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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 April 30, 2020 there were 55,859,274 shares of Common Stock, $0.01 par value per share, outstanding.

Deciphera Pharmaceuticals, Inc.

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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:

- the success, cost, and timing of our product development activities and clinical trials, including the timing of our ongoing Phase 3 trial of ripretinib for the treatment of second line gastrointestinal stromal tumors (GIST) patients and results therefrom;
- our ability to obtain and maintain regulatory approval for ripretinib or any of our other current or future drug candidates, and any related restrictions, limitations, and/or warnings in the label of an approved drug candidate;
- our expectations regarding the size of target patient populations for our drug candidates, if approved for commercial use, and any additional drug candidates we may develop;
- our ability to obtain funding for our operations;
- our ability to manufacture or obtain sufficient quantities of our drug candidates, including, without limitation, ripretinib, on a timely basis, to support our planned clinical trials and, if approved, commercialization;
- our commercial preparedness efforts and our ability to be ready for commercial launch upon approval of a drug candidate, including, without limitation, ripretinib;
- the commercialization of our drug candidates, if approved;
- our plans to research, develop, and commercialize our drug candidates, including the timing of our ongoing Phase 3 trial of ripretinib 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, if approved, commercialize ripretinib 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 our drug candidates;
- future agreements with third parties in connection with the commercialization of ripretinib, if approved, or any of our other current or future drug candidates;
- the size and growth potential of the markets for our drug candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our drug candidates as well as the reimbursement coverage for our drug candidates, and the extent to which patient assistance programs are utilized;
- regulatory and legal developments in the United States (U.S.) and foreign countries;
- 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 recent outbreak of the novel coronavirus (COVID-19), which could harm our potential future commercialization efforts as well as the value of our common stock and the 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;
- the benefits of U.S. Food and Drug Administration (FDA) designations such as Fast Track and Breakthrough Therapy or priority review, and review of our New Drug Application (NDA) under the FDA's Oncology Center of Excellence (OCE) pilot program, Real-Time Oncology Review (RTOR), and the FDA's Project Orbis initiative (Project Orbis);
- the timing or likelihood of approval of our NDA submission to the FDA in the U.S., our New Drug Submission (NDS) with Health Canada, or our market authorisation application (AUS MAA) with the Therapeutic Goods Administration (TGA) in Australia, for ripretinib, and potential regulatory approval for and commercial launch of ripretinib in these jurisdictions;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act); and
- our use of the proceeds from our initial public offering and 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 229,652	$ 120,320
Marketable securities	461,848	459,256
Prepaid expenses and other current assets	11,979	13,832
Total current assets	703,479	593,408
Long-term investment—restricted	2,125	1,510
Property and equipment, net	6,693	6,333
Operating lease assets	20,630	21,158
Total assets	$ 732,927	$ 622,409
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,337	$ 19,575
Accrued expenses and other current liabilities	32,234	38,716
Operating lease liabilities	1,501	1,747
Total current liabilities	45,072	60,038
Operating lease liabilities, net of current portion	15,595	15,904
Total liabilities	60,667	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; 55,681,027 shares and 51,617,639 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	557	516
Additional paid-in capital	1,231,726	1,033,819
Accumulated other comprehensive income (loss)	763	111
Accumulated deficit	(560,786)	(487,979)
Total stockholders' equity	672,260	546,467
Total liabilities and stockholders' equity	$ 732,927	$ 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 March 31,	
	2020	2019
Revenues	$ 62	$ —
Operating expenses:		
Research and development	51,388	35,789
Selling, general, and administrative	23,936	13,236
Total operating expenses	75,324	49,025
Loss from operations	(75,262)	(49,025)
Other income (expense):		
Interest and other income, net	2,455	1,654
Interest expense	—	(13)
Total other income (expense), net	2,455	1,641
Net loss	$ (72,807)	$ (47,384)
Net loss per share—basic and diluted	$ (1.36)	$ (1.25)
Weighted average common shares outstanding—basic and diluted	53,567,434	38,057,018
Comprehensive loss:		
Net loss	$ (72,807)	$ (47,384)
Other comprehensive income (loss):		
Unrealized gains (losses) on marketable securities	652	21
Total other comprehensive income (loss)	652	21
Total comprehensive loss	$ (72,155)	$ (47,363)

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, 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	—	—	404,298	4	2,565	—	—	2,569
Stock-based compensation expense	—	—	—	—	6,994	—	—	6,994
Unrealized gains (losses) on marketable securities	—	—	—	—	—	652	—	652
Net loss	—	—	—	—	—	—	(72,807)	(72,807)
Balance, March 31, 2020	—	$ —	55,681,027	$ 557	$ 1,231,726	$ 763	$ (560,786)	$ 672,260

	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	—	—	512,292	5	1,144	—	—	1,149
Stock-based compensation expense	—	—	—	—	6,229	—	—	6,229
Unrealized gains (losses) on marketable securities	—	—	—	—	—	21	—	21
Net loss	—	—	—	—	—	—	(47,384)	(47,384)
Balance, March 31, 2019	—	$ —	38,189,052	$ 382	$ 582,700	$ 21	$ (343,107)	$ 239,996

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

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

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (72,807)	$ (47,384)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Stock-based compensation expense	6,994	6,229
Depreciation expense	460	104
Net accretion of discounts on marketable securities	(1,532)	(486)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,853	3,170
Operating lease assets	528	143
Accounts payable	(8,511)	2,629
Accrued expenses and other current liabilities	(6,800)	2,637
Operating lease liabilities	(555)	(148)
Other long-term liabilities	—	100
Net cash flows used in operating activities	(80,370)	(33,006)
Cash flows from investing activities:		
Purchases of marketable securities	(203,527)	(179,607)
Maturities of marketable securities	203,120	—
Purchases of property and equipment	(669)	(41)
Increase in restricted investments	(614)	—
Net cash flows used in investing activities	(1,690)	(179,648)
Cash flows from financing activities:		
Proceeds from public offerings, net of underwriting discounts and commissions	189,175	—
Repayment of notes payable to related party	—	(31)
Payments of public offering costs	(352)	—
Proceeds from exercise of stock options	2,569	1,149
Net cash flows provided by financing activities	191,392	1,118
Net increase (decrease) in cash and cash equivalents	109,332	(211,536)
Cash and cash equivalents at beginning of period	120,320	293,764
Cash and cash equivalents at end of period	$ 229,652	$ 82,228
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 13
Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities	$ 152	$ —
Offering costs included in accounts payable and accrued expenses and other current liabilities	$ 438	$ —

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 clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. The Company's small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. The Company uses its understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic-resistance-causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. The Company has used its platform to develop a 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 three clinical-stage, one preclinical-stage, and one research-stage program. The Company wholly owns all of its drug candidates with the exception of a development and commercialization out-license agreement for the Company's lead drug candidate, ripretinib, 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, protection of proprietary technology, ability to complete late-stage clinical trials, ability to obtain and maintain regulatory approvals, ability to prepare for and successfully launch drug candidates that are approved for marketing, 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. Drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and/or clinical testing and regulatory approval, as well as further development of the Company's commercial capabilities and infrastructure, prior to commercialization for the Company's drug candidates, including ripretinib, if approved. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The 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 future commercialization efforts, will depend on future developments, which are highly uncertain and cannot be predicted at this time, including the scope, severity, and duration of such pandemic, 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 monitoring the potential impact of COVID-19, if any, on its financial condition and results of operations. The rapid development and 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 candidates for its clinical trials and potential commercial launch, 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 a potential product launch.

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 $72.8 million and $192.3 million for the three months ended March 31, 2020 and the year ended December 31, 2019, respectively. As of March 31, 2020, the Company had an accumulated deficit of $560.8 million. The Company expects to continue to generate operating losses in 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 expects its expenses to increase in connection with ongoing activities, particularly as the Company advances its clinical trials for its drug candidates in development and engages in efforts to support commercialization should ripretinib receive regulatory approval. Accordingly, the Company will need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce, or eliminate its research or drug development programs or any future 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 United States (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 March 31, 2020 and for the three months ended March 31, 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 March 31, 2020 and consolidated results of operations and comprehensive loss for the three months ended March 31, 2020 and 2019 and consolidated cash flows for the three months ended March 31, 2020 and 2019 have been made. The consolidated results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

Other than those discussed within the section "Recently Issued Accounting Pronouncements", the significant accounting policies used in preparation of these consolidated financial statements for the three months ended March 31, 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.

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 revenue 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.

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

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 months ended March 31, 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 March 31,	
	2020	2019
Options to purchase common stock	7,339,747	6,713,029
Unvested time-based restricted common stock units	283,690	77,000
Unvested performance-based restricted common stock units	57,000	—
Total	7,680,437	6,790,029

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. License Agreement

Zai License Agreement

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 ripretinib, 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

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

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.

No revenues were recognized under the Zai License Agreement during the three months ended March 31, 2020 or 2019.

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 ripretinib 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.

Under the Zai Supply Agreement, the Company recognized revenues of $0.1 million associated with external manufacturing services provided during the three months ended March 31, 2020. As of March 31, 2020, receivables of $0.1 million related to external manufacturing services were included within prepaid expenses and other current assets in the consolidated balance sheets.

3. Marketable Securities and Fair Value Measurements

The following tables present marketable securities by security type:

As of March 31, 2020 (in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper (due within one year)	$ 270,577	$ 174	$ (115)	$ 270,636
U.S. Government securities (due within one year)	134,685	608	—	135,293
Certificates of deposit (due within one year)	45,836	84	—	45,920
Other debt securities (due within one year)	9,987	12	—	9,999
Total	$ 461,085	$ 878	$ (115)	$ 461,848

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

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

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

As of March 31, 2020 (in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 93,156	$ —	$ 93,156
U.S. Government Securities	—	21,900	—	21,900
Certificates of deposit	—	17,508	—	17,508
Commercial paper	—	16,495	—	16,495
Marketable securities:				
Commercial paper	—	270,636	—	270,636
U.S. Government securities	—	135,293	—	135,293
Certificates of deposit	—	45,920	—	45,920
Other debt securities	—	9,999	—	9,999
Total	$ —	$ 610,907	$ —	$ 610,907

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

The table above excludes certificates of deposit totaling $2.1 million and $1.5 million as of March 31, 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 investment—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 March 31, 2020	As of December 31, 2019
External research and development expenses	$ 22,979	$ 20,462
Payroll and related expenses	5,331	12,902
Professional fees	3,153	3,810
Other	771	1,542
Total accrued expenses and other current liabilities	$ 32,234	$ 38,716

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

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 March 31, 2020, 1,878,252 shares of common stock were available for issuance under the 2017 Plan. As of March 31, 2020, 1,409,433 shares of common stock were available for issuance to participating employees under the ESPP.

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

	Three Months Ended March 31,	
(in thousands)	**2020**	**2019**
Research and development expenses	$ 3,271	$ 1,692
Selling, general, and administrative expenses	3,723	4,537
Total stock-based compensation	$ 6,994	$ 6,229

As of March 31, 2020, total unrecognized compensation cost related to the unvested share-based awards was $102.4 million, which is expected to be recognized over a weighted average of 2.9 years. During the three months ended March 31, 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.

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.

Lease and Associated Letter of Credit

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. In addition to paying its share of operating expenses, taxes, and other expenses related to the additional leased premises, the Company will also be required to increase the amount of cash to secure its letter of credit associated with its lease at the Premises upon substantial completion. As of March 31, 2020, the Company had not been required to record an operating lease asset or any lease liabilities associated with this lease within its consolidated balance sheets or increase the amount of cash related to the letter of credit. For additional information, please read Note 6, *Leases*, to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2019.

Purchase Commitments Associated with Commercial Supply Agreements

The Company has entered into commercial supply agreements related to the supply of ripretinib that require the Company to make binding forecasts for a certain amount of purchases. The related cancellation clauses would as a general matter require the Company to pay the full amount of these binding forecasts. As of March 31, 2020, the Company's contractual commitments for such obligations were $4.6 million, which are expected to be paid within one year.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the

authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred.

Indemnification Agreements

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

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 clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic-resistance-causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. 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 three clinical-stage, one preclinical-stage, and one research-stage program. We wholly own all of our drug candidates with the exception of a development and commercialization out-license agreement for our lead drug candidate, ripretinib, in the Greater China region.

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. We do not have any products approved for sale and have not generated any 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 development and eventual commercialization of one or more of our drug candidates. Our net loss was $72.8 million for the three months ended March 31, 2020 and $192.3 million for the year ended December 31, 2019. As of March 31, 2020 we had an accumulated deficit of $560.8 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase in connection with our ongoing activities, particularly as we:

- continue enrollment in and proceed with the expansion cohorts of our Phase 1 clinical trial for ripretinib;
- continue with our ongoing pivotal Phase 3 clinical trial of ripretinib;
- 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 and initiate additional clinical trials;
- seek marketing approval for any of our drug candidates that successfully complete clinical development, including ripretinib;
- 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 our drug candidates, including ripretinib, 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.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our drug candidates. As we continue to seek regulatory approval for our drug candidates, including ripretinib, we expect to incur significant expenses related to developing and maintaining 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. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations 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, 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 product sales, 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 March 31, 2020, we had cash, cash equivalents, and marketable securities of $691.5 million. We believe that our cash, cash equivalents, and marketable securities as of March 31, 2020, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone payments, royalty payments, or

payments for external manufacturing services, if any, that we may receive pursuant to our license and supply agreements with Zai. For additional information, please read the "Liquidity and Capital Resources" section included below.

Recent Developments

Equity Offering

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. For additional information, please read the "Overview" section included above.

Coronavirus (COVID-19)

The 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 future commercialization efforts will depend on future developments, which are highly uncertain and cannot be predicted at this time, including the scope, severity, and duration of such pandemic, 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 rapid development and 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 candidates for our clinical trials and potential commercial launch, disruptions in health regulatory agencies' operations globally, the volatility of our common stock, and our ability to access capital markets, and our ability to successfully launch, commercialize, and generate revenue from a potential product launch.

We are actively monitoring the evolving impact of COVID-19 on our business operations in an effort to mitigate interruption to our clinical programs, research efforts, 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. Additional, more restrictive orders, proclamations, and/or directives may be issued in the future. As a result of these developments, in early March 2020, we began precautionary measures to protect the health and safety of our employees, partners, and patients during the COVID-19 pandemic, including the adoption of a work-from-home policy for our employees with limited exceptions for certain business-critical activities including ongoing laboratory research activities. For business-critical employees, we have implemented appropriate safety measures designed to comply with federal, state, and local guidelines.

In addition, we are actively monitoring 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 imposed 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 are working closely with our study sites and CROs to allow for utilization of remote and local assessments, such as televisits, in accordance with recent 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, we cannot guarantee that COVID-19 precautions, or the impact of the pandemic, will not directly or indirectly affect the expected timelines for some of our clinical trials.

At this stage of the COVID-19 pandemic, the operating environment remains fluid and uncertain, and our outlook is based on the assumption that the most severe impacts are of a short-term nature over the next few months, rather than a prolonged and sustained disruption to everyday life.

As of this time, while there has been a slowdown in patient enrollment in the current environment, we currently expect to achieve our previously stated clinical milestones in the second half of 2020, including:

- full enrollment in our Phase 3 INTRIGUE study in second-line GIST patients;
- updated clinical data for DCC-3014 from the dose escalation portion of the study in patients with tenosynovial giant cell tumor (TGCT), and both of the Phase 1b/2 studies in our rebastinib program;
- selection of a Phase 2 dose for DCC-3014 and opening the expansion portion of the study in TGCT patients; and

- filing of an IND for DCC-3116, our ULK kinase inhibitor.

In addition, we believe we have commercial drug supply sufficient to support the potential launch of ripretinib in fourth-line GIST. Based on current inventories and plans, we do not anticipate any COVID-19-related supply interruptions to our clinical programs at this time.

Given the evolving landscape, we have also been preparing for a potential launch of ripretinib in a healthcare environment with limited to no physical, in-person promotional activities and therefore we have been preparing for the possible need to launch and promote using a virtual interaction model, if necessary.

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.

Ripretinib Development Update

We are studying our lead drug candidate, ripretinib, in INTRIGUE, our ongoing Phase 3 study, to evaluate ripretinib compared to sunitinib in 426 patients in second-line GIST, and in an ongoing Phase 1 trial in patients with multiple advanced malignancies, including GIST. In December 2019, we submitted a NDA to the FDA for ripretinib, for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. Our NDA is based on positive results from our first Phase 3 study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies in the U.S. other than avapritinib which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated to be approximately 6% of all patients with newly-diagnosed GIST).

In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with fourth-line and fourth-line plus GIST, granted priority review and set an action date of August 13, 2020, under the Prescription Drug User Fee Act (PDUFA).

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.

Rebastinib in combination with paclitaxel: In May 2020, we announced that we have observed in the paclitaxel combination study the required number of responses 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.

Rebastinib in combination with carboplatin: In January 2020, we activated Part 2 of this Phase 1b/2 study in combination with carboplatin. We continue to enroll patients with breast cancer, ovarian cancer, and mesothelioma in Part 2 of the study at the recommended Phase 2 dose of 50 mg twice daily (BID), which was reduced from 100 mg BID based on the observed frequency of muscular weakness in preliminary data from the ongoing Part 2 portion of the study.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and may not generate any revenue from the sale of products in the near future, if ever. If our development efforts for our drug candidates are successful and result in regulatory approval, including ripretinib, we may generate revenue in the future from product sales. 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, if any, in the near future will be derived primarily from the license agreement (the Zai License Agreement) and supply agreement (the Zai Supply Agreement) 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 predict if, when, or to what extent we will generate revenue from the commercialization and sale of our drug candidates. We may never succeed in obtaining regulatory approval for any of our drug candidates.

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 ripretinib, including certain follow-on compounds (the Licensed Products) 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.

No revenues were recognized under the Zai License Agreement during the three months ended March 31, 2020 or 2019.

The next development milestone under the Zai License Agreement that we may achieve in the future would be upon the submission of the Regulatory Approval Application by Zai in the People's Republic of China for ripretinib for fourth-line GIST. If this milestone is achieved, we would be entitled to receive a $2.0 million payment.

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 associated with external manufacturing services provided during the three months ended March 31, 2020.

We do not expect to recognize significant revenues associated with external manufacturing services during 2020.

Operating Expenses

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 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 manufacturing of ripretinib inventory to be sold if ripretinib is approved by the FDA; 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.

The successful development and commercialization of our 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 our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection, and regulatory exclusivity for our drug candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others such as Zai, our licensee for ripretinib in the Greater China region;
- acceptance of our 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 products following approval.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate. We may never succeed in obtaining regulatory approval for any of our drug candidates.

Research and development activities are central to our business model. 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 for the foreseeable future as our 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 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 in the future as we increase our headcount to support our continued research activities and development of our drug candidates and to support commercialization should ripretinib receive regulatory approval. 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 months ended March 31, 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 March 31, 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 of our critical accounting policies described under the heading "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, the following involve the most judgment and complexity:

- 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.

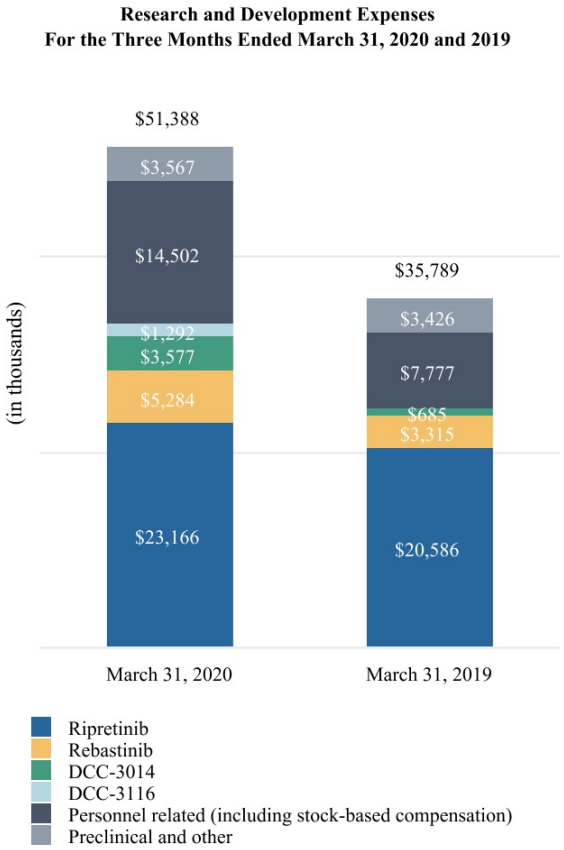
Results of Operations

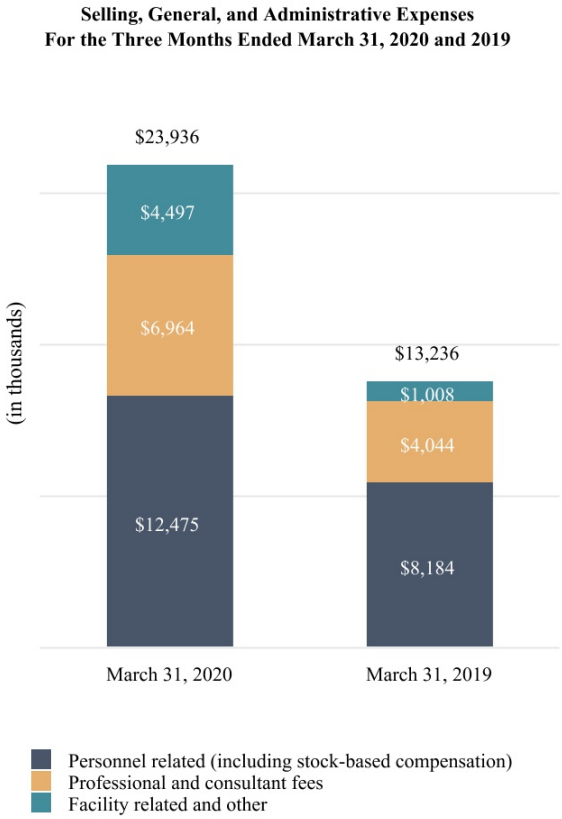
Comparison of the Three Months Ended March 31, 2020 and 2019

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
(in thousands)	**2020**	**2019**
Revenues	$ 62	$ —
Operating expenses:		
Research and development	51,388	35,789
Selling, general, and administrative	23,936	13,236
Total operating expenses	75,324	49,025
Loss from operations	(75,262)	(49,025)
Other income (expense):		
Interest and other income, net	2,455	1,654
Interest expense	—	(13)
Total other income (expense), net	2,455	1,641
Net loss	$ (72,807)	$ (47,384)

Operating Expenses





Research and Development Expenses

Ripretinib

For the three months ended March 31, 2020 and 2019, expenses related to our ripretinib program increased primarily as a result of an increase in manufacturing costs of $2.8 million. Manufacturing costs for the ripretinib program increased primarily as a result of increased activities to support anticipated drug requirements for commercialization and clinical trials. Clinical trial expenses for the ripretinib program decreased $0.1 million during the three months ended March 31, 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 with respect to which we filed an NDA in December 2019, partially offset by increased costs related to our pivotal Phase 3 trial in second-line GIST, INTRIGUE, which we initiated in December 2018 and which is ongoing.

Rebastinib

For the three months ended March 31, 2020 and 2019, expenses related to our rebastinib program increased primarily as a result of an increase in clinical trial costs of $1.1 million and manufacturing costs of $0.8 million. The increase in clinical trial costs was 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-3014

For the three months ended March 31, 2020 and 2019, expenses related to our DCC-3014 program increased primarily as a result of an increase in clinical trial costs of $1.0 million, an increase in manufacturing costs of $1.0 million, and an increase in preclinical costs of $0.8 million. The increase in clinical trial costs was due primarily 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 increase in preclinical costs was primarily due to ongoing studies.

DCC-3116

For the three months ended March 31, 2020 and 2019, expenses related to our DCC-3116 program increased as a result of preclinical activities, including IND-enabling studies, related to this new drug candidate, which we announced as an addition to our pipeline in June 2019.

Unallocated Expenses

For the three months ended March 31, 2020 and 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 for the three months ended March 31, 2020 and 2019 included stock-based compensation expense of $3.3 million and $1.7 million, 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. The increase in preclinical and other costs included in unallocated expenses was primarily due to increased consultant fees of $0.6 million.

We expect research and development expenses will continue to increase during 2020 as compared to 2019 as we continue to expand our clinical development activities.

Selling, General, and Administrative Expenses

For the three months ended March 31, 2020 and 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 for the three months ended March 31, 2020 and 2019 included stock-based compensation expense of $3.7 million and $4.5 million, respectively. The decrease in stock-based compensation expense was primarily related to the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer during the three months ended March 31, 2019 resulting in expense of $2.4 million, which was partially offset by increased headcount and increased valuations of share-based awards granted to our employees during the three months ended March 31, 2020. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness. The increase in facility related and other costs was primarily due to increased expenses incurred in connection with our new headquarters that commenced in October 2019 and technology related costs to support the growth of the business.

We expect selling, general, and administrative expenses will continue to increase during 2020 as compared to 2019 as we continue to build our commercial organization.

Interest and Other Income, Net

For the three months ended March 31, 2020 and 2019, the increase in interest and other income, net, was primarily due to an increase in interest income earned on our invested cash, cash equivalents, and marketable securities balances resulting from 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 license and supply agreements with Zai, a concluded collaboration agreement, and research and development grants from the KBA. We have not yet commercialized any of our drug candidates and 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, ripretinib, or our other 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 March 31, 2020, our principal sources of liquidity were cash, cash equivalents, and marketable securities of $691.5 million.

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

	Three Months Ended March 31,	
(in thousands)	**2020**	**2019**
Cash flows used in operating activities	$ (80,370)	$ (33,006)
Cash flows used in investing activities	(1,690)	(179,648)
Cash flows provided by financing activities	191,392	1,118
Net increase (decrease) in cash and cash equivalents	$ 109,332	$ (211,536)

Operating Activities

During the three months ended March 31, 2020, operating activities used $80.4 million of cash, primarily resulting from our net loss of $72.8 million and cash used in changes in our operating assets and liabilities of $14.0 million, partially offset by net non-cash charges of $5.9 million, primarily resulting from share-based compensation expense of $7.0 million. Net cash used in changes in our operating assets and liabilities for the three months ended March 31, 2020 consisted primarily of a $15.3 million decrease in accounts payable and accrued expenses and other current liabilities, partially offset by a decrease in prepaid expenses and other current assets of $1.9 million. Changes in accounts payable, accrued expenses, and prepaid expenses were generally due to the timing of vendor invoicing and payments.

During the three months ended March 31, 2019, operating activities used $33.0 million of cash, primarily resulting from our net loss of $47.4 million, offset by non-cash charges of $5.8 million and cash provided by changes in our operating assets and liabilities of $8.4 million. Net cash provided by changes in our operating assets and liabilities for the three months ended March 31, 2019 consisted primarily of a $5.3 million increase in accounts payable and accrued expenses and other liabilities, partially offset by an increase in prepaid expenses and other current assets of $3.2 million. Changes in accounts payable, accrued expenses, and prepaid expenses were generally due to growth in our business.

Investing Activities

During the three months ended March 31, 2020, investing activities used $1.7 million of cash, consisting of $0.7 million to purchase property and equipment, an increase in our restricted investments by $0.6 million to increase our Company credit card limit to support the growth of the business, and $0.4 million for the net purchases of marketable securities.

During the three months ended March 31, 2019, investing activities used $179.6 million of cash, primarily consisting of $179.6 million for the net purchases of marketable securities.

Financing Activities

During the three months ended March 31, 2020, net cash provided by financing activities was $191.4 million, consisting of proceeds from our follow-on public offering in February 2020, net of underwriting discounts and commissions, of $189.2 million and the exercise of stock options of $2.6 million, partially offset by $0.4 million of payments of offering costs.

During the three months ended March 31, 2019, net cash provided by financing activities was $1.1 million, primarily consisting of proceeds from the exercise of stock options of $1.1 million.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance clinical trials for our drug candidates in development and engage in efforts to support commercialization, should ripretinib receive regulatory approval. In addition, we expect to incur additional costs associated with supporting the growth of the business and continued operations as a public company. 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 timing and outcome of regulatory review of our 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, if any of our drug candidates are approved, 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 future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our drug candidates for which we obtain marketing approval, and advance preparations therefor;
- 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 March 31, 2020, we had cash, cash equivalents, and marketable securities of $691.5 million. We believe that our cash, cash equivalents, and marketable securities as of March 31, 2020, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone payments, royalty payments, or payments for external manufacturing services, if any, that we may receive pursuant to our license and supply agreements with Zai. 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 such time, if ever, as we can generate substantial product revenues, we expect to finance our operations 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 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 future commercialization efforts or planning or grant rights to develop and market 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 ripretinib 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 March 31, 2020, our contractual commitments for such obligations were $4.6 million, which are expected to be paid within one year.

As of March 31, 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 March 31, 2020 consisted of cash, money market funds, commercial paper, certificates of deposit, U.S. government securities, and other debt securities. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. 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 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 March 31, 2020, we estimate that such hypothetical 100 basis point adverse movement would result in a hypothetical loss in fair value of approximately $4.6 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 one financial institution 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.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 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 March 31, 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 any 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 are a clinical-stage biopharmaceutical company that was formed and commenced operations in 2003. We have no approved products for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and have incurred losses in each year since inception. For the three months ended March 31, 2020 and the year ended December 31, 2019, we reported a net loss of $72.8 million and $192.3 million, respectively. As of March 31, 2020, we had an accumulated deficit of $560.8 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 our drug candidates, ripretinib, DCC-3014, rebastinib, and DCC-3116, as well as our ongoing preclinical research and discovery programs. To date, we 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 March 31, 2020, our cash, cash equivalents, and marketable securities were $691.5 million.

We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future, particularly as we advance our 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 our research and development expenses to significantly increase in connection with our ongoing and additional clinical trials for ripretinib, 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, if we obtain marketing approval for ripretinib, or any of our other drug candidates, we will incur significant sales, marketing, and outsourced manufacturing expenses. We have and will continue to incur costs associated with advance preparations for a possible marketing approval for ripretinib. We have and will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing 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 any revenue from our drug candidates, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, ripretinib, or our other drug candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our second Phase 3 clinical trial of ripretinib 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 ripretinib as a treatment for GIST or other indications;

- obtain marketing approval for ripretinib in the U.S. pursuant to our NDA, and, subject to obtaining favorable results from our Phase 3 trial for ripretinib 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 ripretinib in the European Union (EU);
- successfully manufacture or contract with others to manufacture ripretinib and our other drug candidates;
- commercialize ripretinib, if approved, by building and deploying a sales force and marketing ripretinib in the U.S. and other jurisdictions where we receive approval, assisting our licensee, Zai, in its efforts to develop and, if approved, commercialize ripretinib 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 ripretinib in the medical community and with third-party payors.

To become and remain profitable, we must succeed in developing, and eventually 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, if applicable, commercial supplies of our drug candidates, obtaining marketing approval for our drug candidates, and manufacturing, marketing, and selling any products for which we may obtain marketing approval. 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 will require substantial additional funding. If we are unable to raise capital when needed, or on attractive terms, we could be forced to delay, reduce, or eliminate our research or drug development programs or any future commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our drug candidates, ripretinib, 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 and commercial supplies of and seek marketing approval for our lead program and our other drug candidates. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. 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 any future commercialization efforts.

We believe that our cash, cash equivalents, and marketable securities as of March 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2022. This excludes any potential milestone payments, royalty payments, or payments for external manufacturing services, if any, that we may receive pursuant to our license and supply agreements with Zai. 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 ripretinib;
- the scope, progress, costs, and results of drug discovery, preclinical development, and clinical trials for our other drug candidates;
- the number and development requirements of other 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, if applicable, commercial supplies of ripretinib and our other drug candidates;
- the costs, timing, and outcome of regulatory review of ripretinib and our other drug candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for ripretinib and any of our other 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 ripretinib and our other 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 other drug candidates, technologies, and associated intellectual property rights.

Identifying potential drug candidates and conducting preclinical testing and clinical trials 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 marketing approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available until the FDA approves those product candidates, if at all. 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 such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs 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 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 future commercialization efforts, or grant rights to develop and market 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 ripretinib, and have not generated revenue from product sales or profits. We may never obtain approval for any of our drug candidates or 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, and establishing arrangements with third parties for the manufacture of initial quantities of our drug candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials other than for ripretinib in fourth- and fourth-line plus GIST, obtain marketing approvals, timely manufacture ourselves or via a third party a commercial product on a commercial scale, or build a commercial organization and infrastructure and conduct sales, marketing and distribution activities necessary for successful product commercialization, and we have not generated 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 will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. 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 the Discovery and Development of Our Drug Candidates

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

We currently have no products that are approved for sale. While ripretinib is a later-stage asset with respect to fourth- and fourth-line plus GIST, we are early in our development efforts for ripretinib in other indications and for all of our other drug candidates. Two of our drug candidates are only in Phase 1 or Phase 1b/2 clinical trials. We initiated our first Phase 3 clinical trial for our lead drug candidate, ripretinib, in January 2018, for which we announced top-line data in August 2019, and our second Phase 3 clinical trial for ripretinib in second-line GIST in December 2018. In December 2019, we submitted a NDA to the FDA for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020, under the PDUFA.

All of our drug candidates target key interactions with kinase switch regions to inhibit kinase activity. There are no currently approved kinase switch control inhibitors and there can be no assurance that kinase switch control inhibitors will ever receive regulatory approval. 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 product revenues, which we do not expect will occur unless and until the FDA approves any of our product candidates, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our drug candidates. The success of our drug candidates, including ripretinib, will depend on several factors, 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 our drug candidates;
- obtaining and maintaining patent, trade secret, and other intellectual property protection and regulatory exclusivity for our 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 candidates;
- developing and implementing marketing and reimbursement strategies;

- establishing sales, marketing, and distribution capabilities and launching commercial sales of our drug candidates, if and when approved, whether alone and/or in collaboration with others, such as Zai, our licensee for ripretinib in Greater China, and building infrastructure to support such sales;
- acceptance of our 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 products 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 our drug candidates, 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 ripretinib or our ongoing Phase 1 clinical trial of ripretinib 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 drug candidates, including ripretinib, 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 ripretinib and our other drug candidates.

We currently have several drug candidates in clinical development and their risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. 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 ripretinib, the primary objectives were to determine the safety, tolerability, and maximum tolerated dose of ripretinib and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from the Phase 1 clinical trial of ripretinib were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of ripretinib, including our ongoing Phase 3 clinical trial. These factors also apply to the Phase 1 and Phase 1b/2 trials for our other drug candidates. We did not observe a maximum tolerated dose in the dose escalation stage of our Phase 1 trial of ripretinib. The FDA has stated that our initiation of Phase 3 clinical trials prior to the completion of our Phase 1 trial, and with limited dose-response information at the various dose levels, may place our development program at risk if we have not identified the optimal dosing regimen.

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 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 for our drug candidates 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 our drug candidates 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 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 candidates or other materials necessary to conduct clinical trials for our drug candidates 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 ripretinib 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 ripretinib have or develop mutations that confer resistance to treatment. We are aware of a secondary mutation in PDGFRα, in a patient not treated with ripretinib, where the potency of inhibition determined in *in vitro* assays by ripretinib suggests that this mutation may confer resistance to ripretinib in patients. We may identify additional mutations in PDGFRα or mutations in KIT that are resistant to ripretinib. If patients have or develop resistance to treatment with our drug candidates, we may be unable to successfully complete our clinical trials, and may not be able to obtain regulatory approval of, and commercialize, 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 of ripretinib 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 ripretinib 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 for our drug candidates. 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 and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and potential future 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 originated in Wuhan, China, and has since spread to a number of other countries, 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 is continually evolving and, as additional cases of the virus are identified, many countries, including the U.S., have reacted by instituting 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 reacted by instituting quarantines, restrictions on travel, "shelter in place" rules, restrictions on types of business that may continue to operate, and/or restrictions on the types of construction projects that may continue. For example, on March 23, 2020, the Governor of Massachusetts ordered all individuals living in the Commonwealth of Massachusetts to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts business, including our preclinical studies, clinical trial operations or future commercialization efforts will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, 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 rapid development and 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, and it may have the effect of heightening many of the risks described herein, including the below.

- 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, 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 recent 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 travel restrictions 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, 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 potential 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 potential commercial launch of any of our product candidates, if approved.
- We have closed our offices and requested that most of our personnel, including all of our administrative employees, work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given research and development laboratory. 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 further 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 other product 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 product 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 a drug candidate. For example, the FDA may find our actions, including the use of televisits and local labs 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.
- If any of our drug candidates are ultimately approved, our ability to successfully launch, commercialize and generate revenue from the product 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 our product candidates, if approved. While we have developed a virtual sales model, if necessary, to support a potential launch of ripretinib in the U.S., hospitals and other medical institutions have limited hospital access for non-patients, which would include our sales personnel. In addition, travel restrictions due to COVID-19 would impact the ability of our sales personnel to travel to customers. Recent industry surveys suggest in-person interactions between oncologists and sales representatives has declined dramatically. As a result, we would need to limit our interactions with physicians and patients and potentially use various technology-enabled platforms for virtual engagement such as remote detailing, digital and other non-personal marketing channels, telemedicine, and social media. These circumstances may adversely affect the ability of our sales professionals to effectively market our product, if approved, to physicians, which may have a negative impact on our potential 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.

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 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, potential commercialization efforts including any potential 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 ripretinib in fourth-line and fourth-line plus GIST, INVICTUS, 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 each indication of fourth-line and fourth-line plus GIST and second-line GIST, for a single randomized trial to support submission to the FDA of 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. 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 ripretinib, there have been 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 Phase 3 trials of ripretinib centrally reviewed. The results from our Phase 3 trials of ripretinib in which all data will be subject to central review may be less favorable than the results of our Phase 1 trial of ripretinib 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 candidates before a local regulatory authority will approve any marketing application. These local studies, if required, may involve, among other things, exploration of the effect our 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 ripretinib in anticipation of greater drug requirements for commercialization, if we obtain regulatory approval. If we are unable to manufacture sufficient quantities of ripretinib 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 ripretinib or our other 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 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 second Phase 3 clinical trial of ripretinib, 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 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 ripretinib 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 second Phase 3 trial. 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 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 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 ripretinib 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 candidates, we may need to abandon or limit our development of some of our drug candidates.

If our 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 Risk Evaluation and Mitigation Strategy (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 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 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 the Commercialization of Our Drug Candidates

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our 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 candidates, are based on estimates, which are inherently uncertain.

The total addressable market opportunity for ripretinib, 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 each such drug candidate, if our drug candidates are approved 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 drugs, 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.

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient 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 our drug candidates 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 our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, 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 of marketing and distribution support, including, without limitation, our own and that of our licensees and distributors;
- the existence of distribution and/or use restrictions, such as through a 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.

If we and/or our licensees are unable to successfully establish sales and marketing capabilities, we or our licensees may not be successful in commercializing our drug candidates if and when they are approved.

We have only recently established our sales and marketing infrastructure and have no experience in the sale, marketing, or distribution of biopharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to successfully establish sales, marketing, and distribution capabilities, either ourselves or through collaboration, licensing, distribution, or other arrangements with third parties. In addition, our licensee for ripretinib 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 continue to build our own focused, specialized sales and marketing organization in the U.S. Outside of the U.S., in addition to our existing ripretinib license to Zai for Greater China, we are currently exploring selectively establishing partnerships in markets outside the U.S. to support the commercialization of 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 and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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 continue to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate physicians about the benefits, safety, and effectiveness of any future approved products, in particular in light of current restrictions on 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 candidates 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 establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our drug candidates for which we receive marketing approval.

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 current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our drug candidates. 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 the drug candidates we are developing, if our 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 ripretinib, 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 (BMC), 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., Allakos Inc., ARIAD Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceuticals U.S.A., Arog Pharmaceuticals, Inc., BMC, Bristol-Myers Squibb Company (BMS), Celldex Therapeutics, Inc., Exelixis, Inc., Ningbo Tai Kang Medical Technology Co. Ltd., Novartis, Plexxikon Inc., a wholly owned subsidiary of Daiichi Sankyo Company, Limited (Plexxikon), Taiho Pharmaceutical Co. Ltd, 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., Amgen, Inc. (Amgen), BMS, Daiichi Sankyo Company, Limited, Eli Lilly and Company (Eli Lilly), Five Prime Therapeutics, Inc. (Five Prime), LifeMax Laboratories, Inc., Novartis, Pfizer, Roche Holding Ltd. (Roche), and Syndax Pharmaceuticals, Inc. (Syndax). 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 BMS, Novartis, Plexxikon, and antibody therapeutics from Amgen, Eli Lilly, Roche, Five Prime, Novartis, Pfizer, and Syndax.

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 any 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. If our drug candidates achieve marketing approval, we expect that they 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.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our drug candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates or products that we may develop;
- 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 any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate for the U.S. and certain other jurisdictions, with a per incident limit of $10.0 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 likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our 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 Our Dependence on Third Parties

We may enter into license and/or collaborations with third parties for the development and commercialization of our drug candidates. If those license and/or collaborations, including, without limitation, our license arrangement with Zai for the development and commercialization of ripretinib in Greater China, are not successful, we may not be able to capitalize on the market potential of these 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 some of our 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 ripretinib 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 ripretinib 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 ripretinib 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 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 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 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 a 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 products 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 products 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 drug candidates;
- license and/or collaboration agreements may not lead to development or commercialization of 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 potential commercialization of our drug candidates 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 ripretinib in Greater China. We may in the future decide to enter into additional licenses for ripretinib or license to or collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of other 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 candidate;
- the costs and complexities of manufacturing and delivering such 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 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 potential commercialization, or reduce the scope of any sales or marketing activities for such 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.

We currently rely on various third-party CROs to conduct our ongoing clinical trials for ripretinib, 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 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 (GCP), 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 drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize 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 commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products 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 future commercial manufacture of any of our drug candidates that obtain marketing approval. 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 candidates or products 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. For example, we have relied on third parties located in China to manufacture and supply certain raw materials used in our drug candidates, and we expect to continue to use such third-party manufacturers for such purposes. 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 ripretinib. We acquire many key materials on a purchase order basis. As a result, other than our commercial supply arrangements for our drug substance and finished drug product for ripretinib, 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. If we obtain marketing approval for ripretinib, we will rely on our sole source suppliers to manufacture all of our drug substance and finished drug product for commercialization unless and until we add additional sources. If we obtain marketing approval for any of our other 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 of ripretinib, if approved. 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 candidates, including ripretinib. 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 ripretinib, 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 ripretinib, 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 ripretinib will initially use to manufacture commercial supply of our drug candidate, if approved, has limited experience manufacturing commercial finished drug product.

For our other potential drug 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 current good manufacturing practice requirements (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 candidates and any products that we may develop may compete with other drug candidates and products 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 ripretinib. 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 candidates or in the manufacturing facilities in which our 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 candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval 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 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 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 drug candidates, for example, ripretinib, 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, which could harm our business and 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 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 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 drug candidates might expire before or shortly after such 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 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 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.

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 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 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 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 candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our 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 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 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 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 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 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 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 expect to seek extensions of patent terms in the U.S. 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 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 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 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 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 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 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 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 Candidates and Other Legal Compliance Matters

We have not received approval 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 and 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, 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 National Medicinal Products Administration (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. We have not received approval to market 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, the commercial prospects for our drug candidates may be harmed and our ability to generate revenues will be materially impaired.

We may not be able to obtain or, if granted, retain orphan drug exclusivity for our 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, including ripretinib, 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, as we have for ripretinib for the treatment of fourth-line and fourth-line plus GIST patients, 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, including ripretinib, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will obtain marketing approval.

In October 2019, the FDA granted BTD for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. We may also seek a BTD for some of our other 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.

Priority review of our NDA for ripretinib under the FDA's RTOR pilot program and our marketing applications to Australia and Canada pursuant to the FDA's Project Orbis initiative, may not lead to a faster regulatory review or approval, and do not increase the likelihood that ripretinib will obtain marketing approval.

The FDA or other regulatory bodies periodically introduce pilot programs with the goal of a more efficient review of applications, including the FDA OCE's RTOR pilot program, which is currently being tested by the FDA. The RTOR pilot program allows the FDA to review data before the applicant formally submits its completed application, aiming to explore a more efficient review process. The FDA's Project Orbis is an initiative of the OCE and, according to the FDA, is designed to provide a framework for concurrent submission and review of oncology products among international partners.

In December 2019, we submitted a NDA to the FDA for ripretinib for the treatment of patients with GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The NDA is being reviewed under the RTOR pilot program. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020, under the PDUFA. In December 2019, we filed a NDS with Health Canada, and a AUS MAA with the TGA in Australia, for ripretinib in advanced GIST, under Project Orbis. Both the NDS and the AUS MAA have received priority review. Acceptance into the RTOR pilot program and Project Orbis initiative does not guarantee or influence approvability of our NDA, NDS, and AUS MAA for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by the FDA, and the review standards of Health Canada and the TGA, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process compared to drugs considered for approval under conventional FDA procedures. These programs are not formal regulatory pathways and may be changed, suspended, or halted at any time, including, without limitation, because the FDA decides not to continue these programs, or because the FDA determines that our application no longer meets its criteria for inclusion in one or both of these programs.

Priority review is an FDA designation under which the FDA sets the target date for FDA action on a NDA at six months after the FDA accepts the application for filing, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition.

Although priority review designation and the RTOR pilot program and Project Orbis initiative, and other designations we may receive or programs we may participate in, are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe, or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant designations for expedited review or include drug candidates within various programs, and, even if we or our partners believe a particular drug candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even though the FDA has granted priority review designation for our NDA for ripretinib, and even if we or our partners receive such designations or our drug candidates are eligible for inclusion in expedited review programs in the future, we may not experience a faster development, review, or approval process compared to conventional procedures. Furthermore, these designations and programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for drug candidates granted priority review or other expedited review designations or subject to these various programs may be denied based on study data, study design, or other factors.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad, and any approval we are granted for our drug candidates in the U.S. would not assure approval of 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 ripretinib. 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.

Even if we obtain marketing approval for our drug candidates, the terms of approvals 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 if 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 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 any products we develop 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, assuming we obtain marketing approval for one or more of our drug candidates, 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 our products withdrawn by regulatory authorities and our ability to market any future 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.

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 our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

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 product, 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 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 any 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. 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. 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 one or more drug candidates, even if any drug candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our 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 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 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 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 any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize 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 candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, 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 any of our drug candidates, 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. If we receive FDA approval of ripretinib, or any of our drug candidates, we will participate in the 340B program. 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 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 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 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 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.

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 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 any 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 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 any approved product. 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 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 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 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 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 any approved product. 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 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 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, if approved, 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 expect to expand our development and regulatory capabilities and implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect 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, if any of our drug candidates receives marketing approval, 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 developing 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 March 31, 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 41% 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 the Court of Chancery of the State of Delaware as the sole and 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 (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim 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 that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. 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 this provision of our amended and restated bylaws. This choice of forum provision 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 such lawsuits against us and our directors, officers, and

employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery 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. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition, or results of operations.

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 March 31, 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;
- 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 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 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 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.

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 particularly after we are no longer an emerging growth company or a smaller reporting company, 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company and smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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: May 5, 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 3.2 to the Registrant's Current Report on Form 8-K filed on October 5, 2017).
10.1*	Deciphera Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy.
10.2*	Letter Agreement, made as of January 17, 2020, by and between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. (2)
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.

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.

Deciphera Pharmaceuticals, Inc.

Amended and Restated Non-Employee Director Compensation Policy

The purpose of this Amended and Restated Non-Employee Director Compensation Policy (this "Policy") of Deciphera Pharmaceuticals, Inc., a Delaware corporation (the "Company"), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company to become members of the Company's Board of Directors (the "Board"). In furtherance of this purpose, effective as of March 24, 2020 (the "Effective Date"), all non-employee directors of the Board shall be paid compensation for services provided to the Company as set forth below:

Cash Retainers

Annual Retainer for Board Membership: $50,000 for general availability and participation in meetings and conference calls of our Board (the "Annual Board Retainer"). No additional compensation for attending individual Board meetings.

Additional Annual Retainer for Non-Executive Chairperson of the Board: $30,000

Additional Annual Retainers for Committee Membership:

Audit Committee Chairperson:	$15,000
Audit Committee member:	$7,500
Compensation Committee Chairperson:	$10,000
Compensation Committee member:	$5,000
Nominating and Corporate Governance Committee Chairperson:	$7,500
Nominating and Corporate Governance Committee member:	$3,750
Science Committee Chairperson:	$10,000
Science Committee member:	$5,000

No additional compensation for attending individual committee meetings.

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the non-employee director. Cash retainers owing to non-employee directors shall be annualized, meaning that non-employee directors who join the Board during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

In lieu of receiving cash for her or his Annual Board Retainer, each non-employee director may elect to receive all (but not a portion) of her or his Annual Board Retainer in the form of an equity award of a stock option to purchase that number of shares of the Company's common stock, par value $0.01 per share (the "Common Stock") with a grant date fair value (based on the Black-Scholes option-pricing model), determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under ASC 718. Any such election shall be made (i) for any continuing non-employee director, during the month of December that is before the start of the calendar year with respect to any cash compensation for such calendar year and (ii) for any new non-employee director, within 30 days of her or his election to the Board of Directors; provided that, with respect to

calendar year 2020, non-employee directors of the Board as of the Effective Date may make any such election within 30 days following the Effective Date for the portion of the Annual Board Retainer to be earned in 2020 on or following July 1, 2020. Any election (A) shall be irrevocable with respect to such calendar year and (B) shall automatically apply to the Annual Board Retainer for each subsequent calendar year unless otherwise revoked prior to the start of such calendar year. Each such stock option shall be granted effective January 15 of the applicable year (or July 15, in the case of 2020) (noting that if any such date is not a trading day, the next trading day shall be the grant date) and shall vest in four equal quarterly installments as of the last date of each calendar quarter subject to the non-employee director's continued board service through such date (other than the stock options granted in 2020, which shall vest in two equal installments as of the last day of each remaining calendar quarter of 2020).

All of the foregoing option grants will have an exercise price equal to the fair market value of a share of Common Stock on the date of grant.

Equity Retainers

Initial Equity Grant: One-time option grant to each new non-employee director upon his/her election to the Board after the Effective Date to purchase shares of Common Stock in such amount and on such terms as authorized by the Board, or by a committee appointed by the Board.

On the date of each Annual Meeting of Stockholders: Annual option grant to each non-employee director serving on the Board immediately following the Company's annual meeting of stockholders to purchase shares of Common Stock in such amount and on such terms as authorized by the Board, or by a committee appointed by the Board.

All of the foregoing option grants will have an exercise price equal to the fair market value of a share of Common Stock on the date of grant.

Expenses

The Company shall reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending Board and committee meetings.

AMENDED AND RESTATED: March 24, 2020

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.

This letter agreement (this "**Letter Agreement**") is made as of January 17th, 2020 (the "Effective Date"), by and between Deciphera Pharmaceuticals, LLC a limited liability company organized and existing under the laws of Delaware, U.S.A., located at 200 Smith Street, Waltham, MA 02451, U.S.A., ("Deciphera"), and Zai Lab (Shanghai) Co., Ltd., an exempted company organized and existing under the laws of P.R. of China, located at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210 ("Zai") in connection with that certain License Agreement entered by and between Deciphera and Zai, dated as of June 10, 2019 (the "**License Agreement**"). Capitalized terms used herein and not otherwise defined shall have the meanings given to them in the License Agreement. The purpose of this Letter Agreement is to clarify several operational matters contemplated by the License Agreement. In connection therewith, the undersigned hereby agrees and acknowledges as follows:

1. [***]

2. For clarity, for Article 6 (Regulatory), Section 13.1(e) (By Zai) and Section 15.8 (Effect of Termination) of the License Agreement, the definition of "Regulatory Approval" shall be amended to mean,

   > "with respect to a Licensed Product in a region or a country, each approval from the necessary Governmental Authority or Regulatory Authority necessary to conduct Clinical Trials, import, market or sell such Licensed Product in such region, including pricing approvals (but excluding reimbursement approvals)."

3. [***]

4. [***]

5. [***]

6. Zai shall comply, and shall cause its Affiliates, Sublicensees and subcontractors to comply, with all Applicable Laws, including without limitation GCP and regulations promulgated by the NMPA, in their conduct of all Clinical Trials in the Territory.

7. Notwithstanding anything to the contrary in Section 6.4 (Adverse Event Reporting) of the License Agreement, Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Territory for all Clinical Trials conducted in the Territory and the Parties shall execute a Pharmacovigilance Agreement per the License Agreement to reflect the agreement among the Parties with respect to such matters, including that Zai will provide in English adverse events from Regional Studies for inclusion in a reporting system chosen by Deciphera.

8. Prior to Zai initiating any Clinical Trial in the Territory, Zai (a) shall have and maintain such type and amounts of clinical trial insurance covering the conduct of each such Clinical Trial in the Territory that is normal and customary in the pharmaceutical industry generally for similarly situated companies to conduct each such Clinical Trial; and (b)

shall name Deciphera and all its Affiliates as full named insureds thereunder who are each entitled to the full benefits of such insurance policy.

9. [***]

10. The governing law and dispute resolution provisions of the License Agreement, as amended from time to time, shall apply to the provisions of this letter agreement. Any notices or other communication required to be provided under the provisions of this Letter Agreement shall be provided in accordance with the notice provision of the License Agreement as amended from time to time. In the event of a conflict between a term or condition of this Letter Agreement and a term or condition of the License Agreement, the term or condition of this Letter Agreement shall control. This Letter Agreement may be executed in multiple counterparts which, taken together, shall constitute one and the same agreement. This Letter Agreement may only be amended with the written consent of both Parties hereto.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Letter Agreement to be executed by their duly authorized representatives as of the Effective Date.

Deciphera Pharmaceuticals, LLC	**Zai Lab (Shanghai) Co., Ltd.**
By: /s/ Steve Hoerter	By: /s/ Samantha Du
Name: Steve Hoerter	Name: Samantha Du
Title: President and Chief Executive Officer	Title: Chairman and Chief Executive Officer
Date: 17th, Jan., 2020	Date: 17th, Jan., 2020

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: May 5, 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: May 5, 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 March 31, 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: May 5, 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 March 31, 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: May 5, 2020

By: /s/ Thomas P. Kelly

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