into bankruptcy, liquidation or receivership, or is admitted to the benefits of any procedure for the settlement of debts or becomes a party to dissolution proceedings.

12.4 [***]

12.5 **Consequences of Termination.**

12.5.1 In the event of termination hereunder by Customer pursuant to Section 12.2 [***]:

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process as of such date of termination, and (ii) all costs incurred by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) except as otherwise set forth in subsection (d) below, all Purchase Orders, [***] Firm Orders and DP Firm Orders received by Lonza from Customer prior to the date that Customer's written termination notice was received by Lonza, shall be deemed cancelled as of the date that Customer's written termination notice was received by Lonza, and Customer shall pay [***] in respect of such cancelled Purchase Orders, [***] Firm Orders and DP Firm Orders; and

(c) from and after the date of notice of termination, Customer will not be responsible for the relevant Minimum Quantities commitments that are provided under Section 3.5.

(d) Notwithstanding termination of this Agreement as contemplated by this Section 12.5.1, Lonza shall complete under the terms of this Agreement all Purchase Order(s) that that were accepted by Lonza prior to the date that Customer's written termination notice was received by Lonza, and that Customer informed Lonza in such written termination

notice of Customer's election that Lonza complete such Purchase Order(s) under the terms of this Agreement. If Customer cancels any such Purchase Order(s), then Customer shall pay the Cancellation Fee in respect of such cancelled Purchase Order.

(e) Upon receipt by Lonza of Customer's written termination notice, Lonza shall promptly cease performance of the applicable Services (other than Services in connection with pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with pending Purchase Order(s) Customer has elected that Lonza complete as provided in subsection (d) above.

12.5.2 In the event of termination hereunder by Lonza pursuant to Section 12.2 [***]:

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process as of such date of termination, and (ii) all costs incurred by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) except as otherwise set forth in subsection (d) below, all Purchase Orders, [***] Firm Orders and DP Firm Orders received by Lonza from Customer prior to the date that Lonza's written termination notice was received by Customer, shall be deemed cancelled as of the date that Lonza's written termination notice was received by Customer, and Customer shall pay [***] in respect of such cancelled Purchase Orders, [***] Firm Orders and DP Firm Orders; and

(c) from and after the date of notice of termination, Customer will not be responsible for the relevant Minimum Quantities commitments provided under Section 3.5.

(d) Notwithstanding termination of this Agreement as contemplated by this Section 12.5.2, Lonza shall complete under the terms of this Agreement all Purchase Order(s) that that were accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, and that Customer elects that Lonza complete by written notice to Lonza within [***] of Customer's receipt of Lonza's notice of termination. If Customer cancels any such Purchase Order, then Customer shall pay the Cancellation Fee in respect of such cancelled Purchase Order.

(e) Upon receipt by Customer of Lonza's written termination notice, Lonza shall promptly cease performance of the applicable Services (other than Services in connection with pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with pending Purchase Order(s) Customer has elected that Lonza complete as provided in subsection (d) above.

12.5.3 In the event of termination hereunder by Customer in accordance with Section 12.3 (Breach; Insolvency):

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, including any Product in-process as of such date of termination, and (ii) all costs incurred by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) except as otherwise set forth in subsection (d) below, all Purchase Orders, [***] Firm Orders and DP Firm Orders received by Lonza from Customer prior to the date that Lonza received Customer's written termination notice, shall be deemed cancelled as of the date that Customer's written termination notice was received by Lonza and [***] by Customer with respect to such Purchase Orders, [***] Firm Orders and DP Firm Orders; and

(c) from and after the date of notice of termination, Customer will not be responsible for the relevant Minimum Quantities commitments provided under Section 3.5.

(d) Notwithstanding termination of this Agreement as contemplated by this Section 12.5.3, Lonza shall complete under the terms of this Agreement all Purchase Order(s) that that were accepted by Lonza prior to the date that Customer's written termination notice was received by Lonza, and that Customer informed Lonza in such written termination notice of Customer's election that Lonza complete such Purchase Order(s) under the terms of this Agreement. If Customer cancels any such Purchase Order(s), then Customer shall pay the Cancellation Fee in respect of such cancelled Purchase Order.

(e) Upon receipt by Lonza of Customer's written termination notice, Lonza shall promptly cease performance of the applicable Services (other than Services in connection with pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above) and will take all reasonable steps to mitigate the out-of-pocket

expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession (other than as needed for pending Purchase Order(s) Customer has elected Lonza complete as provided in subsection (d) above), to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with pending Purchase Order(s) Customer has elected that Lonza complete as provided in subsection (d) above.

(f) Upon notice of termination by Customer pursuant to Section 12.5.3, Lonza shall perform the transition services pursuant to Section 12.5.7.

12.5.4 In the event of termination hereunder by Lonza in accordance with Section 12.3 (Breach; Insolvency):

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process as of such date of termination and (ii) all costs incurred by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) all Purchase Orders, [***] Firm Orders and DP Firm Orders shall be deemed cancelled as of the date that Lonza's written termination notice was received by Customer and Customer shall [***] in respect of such cancelled Purchase Orders, [***] Firm Orders and DP Firm Orders; and

(c) Customer shall be responsible for the relevant Minimum Quantities commitments provided under Section 3.5 [***].

(d) Upon receipt by Customer of Lonza's written termination notice, Lonza shall promptly cease performance of the applicable Services and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations, (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order, (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession, to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with the close-out of any pending Purchase Order.

12.5.5 In the event of termination hereunder by Customer pursuant to Section 12.4 [***]:

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process as of such date of termination and (ii) all

costs incurred by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) during [***], Lonza shall continue to accept or reject, in the ordinary course consistent with past practice under this Agreement prior to such notice of termination, any Purchase Orders submitted by Customer. If Customer cancels any such Purchase Order, then Customer shall [***] in respect of such cancelled Purchase Order;

(c) during [***], Customer shall be responsible for the relevant Minimum Quantities commitments provided under Section 3.5; and

(d) Customer shall be responsible for [***] Firm Orders and DP Firm Orders that Lonza received from Customer prior to the date that Customer's written termination notice was received by Lonza.

(e) Notwithstanding termination of this Agreement as contemplated by this Section 12.5.5, Lonza shall complete under the terms of this Agreement all (1) Purchase Orders accepted by Lonza during the [***] in accordance with subsection (b) above, and (2) any Purchase Orders that were accepted by Lonza prior to the date that Customer's written termination notice was received by Lonza. If Customer cancels any such Purchase Order, then Customer shall [***] in respect of such cancelled Purchase Order.

(f) Upon receipt by Lonza of Customer's written termination notice, Lonza shall promptly cease performance of the applicable Services (other than Services in connection with pending Purchase Order(s) accepted by Lonza [***] or prior to the date that Customer's written termination notice was received by Lonza, as provided in subsection (e) above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending Purchase Order(s) accepted by Lonza during the termination notice period or prior to the date that Customer's written termination notice was received by Lonza, as provided in subsection (e) above), (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession (other than as needed for pending Purchase Order(s) accepted by Lonza [***] or prior to the date that Customer's written termination notice was received by Lonza, as provided in subsection (e) above), to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with pending Purchase Order(s) accepted by Lonza [***] or prior to the date that Customer's written termination notice was received by Lonza, as provided in subsection (e) above.

12.5.6 In the event of termination hereunder by Lonza pursuant to Section 12.4 [***]:

(a) Lonza shall be compensated for (i) Services rendered up to the date of termination, excluding any Product in-process as of such date of termination and (ii) all costs incurred

by Lonza in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable Purchase Order, including the cost of Raw Materials (other than API supplied by Customer) used or purchased for use in connection with such Purchase Order;

(b) [***], Lonza shall continue to accept or reject, in the ordinary course consistent with past practice under this Agreement prior to such notice of termination, any Purchase Orders submitted by Customer;

(c) with respect to any Purchase Orders accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, Customer may cancel any portions of such Purchaser Orders that would result in the delivery of Product after the effective date of termination, and [***] by Customer with respect to such Purchase Orders as a result of the cancelation of such portions;

(d) from and after the date of notice of termination, Customer will not be responsible for the relevant Minimum Quantities commitments provided under Section 3.5; and

(e) Customer will not be responsible for [***] Firm Orders and DP Firm Orders that Lonza received from Customer prior to the date that Lonza's written termination notice was received by Customer.

(f) Notwithstanding termination of this Agreement as contemplated by this Section 12.5.6, and except as otherwise set forth in subsection (c) above, Lonza shall complete under the terms of this Agreement all (1) Purchase Orders accepted by Lonza [***] and (2) any Purchase Orders that were accepted by Lonza prior to notice of termination. If Customer cancels any such Purchase Order, Customer shall [***] in respect of such cancelled Purchase Order.

(g) Upon receipt by Customer of Lonza's written termination notice, Lonza shall promptly cease performance of the applicable Services (other than Services in connection with pending Purchase Order(s) accepted by Lonza [***] or that were accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, as provided in subsection (f) above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Lonza will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending Purchase Order(s) accepted by Lonza [***] or that were accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, as provided in subsection (f) above), (ii) promptly inform Customer of any irrevocable commitments made in connection with any pending Purchase Order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in Lonza's possession (other than as needed for pending Purchase Order(s) accepted by Lonza [***] or that were accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, as provided in subsection (f) above), to the extent possible, (iv) promptly inform Customer of the cost of any Raw Materials remaining unused and unreturnable, and (v) perform only those services and activities mutually agreed upon by the Parties as being necessary or advisable in connection with pending Purchase Order(s) accepted by Lonza [***] or that were

accepted by Lonza prior to the date that Lonza's written termination notice was received by Customer, as provided in subsection (f) above.

(h) Upon notice of termination by Lonza pursuant to Section 12.4, Lonza shall perform the transition services pursuant to Section 12.5.7.

12.5.7 In the event of termination by Customer for Lonza's material breach in accordance with Section 12.3 (Breach; Insolvency) or by Lonza pursuant to Section 12.4 [***], then from the date of the applicable notice of termination, until the earlier of either (i) [***] or (ii) [***] from the date of the notice of termination, Lonza will make available Lonza employees to Customer [***] to the extent necessary to provide reasonable technical support and assistance at no charge to Customer.

12.6 **Environmental Effects; Health and Safety.** Lonza reserves the right to terminate immediately this Agreement if, for any reason, (a) a Lonza occupational health and safety officer reasonably determines that any information provided by Customer pursuant to Section 5.2 (and which was not previously provided by Customer prior to entry into this Agreement) is incomplete, inadequate, or inaccurate to protect the environment or the health, safety and well-being of Lonza's employees (or those of its Affiliate) or (b) a Lonza occupational health and safety officer reasonably determines that the API or Product hereunder may adversely affect the environment or the health, safety and well-being of Lonza's employees (or those of its Affiliate); provided, however, that Lonza has used commercially reasonable efforts implement the necessary measures to prevent such adverse effects.

12.7 **Survival.** Termination or expiration of this agreement shall not relieve either Party of any liabilities, rights or obligations accruing prior to such termination or expiration. In the event of any termination or expiration of this Agreement, the provisions of this Section 12.7, and Sections 4, 5.2, 5.3, 6.1, 7, 9, 10, 11, 12.5, 15.1, and 15.3 shall survive such termination or expiration, together with any other provision hereof that by its terms survives termination or expiration hereof and any other obligations that have accrued prior to the termination or expiration of this Agreement.

13. **NOTICES**

13.1 Notices hereunder shall be deemed given as of the date sent. All notices shall be in writing mailed via certified mail, return receipt requested, or a reputable overnight courier, addressed as follows, or to such other address as may be designated from time to time:

If to Lonza: [***]

Copy to: Lonza
[***]

If to Customer: Deciphera Pharmaceuticals, LLC
500 Totten Pond Road Road, 6th Floor
Waltham, MA 02451
Attention: Chief Technical Officer
With a copy to: General Counsel

14. **FORCE MAJEURE**

14.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of [***], Customer may terminate this Agreement by delivering written notice to Lonza.

14.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply.

14.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

15 **MISCELLANEOUS**

15.1 **Entire Agreements; Amendments; Waivers.** The terms and provisions contained in this Agreement and all Exhibits hereto constitute the entire agreement between the Parties with respect to the commercial terms and conditions related to the commercial supply of Product, superseding all prior and contemporaneous agreements or understandings between the Parties with respect to the commercial terms and conditions related to the Product. In the event of a conflict between the terms of the Agreement, any Purchase Order, Exhibit or the Quality Agreement (subject to Section 8.1), the terms of this Agreement shall control. Any amendments of this Agreement must be in writing and signed by the Parties. A waiver of any breach or failure to enforce any of the terms or conditions of this Agreement shall in no way affect, limit or waive a Party's rights at any time to enforce strict compliance therafter with every term or condition of this Agreement.

15.2 **Successors and Assigns.** Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) either Party may assign this Agreement to (i) any Affiliate of such Party or (ii) any third party in connection with a merger, sale or transfer (by whatever method) involving all or substantially all of the assets of the business related to this Agreement, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer. For purposes of this Section 15.2, the terms "assign" and "assignment" shall include, without limitation (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

15.3 **Independent Contractor.** The relationship of the Parties under this Agreement is that of independent contractors and nothing contained herein shall be construed to create a partnership, joint venture or agency relationship between Customer and Lonza, nor shall either Party be authorized to bind the other in any way.

15.4 **Governing Law; Dispute Resolution.** This Agreement is governed in all respects by the laws of the State of New York, USA, without regard to its conflicts of laws principles. The Parties agree to submit to the jurisdiction of the courts of the State of New York, USA. The Parties shall have the right to proceed to a suitable jurisdiction for the purpose of enforcing a judgment, award, or order (including without limitation seeking specific performance) and injunctive reliefs.

15.5 **Severability.** If any provision of this Agreement is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the business purpose of this Agreement.

15.6 **Counterparts; Electronic Signatures.** This Agreement may be executed in one or more counterparts, and by Parties in separate counterparts, each of which when so executed shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement, to the extent signed and delivered by electronic means, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

15.7 **No Third Party Beneficiaries.** No third party including any employee of any Party to this Agreement shall have or acquire any rights by reason of this Agreement whether by way of statute or otherwise.

15.8 **Miscellaneous**. The division of this Agreement into articles, sections, subsections and exhibits, and the insertion of headings, are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa. Any reference herein to a “day” or “days” shall be references to a calendar day or days. Any period of days specified in this Agreement ending a Saturday, Sunday or public holiday shall automatically be extended to the first business day in the country of manufacture ending after such Saturday, Sunday or public holiday.

15.9 **Construction.** Each of the Parties agrees that it has read and had the opportunity to review this Agreement with its legal counsel and, accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Deciphera Pharmaceuticals, LLC [***]

By: /s/ Steven L. Hoerter By: [***]
Name: Steven L. Hoerter Name: [***]
Title: President and CEO Title: [***]
Date: April 2, 2019 Date: April 11, 2019

Exhibit 10.1

Execution version

EXHIBIT A
COMMERCIAL TERMS

[***]

EXHIBIT B
Specifications

[***]

EXHIBIT C
ENVIRONMENTAL AND HEALTH AND SAFETY INFORMATION

[***]

EXHIBIT D
Safety Data Sheets (SDS)

[***]

EXHIBIT E

License Agreement

[***]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "Agreement") dated as of February 28, 2020 (the "Effective Date"), is by and between Deciphera Pharmaceuticals, LLC, a limited liability company organized under the laws of Delaware, with places of business including executive offices at 200 Smith Street, Waltham, Massachusetts 02451, and research offices at 643 Massachusetts Street, Suite 200, Lawrence, Kansas 66044 ("BUYER"), and Cambrex [***], a corporation organized under the laws of the [***] ("SUPPLIER").

WITNESSETH:

RECITALS

WHEREAS, BUYER is engaged in the production, development, distribution, marketing and/or sale of certain pharmaceutical products containing the active pharmaceutical ingredient, DCC-2618 (the "API"); and

WHEREAS, SUPPLIER owns certain intellectual property, including technology and know-how for the manufacture of the API, and is in the business of manufacturing and selling active pharmaceutical ingredients; and

WHEREAS, SUPPLIER owns and operates a manufacturing facility at [***] (the "Facility") that has the capability to produce the API for BUYER; and

WHEREAS, BUYER desires to purchase certain quantities of the API from SUPPLIER, and SUPPLIER desires to manufacture such quantities of the API for BUYER, subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual representations, warranties and covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties intending to be legally bound hereby agree as follows:

1. Definitions. As used in this Agreement, the following words and phrases shall have the meanings set forth below.
    1.1. "Affiliate" means with respect to a person any other person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such person. For the purposes of this Section 1.1 only, "control" and, the terms "controlled by" and "under common control with", shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting securities, by contract or otherwise, and/or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a person.
    1.2. [***]
    1.3. "Annual Yield" has the meaning set forth in Section 3.9.
    1.4. "API" has the meaning set forth in the Recitals.

1.5. “API Warranty” shall have the meaning set forth in Section 11.2.

1.6. “Approval” means, with respect to any jurisdiction, any approval, license, registration, authorization or permit by a regulatory authority, including, without limitation, the FDA or EMA, necessary to market, sell or distribute in such jurisdiction the Product containing API that is manufactured at the Facility.

1.7. “Approved Subcontractor” has the meaning set forth in Section 3.5.

1.8. “Batch” means the quantity of API derived from a single run of the manufacturing process for the API.

1.9. [***]

1.10. “BUYER Background IP” means any Intellectual Property (a) developed or acquired by BUYER independently of this Agreement without reference to, or reliance upon, SUPPLIER’s Confidential Information or (b) owned or controlled by BUYER as of the Effective Date.

1.11. “BUYER Indemnitees” has the meaning set forth in Section 14.1.

1.12. “BUYER IP” has the meaning set forth in Section 13.3.

1.13. “BUYER Materials” has the meaning set forth in Section 3.5.

1.14. “Cancellation Fees” has the meaning set forth in Section 5.4.

1.15. “Certificate of Analysis” means a document prepared by SUPPLIER listing tests performed by SUPPLIER or an approved contract laboratory organization, the Specifications and the test results with respect to a Batch and such other information and certifications as are required to be in such document pursuant to the Quality Agreement.

1.16. “cGMP” means all applicable laws and regulations relating to manufacturing practices of medicinal products for human use promulgated by any relevant governmental or regulatory authority, as may be updated, supplemented or amended from time to time, the current good manufacturing practices as specified in the ICH guidelines and ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21 CFR (Chapters 210 and 211) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC.

1.17. “Change” has the meaning set forth in Section 7.1.

1.18. “Change Order” has the meaning set forth in Section 7.3.

1.19. “Claim” has the meaning set forth in Section 14.3.

1.20. “Confidential Information” has the meaning set forth in Section 20.1.

1.21. “Contract Year” means each consecutive twelve (12) month period beginning on the Effective Date or anniversary thereof, as applicable.

1.22. [***]

1.23. “[***] Purchased API” means [***].

1.24. “Defective API” has the meaning set forth in Section 12.1.

1.25. “Deficit” has the meaning set forth in Section 3.3.

1.26. “Disclosing Party” has the meaning set forth in Section 20.1.

1.27. [***]

1.28. “EMA” means the European Medicines Agency or any successor agency thereto.

1.29. “Excess Loss” has the meaning set forth in Section 3.7.

1.30. “EX-US Territory” means all countries in the world excluding the U.S.

1.31. [***]

1.32. “Facility” has the meaning set forth in the Recitals.

1.33. “FDA” means the United States Food and Drug Administration or any successor agency thereto.

1.34. “Firm Order” has the meaning set forth in Section 5.1.

1.35. “Force Majeure Event” has the meaning set forth in Section 18.1.

1.36. “Forms” has the meaning set forth in Section 22.2.

1.37. “Hidden Defect” means any defect in the API that is not discoverable at the time of delivery upon reasonable visual inspection and testing customarily conducted by BUYER or its designee in accordance with its or its designee’s standard operating procedures that is the result of the API failing to comply with the API Warranty.

1.38. “Indemnitee” has the meaning set forth in Section 14.3.

1.39. “Indemnitor” has the meaning set forth in Section 14.3.

1.40. “Infringement Claim” has the meaning set forth in Section 11.2.

1.41. “Initial Term” has the meaning set forth in Section 2.1.

1.42. “Intellectual Property” means all discoveries, inventions, know-how, developments, methods, techniques, trade secrets, innovations, updates, modifications, enhancements, improvements, copyrights, data, documentation, processes, procedures, specifications and other intellectual property of any kind, whether or not protectable under patent, trademark, copyright or similar laws.

1.43. [***]

1.44. “Losses” has the meaning set forth in Section 14.1.

1.45. “Master Batch Record” means the document approved by SUPPLIER and BUYER, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of the API, including the starting Batch size (in units or kilograms, as applicable) and the Raw Materials required.

1.46. [***]

1.47. [***]

1.48. “Non-Conforming API” has the meaning set forth in Section 12.1.

1.49. “Notice Period” has the meaning set forth in Section 12.1.

1.50. “PPQ” means process performance qualification.

1.51. “Process Validation Batch” means a Batch that is produced according to the Master Batch Record and approved validation protocol(s) with the intent to show reproducibility of the manufacturing process for the API and is required to complete process validation studies.

1.52. “Product” means any pharmaceutical drug product containing the API.

1.53. “Purchased API” means, [***].

1.54. “Quality Agreement” has the meaning set forth in Section 7.4.

1.55. “[***] Rolling Forecast” has the meaning set forth in Section 5.1.

1.56. “Raw Materials” means the raw materials as specified in the Master Batch Record.

1.57. “Receiving Party” has the meaning set forth in Section 20.1.

1.58. “Records” has the meaning set forth in Section 3.3.

1.59. “Renewal Term” has the meaning set forth in Section 2.2.

1.60. “Requirements” means [***].

1.61. “Rescheduling Fee” has the meaning set forth in Section 5.4.

1.62. “RSMs” means regulatory starting materials for the manufacture of the API.

1.63. “Specifications” means the release specifications for the manufacture, processing, bulk packaging, testing and testing procedures, shipping, storage and supply of the API under this Agreement, any Raw Material requirements, analytical procedures and standards of quality control and quality assurance, in each case, as established by the parties for the API to be manufactured under this Agreement. The initial Specifications are attached as **Exhibit 2**, which may be amended from time to time as mutually agreed to by the parties in writing in accordance with this Agreement.

1.64. “Steering Committee” has the meaning set forth in Section 3.10.

1.65. “SUPPLIER Background IP” means all Intellectual Property (a) developed or acquired by SUPPLIER independently of this Agreement without reference to, or reliance upon, BUYER’s Confidential Information or (b) owned or controlled by SUPPLIER as of the Effective Date.

1.66. “SUPPLIER IP” means the Supplier Background IP and all improvements to the Supplier Background IP developed by the SUPPLIER without reference to, or reliance upon, BUYER’s Confidential Information, the BUYER Background IP or the BUYER IP, during the course of this Agreement that are of general applicability to SUPPLIER’s service offerings as a manufacturer of active pharmaceutical ingredients.

1.67. “SUPPLIER Indemnitees” has the meaning set forth in Section 14.2.

1.68. “Term” has the meaning set forth in Section 2.2.

2. TERM

2.1. Subject to earlier termination as provided in Section 17 below, the term of this Agreement shall commence on the Effective Date and continue until [***] (the “Initial Term”).

2.2. This Agreement shall automatically renew for successive periods of [***] (each such period being a “Renewal Term”) unless terminated by either party providing a minimum of [***] written notice of cancellation to the other party. The Initial Term and any Renewal Term(s) shall be collectively referred to as the “Term.”

3. SUPPLY AND PURCHASE OF API; CAPACITY; [***]; STEERING COMMITTEE

3.1. During the Term of this Agreement, SUPPLIER shall manufacture the API at SUPPLIER's Facility in accordance with the terms and conditions of this Agreement, the Quality Agreement and the Specifications and in compliance with applicable laws and regulations and cGMP, and BUYER shall purchase from SUPPLIER such API, subject to the terms and conditions of this Agreement.

3.2. During the Term of this Agreement and subject to the manufacturing capacity at the Facility set forth in Section 3.4 below, BUYER shall purchase from SUPPLIER [***].

3.3. BUYER shall keep complete and accurate records in sufficient detail for SUPPLIER to confirm the [***] (the "Records"). BUYER shall retain such Records for a period of [***] from the creation of individual Records. No later than [***], commencing with [***], BUYER shall provide [***]. Upon the written request of SUPPLIER, BUYER shall permit an independent certified public accounting firm of nationally recognized standing selected by SUPPLIER and reasonably acceptable to BUYER, at SUPPLIER's expense, to have access during normal business hours to such Records as may be reasonably necessary to verify the accuracy of the [***]. SUPPLIER's right to audit such Records shall be limited to once per calendar year (provided that the foregoing frequency limit shall not apply if in good faith SUPPLIER has cause). SUPPLIER shall provide BUYER with a copy of the accounting firm's written report within [***] of completion of such report. If such accounting firm correctly concludes that, for any given calendar year, [***], then BUYER shall [***]. SUPPLIER shall bear the full cost of such audit unless such audit correctly discloses that the [***], in which case BUYER shall pay the reasonable fees and expenses charged by the accounting firm. SUPPLIER shall treat all Records subject to review under this Section 3.3 in accordance with the confidentiality provisions of Article 20, and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement with BUYER obligating it to treat all such Records in confidence pursuant to such confidentiality provisions. Such accounting firm shall not disclose BUYER's Confidential Information to SUPPLIER, except to the extent such disclosure is necessary to verify the accuracy of the [***]. Any third-party information provided to the third party accounting firm shall be deemed BUYER's Confidential Information for the purposes of this Section 3.3, and any such information requiring prior consent to provide the information shall be obtained (and if not obtained may not be provided).

3.4. During the Initial Term of this Agreement, SUPPLIER agrees to reserve sufficient manufacturing capacity at the Facility to manufacture the quantities of API on an annual basis as follows:

- [***]

3.5. SUPPLIER may not subcontract with any third party (including any Affiliate) to perform its obligations under this Agreement without BUYER's prior written consent, such consent not to be unreasonably withheld. In the event that BUYER provides such consent, (a) SUPPLIER shall cause such approved third party or Affiliate (each, an "Approved Subcontractor") to comply with the terms of this Agreement, as applicable, including obligations related to the ownership and assignment of Intellectual Property and all confidentiality, quality assurance, regulatory and other obligations and requirements of SUPPLIER set forth in this Agreement; and (b) SUPPLIER shall remain liable for the obligations delegated to such Approved Subcontractor and for the acts and

omissions of such Approved Subcontractor as if such acts and omissions were performed by SUPPLIER.

3.6. BUYER shall at all times retain all right, title and interest in and to any and all products, materials (including RSMs) and processes supplied by or on behalf of BUYER to SUPPLIER in connection with the manufacture of API pursuant to this Agreement, [***] ("BUYER Materials"). SUPPLIER shall: (a) not provide BUYER Materials to any third party or Affiliate without the prior written consent of BUYER; (b) not use BUYER Materials for any purpose other than manufacturing API hereunder, and without limiting the generality of the foregoing, will not analyze, characterize, modify or reverse engineer any BUYER Materials or take any action to determine the structure or composition of any BUYER Materials unless required to manufacture API hereunder; and (c) [***]. SUPPLIER shall store the BUYER Materials in accordance with this Agreement, the Quality Agreement and BUYER's written instructions, as applicable. Except as otherwise set forth in this Agreement, unless due to SUPPLIER's breach of this Agreement, fraud, negligence or willful misconduct, [***].

3.7. SUPPLIER's loss allowance for BUYER Materials supplied to SUPPLIER by or on behalf of BUYER [***] shall not exceed [***] ("Loss Allowance"). In the event of any loss or damage to BUYER Materials while in the possession of SUPPLIER in excess of the Loss Allowance ("Excess Loss") that is due to [***]. In the event such Excess Loss is not due to [***].

Within [***] following the end of each Contract Year, SUPPLIER shall perform a reconciliation for the BUYER Materials for the prior Contract Year to calculate the Excess Loss for such BUYER Materials.

3.8. As of the Effective Date of this Agreement, the expected yield of a Batch of API shall be as set forth in **Exhibit 3** (as such expected yield may be adjusted from time to time in accordance with the terms of this Agreement, the "Expected Yield"). From time to time during the Term, and no less frequently than [***], the Steering Committee (as defined below) shall review the Batch records and other production information from SELLER during the period since the previous determination of the Expected Yield and shall make a good faith determination based on such Batch records and other information of the then-current Expected Yield.

3.9. Actual yield will be evaluated on an annual basis at the end of each Contract Year (the "Annual Yield"). In the event that the Annual Yield is less than the Expected Yield for the applicable Contract Year, [***].

3.10. Each party shall mutually agree upon an equal number of management representatives for a joint steering committee (the "Steering Committee"), which shall meet at least quarterly during the first two (2) years of the Term and two (2) times per calendar year thereafter or for additional times as mutually agreed to by the parties. The location of the Steering Committee meetings, decision-making processes and dispute resolution shall be mutually agreed to by the parties. The primary function of the Steering Committee is to ensure the ongoing communication between the parties and discuss and resolve any issues arising under this Agreement. The Steering Committee may not amend or modify the terms of this Agreement.

4. PRICE

4.1. The price of API, exclusive of RSMs listed on **Exhibit 1 – Table 2** attached hereto, shall be as set forth on **Exhibit 1 – Table 1** attached hereto, and the price of RSMs shall be as set forth on **Exhibit 1 – Table 2** attached hereto, each as may be amended from time to time by mutual consent of the parties. Such prices may be adjusted in accordance with the provisions of Sections 4.2 and 4.3 hereof. SUPPLIER shall invoice BUYER the price of the API listed in **Exhibit 1 – Table 1** for the quantity of API delivered to BUYER in accordance with the terms of this Agreement and the applicable purchase order, [***].

4.2. Cost & Regulatory Price Increases: If circumstances beyond SUPPLIER's control arise such that current raw material prices for a certain product, export and/or import duties, customs charges, taxes at export, import and delivery, or similar charges, should be increased as a result of decision(s) made by third party suppliers, authorities or any other third party, or if new taxes and charges should be introduced and implemented with regard to the material concerned or its conveyance, then SUPPLIER shall advise BUYER by written notice of its intent to adjust the price of the API to account for such increases. Following receipt of such notice, SUPPLIER and BUYER shall promptly meet to discuss in good faith the timing of such price adjustment and potential alternatives, if any. Such price increase shall account for any costs arising out of the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH").

4.3. Other API price increases: Beginning on January 1, 2021, SUPPLIER shall have the right, in its discretion, to adjust the price of the API on each anniversary of such date (the "Adjustment Date") in an amount not to exceed the annual percentage increase, if any, for the most recent twelve (12) month period for which figures are available in the Producer Price Index – Pharmaceuticals for human use, prescription – (code SI07003) (the "PPI") published by the U.S. Bureau of Labor Statistics (the "BLS"), or if the same is no longer published, the successor index published by the BLS that is most similar thereto. [***] prior to the Adjustment Date during the Term, SUPPLIER shall advise BUYER of the proposed price to be charged for the API during the succeeding year, together with a statement of the manner by which said price was determined.

4.4. Any increase or decrease in the price of the API shall be applicable to all API delivered on or after the applicable price increase or decrease date.

4.5. The price for the API is exclusive of taxes, which taxes (other than taxes based upon SUPPLIER's income) shall be for the account of BUYER. Taxes that SUPPLIER is required by applicable laws or regulations to collect from BUYER, will be separately stated in SUPPLIER's invoice and will be paid by BUYER to SUPPLIER.

4.6. SUPPLIER shall manufacture Process Validation Batches as mutually agreed by the parties sufficient to document the operability and reproducibility of the manufacturing process for the API at the Facility and permit the parties to complete and file the necessary regulatory documents. Prior to commencement of Process Validation Batches, SUPPLIER and BUYER shall agree on a process validation plan identifying the validation requirements of the manufacturing process for the API. Any regulatory support activities (including pre-Approval inspection) required by BUYER and agreed to by SUPPLIER to support the Approval of the API from the Facility shall be performed and supported by SUPPLIER as reasonably requested by BUYER.

5. FORECASTING

5.1. On the [***] during the Term of this Agreement, commencing with the [***], BUYER shall provide SUPPLIER with a written estimated [***] rolling forecast of BUYER's [***] (in kilograms) for the next [***] (commencing with the [***] in which such forecast is provided) or, if the remainder of the Term is less than [***], for each remaining [***] during the remainder of the Term (the "[***] Rolling Forecast"). The forecast for the [***] of each such [***] Rolling Forecast shall be firm and binding on both of the parties hereto (the "Firm Order"). It is understood that the other [***] set forth in the [***] Rolling Forecast are good faith estimates only, and shall not be binding on the parties hereto [***].

5.2. BUYER shall place binding, non-cancellable purchase orders, in kilograms, from time to time, with SUPPLIER for the quantities of API indicated in the Firm Order. SUPPLIER may not reject or modify any such purchase order, except if it exceeds the quantities of API indicated in the applicable Firm Order. If such quantity is exceeded, SUPPLIER agrees to notify BUYER [***] after receipt of the relevant purchase order if SUPPLIER can or cannot comply and deliver any portion of such purchaser order. SUPPLIER shall use its commercially reasonable efforts to comply with such purchase order. In the event SUPPLIER delivers the quantities of API specified in any binding purchase order on or before the delivery date set forth therein, the price for such delivered quantities of API shall be the API price set forth in **Exhibit 1 – Table 1** [***]. In the event SUPPLIER fails to deliver the quantities of API specified in any binding purchase order by the delivery date set forth therein, [***]; provided that after any such [***] delay, BUYER may, in its sole discretion, (a) require SUPPLIER to use [***] to promptly remedy such shortfall, or [***]. Notwithstanding the foregoing, to the extent any failure of SUPPLIER to deliver the quantities of API specified in any binding purchase order is the result of circumstances beyond its reasonable control, including without limitation to the extent resulting from delays in the supply of RSM's, such delay shall not be subject to the foregoing. Except with respect to the [***] after the Effective Date, each purchase order shall be placed no later than [***] prior to the intended delivery date for such ordered quantities of API. Supplier shall use commercially reasonable efforts to satisfy, but shall have no obligation to fulfill any purchase orders submitted without such required lead time. Each purchase order issued hereunder shall be governed by the terms and conditions of this Agreement only. Unless mutually agreed by both parties, any different or additional terms and/or conditions contained in any notification or document (such as, for instance, in any purchase order) shall be disregarded. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any purchase order, the terms of this Agreement will control. BUYER shall pay SUPPLIER for the quantity of API, if any, specified in a Firm Order, but not purchased during such Firm Order, subject to the terms and conditions in this Agreement.

5.3. If BUYER's [***] exceed the forecast for the prior [***] by more than [***], SUPPLIER shall use its commercially reasonable efforts to meet such demand; provided that SUPPLIER shall not be required to displace other committed production. The foregoing shall not in any way limit SUPPLIER's obligation to reserve the manufacturing capacity set forth in Section 3.4.

5.4. (a) If BUYER requests to change the delivery date of a purchase order, SUPPLIER will use commercially reasonable efforts to accommodate the request. Any such change requested by BUYER may result in a rescheduling fee as calculated below (the "Rescheduling Fee"), subject to Section 5.5.

Number of days in advance of the scheduled commencement of the manufacturing date that the rescheduling notice is received	% of purchase order that is payable
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) In the event that, with respect to any jurisdiction, (i) BUYER decides to withdraw the Product from the market in such jurisdiction or (ii) BUYER fails to achieve Approval for the Product or such Approval is withdrawn in such jurisdiction, BUYER may cancel the applicable purchase order, upon written notice to SUPPLIER, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"), subject to Section 5.5

Number of days in advance of the scheduled commencement of the manufacturing date that the cancellation notice is received	% of purchase order that is payable
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5.5. [***]

5.6. SUPPLIER shall procure and maintain, for the manufacturing of the API, (i) a minimum of [***] (based on the most recent [***] Rolling Forecast) safety stock for all long-lead time starting materials, reagents and other critical components, including long-lead time Raw Materials and RSMs, and (ii) a minimum of [***] (based on the most recent [***] Rolling Forecast) inventory for short-lead time critical components, including short-lead time Raw Materials unique to BUYER. [***].

6. SHIPPING AND INVOICING

6.1. SUPPLIER shall deliver the API to BUYER's designated common carrier on the delivery date set forth in the applicable purchase order, EXW (INCOTERMS 2010) the Facility. Title and risk of loss to the API shall pass to BUYER when the API is made available to such designated carrier.

6.2. SUPPLIER shall invoice BUYER immediately following delivery of the API to BUYER. A bill of lading for each shipment will accompany the shipment. Payment of undisputed amounts shall be due from BUYER within [***] of BUYER's receipt of SUPPLIER's invoice. SUPPLIER shall be entitled to charge interest on any undisputed invoiced amount which is not paid by its due date sum at the rate of [***] for the time from the due date, until the date of actual payment.

7. SPECIFICATIONS, CHANGE IN SPECIFICATIONS OR PROCESS, QUALITY

7.1. The API manufactured by SUPPLIER hereunder shall, at the time of delivery to BUYER, meet the Specifications. Any changes (each, a "Change") to the Specifications must be approved and signed by authorized representatives of both parties as may be designated from time to time.

7.2. SUPPLIER shall obtain prior written approval of BUYER for any change in materials or methods of manufacture employed in producing API hereunder, which approval shall not be unreasonably withheld.

7.3. BUYER shall have the right to request a Change by delivering written notice to SUPPLIER describing a proposed Change. Within [***] of receipt of such notice, SUPPLIER shall submit to BUYER a change order (each, a "Change Order") containing a written assessment of the feasibility of making such Change, an estimate of the costs associated with such Change and a proposed time-line for implementation. The parties shall negotiate in good faith such Change Order, and upon the parties' written approval of the Change Order, SUPPLIER shall implement such Change Order as soon as it is commercially practical to do so or as otherwise stated in the Change Order. The costs associated with implementation of any such Change Order [***]. If after good faith negotiations (but in any event within [***] of BUYER's receipt of the applicable Change Order), the parties fail to agree with respect to any Change Order under this Section, [***].

7.4. If a Change is required by a regulatory authority or is required as the result of any new laws or regulations, the party receiving notice of such Change shall promptly notify the other party. In response to such Change, SUPPLIER shall provide BUYER with a Change Order describing any actions proposed to be taken to comply with such requirement or new laws or regulations, and a cost estimate for implementing such Change. The costs associated with implementation of such Change under this Section [***]. If after good faith negotiations (but in any event within [***] of BUYER's receipt of the applicable Change Order), the parties fail to agree with respect to any Change Order under this Section, [***].

7.5. The parties agree to negotiate in good faith and enter into a mutually acceptable quality agreement within [***] following the Effective Date that will set out the responsibilities of the parties in relation to quality assurance and quality control of API as required for compliance with cGMPs ("Quality Agreement"). The parties shall comply with the Quality Agreement. If there are any conflicts between the Quality Agreement and the Agreement, the provisions of the Agreement shall govern and control, with the exception that the Quality Agreement shall control for matters relating to the quality and disposition of the API.

7.6. SUPPLIER shall not transfer the API manufacturing process to any of its Affiliates' facilities without BUYER's prior written consent. [***]

7.7. Upon request by BUYER, SUPPLIER shall accept RSMs which are procured by BUYER for the production of the API, provided that the supplier(s) of such RSMs meet the quality standards established in SUPPLIER QMS and associated third party vendor qualification procedures.

8. ANALYTICAL SERVICES

8.1. SUPPLIER shall provide a Certificate of Analysis for each lot of API manufactured by SUPPLIER for BUYER and the Certificate of Analysis will accompany each lot of API shipped to BUYER.

9. INSPECTIONS AND AUDITS

9.1. BUYER shall have the right to perform, directly or through its representatives, one manufacturing audit to audit SUPPLIER's Facility and relevant records, including the Records, per [***] period to confirm that the API is being or has been manufactured in compliance with this Agreement as well as a follow-up audits to confirm that any deficiencies highlighted during the initial audit were addressed. All SUPPLIER personnel time and resources necessary to complete such manufacturing audits shall be provided at no cost to BUYER; provided, however, that except for "for cause" audits, any SUPPLIER personnel time and resources necessary to complete any additional manufacturing audits (over and above one audit (including any follow-up audits per the foregoing)) shall be invoiced to BUYER as additional services at SUPPLIER's then current standard rates. BUYER shall be responsible for reasonable third party costs of manufacturing audits, other than "for cause" audits. Such audits shall be subject to any confidentiality obligations with respect to SUPPLIER's or any third party's Confidential Information. As used herein, "for cause" audit means an audit conducted to investigate a specific quality failure at the Facility that relates to or affects the API.

9.2. BUYER employees who are present at the Facility shall comply with all of SUPPLIER's rules, regulations and instructions that are communicated to BUYER from SUPPLIER's employees, and BUYER assumes all liability, costs and loss of whatever kind resulting from the presence, actions or omissions of BUYER's employees at the Facility.

10. REGULATORY MATTERS

10.1. SUPPLIER is responsible for securing and maintaining the necessary permits, licenses and any other regulatory or governmental approvals necessary for the manufacture, storage and sale of the API at the Facility, and complying with the regulatory and governmental requirements for the manufacture, storage and sale of the API at the Facility, provided that if laws or regulatory requirements change after the date hereof, and such changes solely relate to the manufacture, packaging or storage of the API, subject to Section 7.4, [***].

10.2. BUYER is responsible for securing and maintaining the necessary Approvals and complying with the regulatory requirements for any product or material incorporating the API, or otherwise use of the API, in each case after delivery of the API by SUPPLIER to BUYER. Whenever the Approval is amended in a manner which affects the manufacture or control of the API that is the responsibility of SUPPLIER, BUYER will notify SUPPLIER thereof sufficiently in advance to the extent reasonably possible and necessary so as to enable SUPPLIER to take required measures before the date upon which such revisions are effective, provided that SUPPLIER's time to take such measures may, for good and sufficient cause, be extended as necessary for SUPPLIER to complete such action in accordance with Sections 7.3 or 7.4.

10.3. As between the parties, BUYER shall be the sole owner of all Approvals from any regulatory authority with respect to the API and any Product incorporating the API (including all associated

contents and correspondences) and all applications or submissions related thereto and to the API and any Product incorporating the API. BUYER is responsible for compiling the registration dossiers (with reasonable and necessary assistance and cooperation from SUPPLIER), filing the Approvals with any regulatory authority, and maintaining Approvals with respect to the API and any Product incorporating the API and the costs associated with the same.

10.4. In the event any regulatory authority issues, or BUYER voluntarily undertakes, a recall of API or any Product containing API, SUPPLIER and BUYER shall fully cooperate with each other in connection therewith. [***].

10.5. During the Term of this Agreement and for a period of [***] thereafter, or such longer period as may otherwise be required under applicable laws and regulations, SUPPLIER shall maintain complete and accurate records covering the manufacturing of API at the Facility by SUPPLIER.

10.6. Subject to the terms of the Quality Agreement, SUPPLIER will: (a) allow full access to any governmental regulatory inspection; (b) allow BUYER's representatives or agents to be on-site at any inspection by any regulatory authority to the extent such inspection relates to the API or the manufacturing of the API; (c) give BUYER reasonable advance notice of any such inspection; (d) promptly inform BUYER of the results of such inspection to the extent such inspection relates to the API, the manufacturing of the API or that affects SUPPLIER's performance under this Agreement; (e) comply with all reasonable requests and comments by BUYER with respect to all contacts and communications with any regulatory authority relating in any way to the API or the manufacturing of the API; (f) promptly inform BUYER in the event any regulatory authority takes regulatory action against SUPPLIER that could have a direct adverse effect on SUPPLIER's manufacturing of the API; and (g) take such actions that are commercially reasonable to correct any deficiencies identified by any inspection or audit conducted by such regulatory authority.

11. REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1. Each party represents, warrants and covenants to the other party:

(a) that it has the legal corporate power, authority and right to enter into this Agreement and to carry out the terms and obligations in this Agreement;

(b) that it is not a party to any agreement or arrangement with any third party which in any way limits or conflicts with its ability to fulfill any of its obligations in this Agreement;

(c) that it shall comply with all applicable laws, statutes, rules, regulations and ordinances (federal, state or local) applicable to its performance under this Agreement; and

(d) that it shall comply with the Quality Agreement.

11.2. SUPPLIER further represents, warrants and covenants to BUYER:

(a) that all API manufactured by SUPPLIER hereunder shall meet the Specifications at the time of transfer of title and risk of loss, shall not be adulterated within the meaning of applicable laws or regulations, and shall be manufactured and released by SUPPLIER in a manner compliant with the Quality Agreement and cGMP (collectively, the "API Warranty");

(b) that upon transfer of title, good valid title to the API will be conveyed by SUPPLIER to BUYER free and clear of any lien or encumbrance;

(c) that the Facility is, and shall remain during the Term of this Agreement, in compliance in all material respects with all applicable laws, statutes, rules, regulations or ordinances (federal, state or local);

(d) that as of the Effective Date, and at all times during the Term of this Agreement, it holds all necessary permits, approvals, consents and licenses necessary to manufacturing the API at the Facility;

(e) that SUPPLIER shall comply with the Quality Agreement;

(f) that as of the Effective Date and at all times during the Term of this Agreement, neither SUPPLIER nor any of its Approved Subcontractors is debarred, or to its knowledge, threatened to be debarred by the FDA (or subject to any similar sanction of the EMA or any other applicable foreign equivalent), and neither SUPPLIER nor any of its Approved Subcontractors shall, during the Term of this Agreement, use in any capacity the services of any person debarred by any government authority. In the event SUPPLIER learns that it, any Approved Subcontractor or any of SUPPLIER's or its Approved Subcontractor's employees have been debarred, SUPPLIER shall notify BUYER promptly and in any event within [***] of learning of such debarment.

(g) that SUPPLIER has all the rights necessary to permit SUPPLIER to manufacture the API in accordance with this Agreement without infringing or misappropriating the Intellectual Property of any third party, and to its knowledge no claims are pending or threatened against SUPPLIER by any third party with respect to any such infringement or misappropriation (each an "Infringement Claim"). SUPPLIER shall not incorporate any third party Intellectual Property into the manufacturing process for the API or the API manufactured by SUPPLIER under this Agreement. SUPPLIER shall notify BUYER promptly in writing if it becomes aware of any Infringement Claim.

11.3. [***]

11.4. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED OR STATUTORY, WITH RESPECT TO THIS AGREEMENT (INCLUDING THE MANUFACTURE AND SUPPLY OF THE API), INCLUDING ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR ANY PURPOSE.

12. NON-CONFORMING API; REJECTION

12.1. Within [***] of receipt of any shipment of API by or on behalf of BUYER (the "Notice Period"), BUYER or its designee shall inspect such shipment of API for any defect in the API that is readily discernible after visual inspection, sampling and identity testing to determine whether or not the API delivered by SUPPLIER is in conformity with the API Warranty (each, a "Defective API"). BUYER may reject a Defective API by giving written notice to SUPPLIER within the Notice Period. Notwithstanding the foregoing, the Notice Period shall be in the case of a Hidden

Defect in the API [***]; provided, however, that notice of such Hidden Defect to SUPPLIER must be provided [***] and within [***] of discovery of such Hidden Defect (each such API with a Hidden Defect or a Defective API, a "Non-Conforming API").

12.2. For any Non-Conforming API that BUYER rejects within the applicable Notice Period, SUPPLIER shall use its [***] to replace such rejected Non-Conforming API as soon as practically possible (but in any event within [***] of receipt by SUPPLIER of an applicable written notice of rejection) [***]. SUPPLIER shall inform BUYER within [***] of receipt of an applicable written notice of rejection if SUPPLIER is unable to replace such Non-Conforming API within such [***] period despite its [***] to do so. In such event, [***]. The provisions of this Section 12 shall survive termination or expiration of this Agreement. [***]. Non-Conforming API shall be returned to SUPPLIER at SUPPLIER's cost. Except for [***], the foregoing shall be BUYER's sole and exclusive remedy and SUPPLIER's sole and exclusive liability to BUYER for any and all Non-Conforming API.

12.3. If the parties are unable to agree whether or not any shipment of API is a Non-Conforming API, then parties shall appoint a mutually acceptable independent reputable laboratory to review records, test data and perform comparative tests and/or analyses on samples of API. Such analytical procedures performed by the independent laboratory shall be mutually agreed upon by the parties. The independent laboratory shall complete and report its findings in writing within [***], the findings of which shall be binding on the parties, absent manifest error. The parties shall ensure that such independent laboratory is bound to the parties by obligations of confidentiality no less exacting than those applying between the parties. The party whose opinion is not supported by such laboratory analysis shall bear the costs for the analysis.

13. INTELLECTUAL PROPERTY; TECHNOLOGY TRANSFER

13.1. As between BUYER and SUPPLIER, all right, title and interest in and to the BUYER Background IP shall be and remain the exclusive property of BUYER. SUPPLIER does not acquire any license or right to such BUYER Background IP, except that BUYER hereby grants to SUPPLIER during the Term a non-exclusive, non-transferable, non-assignable, royalty-free license under the BUYER Background IP solely for the purpose of SUPPLIER performing its obligations under this Agreement.

13.2. As between BUYER and SUPPLIER, all right, title and interest in and to the SUPPLIER IP shall be and remain the exclusive property of SUPPLIER. BUYER does not acquire any license or right to such SUPPLIER IP, except that SUPPLIER hereby grants to BUYER a non-exclusive, worldwide, royalty-free, fully paid-up, irrevocable, perpetual, transferable and sublicensable (through multiple tiers) license under the SUPPLIER IP to the extent necessary to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, export and import and otherwise fully exploit the API.

13.3. Any and all improvements, discoveries and/or inventions, whether or not patentable, which may be developed, made, conceived or reduced to practice by SUPPLIER during the Term of this Agreement and which are not SUPPLIER IP (and all related Intellectual Property Rights therein, the "BUYER IP") shall be the sole and exclusive property of BUYER and shall be considered the Confidential Information of BUYER. SUPPLIER shall promptly provide full disclosure to BUYER of all such BUYER IP, and hereby assigns to BUYER all of its right, title and interest in and to such BUYER IP to BUYER. SUPPLIER shall take such steps as BUYER may reasonably

request (at BUYER's sole cost and expense at SUPPLIER's then standard rates) to vest in BUYER (or its designee) ownership of such BUYER IP. SUPPLIER does not acquire any license or right to such BUYER IP, except that BUYER hereby grants to SUPPLIER a non-exclusive, non-transferable, non-assignable, royalty-free license under the SUPPLIER IP solely for the purpose of SUPPLIER performing its obligations under this Agreement.

13.4. Upon BUYER's request, SUPPLIER shall provide reasonable assistance to BUYER to implement the transfer of manufacturing responsibility for API to BUYER or its designee. Such reasonable assistance shall include transfer of all processes, procedures, know-how, Master Batch Record, materials and data required to manufacture API in accordance with the Specifications as then in effect. BUYER shall pay SUPPLIER's reasonable and documented out-of-pocket expenses at costs and FTE costs at the applicable rate to provide such assistance. For the avoidance of doubt, nothing in this Section 13.4 provides BUYER any additional termination rights separate from Section 17 of this Agreement.

14. INDEMNIFICATION

14.1. SUPPLIER shall defend, indemnify and hold harmless BUYER and its Affiliates and its and their directors, officers and employees (collectively, the "BUYER Indemnitees"), from and against any and all liability, loss, damage, cost or expense (including reasonable attorney's fees) (collectively, "Losses") arising out of any third party claim to the extent arising from: (a) SUPPLIER's breach of this Agreement; (b) the failure of the API to meet the API Warranty; or (c) the negligence or willful misconduct of SUPPLIER; except to the extent such Losses arise from or result from a breach of this Agreement by BUYER or its negligence or willful misconduct.

14.2. BUYER shall defend, indemnify and hold harmless SUPPLIER and its Affiliates and its and their directors, officers and employees (collectively, the "SUPPLIER Indemnitees"), from and against any and all Losses arising out of any third party claim to the extent arising from: (a) BUYER's breach of this Agreement, except to the extent such Losses arise from or result from a breach of this Agreement by SUPPLIER or its negligence, gross negligence or willful misconduct; (b) the negligence or willful misconduct of BUYER, except to the extent such Losses arise from or result from a breach of this Agreement by SUPPLIER or its negligence, gross negligence or willful misconduct; or (c) the distribution, sale or use of the API or any product or material made from or incorporating the API by or on behalf of BUYER, [***].

14.3. A party that intends to seek indemnification ("Indemnitee") under this Article 14 shall promptly notify the indemnifying party ("Indemnitor") in writing of any claim (each, a "Claim") for which the Indemnitee intends to claim indemnification (provided that failure to provide prompt notice shall not eliminate the Indemnitor's obligation to indemnify the Indemnitee under this Article 14 except (and to the extent) the Indemnitor has been prejudiced by such failure). The Indemnitor shall have sole control of the defense and settlement of such Claim, which shall be at the Indemnitor's sole cost and expense. The Indemnitor shall not enter into a settlement or otherwise compromises any Claim in any manner which requires the Indemnitee to admit fault or take any action that would be binding on the Indemnitee, in each case without the Indemnitee's prior written consent, such consent not to be unreasonably withheld. The Indemnitee shall have the right to participate, at its sole cost and expense, with counsel of its own choosing in the defense or settlement of the Claim. The indemnification obligations under this Article 14 shall not apply to amounts paid in settlement of any Claim if such settlement is affected without the consent of the Indemnitor, such consent not to be unreasonably withheld. The Indemnitee and its employees, at

its own expense, shall provide full information and reasonable assistance to Indemnitor and its legal representatives with respect to Claims.

15. LIMITATION OF LIABILITY

15.1. EXCEPT WITH RESPECT TO: (A) A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 14; (B) LIABILITY ARISING FROM A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER SECTION 20; OR (C) LIABILITY FOR MISAPPROPRIATION OR INFRINGEMENT OF THE INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY THE OTHER PARTY, IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, LOST PROFITS, OR OPPORTUNITY OR GOODWILL, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

15.2. BOTH PARTIES HEREBY AGREE THAT TO THE FULLEST EXTENT PERMITTED BY LAW, EXCEPT WITH RESPECT TO: (A) SUPPLIER'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (B) BUYER'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 14.2, (C) LIABILITY ARISING FROM a party'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER SECTION 20, (D) [***] (E) EITHER PARTY'S LIABILITY FOR MISAPPROPRIATION OR INFRINGEMENT OF THE INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY THE OTHER PARTY, (F) BUYER'S LIABILTY TO SUPPLIER FOR NON PAYMENT OF ANY AMOUNT OWED PURSUANT TO A PURCHASE ORDER, (G) EITHER PARTY'S OBLIGATIONS PURSUANT TO SECTION 17, OR (F) [***] A PARTY'S LIABILITY TO THE OTHER PARTY, FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT FROM ANY CAUSE OR CAUSES, INCLUDING, BUT NOT LIMITED TO, NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY, SHALL NOT EXCEED [***]. TO THE EXTENT THAT THIS CLAUSE CONFLICTS WITH ANY OTHER CLAUSE, THIS CLAUSE SHALL TAKE PRECEDENCE OVER SUCH CONFLICTING CLAUSE. IF APPLICABLE LAW PREVENTS ENFORCEMENT OF THIS CLAUSE, THEN THIS CLAUSE SHALL BE DEEMED MODIFIED TO PROVIDE THE MAXIMUM PROTECTION TO THE AGGRIEVED PARTY AS IS ALLOWABLE UNDER APPLICABLE LAW.

16. INSURANCE

16.1. During the Term of this Agreement and for as long as any relevant statute of limitation does not bar a third party action against either party, SUPPLIER shall at their sole cost and expense maintain the following insurance coverages with insurers maintaining a rating of at least an A-:X or better by A.M. Best:

INSURANCE TYPE	MINIMUM LIMITS	MINIMUM COVERAGE
Workers Comp	Statutory	Statutory coverage and limits pursuant to the laws, rules and regulations of the jurisdictions in which any respective employee of Service Provider, as applicable, performs work under this Agreement.
Employers Liability	[***] each accident or disease	Coverage for suits against respective Party for injury to its covered employees.
Commercial General Liability	[***] per occurrence and [***] annual aggregate	Coverage arising from premises, operations, personal injury, advertising injury, bodily injury and property damage, including contractual liability.
Umbrella Liability	[***] per occurrence and [***] annual aggregate	Coverage provides excess, follow-form coverage above all liability limits required herein.
Products Liability	[***] per occurrence and [***] annual aggregate	Products and completed operations,
Professional Errors & Omissions Liability	[***] per claim [***] annual aggregate	Coverage for respective Party and its own employees, as applicable, arising from performance or failure to perform any professional services arising under this Agreement, including errors, omissions, wrongful acts, negligent acts.

SUPPLIER shall include BUYER as an additional insured under its Commercial General Liability and Products Liability insurance coverage. All insurance required to be maintained by SUPPLIER hereunder shall: (a) be written to insure losses on an “occurrence basis”, except for Products Liability coverage which if written on a “claims made” basis, then such “claims made” policy must be kept in force for not less than [***] immediately following termination or expiration of this Agreement; (b) provide that the coverage is “primary coverage” and shall be non-contributory. The Commercial General Liability and Product Liability policies shall contain a provision or endorsement waiving all rights of subrogation against BUYER. Each party shall upon request furnish to the other party a certificate evidencing such insurance and shall provide the other with prompt written notice of cancellation or non-renewal of such insurance.

16.2. Each party represents that it maintains a policy or program of insurance or self-insurance at levels sufficient to support its indemnification obligations assumed herein and as set forth in Section 14 above.

17. RIGHT OF TERMINATION; EFFECT OF TERMINATION

17.1. Either party may terminate this Agreement, by giving the other party [***] written notice thereof, in any of the following events:

17.1.1. the cessation of business activities by the other party;

17.1.2. the admission by the other party of its inability to pay its debts as they mature;

17.1.3. the filing of a petition for bankruptcy or similar proceedings by the other party, but excluding a proceeding for reorganization pursuant to Chapter 11 of the Federal Bankruptcy Code by the other party providing that the party continues in the operation of its business and further provided that the party shall otherwise continue to perform its obligations under this Agreement;

17.1.4. a general assignment for the benefit of creditors or similar acts by the other party; or

17.1.5. any material breach of the Agreement; provided, such material breach is not cured within [***] of receipt of notice of such breach. The parties acknowledge and agree that the following shall constitute a material breach of this Agreement for which BUYER shall have the right to immediately terminate this Agreement without a cure period upon written notice to SUPPLIER: [***].

17.2. [***]

17.3. [***]

17.4. Termination of this Agreement, for whatever reason, shall not affect the obligations of either party specified in Sections 1, 3, 5.5, 9-16, this Section 17, and Sections 18-27.

17.5. In the event of termination hereunder by BUYER in accordance with Section 17.1 (Material Breach or Insolvency):

17.5.1. SUPPLIER shall be compensated for (a) a pro rata amount of the amount set forth in the applicable purchase order for services rendered pursuant to such purchase order, including pro rata work performed under any purchase orders, up to the date of termination, and (b) all costs incurred by SUPPLIER in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable purchase order;

17.5.2. except as otherwise set forth in subsection 17.5.4 below, all purchase orders and Firm Orders received by SUPPLIER from BUYER prior to the date that SUPPLIER received BUYER’s written termination notice, shall be deemed cancelled as of the date that BUYER’s written termination notice was received by SUPPLIER [***]; and

17.5.3. from and after the date of notice of termination, BUYER will not be responsible for the relevant [***].

17.5.4. Notwithstanding termination of this Agreement as contemplated by Section 17.1, SUPPLIER shall complete under the terms of this Agreement all purchase order(s) that were accepted by SUPPLIER prior to the date that BUYER’s written termination notice was received by SUPPLIER, and that BUYER informed SUPPLIER in such written termination notice of BUYER’s election that SUPPLIER complete such purchase order(s) under the terms of this Agreement.

17.5.5. Upon receipt by SUPPLIER of BUYER's written termination notice, SUPPLIER shall promptly cease performance of the applicable services (other than services in connection with pending purchase order(s) BUYER has elected SUPPLIER complete as provided in subsection 17.5.4 above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, SUPPLIER will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending purchase order(s) BUYER has elected SUPPLIER complete as provided in Section 17.5.4), (ii) promptly inform BUYER of any irrevocable commitments made in connection with any pending purchase order(s), (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in SUPPLIER's possession (other than as needed for pending purchase order(s) BUYER has elected SUPPLIER complete as provided in Section 17.5.4), to the extent possible, (v) promptly inform BUYER of the cost of any Raw Materials remaining unused, unreturnable and otherwise unusable, and (vi) perform only those services and activities mutually agreed upon by the parties as being necessary or advisable in connection with pending purchase order(s) BUYER has elected that SUPPLIER complete as provided in Section 17.5.4.

17.5.6. At BUYER's election and in its sole discretion, SUPPLIER will (i) promptly return to the vendor for refund to BUYER all unused, unopened RSMs [***] that are in SUPPLIER's possession (other than as needed for pending purchase order(s) BUYER has elected SUPPLIER complete as provided in Section 17.5.4), to the extent possible, and/or transfer such RSMs to BUYER or BUYER's designee, and (ii) promptly return all other BUYER Materials to BUYER or BUYER's designee.

17.6. In the event of termination hereunder by SUPPLIER in accordance with Section 17.1 (Material Breach or Insolvency):

17.6.1. SUPPLIER shall be compensated for (a) all services rendered up to the date of termination and (b) all costs incurred by SUPPLIER in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable purchase order;

17.6.2. all purchase orders and Firm Orders shall be deemed cancelled as of the date that SUPPLIER's written termination notice was received by BUYER [***]; and

17.6.3. BUYER shall be responsible for the relevant [***]; and

17.6.4. [***]

17.6.5. Upon receipt by BUYER of SUPPLIER's written termination notice, SUPPLIER shall promptly cease performance of the applicable services and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, SUPPLIER will use its commercially reasonable efforts to (i) immediately cancel any third party obligations, (ii) promptly inform BUYER of any irrevocable commitments made in connection with any pending purchase order, (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in SUPPLIER's possession, to the extent possible, (iv) promptly inform BUYER of the cost of any Raw Materials remaining unused, unreturnable and otherwise unusable, and (v) perform only

those services and activities mutually agreed upon by the parties as being necessary or advisable in connection with the close-out of any pending purchase order.

17.6.6. At BUYER's election and in its sole discretion, SUPPLIER will (i) promptly return to the vendor for refund to BUYER all unused, unopened RSMs [***] that are in SUPPLIER's possession, to the extent possible, and/or transfer such RSMs to BUYER or BUYER's designee, and (ii) promptly return all other BUYER Materials to BUYER or BUYER's designee.

17.7. In the event of termination hereunder by BUYER pursuant to Section 17.2 [***]:

17.7.1. SUPPLIER shall be compensated for (a) services rendered up to the date of termination, including in respect of any API in-process as of such date of termination and (b) all costs incurred by SUPPLIER in connection with non-cancelable obligations entered into prior to the date of termination in accordance all outstanding purchase orders;

17.7.2. during [***], SUPPLIER shall continue to accept or reject, in the ordinary course consistent with past practice under this Agreement prior to such notice of termination, any purchase orders submitted by BUYER, in accordance with SUPPLIER's obligations under this Agreement. If BUYER cancels any such purchase order, then BUYER shall [***] in respect of such cancelled purchase order;

17.7.3. during [***], BUYER shall be responsible for the relevant [***]; and

17.7.4. BUYER shall be responsible for Firm Orders that SUPPLIER received from BUYER prior to the date that BUYER's written termination notice was received by SUPPLIER and any Firm Orders that are made [***].

17.7.5. Notwithstanding termination of this Agreement as contemplated by Section 17.2, SUPPLIER shall complete under the terms of this Agreement all (a) purchase orders accepted by SUPPLIER [***] in accordance with subsection 17.7.2 above, and (b) any purchase orders that were accepted by SUPPLIER prior to the date that BUYER's written termination notice was received by SUPPLIER. If BUYER cancels any such purchase order, then BUYER shall [***] in respect of such cancelled purchase order.

17.7.6. Upon receipt by SUPPLIER of BUYER's written termination notice, SUPPLIER shall promptly cease performance of the applicable services (other than services in connection with pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by SUPPLIER, as provided in subsection 17.7.5 above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, SUPPLIER will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by SUPPLIER, as provided in Section 17.7.5 above), (ii) promptly inform BUYER of any irrevocable commitments made in connection with any pending purchase orders, (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in SUPPLIER's possession (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by

SUPPLIER, as provided in Section 17.7.5 above), to the extent possible, (iv) promptly inform BUYER of the cost of any Raw Materials remaining unused, unreturnable and otherwise unusable, and (v) perform only those services and activities mutually agreed upon by the parties as being necessary or advisable in connection with pending purchase orders accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by SUPPLIER, as provided in Section 17.7.5.

17.7.7. At BUYER's election and in its sole discretion, SUPPLIER will (i) promptly return to the vendor for refund to BUYER all unused, unopened RSMs [***] that are in SUPPLIER's possession (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by SUPPLIER, as provided in Section 17.7.5 above), to the extent possible, and/or transfer such RSMs to BUYER or BUYER's designee, and (ii) promptly return all other BUYER Materials to BUYER or BUYER's designee (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that BUYER's written termination notice was received by SUPPLIER, as provided in Section 17.7.5 above).

17.8. In the event of termination hereunder by SUPPLIER pursuant to Section 17.2 [***]

17.8.1. SUPPLIER shall be compensated for (a) services rendered up to the date of termination and (b) all costs incurred by SUPPLIER in connection with non-cancelable obligations entered into prior to the date of termination in accordance with the applicable purchase order, including the cost of Raw Materials (other than RSMs supplied by BUYER) used or purchased for use in connection with such purchase order;

17.8.2. [***], SUPPLIER shall continue to accept or reject, in the ordinary course consistent with past practice under this Agreement prior to such notice of termination, any purchase orders submitted by BUYER, in accordance with SUPPLIER's obligations under this Agreement;

17.8.3. with respect to any purchase orders accepted by SUPPLIER prior to the date that SUPPLIER's written termination notice was received by BUYER, BUYER may cancel any portions of such purchase orders that would result in the delivery of API after the effective date of termination [***] with respect to such purchase orders as a result of the cancellation of such portions;

17.8.4. from and after the date of notice of termination, BUYER will not be responsible for the relevant [***]; and

17.8.5. BUYER will be responsible for Firm Orders that SUPPLIER received from BUYER prior to the date that SUPPLIER's written termination notice was received by BUYER.

17.8.6. Notwithstanding termination of this Agreement as contemplated by Section 17.2, and except as otherwise set forth in subsection 17.8.3 above, SUPPLIER shall complete under the terms of this Agreement all (a) purchase orders accepted by SUPPLIER [***] and (b) any purchase orders that were accepted by SUPPLIER prior to notice of termination. If BUYER cancels any such purchase order, then BUYER shall [***] in respect of such cancelled purchase order.

17.8.7. Upon receipt by BUYER of SUPPLIER's written termination notice, SUPPLIER shall promptly cease performance of the applicable services (other than services in connection with pending purchase order(s) accepted by SUPPLIER [***] or that were accepted by SUPPLIER prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in subsection 17.8.6 above) and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, SUPPLIER will use its commercially reasonable efforts to (i) immediately cancel any third party obligations (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in Section 17.8.6 above), (ii) promptly inform BUYER of any irrevocable commitments made in connection with any pending purchase orders, (iii) promptly return to the vendor for refund all unused, unopened Raw Materials that are in SUPPLIER's possession (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in Section 17.8.6 above), to the extent possible, (iv) promptly inform BUYER of the cost of any Raw Materials remaining unused, unreturnable and otherwise unusable, and (v) perform only those services and activities mutually agreed upon by the parties as being necessary or advisable in connection with pending purchase orders accepted by SUPPLIER [***] or prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in Section 17.8.6.

17.8.8. At BUYER's election and in its sole discretion, SUPPLIER will (i) promptly return to the vendor for refund to BUYER all unused, unopened RSMs [***] that is in SUPPLIER's possession (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in Section 17.8.6 above), to the extent possible, and/or transfer such RSMs to BUYER or BUYER's designee, and (ii) promptly return all other BUYER Materials to BUYER or BUYER's designee (other than as needed for pending purchase order(s) accepted by SUPPLIER [***] or prior to the date that SUPPLIER's written termination notice was received by BUYER, as provided in Section 17.8.6 above).

18. FORCE MAJEURE

18.1. No party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement) occasioned by any reason beyond the control and without the fault or negligence of the party affected thereby, including, without limitation, an act of God, fire, flood, act of government or state, war, civil commotion, insurrection, acts of terrorism, embargo, sabotage, and labor disputes of whatever nature (a "Force Majeure Event"), provided that the party affected thereby gives prompt written notice of the Force Majeure Event and its effects on the party's performance to the other party. Such excuse shall continue as long as the Force Majeure Event continues; provided, however, that if the Force Majeure Event continues for a period of [***] or more, either party terminate this Agreement.

18.2. The party affected by the Force Majeure Event will use commercially reasonable efforts to resume performance or mitigate the effects of the Force Majeure Event as quickly as practicable. In the event of partial failure or delay of performance hereunder by reason of a Force Majeure

Event, unaffected portions of the Facility may be allocated by SUPPLIER to perform hereunder on an equitable basis.

19. APPLICABLE LAW AND DISPUTES

This Agreement shall be governed by, interpreted and enforced in accordance with the procedural and substantive laws of Delaware, without giving effect to its choice of law provisions. The Parties consent and agree to the exclusive jurisdiction of the Courts of the State of Delaware for the resolution of any dispute between the parties. The parties expressly reject any application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

20. CONFIDENTIALITY

20.1. As used in this Agreement, "Confidential Information" shall mean all proprietary information, including know-how, trade secrets, business plans, pharmaceuticals, materials, operations, equipment, processes, methods, strategies and systems, and financial information, prices, materials, building techniques and any drawings, specifications, designs and other information or data, or any fact with respect to any of the foregoing relating to the services performed under this Agreement, that is disclosed in any manner by or on behalf of a party (the "Disclosing Party") to the other party (the "Receiving Party") or its permitted recipients pursuant to this Agreement, whether disclosed or made available in visual, oral, written, electronic, graphic or any other form, whether or not marked as "confidential" or "proprietary". For avoidance of doubt, Confidential Information of BUYER shall include without limitation all BUYER IP, BUYER Background IP and BUYER Materials.

20.2. Both SUPPLIER and BUYER agree, during the term of this Agreement and for a period of [***] thereafter, to (a) keep any and all "Confidential Information" of the Disclosing Party confidential using at least the same degree of care that the Receiving Party would use to protect its own Confidential Information, (b) not disclose Confidential Information to any third party, including any Affiliate, other than employees, consultants, agents or Approved Subcontractors of SUPPLIER or BUYER, as the case may be, who are bound by obligations of confidentiality and nonuse at least as restrictive as those restrictions contained this Section 20 and who have a need to know such information in order to perform their duties or services in connection with such party's obligations under this Agreement and (c) not use Confidential Information for any purpose other than to perform its obligations, or exercise its rights, herein; provided, however, that the obligations of confidentiality for Confidential Information identified as a trade secret will survive indefinitely until such trade secret information no longer qualifies as a trade secret.

20.3. Neither party shall disclose the existence of this Agreement or any terms or conditions thereof to any third parties without the prior written consent of the other party with respect to any intended disclosure and in the event of any permitted disclosure, the other party shall approve the content of such disclosure; provided, however, that BUYER shall have the right to disclose the existence of this Agreement and the terms of this Agreement to its actual or prospective investors, lenders, acquirers, collaborators, licensors, (sub) licensees or strategic partners, and their respective accountants, financial advisors and other professional representatives, in each case, who have a need to know such Confidential Information and are bound by customary obligations of confidentiality.

20.4. The confidentiality and non-use obligations set forth in this Section 20 shall not apply to information that Receiving Party can demonstrate: (a) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the Receiving Party, its Affiliates, their employees, consultants, agents, subcontractors or sublicensees; (b) becomes available to the Receiving Party from a third party which is not legally prohibited from disclosing such information; (c) was developed by the Receiving Party independently of information obtained from the Disclosing Party as evidenced by written records; (d) was already known to the Receiving Party before receipt from the Disclosing Party, as evidenced by its prior written records; (e) is released with the prior written consent of the Disclosing Party; or (f) is required to comply with national, federal or state laws, rules or regulations (including the rules and regulations of any national stock exchange on which such party's securities are traded), provided that the Receiving Party promptly notifies the Disclosing Party of such required disclosure, takes all reasonable and lawful actions to obtain confidential treatment of such disclosure and furnishes only that portion of the Confidential Information which is legally required to be disclosed. In determining whether or not the Disclosing Party's Confidential Information has entered the public domain, the obligations of confidentiality shall no longer apply to only that portion of said Confidential Information that has become public, and portions remaining confidential shall retain their status as Confidential Information.

20.5. Upon termination or expiration of this Agreement, or at any other time upon the request of the Disclosing Party, the Receiving Party shall, as requested by the Disclosing Party in writing, promptly return to the Disclosing Party or destroy all of the Confidential Information of the Disclosing Party in its possession or control, except that one (1) copy may be retained by the Receiving Party solely for record-keeping purposes.

21. NOTICES

Any notice required or permitted to be given under this Agreement by any party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with documented evidence of transmission), to the addresses or facsimile numbers of the other party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any party in accordance with the provisions of this Section 21. The effective date of any notice under this Agreement shall be the date of receipt by the receiving party.

If to BUYER:

For invoices:

Deciphera Pharmaceuticals, LLC
200 Smith Street
Waltham, Massachusetts 02451
Attn: Chief Technical Officer

For other:

Deciphera Pharmaceuticals, LLC

200 Smith Street
Waltham, Massachusetts 02451
Attn: Legal

If to SUPPLIER:

Cambrex [***]

With a copy to:

Cambrex Corporation
One Meadowlands Plaza, 15th floor
East Rutherford, NJ 07073
Attn: General Counsel
Facsimile: [***]

22. ENTIRE AGREEMENT, MODIFICATION; OTHER FORMS

22.1. This Agreement constitutes the entire agreement between the parties, and it is expressly agreed that any and all prior representations, negotiations, understandings or agreements relating to the subject matter of this Agreement, whether oral or written, are automatically canceled by the execution of this Agreement. The terms and conditions set forth herein may only be modified or waived in a subsequent writing signed by both parties. The waiver by any party hereto of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

22.2. The parties recognize that, during the Term of this Agreement, a purchase order, acknowledgment form or similar routine document (collectively, “Forms”) and/or the Quality Agreement may be used to implement or administer provisions of this Agreement. Therefore, the parties agree that the terms of this Agreement, together with any amendments hereto, shall prevail in the event of any conflict between the express terms of this Agreement and any statements or provisions contained in the Forms. The parties further agree that any pre-printed terms or conditions contained in a purchase order (or other Form) are null and void and are not binding on the parties.

23. HEADINGS

All headings in this Agreement are for convenience of reference only and shall not be deemed to constitute part of this Agreement or to affect the construction or interpretation of this Agreement.

24. EXHIBITS

All exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

25. COUNTERPARTS

This Agreement may be executed in any number of counterparts by original, facsimile or ".pdf" signature, each such counterpart shall be an original instrument, and all such counterparts together shall constitute one and the same agreement.

26. ASSIGNMENT

This Agreement shall be binding upon the successors and assigns of the parties and the name of a party appearing herein shall be deemed to include the names of its successors and assigns. Neither party may assign its interest under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld; provided, however, that either party may assign its rights and obligations under this Agreement, without the prior written consent of the other party, (a) in connection with the transfer or sale of all or substantially all of the assets of such party or the line of business or API to which this Agreement relates, (b) to the successor entity or acquiror in the event of the merger, consolidation or change of control of such party, or (c) to any Affiliate of such party or (d) in the case of BUYER, to a collaborator or licensee of the Product; provided, in each case of '(a)'-'(c)', that such assignee agrees in writing to comply with all the terms and conditions contained in this Agreement. Any assignment of this Agreement permitted by prior written consent will be conditioned upon such permitted assignee agreeing in writing to comply with all the terms and conditions contained in this Agreement. Any purported assignment without a required consent shall be void. No assignment shall relieve any party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

27. SEVERABILITY

If any part of this Agreement shall be found to be invalid, illegal, or unenforceable under applicable law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is found to be invalid, illegal, unenforceable under applicable law in any jurisdiction shall be reformed in a mutually agreeable manner so as to (a) conform to the applicable laws of such jurisdiction, and (b) as nearly approximate the original intent of the parties as possible. If the offending provision cannot be so reformed without materially altering the original intent of the parties: (a) it shall be stricken, and (b) the parties shall discuss in good faith possible changes to this Agreement to conform as close as possible to the parties' original intent without the unenforceable provision.

28. INDEPENDENT CONTRACTOR

The relationship between BUYER and SUPPLIER hereunder is that of an independent contractor. Neither party shall have any power, right, or authority to bind or obligate the other party, or represent itself as the other party's agent or representative. Further, neither party shall contact or communicate with the other party's customers in any manner or for any reason unless the other party shall have consented thereto in advance.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

BUYER

DECIPHERA PHARMACEUTICALS, LLC

By:___/s/ Steve Hoerter_____

Title:__President & CEO_____

SUPPLIER

CAMBREX [***]

By:____[***]_____

Title: ___[***]_____

EXHIBIT 1

TABLE 1

PRICE OF API
DCC-2618

Size of Campaign	Price per kg of API supplied in USD ($)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The prices listed above include Raw Materials but are exclusive of the costs of the RSMs listed in Exhibit 1, Table 2.

EXHIBIT 1

TABLE 2

RSMs FOR DCC-2618

[***]

EXHIBIT 2

SPECIFICATIONS

[Exhibit begins on following page]

[***]

EXHIBIT 3

As of the Effective Date, the Expected Yield will be [***]

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

THIS AMENDMENT NO. 1 ("**Amendment 1**") is made effective as of **June 10, 2020** ("**Amendment 1 Effective Date**") by and between **Deciphera Pharmaceuticals, LLC** with offices located at 200 Smith Street, Waltham, MA 02451 ("**Company**") and Thomas P. Kelly ("**Executive**")**.**

BACKGROUND. Company and Executive have entered into and executed an Employment Agreement dated October 17, 2017 (the "**Agreement**") and following a review of executive compensation by the Board of Directors of Deciphera Pharmaceuticals, Inc., the Parties desire to amend the Agreement to revise certain Change in Control benefits.

NOW THEREFORE, intending to be legally bound, the Parties agree as follows:

1. Section 5(a)(i) of the Agreement is hereby deleted and replaced in its entirety as follows: "the Company shall pay the Executive a lump sum amount equal to one-and-a-half (1.5) times the sum of (A) the Executive's then current Base Salary plus (ii) the Executive's Target Annual Cash Incentive Compensation for the then-current year."

2. The reference to "12 months" of COBRA health continuation payments in Section 5(a)(ii)(i) of the Agreement shall be changed to "18 months."

3. All capitalized terms used, but not otherwise defined, in this Amendment 1 will have the same meaning given to them in the Agreement. All references to "Agreement" in the Agreement and this Amendment 1 are deemed to include this Amendment 1.

4. Except as specifically set forth in this Amendment 1, the Agreement remains unchanged and in full force and effect.

IN WITNESS WHEREOF, each Party has caused this Amendment 1 to be executed as of the Amendment 1 Effective Date.

Deciphera Pharmaceuticals, LLC	**EXECUTIVE**
By:_____	_____
Name: Steven Hoerter	Name: Thomas P. Kelly
Title: President and Chief Executive Office	

Exhibit 31.1

CERTIFICATIONS

I, Steven L. Hoerter, certify that:

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

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

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

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

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

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

Date: August 4, 2020

By: /s/ Steven L. Hoerter

Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Thomas P. Kelly, certify that:

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

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

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

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

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

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

Date: August 4, 2020

By: /s/ Thomas P. Kelly

Thomas P. Kelly

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven L. Hoerter, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 4, 2020

By: /s/ Steven L. Hoerter

Steven L. Hoerter
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas P. Kelly, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 4, 2020

By: /s/ Thomas P. Kelly

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