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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-38219

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**30-1003521**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
500 Totten Pond Road 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 June 30, 2019 there were 38,215,108 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 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 Quarterly Report on 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 trials and results therefrom;
- our ability to obtain and maintain regulatory approval for ripretinib (DCC-2618) 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, to support our planned clinical trials and, if approved, commercialization;
- 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 trials and the timing of investigational new drug, or 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., or Zai, to successfully develop and, if approved, commercialize ripretinib in Greater China under the terms and conditions of our license agreement;
- our ability to attract additional licensees and/or collaborators 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, 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;
- regulatory and legal developments in the United States 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;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our use of the proceeds from our initial public offering and our follow-on public offering 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 Quarterly Report on Form 10-Q and our prior filings with the SEC. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on 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

(In thousands, except share and per share data)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 57,237	$ 293,764
Marketable securities	168,179	—
Accounts receivable	20,000	—
Unbilled receivable	5,000	—
Prepaid expenses and other current assets	6,010	7,273
Total current assets	256,426	301,037
Long-term investment—restricted	1,510	1,069
Property and equipment, net	1,595	13,453
Operating lease, right-of-use assets	476	—
Total assets	$ 260,007	$ 315,559
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,900	$ 8,308
Accrued expenses and other current liabilities	20,935	13,709
Operating lease liabilities	313	539
Notes payable to related party	187	187
Total current liabilities	35,335	22,743
Notes payable to related party, net of current portion	1,014	1,107
Operating lease liabilities, net of current portion	164	11,347
Other long-term liabilities	616	381
Total liabilities	37,129	35,578
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 38,215,108 shares and 37,676,760 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	382	377
Additional paid-in capital	586,888	575,327
Accumulated other comprehensive income	175	—
Accumulated deficit	(364,567)	(295,723)
Total stockholders' equity	222,878	279,981
Total liabilities and stockholders' equity	$ 260,007	$ 315,559

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

Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ 25,000	$ —	$ 25,000	$ —
Operating expenses:				
Research and development	34,811	17,976	70,600	34,901
General and administrative	13,164	4,453	26,400	9,479
Total operating expenses	47,975	22,429	97,000	44,380
Loss from operations	(22,975)	(22,429)	(72,000)	(44,380)
Other income (expense):				
Interest expense	(25)	(21)	(38)	(43)
Interest and other income, net	1,540	760	3,194	1,303
Total other income (expense), net	1,515	739	3,156	1,260
Net loss	$ (21,460)	$ (21,690)	$ (68,844)	$ (43,120)
Net loss per share—basic and diluted	$ (0.56)	$ (0.65)	$ (1.81)	$ (1.30)
Weighted average common shares outstanding—basic and diluted	38,200,288	33,567,314	38,129,049	33,083,383
Comprehensive loss:				
Net loss	$ (21,460)	$ (21,690)	$ (68,844)	$ (43,120)
Other comprehensive income:				
Unrealized gains on marketable securities	154	—	175	—
Total other comprehensive income	154	—	175	—
Total comprehensive loss	$ (21,306)	$ (21,690)	$ (68,669)	$ (43,120)

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

Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at 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 on marketable securities	—	—	—	21	—	21
Net loss	—	—	—	—	(47,384)	(47,384)
Balances at March 31, 2019	38,189,052	382	582,700	21	(343,107)	239,996
Issuance of common stock upon exercise of stock options	26,056	—	81	—	—	81
Stock-based compensation expense	—	—	4,107	—	—	4,107
Unrealized gains on marketable securities	—	—	—	154	—	154
Net loss	—	—	—	—	(21,460)	(21,460)
Balances at June 30, 2019	38,215,108	$ 382	$586,888	$ 175	$ (364,567)	$ 222,878

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2017	32,591,686	$ 326	$379,516	$ —	$ (195,869)	$ 183,973
Issuance of common stock upon exercise of stock options	2,442	—	10	—	—	10
Stock-based compensation expense	—	—	2,037	—	—	2,037
Net loss	—	—	—	—	(21,430)	(21,430)
Balances at March 31, 2018	32,594,128	326	381,563	—	(217,299)	164,590
Issuance of common stock sold in public offering, net of underwriting discounts, commissions and offering costs	4,945,000	49	185,209	—	—	185,258
Issuance of common stock upon exercise of stock options	94,322	1	706	—	—	707
Stock-based compensation expense	—	—	2,232	—	—	2,232
Net loss	—	—	—	—	(21,690)	(21,690)
Balances at June 30, 2018	37,633,450	$ 376	$569,710	$ —	$ (238,989)	$ 331,097

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

Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (68,844)	$ (43,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,336	4,269
Depreciation and amortization expense	216	130
Net accretion of discounts on marketable securities	(1,297)	—
Changes in operating assets and liabilities:		
Accounts receivable	(20,000)	—
Unbilled receivable	(5,000)	—
Prepaid expenses and other current assets	1,263	(793)
Operating lease, right-of-use assets	337	—
Accounts payable	5,592	2,225
Accrued expenses and other current liabilities	7,239	2,272
Operating lease liabilities	(349)	—
Other long-term liabilities	235	34
Net cash used in operating activities	(70,272)	(34,983)
Cash flows from investing activities:		
Purchases of marketable securities	(253,759)	—
Maturities and sales of marketable securities	87,052	—
Purchases of property and equipment	(244)	(606)
Increase in restricted investments	(441)	(1,069)
Net cash used in investing activities	(167,392)	(1,675)
Cash flows from financing activities:		
Proceeds from public offerings, net of underwriting discounts and commissions	—	185,932
Repayment of notes payable to related party	(93)	(93)
Payments of public offering costs	—	(125)
Proceeds from exercise of stock options	1,230	717
Net cash provided by financing activities	1,137	186,431
Net increase (decrease) in cash and cash equivalents	(236,527)	149,773
Cash and cash equivalents at beginning of period	293,764	196,754
Cash and cash equivalents at end of period	$ 57,237	$ 346,527
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 38	$ 43
Supplemental disclosure of non-cash investing activities:		
Amounts capitalized under build-to-suit lease transactions	$ —	$ 17,028
Supplemental disclosure of non-cash financing activities:		
Offering costs included in accounts payable and accrued expenses	$ —	$ 549

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 Basis of Presentation

Deciphera Pharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing new drugs to improve the lives of cancer patients by addressing key mechanisms of drug resistance that limit the rate and durability of response of many cancer therapies. The Company's targeted, small molecule drug candidates, designed using its proprietary kinase switch control inhibitor platform, inhibit the activation of kinases, an important family of enzymes, that, when mutated or over expressed, are known to be directly involved in the growth and spread of many cancers.

The Company is subject to risks and uncertainties common to early-stage 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, compliance with government regulations 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 clinical testing and regulatory approval prior to commercialization. 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.

On October 2, 2017, immediately prior to the completion of its initial public offering ("IPO"), the Company engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis (the "Conversion").

In October 2017, Deciphera Pharmaceuticals, Inc., completed the IPO, pursuant to which it issued and sold 8,166,496 shares of common stock at the IPO price of $17.00 per share, resulting in net proceeds of $124.6 million after deducting underwriting discounts and commissions and other offering expenses. Upon the closing of the IPO, the Company's outstanding convertible preferred shares automatically converted into shares of common stock. 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.

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 $68.8 million and $99.9 million for the six months ended June 30, 2019 and the year ended December 31, 2018, respectively. As of June 30, 2019, the Company had an accumulated deficit of $364.6 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, capital expenditure requirements and debt service payments 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 substantially in connection with ongoing activities, particularly as the Company advances its preclinical activities and 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.

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

2. Summary of Significant Accounting Policies

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.

Unaudited Interim Financial Information

The consolidated balance sheet at December 31, 2018 was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The accompanying unaudited consolidated financial statements as of June 30, 2019 and for the three and six months ended June 30, 2019 and 2018 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 condensed or omitted pursuant to such rules and regulations. The Company believes, however, that the disclosures are adequate to make the information presented not misleading. 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, 2018 included in the Company’s Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s consolidated financial position as of June 30, 2019 and consolidated results of operations for the three and six months ended June 30, 2019 and 2018 and consolidated cash flows for the six months ended June 30, 2019 and 2018 have been made. The consolidated results of operations for the six months ended June 30, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company’s accounts receivable, unbilled receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities. The fair value of the Company’s outstanding notes payable to a related party (see Note 6) as of each of June 30, 2019 and December 31, 2018 approximated $1.1 million. The fair value of the outstanding debt was estimated using a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk, which represents a Level 3 measurement.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

Revenue

The Company accounts for its one license arrangement, entered into in June 2019 (see Note 4), under Accounting Standards Codification ("ASC") Topic 606, *Revenue From Contracts With Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about technical feasibility and the probability of developing a candidate that would be subject to the option rights. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Leases

The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its operating right-of-use asset and operating lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's only existing leases are for office and laboratory space.

In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance and other expenses, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with shareholders. For the three months and six months ended June 30, 2019, the Company's other comprehensive income (loss) consisted of unrealized gains (losses) on marketable securities. For the three months and six months ended June 30, 2018, there was no difference between net loss and comprehensive loss.

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 antidilutive. The Company reported a net loss for each of the three and six months ended June 30, 2019 and 2018.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

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

	As of June 30,	
	2019	2018
Options to purchase common stock	6,891,799	5,583,058
Unvested restricted common stock units	77,000	—
	6,968,799	5,583,058

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases are classified as either operating or finance, and classification is based on criteria similar to current lease accounting, but without explicit bright lines. The guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years, and early adoption is permitted. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the new leasing standards on the effective date of January 1, 2019 using a modified retrospective approach applied at the beginning of the period of adoption.

The Company elected the "package of practical expedients", which permits the Company not to reassess under the new standards for prior conclusions about lease identification, lease classification and initial direct costs. The Company did not apply the hindsight practical expedient when determining the lease term for existing leases and assessing impairment of expired or existing leases. The Company did not apply the recognition requirements to short-term leases and recognizes those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. The Company elected the practical expedient to not separate lease and non-lease components for real estate leases. The Company elected to utilize its incremental borrowing rate based on the remaining lease term as of the date of adoption.

In connection with the adoption, the Company recognized right-of-use assets of $0.8 million and lease liabilities of $0.8 million on its consolidated balance sheet. The underlying assets of the Company's leases consist of office and laboratory space. In addition, the Company reversed its build to suit asset of $11.9 million and related liabilities of $11.9 million under the new guidance as the Company is no longer deemed the owner of the leased space (see Note 8). The adoption of the standard did not have a material impact on the Company's results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. The guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years, and early adoption is permitted. The Company adopted ASU 2018-07 as of January 1, 2019 and it had no impact on the Company's financial position, results of operations or cash flows.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

3. Marketable Securities and Fair Value Measurements

As of June 30, 2019, marketable securities by security type consisted of (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper (due within one year)	$ 92,698	$ 91	$ —	$ 92,789
U.S. Government securities (due within one year)	36,505	62	—	36,567
Certificates of deposit (due within one year)	38,801	22	—	38,823
Total	$168,004	$ 175	$ —	$168,179

The Company had no marketable securities as of December 31, 2018.

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 (in thousands):

	Fair Value Measurements at June 30, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 35,452	$ —	$ 35,452
Commercial paper	—	13,459	—	13,459
Certificates of deposit	—	3,235	—	3,235
Marketable securities:				
Commercial paper	—	92,789	—	92,789
U.S. Government securities	—	36,567	—	36,567
Certificates of deposit	—	38,823	—	38,823
Total	$ —	$ 220,325	$ —	$ 220,325

	Fair Value Measurements at December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 267,145	$ —	$ 267,145
Total	$ —	$ 267,145	$ —	$ 267,145

The table above excludes certificates of deposit totaling $1.5 million and $1.1 million as of June 30, 2019 and December 31, 2018, respectively, that the Company held to secure a letter of credit associated with a lease (see Note 8) and to secure a credit card account.

During the three and six months ended June 30, 2019 and 2018, there were no transfers between Level 1, Level 2 and Level 3.

4. License Agreement

Zai Lab (Shanghai) Co., Ltd. (Zai) License Agreement

In June 2019, the Company entered into a License Agreement, or the Zai License Agreement, with an affiliate of Zai Lab (Shanghai) Co., Ltd. ("Zai"), pursuant to which the Company granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds (the "Licensed Products"), in Mainland China, Hong Kong, Macau and Taiwan, each a Region and collectively the Territory. The Company retains exclusive rights to, among other things, develop, manufacture and commercialize the Licensed Products outside the Territory.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

Pursuant to the terms of the Zai License Agreement, the Company has received an upfront cash payment of $20.0 million and will be eligible to receive up to $185.0 million in development and commercial milestone payments, consisting of up to $50.0 million of development milestones, including $5.0 million for an INTRIGUE study-related milestone the Company achieved, and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay the Company tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

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.

Subject to specified exceptions, during the term of the Zai License Agreement, each party has agreed that neither it nor its affiliates nor, with respect to Zai, its sublicensees, will conduct any development, manufacturing and commercialization activities in the Territory that may be deemed competitive with the Licensed Products. In addition, under the Zai License Agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the Zai License Agreement, including license grants to enable each party to conduct research, development and commercialization activities pursuant to the terms of the Zai License Agreement. The Company will supply or have supplied to Zai the Licensed Product pursuant to a supply agreement and for agreed upon consideration.

The Zai License Agreement will continue on a Licensed Product-by-Licensed Product and region-by-region basis until the later of (i) the abandonment, expiry or final determination of invalidity of the last valid claim within the Company's patent rights that covers the Licensed Product in such region in the Territory; (ii) the expiry of the regulatory exclusivity for such Licensed Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of such Licensed Product in such region. Subject to the terms of the Zai License Agreement, Zai may terminate the Zai License Agreement for convenience by providing written notice to the Company, which termination will be effective following a prescribed notice period. In addition, the Company may terminate the Zai License Agreement under specified circumstances if Zai or certain other parties challenge our patent rights or if Zai or its affiliates do not conduct certain development activities with respect to one or more Licensed Products for a specified period of time, subject to specified exceptions. Either party may terminate the Zai License Agreement for the other party's uncured material breach of a material term of the Zai License Agreement, with a customary notice and cure period, or insolvency. After termination (but not natural expiration), the Company is entitled to retain a worldwide and perpetual license from Zai to exploit the Licensed Products. On a region-by-region and a Licensed Product-by-Licensed Product basis, upon the natural expiration of the Zai License Agreement as described above, the licenses granted by the Company to Zai under the Zai License Agreement in such region with respect to the Licensed Product become fully paid-up, perpetual and irrevocable.

The Company identified the following promises under the Zai License Agreement: (1) the exclusive license, with the right to grant sublicenses, granted in the Territory for the Licensed Products; (2) initial and continuing know-how transfer for the Licensed Products; (3) clinical supply of the Licensed Products; (4) participation in the joint steering committee (the "JSC"); and (5) regulatory and technical assistance responsibilities.

The Company determined that the exclusive license is distinct and constitutes one performance obligation that is a right to use the Company's intellectual property. The Company determined that the promises under the Zai License Agreement related to the know-how transfer, clinical supply, participation in the JSC and the assistance responsibilities are immaterial in the context of the Zai License Agreement and therefore are excluded from the assessment of performance obligations. The Company also evaluated certain options and contingent obligations contained within the Zai License Agreement to determine if they provide Zai with any material rights. The Company concluded that the options and contingent obligations were not issued at a significant and incremental discount, and therefore do not provide Zai with a material right. As such, these options and contingent obligations were excluded as performance obligations and will be accounted for if, and when they occur or are exercised.

The Company determined that the upfront payment of $20.0 million and the $5.0 million development milestone that the Company believed was probable of achievement and that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty constitutes the consideration to be included in the transaction price as of the outset of the arrangement. The transaction price was allocated to the one performance obligation which was satisfied at a point in time upon delivery of the license in June 2019, and therefore the Company recognized license revenue of $25.0 million in the three months ended June 30, 2019. The first development milestone was achieved in July 2019. The remaining potential milestone payments that the Company is eligible to receive were excluded from the transaction price and were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the

end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price. Because the performance obligation has been satisfied, any addition to the transaction price would be reflected in the period as a cumulative revenue catch-up.

The Company assessed the License Agreement to determine whether a significant financing component exists and concluded that a significant financing component does not exist.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued external research and development expenses	$ 14,673	$ 8,761
Accrued payroll and related expenses	4,529	4,139
Accrued professional fees	1,639	747
Accrued other	94	62
	$ 20,935	$ 13,709

6. Notes Payable to Related Party

Notes payable to related party as of June 30, 2019 and December 31, 2018 consisted of outstanding borrowings under a loan agreement and a security agreement (together, the "CRL Construction Loan") with Clinical Reference Laboratory, Inc. ("CRL"), a related party (see Note 10), as follows (in thousands):

	June 30, 2019	December 31, 2018
Notes payable to related party	$ 1,201	$ 1,294
Less: Current portion	(187)	(187)
Notes payable to related party, net of current portion	$ 1,014	$ 1,107

Total interest expense was less than $0.1 million for each of the three and six months ended June 30, 2019 and 2018.

7. Stock-Based Awards

The Company grants stock-based awards under its 2017 Stock Option and Incentive Plan (the "2017 Plan") and is authorized to issue common stock under its 2017 Employee Stock Purchase Plan ("ESPP"). The Company also has outstanding stock options under its 2015 Equity Incentive Plan but is no longer granting awards under this plan. As of June 30, 2019, 1,912,057 shares of common stock were available for issuance under the 2017 Plan. As of June 30, 2019, 1,009,433 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 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development expenses	$ 1,790	$ 983	$ 3,482	$ 1,945
General and administrative expenses	2,317	1,249	6,854	2,324
	$ 4,107	$ 2,232	$ 10,336	$ 4,269

As of June 30, 2019, total unrecognized compensation cost related to the unvested share-based awards was $48.6 million, which is expected to be recognized over a weighted average of 2.8 years. During the six months ended June 30, 2019, the Company recorded $2.4 million of stock-based compensation expense related to the modification of stock options pursuant to the transition agreement with its former President and Chief Executive Officer.

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

8. Commitments and Contingencies

Leases

The Company has a three-year sublease agreement for office space in Waltham, Massachusetts that began in September 2016 and expires in September 2019.

The Company has two five-year lease agreements for office and laboratory space in Lawrence, Kansas that began on January 1, 2016 and expire on December 31, 2020. The Company has two leases for additional office space in Lawrence, Kansas, that expire in December 2020. The lease agreements contain options to extend the lease terms however these extensions were not included in the right-of-use assets and lease liabilities as they were not reasonably certain of being exercised.

In addition, in August 2018, the Company entered into a nine-month sublease for additional office space in Waltham, Massachusetts that expired in May 2019. The expense related to this sublease is included in short-term lease costs for the three and six months ended June 30, 2019.

The Company's leases require the Company to pay for certain operating expenses based on actual costs incurred and therefore as the amounts are variable in nature are expensed in the period incurred and included in variable lease costs for the three and six months ended June 30, 2019. Payment escalations specified in the lease are recognized on a straight-line basis over the lease terms.

The components of lease expense were as follows (in thousands):

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	$ 203	$ 358
Short-term lease cost	94	188
Variable lease cost	117	209
	$ 414	$ 755

Other information:

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of operating lease liabilities (in thousands)	$ 160	$ 320
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	$ —	$ —

	June 30, 2019
Weighted-average remaining lease term - operating leases (in years)	1.42
Weighted-average discount rate - operating leases	6.03%

Deciphera Pharmaceuticals, Inc.

Notes to the Consolidated Financial Statements
(Unaudited)

Future annual minimum lease payments under operating leases as of June 30, 2019 were as follows (in thousands):

Year ending December 31,	
2019	$ 166
2020	333
Total future minimum lease payments	499
Less: imputed interest	(22)
Total operating lease liabilities	$ 477

Included in the consolidated balance sheet (in thousands):	June 30, 2019
Current operating lease liabilities	$ 313
Operating lease liabilities, net of current portion	164
Total operating lease liabilities	$ 477

As previously disclosed in the Company's 2018 Annual Report on Form 10-K and under the previous lease accounting standard, *ASC 840, Leases*, the following table summarizes the future minimum lease payments due under the operating leases as of December 31, 2018 (in thousands):

Year Ending December 31,	
2019	$ 726
2020	333
	$1,059

In May 2018, the Company entered into a lease for office space in Waltham, Massachusetts, which is expected to commence in 2019. The initial term of the lease expires in November 2029, unless terminated earlier in accordance with the terms of the lease. The Company is entitled to two five-year options to extend. The initial annual base rent is approximately $2.0 million and will increase annually for a total of $22.4 million over the lease term. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement and management of the new leased premises. The Company is required to maintain a cash balance of $1.1 million to secure a letter of credit associated with the lease. This amount was classified as long-term investment—restricted in the consolidated balance sheet as of June 30, 2019.

Prior to the adoption of ASU 2016-02, the Company was deemed to be the owner of this leased space during the construction period because of certain provisions within the lease agreement. As a result, as of December 31, 2018, the Company capitalized approximately $11.9 million (equal to the estimated cost of its leased portion of the premises) as construction-in-progress within property and equipment and recorded a corresponding build-to-suit facility lease financing obligation. Under ASU 2016-02, the Company is no longer considered the owner of the leased space and therefore the build-to suit asset and corresponding liabilities at December 31, 2018 were reversed as of the date of adoption on January 1, 2019 as the lease commencement date had not yet been met. As of June 30, 2019, the lease commencement date under ASU 2016-02 has not yet been met.

As previously disclosed in the Company's 2018 Annual Report on Form 10-K and under the previous lease accounting standard, *ASC 840, Leases*, as of December 31, 2018, minimum commitments under this lease were as follows (in thousands):

Year Ending December 31,	
2019	$ 170
2020	2,043
2021	2,088
2022	2,132
2023	2,177
Thereafter	13,783
	$22,393

In April 2019, the Company amended its lease for office space in Waltham, Massachusetts to add an additional 38,003 square feet of space for a total of 82,346 square feet of space, which is expected to commence in early 2020. The initial term of the lease for the additional space will expire in November 2029 unless terminated earlier in accordance with the terms of the lease and the Company is entitled to two five-year options to extend the lease. The initial annual base rent for the additional space is approximately

$1.9 million and will increase annually for a total of $18.2 million over the lease term. The Company will be required to pay its share of operating expenses, taxes and other expenses related to the additional leased premises. The Company will be required to increase the amount of cash to secure the letter of credit by $0.9 million upon substantial completion of the additional premises. As of June 30, 2019, the lease commencement date under ASU 2016-02 has not yet been met.

KBA Grants

Prior to 2014, the Company received funding from two research and development grants from the Kansas Bioscience Authority, or 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.

Legal Proceedings

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of June 30, 2019 or December 31, 2018.

9. 401(k) Savings Plan

Effective January 1, 2018, the Company adopted the Deciphera Pharmaceuticals 401(k) Plan (the “401(k) Plan”), a defined contribution plan under Section 401(k) of the Internal Revenue Code, whereby the Company provides matching contributions of 100% of each employee’s contribution up to a maximum matching contribution of 3% of the employee’s eligible compensation and at a rate of 50% of each employee’s contribution in excess of 3% up to a maximum of 5% of the employee’s eligible compensation.

Total employer matching contributions related to the 401(k) Plan were $0.2 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively, and $0.5 million and $0.2 million for the six months ended June 30, 2019 and 2018, respectively.

10. Related Parties

Clinical Reference Laboratory, Inc.

One of the members of the Company’s board of directors is the Chief Executive Officer of CRL. CRL is the owner of approximately 31% of Brightstar, a holder of more than 5% of the Company’s common stock.

The Company is a party to a loan agreement and a security agreement, each dated as of June 11, 2010, with CRL. The Company borrowed an aggregate of $2.8 million under the loan agreement to finance improvements to the Company’s biology and chemistry laboratories in Lawrence, Kansas. In December 2016, the loan was assigned to CHC, Inc., a related party, which owns 100% of CRL.

Deciphera Pharmaceuticals, Inc.

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Borrowings under the loan bear interest at a fixed rate equal to 6.0% per annum and the Company is required to make monthly payments of principal and interest, based on a 15-year straight-line amortization schedule. For each of the three months ended June 30, 2019 and 2018, the Company recorded less than $0.1 million of interest expense related to this loan. For each of the three months ended June 30, 2019 and 2018, the Company made less than $0.1 million in principal and interest payments under the loan. For each of the six months ended June 30, 2019 and 2018, the Company recorded less than $0.1 million of interest expense related to this loan. For each of the six months ended June 30, 2019 and 2018, the Company made $0.1 million in principal and interest payments under the loan. As of June 30, 2019 and December 31, 2018, principal amounts owed under the loan agreement totaled $1.2 million and $1.3 million, respectively (see Note 6).

The Company is party to a master services agreement, effective as of May 20, 2013, with CRL under which the Company purchased and expects to continue to purchase laboratory services. Under the agreement, the Company has agreed to use CRL on an exclusive basis for certain laboratory testing needs. For the three months ended June 30, 2019 and 2018, the Company recorded $0.2 million and $0.3 million, respectively, of research and development expense incurred under this agreement, and $0.1 million and $0.3 million, respectively, was paid to CRL during those same periods. For each of the six months ended June 30, 2019 and 2018, the Company recorded $0.4 million of research and development expense incurred under this agreement and $0.3 million and $0.4 million, respectively, was paid to CRL during those same periods. As of June 30, 2019 and December 31, 2018, total amounts owed to CRL for laboratory services were $0.2 million, which amount was included in accounts payable and accrued expenses. The Company is not committed to purchase any minimum amounts under the agreement.

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 Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2018 on file with the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on 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 Quarterly Report on 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 developing new drugs to improve the lives of cancer patients by addressing key mechanisms of drug resistance that limit the rate and durability of response of many cancer therapies. Our targeted, small molecule drug candidates, designed using our proprietary kinase switch control inhibitor platform, inhibit the activation of kinases, an important family of enzymes, that, when mutated or over expressed, are known to be directly involved in the growth and spread of many cancers. We have built a diverse pipeline of wholly owned, orally administered drug candidates that include three clinical-stage, one preclinical-stage and one research-stage programs.

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, and conducting research and development activities for our drug candidates. 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, or 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 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.

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 construction loan and research and development grants from the Kansas Bioscience Authority, or KBA.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue 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 $68.8 million for the six months ended June 30, 2019 and $99.9 million for the year ended December 31, 2018. As of June 30, 2019 we had an accumulated deficit of $364.6 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 substantially 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 (DCC-2618);
- continue with our ongoing pivotal Phase 3 clinical trials 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;
- 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 for which we obtain marketing approval, if any; 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.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our drug candidates. If we obtain regulatory approval for any of our drug candidates, we expect to incur significant expenses related to developing 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 operating 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 June 30, 2019, we had cash, cash equivalents and marketable securities of $225.4 million. We believe that our cash, cash equivalents and marketable securities as of June 30, 2019, along with the $20.0 million up-front payment from our recent license agreement with Zai, received in the third quarter of 2019, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the fourth quarter of 2020. This excludes any potential milestone or royalty payments, if any, under our license agreement with Zai. See “Liquidity and Capital Resources.”

Recent Developments

Rebastinib Development Update

We completed enrollment of 43 patients in Part 1 of the Phase 1b/2 combination study of rebastinib with paclitaxel and selected the 100 mg BID dose of rebastinib in combination with a weekly dose of 80 mg/m^2 of paclitaxel as the recommended Phase 2 dose for Part 2 of the study, which began enrollment in the second quarter of 2019. We expect to report initial data from Part 1 of this study in the second half of 2019.

Lease Amendment

In April 2019, we and 200 Smith NWALP Property Owner LLC, or the Landlord, entered into a Third Amendment to Lease, or the Amendment, to the Lease between the Company and the Landlord dated May 29, 2018, as amended, or the Lease, to add an additional 38,003 square feet of space, or the Expansion Premises to the existing premises of 44,343 square feet of space, or the Initial Premises, for a total of 82,346 square feet of space in that building commonly known and numbered as 200 Smith Street in Waltham, Massachusetts, or the Premises. The Premises will become the Company’s new headquarters location.

Zai License Agreement

In June 2019, we entered into a License Agreement, or the Zai License Agreement, with an affiliate of Zai Lab (Shanghai) Co., Ltd., or Zai, pursuant to which we granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds, or the Licensed Products, in Mainland China, Hong Kong, Macau and Taiwan, each a Region and collectively the

Territory. We retain 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, we will receive an upfront cash payment of $20.0 million and will be eligible to receive up to $185.0 million in development and commercial milestone payments, consisting of up to $50.0 million of development milestones, including $5.0 million for an INTRIGUE study-related milestone the Company achieved, and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

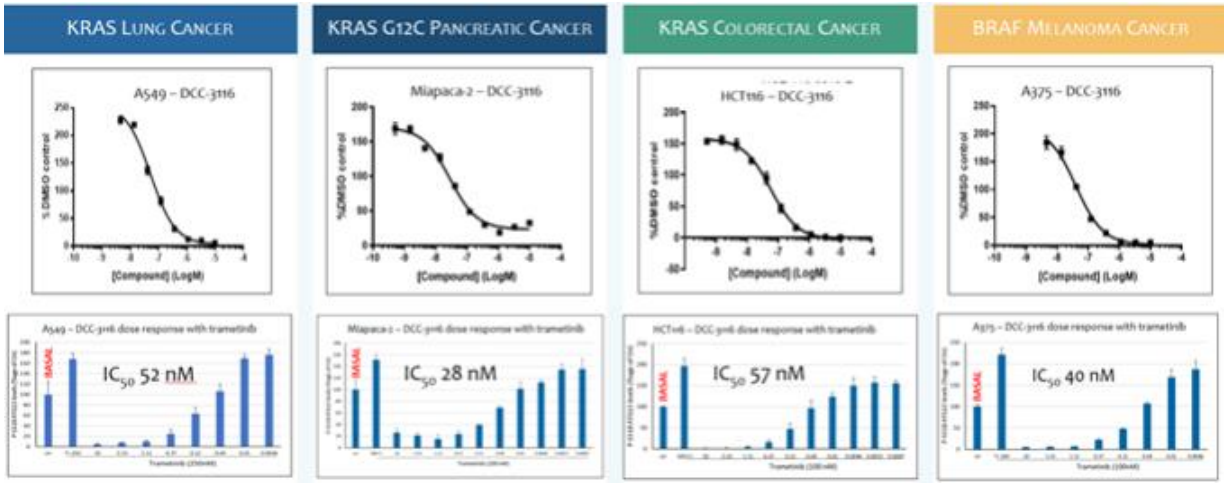
New Preclinical Candidate: DCC-3116

In June 2019, we announced the addition of DCC-3116, a new preclinical candidate, to our pipeline. DCC-3116 is a small molecule designed to inhibit cancer autophagy, a key tumor survival mechanism. DCC-3116, discovered using the Company's novel switch control inhibitor platform, is designed to inhibit autophagy by inhibiting the ULK kinase, believed to be the initiating factor that activates autophagy. Subject to favorable investigational new drug (IND)-enabling studies and filing and activation of an IND, we intend to develop DCC-3116 for the potential treatment of mutant RAS cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

Autophagy is a cellular pathway that has been observed to be upregulated in mutant RAS cancers and is also known to mediate resistance to inhibitors of the RAS signaling pathway. Autophagy is a survival pathway in which cells respond to stress by recycling their own components and/or clearing damaged organelles and proteins from the cell. Mutant RAS cancers, including KRAS, NRAS, and HRAS cancers, are reported to have high basal levels of autophagy, which these cancers use to maintain nutrient supply, regulate cancer cell metabolism, and mitochondria surveillance. Cellular studies in mutant RAS cancers have demonstrated that MAPK pathway inhibitors can also induce autophagy as a compensatory survival mechanism. Such induction is seen with RAF, MEK, and ERK inhibitors as well as with direct inhibitors of mutant KRAS G12C. In *in vitro* models of mutant RAS cancers, inhibition of autophagy combined with inhibition of MAPK signaling using MEK inhibitors or ERK inhibitors has demonstrated synergistic anti-proliferative activity and induction of cell killing. *In vivo* studies conducted by independent research groups have also demonstrated synergistic anti-tumor activity in various mutant RAS cancer models.

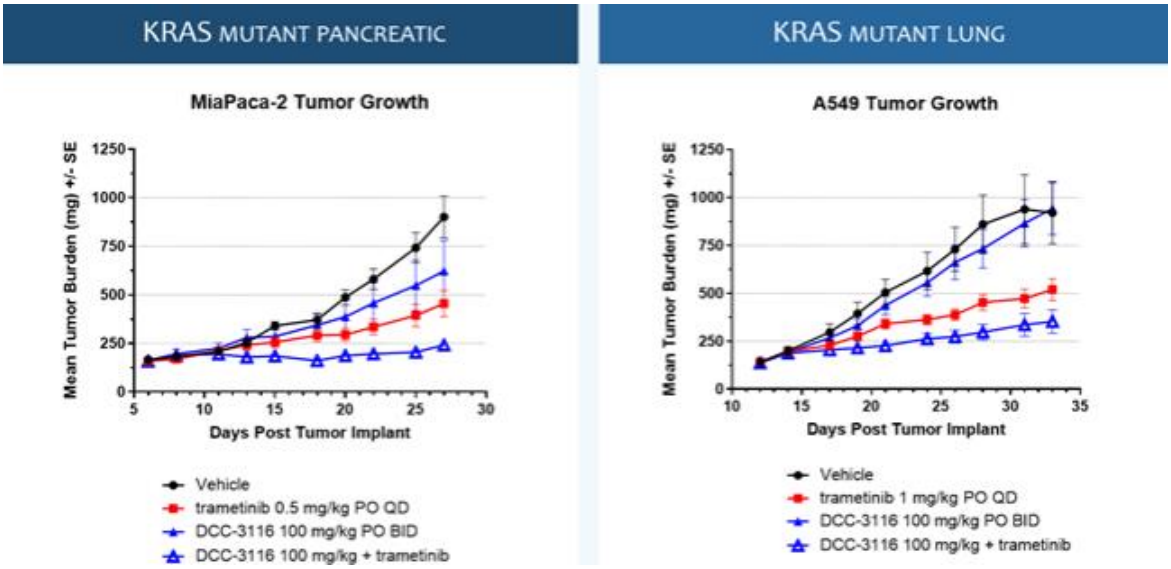
In our preclinical studies, we have observed DCC-3116 to selectively inhibit the ULK kinase. Our *in vitro* studies have also demonstrated that DCC-3116 in combination with inhibitors of the MAPK pathway inhibits both basal autophagy (autophagy in the absence of a MAPK inhibitor) and also MAPK inhibitor-induced increased autophagy in various mutant RAS cancer cell lines as illustrated below. Autophagy inhibition by DCC-3116 was monitored by the decrease in phosphorylation of the cellular ULK autophagy substrate ATG13 in the presence of the MEK inhibitor trametinib.

Preclinical Inhibition of ULK Kinase by DCC-3116 in Multiple RAS Cancer Cell Lines



When evaluated in preclinical *in vivo* models, DCC-3116 in combination with inhibitors of the MAPK pathway demonstrated synergistic inhibition of mutant RAS cancer growth as shown below. In both KRAS mutant pancreatic and lung *in vivo* models, DCC-3116 in combination with trametinib reduced tumor size as compared to the control cohort or either single agent treatment cohort.

DCC-3116 Plus MEK Inhibitors Exhibited Reduced Tumor Growth In KRAS *In Vivo* Cancer Models



As an inhibitor of ULK kinase, DCC-3116 has been designed to address mutant RAS cancers by inhibiting the basal and compensatory autophagy that mutant RAS cancer cells use for survival. We are currently conducting IND-enabling studies for DCC-3116 and, pending favorable results, we expect to submit an IND to the United States FDA in mid-2020.

Ripretinib Development Update

We are studying our lead drug candidate, ripretinib (DCC-2618) in two ongoing Phase 3 studies in gastrointestinal stromal tumors, or GIST, and in an ongoing Phase 1 trial in patients with multiple advanced malignancies, including GIST. Our first Phase 3 study, INVICTUS, is in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies. INVICTUS was fully enrolled as of November 2018 and is expected to report initial top-line results in August 2019. In June 2019, the FDA granted Fast Track designation for ripretinib for the investigation of the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The FDA's Fast Track program is designed to facilitate the development of drugs intended to treat serious conditions and that have the potential to address unmet medical needs. A drug program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, as well as for Rolling Review, which means that a company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review.

The Conversion

On October 2, 2017, immediately prior to the completion of our IPO, we engaged in a series of transactions whereby Deciphera Pharmaceuticals, LLC became a wholly owned subsidiary of Deciphera Pharmaceuticals, Inc., a Delaware corporation. As part of the transactions, shareholders of Deciphera Pharmaceuticals, LLC exchanged their shares of Deciphera Pharmaceuticals, LLC for shares of Deciphera Pharmaceuticals, Inc. on a one-for-5.65 basis and exchanged their outstanding equity incentive awards of Deciphera Pharmaceuticals, LLC for options to purchase the same number of shares of common stock of Deciphera Pharmaceuticals, Inc. multiplied by 5.65, with a corresponding adjustment to divide the exercise price by 5.65. We refer to these transactions as the Conversion.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our drug candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. If we enter into collaboration agreements or additional license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or additional license agreements that we may enter into with third parties. We expect that our revenue, if any, for the next several years will be derived primarily from the license agreement we entered into with Zai in June 2019 as well as any collaborations 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.

Pursuant to the terms of the Zai License Agreement, we will receive an upfront cash payment of $20.0 million and will be eligible to receive up to $185.0 million in development and commercial milestone payments, consisting of up to $50.0 million of development milestones, including $5.0 million for an INTRIGUE study-related milestone that we achieved, and up to $135.0 million of commercial milestones. In addition, during the term of the Zai License Agreement, Zai will be obligated to pay us tiered percentage royalties ranging from low to high teens on annual net sales of the Licensed Products in the Territory, subject to adjustments in specified circumstances.

Under the Zai License Agreement, we recognized revenue of $25.0 million in the three and six months ended June 30, 2019.

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 contract research organizations, or CROs;
- the cost of consultants and contract manufacturing organizations, or CMOs, that manufacture drug products for use in our preclinical studies and clinical trials; 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. 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 products, if and when approved, whether alone or in collaboration with others such as Zai, our licensee for ripretinib in Greater China;
- 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 the 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 significantly 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.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, commercial, legal, finance and administrative functions. 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 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 operating as a public company.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with an outstanding construction loan from a related party. See “Liquidity and Capital Resources—Construction Loan.”

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.

Income Taxes

Prior to the Conversion, we were treated as a partnership for tax purposes and had not been subject to U.S. federal or state income taxation and as a result, had not recorded any U.S. federal or state income tax benefits for the net losses we had incurred in each year or for our earned research and orphan drug credits. Upon the Conversion, we became subject to typical corporate U.S. federal and state income taxation; however, we do not have net operating loss carryforwards from periods prior to October 2, 2017 available to offset taxable income earned in future periods in which we will be treated as a corporation.

Since the Conversion in October 2017, 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. As of December 31, 2018, we had net operating loss carryforwards for federal income tax purposes of $107.1 million, of which $14.5 million begin to expire in 2037 and $92.6 million may be carried forward indefinitely. As of December 31, 2018, we had net operating loss carryforwards for state income tax purposes of $107.7 million, which begin to expire in 2027. We also had federal and state research and orphan drug credits of $12.8 million and $0.9 million, respectively, as of December 31, 2018, which begin to expire in 2037 and 2032, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. 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 Annual Report on Form 10-K for the year ended December 31, 2018 on file with the SEC and for revenue in Note 2 to our consolidated financial statements appearing elsewhere is this Quarterly Report, 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 June 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Revenue	$ 25,000	$ —	$25,000
Operating expenses:			
Research and development	34,811	17,976	16,835
General and administrative	13,164	4,453	8,711
Total operating expenses	47,975	22,429	25,546
Loss from operations	(22,975)	(22,429)	(546)
Other income (expense):			
Interest expense	(25)	(21)	(4)
Interest and other income, net	1,540	760	780
Total other income (expense), net	1,515	739	776
Net loss	$ (21,460)	$ (21,690)	$ 230

Revenue

Revenue recognized during the three months ended June 30, 2019 of $25.0 million was related to our license agreement with Zai. We recognized license revenue of $20.0 million for an upfront fee and $5.0 million for a development milestone related to the license that was determined to be probable of being met as of June 30, 2019.

Research and Development Expenses

	Three Months Ended June 30, 2019	2018	Change
	(in thousands)		
Direct research and development expenses by program:			
Ripretinib	$ 17,822	$ 9,968	$ 7,854
Rebastinib	2,635	670	1,965
DCC-3014	1,532	781	751
DCC-3116	199	—	199
Discontinued program	1	203	(202)
Unallocated expenses:			
Personnel related (including stock-based compensation)	8,393	4,438	3,955
Facility related and other	4,229	1,916	2,313
Total research and development expenses	$ 34,811	$ 17,976	$16,835

Expenses related to our ripretinib program increased as a result of an increase in clinical trial costs of $7.6 million. The increase in clinical trial costs was due primarily to our pivotal Phase 3 trial in second-line GIST, which we initiated in December 2018, and to our pivotal Phase 3 trial in fourth-line and fourth-line plus GIST, which we initiated in January 2018. We also incurred costs related to other supporting clinical trials for ripretinib.

Expenses related to our rebastinib program increased primarily as a result of an increase in clinical trial costs of $1.9 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 our second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which we initiated in January 2019.

The increase in personnel-related costs included in unallocated expenses was due primarily to an increase in headcount and stock-based compensation expense in our research and development function. Personnel-related costs for the three months ended June 30, 2019 and 2018 included stock-based compensation expense of $1.8 million and $1.0 million, respectively. The increase in stock-based compensation expense was primarily related to the granting of employee stock option awards. The increase in facility related and other costs included in unallocated expenses was primarily due to increased consultant fees of $1.0 million and increased costs incurred in connection with our early-stage drug discovery programs of $0.7 million.

General and Administrative Expenses

	Three Months Ended June 30, 2019	2018	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 5,569	$ 2,150	$3,419
Professional and consultant fees	5,504	1,747	3,757
Facility related and other	2,091	556	1,535
Total general and administrative expenses	$ 13,164	$ 4,453	$8,711

The increase in personnel-related costs was primarily a result of increases in headcount and stock-based compensation expense in our general and administrative function. Personnel-related costs for the three months ended June 30, 2019 and 2018 included stock-based compensation expense of $2.3 million and $1.2 million, respectively. The increase in stock-based compensation expense was primarily related to the granting of employee stock option awards. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness.

Interest and Other Income, Net

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 offering in June 2018.

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Revenue	$ 25,000	$ —	$ 25,000
Operating expenses:			
Research and development	70,600	34,901	35,699
General and administrative	26,400	9,479	16,921
Total operating expenses	97,000	44,380	52,620
Loss from operations	(72,000)	(44,380)	(27,620)
Other income (expense):			
Interest expense	(38)	(43)	5
Interest and other income, net	3,194	1,303	1,891
Total other income (expense), net	3,156	1,260	1,896
Net loss	$ (68,844)	$ (43,120)	$(25,724)

Revenue

Revenue recognized during the six months ended June 30, 2019 of $25.0 million was related to our license agreement with Zai. We recognized license revenue of $20.0 million for an upfront fee and $5.0 million for a development milestone related to the license that was determined to be probable of being met as of June 30, 2019.

Research and Development Expenses

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Direct research and development expenses by program:			
Ripretinib	$ 38,408	$ 19,883	$18,525
Rebastinib	5,950	802	5,148
DCC-3014	2,217	1,657	560
DCC-3116	199	—	199
Discontinued program	5	380	(375)
Unallocated expenses:			
Personnel related (including stock-based compensation)	16,170	8,516	7,654
Facility related and other	7,651	3,663	3,988
Total research and development expenses	$ 70,600	$ 34,901	$35,699

Expenses related to our ripretinib program increased as a result of an increase in clinical trial costs of $19.2 million. The increase in clinical trial costs was due primarily to our pivotal Phase 3 trial in second-line GIST, which we initiated in December 2018, and to our pivotal Phase 3 trial in fourth-line and fourth-line plus GIST, which we initiated in January 2018. We also incurred costs related to other supporting clinical trials for ripretinib.

Expenses related to our rebastinib program increased primarily as a result of an increase in clinical trial costs of $5.1 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 our second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which we initiated in January 2019.

The increase in personnel-related costs included in unallocated expenses was due primarily to an increase in headcount and stock-based compensation expense in our research and development function. Personnel-related costs for the six months ended June 30, 2019 and 2018 included stock-based compensation expense of $3.5 million and $1.9 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock options. The increase in facility-related and other costs included in unallocated expenses was primarily due to increased costs of $1.5 million incurred in connection with our early-stage drug discovery programs and increased consultant fees of $1.3 million.

General and Administrative Expenses

	Six Months Ended June 30,		
	2019	2018	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 13,753	$ 4,180	$ 9,573
Professional and consultant fees	9,548	4,200	5,348
Facility related and other	3,099	1,099	2,000
Total general and administrative expenses	$ 26,400	$ 9,479	$16,921

The increase in personnel-related costs was primarily a result of increases in stock-based compensation expense and headcount in our general and administrative function. Personnel-related costs for the six months ended June 30, 2019 and 2018 included stock-based compensation expense of $6.9 million and $2.3 million, respectively. The increase in stock-based compensation expense was primarily related to the granting of employee stock option awards due to an increase in headcount and the modification of stock options pursuant to the transition agreement with our former President and Chief Executive Officer and additional employee stock options. The increase in professional and consultant fees was primarily due to an increase in various advisory fees, including those related to commercialization preparedness.

Interest and Other Income, Net

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 offering in June 2018.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from our license agreement with Zai and a concluded collaboration agreement and research and development grants from the Kansas Bioscience Authority, or 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 for several years, if at all.

On October 2, 2017, we completed the 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 partial exercise of the underwriters' option to purchase additional shares of common stock, resulting in additional net proceeds of $10.5 million after deducting underwriting 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 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.

Prior to our IPO, we had funded our operations 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 construction loan and research and development grants from the KBA.

Cash Flows

As of June 30, 2019, our principal sources of liquidity were cash, cash equivalents and marketable securities of $225.4 million.

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (70,272)	$ (34,983)
Cash used in investing activities	(167,392)	(1,675)
Cash provided by financing activities	1,137	186,431
Net increase (decrease) in cash and cash equivalents	$(236,527)	$ 149,773

Operating Activities

During the six months ended June 30, 2019, operating activities used $70.3 million of cash, primarily resulting from our net loss of $68.8 million and cash used by changes in our operating assets and liabilities of $10.7 million, partially offset by net non-cash charges of $9.3 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2019 consisted primarily of a $20.0 million increase in accounts receivable and a $5.0 million increase in unbilled receivable, partially offset by a $12.8 million increase in accounts payable and accrued expenses and other current liabilities and a decrease in prepaid expenses and other current assets of $1.3 million.

During the six months ended June 30, 2018, operating activities used $35.0 million of cash, primarily resulting from our net loss of $43.1 million, offset by non-cash charges of $4.4 million and cash provided by changes in our operating assets and liabilities of $3.7 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2018 consisted primarily of a $4.5 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by an increase in prepaid expenses and other current assets of $0.8 million.

Changes in accounts payable, accrued expenses and prepaid expenses in all periods were generally due to growth in our business and the timing of vendor invoicing and payments. The change in accounts receivable and unbilled receivable was due to the Zai license agreement entered into in June 2019.

Investing Activities

During the six months ended June 30, 2019, we used $166.7 million for the net purchases of marketable securities and $0.2 million to purchase property and equipment. During the six months ended June 30, 2019, we increased our restricted investments by $0.4 million to secure a Company credit card account.

During the six months ended June 30, 2018, we used $0.6 million to purchase property and equipment and we increased our restricted investments by $1.1 million to secure a letter of credit associated with our Waltham lease.

Financing Activities

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

During the six months ended June 30, 2018, net cash provided by financing activities was $186.4 million, consisting primarily of proceeds from our follow-on public offering in June 2018, net of underwriting discounts and commissions, of $185.9 million and proceeds from the exercise of stock options of $0.7 million, partially offset by $0.1 million of payments of offering costs and $0.1 million of repayments of notes payable to a related party.

Construction Loan

We are party to a loan agreement and a security agreement, each dated as of June 11, 2010, with Clinical Reference Laboratory, Inc., or CRL, a related party. The loan was assigned to CHC, Inc., a related party, in December 2016. As of June 30, 2019 and December 31, 2018, there was $1.2 million and $1.3 million, respectively, in principal outstanding under the loan.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our drug candidates in development, as well as efforts to support commercialization, should ripretinib receive regulatory approval. In addition, we expect to incur additional costs associated with operating 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 personnel;
- our efforts to enhance operational, financial and information management systems, and hire additional personnel, including personnel to support development of our drug candidates;
- 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 or other arrangement, including the terms and timing of any upfront, milestone and/or royalty payments thereunder.

As of June 30, 2019, we had cash, cash equivalents and marketable securities of $225.4 million. We believe that our cash, cash equivalents and marketable securities as of June 30, 2019, along with the $20.0 million up-front payment from our recent license agreement with Zai, received in the third quarter of 2019, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the fourth quarter of 2020. This excludes any potential milestone or royalty payments, if any, under our license agreement 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 revenue, 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. 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

On April 29, 2019, we amended our lease for office space in Waltham, Massachusetts to add an additional 38,003 square feet of space for a total of 82,346 square feet of space. The lease term for the additional space is expected to commence in early 2020 and expire on November 30, 2029. We are entitled to two five-year options to extend the lease. The initial annual base rent for the additional space is approximately $1.9 million and will increase annually for a total of $18.2 million over the lease term.

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 Annual Report on Form 10-K for the year ended December 31, 2018.

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 Securities and Exchange Commission.

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 2 to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Our cash, cash equivalents and marketable securities as of June 30, 2019 consisted of cash, money market funds, commercial paper, certificates of deposit and U.S government securities. 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, a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations. As of June 30, 2019, our outstanding indebtedness accrued interest at a fixed interest rate. As a result, a change in market interest rates would not have had any impact on our financial position or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, 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 Quarterly Report on 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 six months ended June 30, 2019 and the years ended December 31, 2018 and 2017, we reported a net loss of $68.8 million, $99.9 million and $50.3 million, respectively. As of June 30, 2019, we had an accumulated deficit of $364.6 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, rebastinib, DCC-3014 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, borrowings under a construction loan and research and development grants from the Kansas Bioscience Authority, or KBA. Since our inception, we received an aggregate of $573 million in net proceeds from such transactions. As of June 30, 2019, our cash, cash equivalents and marketable securities were $225.4 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, rebastinib and DCC-3014, 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 will also incur costs associated with advance preparations for a possible marketing approval for ripretinib. We will also 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 first Phase 3 clinical trial of ripretinib for the treatment of fourth-line and fourth-line plus gastrointestinal stromal tumors, or GIST;
- 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 required to obtain U.S. and foreign marketing approval for ripretinib as a treatment for GIST or other indications;
- subject to obtaining favorable results from our Phase 3 trials, completing all requirements for the submission of a new drug application, or NDA, and applying for and obtaining marketing approval for ripretinib;
- successfully manufacture or contract with others to manufacture ripretinib and our other drug candidates;
- commercialize ripretinib, if approved, by building a sales force, 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 collaborations 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 most 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 U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or 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, or the development of any of our drug candidates, 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, rebastinib, DCC-3014 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 June 30, 2019, along with the $20.0 million up-front payment from our recent license agreement with Zai, received in the third quarter of 2019, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the fourth quarter of 2020. This excludes any potential milestone or royalty payments, if any, under our license agreement 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;
- 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 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 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 for many years, 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, have not generated revenue from product sales or profits and do not expect to generate revenue or profits for the foreseeable future. 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, including five clinical 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, obtain marketing approvals, manufacture ourselves or via a third party a commercial product on a commercial scale, or 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 at some point from a company with a research and development focus to a company capable of supporting commercial activities. While these efforts have begun, they are in the early stages and 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 are early in our development efforts. 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. We are early in our development efforts. Two of our drug candidates are only in Phase 1 or Phase 1b/2 clinical trials. We initiated our first Phase 3 clinical trial of one of our drug candidates in January 2018 and our second Phase 3 clinical trial for the same drug candidate in a different line of GIST patients in December 2018. 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 for many years, 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 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 products, if and when approved, whether alone and/or in collaboration with others, such as Zai, our licensee for ripretinib in Greater China;
- 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 the 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 Phase 1 clinical trial of ripretinib or our Phase 3 clinical trials of ripretinib vary meaningfully from our expectations.

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 three 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 two ongoing Phase 3 clinical trials. 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. 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, or 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;
- our third-party contractors, including investigators, may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials;
- the cost of clinical trials for our drug candidates may be greater than we anticipate; 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.

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 FDA. FDA may request additional information or data and any such requests could result in clinical trial delays. Furthermore, 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.

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 initiated a pivotal Phase 3 trial of ripretinib in fourth-line and fourth-line plus GIST and a second Phase 3 clinical trial in second-line GIST. 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 FDA of a new drug application, or 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 may be required to conduct additional clinical trials in the local region or regions where the licensees seek to commercialize our product 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 intend to change the manufacturing process we are using to make clinical supplies of ripretinib for our ongoing clinical trials in anticipation of greater drug requirements for commercialization, if we obtain regulatory approval. We will be required to demonstrate comparability, which will include conducting a bioequivalence study, of ripretinib made with the new process to ripretinib from what we have used in clinical trials to date. If we are unable to establish comparability or bioequivalency, or are unable to agree with FDA on a timely basis regarding the study design necessary to do so, the commercialization of ripretinib may be substantially delayed or constrained by supply. If we are unable to manufacture sufficient quantities of ripretinib to meet commercial demand, our business and results of operations will be harmed.

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 Phase 3 clinical trials 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 FDA or similar regulatory authorities outside of the United States. 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;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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 advanced systemic mastocytosis, or ASM. 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, or 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. 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 to us 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, 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 pocket 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, ASM 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.

The total addressable market opportunity for ripretinib, rebastinib, DCC-3014 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 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;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party coverage and adequate reimbursement;
- 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 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 do not have a sales infrastructure and are only in the very early stages of building a 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 establish sales, marketing and distribution capabilities, either ourselves or through collaboration, licensing or other arrangements with third parties. In addition, our licensee for ripretinib for Greater China is building a marketing infrastructure but currently has limited experience in sales, marketing and distribution of a commercial product.

We plan to build, and are in the process of building, our own focused, specialized sales and marketing organization in the United States. Outside of the United States, in addition to our existing ripretinib license to Zai for Greater China, we plan to selectively establish partnerships in markets outside the United States 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 build our commercialization infrastructure;

- the inability of sales personnel to obtain access to physicians or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As a result of any potential partnerships in markets outside of the United States, or if we are unable to establish our own sales and marketing capabilities in the United States 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, no currently marketed drug directly targets certain secondary resistance mutations in KIT and PDGFRα, or 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 Novartis AG, Pfizer Inc., and Bayer AG. We are also aware of pharmaceutical and biotechnology companies developing drugs for the treatment of GIST and systemic mastocytosis including AB Science S.A., Allakos Inc., Arog Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceuticals U.S.A., Blueprint Medicines Corporation, Bristol-Myers Squibb Company, Celldex Therapeutics, Inc., Novartis AG, Plexxikon Inc., a wholly owned subsidiary of Daiichi Sanyko Company, Limited and Xencor, Inc. Some of these competitors are further along in their clinical development programs than we are in ours. 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 Array BioPharma Inc., Bristol-Myers Squibb Company, Novartis AG, Plexxikon Inc., a wholly owned subsidiary of Daiichi Sankyo Company, Limited, and antibody therapeutics from Amgen Inc., Eli Lilly and Company, Roche Holding Ltd, Five Prime Therapeutics, Inc., Novartis AG, and Syndax Pharmaceuticals, Inc. Further, there are a large number of pharmaceutical and biotechnology companies developing antibody or small molecule colony stimulating factor receptor 1, or CSF1R, inhibitors that we are seeking to target in our DCC-3014 program, including Array BioPharma Inc., Amgen Inc., Eli Lilly and Company, Bristol-Myers Squibb Company, Five Prime Therapeutics, Inc., Roche Holding Ltd, Novartis AG, Plexxikon Inc. and Syndax Pharmaceuticals, Inc.

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.

Even if we or our licensees are able to commercialize any drug candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future 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. To obtain reimbursement or pricing approval in some countries, we or our licensees may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our licensees might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we or our licensees 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 such drug candidates obtain marketing approval.

Our ability (and the ability of our licensees) to commercialize any drug candidates successfully 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 healthcare programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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. Increasingly, government authorities and 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. Coverage and reimbursement may not be available for any product that we or our licensees commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any drug candidate for which we or our licensees obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we and/or our licensees may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. 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. 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 United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability (or the inability of our licensees) to promptly obtain coverage and adequate reimbursement rates from both government-funded and private 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.

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 United States 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, we recently 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, 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 face significant competition in seeking appropriate licensees and/or collaborators. Our ability to reach a definitive agreement for a license and/or collaboration will depend, among other things, upon our assessment of the licensee/collaborator’s resources and expertise, the terms and conditions of the proposed transaction and the proposed licensee/collaborator’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 FDA or similar regulatory authorities outside of the United States;
- 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.

The licensee/collaborator 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 or collaborations 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 those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We currently rely on various third-party clinical research organizations, or CROs, to conduct our ongoing clinical trials for ripretinib, rebastinib and DCC-3014, 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. 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, FDA requires us to comply with requirements, commonly referred to as good clinical practices, or 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. 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, and 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. Some of 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.

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 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 a sole source supplier arrangement for our commercial supply of finished drug product for ripretinib. We acquire many key materials on a purchase order basis. As a result, other than our commercial supply arrangement for our finished drug product for ripretinib, we do not have long term supply arrangements with respect to our drug candidates and other materials. If we obtain marketing approval for ripretinib, we will rely on our sole source supplier to manufacture all of our finished drug product for commercialization unless and until we add an additional source. 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. We will 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 FDA or if 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 FDA. If 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 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 current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. 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, license revocation, 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.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for drug substance or drug product. If our current contract manufacturers for preclinical and clinical testing cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

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, rebastinib, DCC-3014 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 United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office, or 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 United States, 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 United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the United States 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 United States 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 United States 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 United States 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 United States 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 United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States 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 United States. 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 product candidates or technology could have an adverse impact on our business.

Changes to the patent law in the United States 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 United States 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 United States and other countries, including the Leahy-Smith

America Invents Act, or 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 United States 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 United States 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 United States. 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 United States. 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.

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 United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States 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 United States 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. Competitors 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 have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 United States, 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 product 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 Action of 1984, or Hatch-Waxman Amendments. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch-Waxman Amendments permit 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 FDA and the USPTO in the United States, 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 prospects our business 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, 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 FDA and other regulatory agencies in the United States, the EMA in the European Union and China's National Medicinal Products Administration (NMPA) and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. 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 United States 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 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 an NDA, the trial must be well-designed, well-conducted, with a favorable risk/benefit ratio, and provide statistically persuasive efficacy findings so compelling that a second trial would be unethical or practically impossible to repeat. 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 United States 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, 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 United States. For example, we have received orphan drug designation for ripretinib for the treatment of GIST and GBM in the United States.

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 United States and ten years in Europe. Orphan drug exclusivity may be lost if FDA or 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, FDA can subsequently approve the same drug 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. 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 FDA 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. 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 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. 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 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 by FDA for our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will obtain marketing approval.

We may seek a breakthrough therapy designation for some of our drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between 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 FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation 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 FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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 United States would not assure approval of drug candidates in foreign jurisdictions.

In order to market and sell our products in the European Union 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 United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, 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 United States on a timely basis, if at all. Approval by FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by 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 Risk Evaluation and Mitigation Strategy 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 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 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.

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, or the FDCA, and other statutes, including the False Claims Act 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 False Claims Act, or 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- 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, or 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, or 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;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or 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, or 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. 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 payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are often not pre-empted by HIPAA, thus complicating compliance efforts.

In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and non-U.S. laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the European Union as well as to those outside the European Union if they collect and use personal data in connection with the offering of goods or services to individuals in the European Union 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.

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 product 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 United States, 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 product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our product 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 third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product 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 product 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 United States. 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

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 United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. 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 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 CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States 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 product 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 United States. Our inability to promptly obtain coverage and profitable reimbursement rates 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 product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product 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 product 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.

Additionally, we may develop companion diagnostic tests for use with our product 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 product candidates, once 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 product 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 product 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 United States 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 United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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;
- expansion of healthcare fraud and abuse laws, including the False Claims Act 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 President of the United States of America, or the President, 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 Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act 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, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the Affordable Care Act are invalid as well. The Trump Administration and CMS have both stated that the ruling will have no immediate effect pending appeal of the decisions, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. A Fifth Circuit US Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it 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 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 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 President signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration has concluded that cost-sharing reduction, or 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. 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 President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-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. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, 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 Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, 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, the American Taxpayer Relief Act of 2012 and the Middle Class Tax Relief and Job Creation Act of 2012. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

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 Trump administration's budget for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 legislative session or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare 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 Trump 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. The U.S. Department of Health and Human Services, or 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. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to pre-authorization (PA) or step therapy for Part B drugs beginning January 1, 2019. Additionally, on May 10, 2019, the Centers for Medicare and Medicaid Services announced a new pricing transparency rule, which was set to go into effect on July 9, 2019, but on July 8, 2019, a federal judge struck down the rule concluding that HHS did not have the statutory authority to implement such regulations on drug companies. This final rule would have required direct-to-consumer television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product, except for a prescription drug or biological product that has a list price of less than $35 per month for a 30-day supply or typical course of treatment. The pricing transparency rule could have had a negative effect on our business, but Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States 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 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 product. Such reforms could have an adverse effect on anticipated revenue from product 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 product 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 product 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 product 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 recently 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 President signed into law H.R. 1, informally titled the Tax Cuts and Jobs Act, or the TCJA. The TCJA makes 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, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, 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. The effect of the significant changes made by the TCJA is highly uncertain, and administrative guidance will be required in order to fully evaluate the effect of many provisions on our business and stockholders.

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, 2018, 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 United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly Canada and the countries of the European Union, 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. In addition, the recent United Kingdom referendum on its membership in the European Union resulted in a majority of United Kingdom voters voting to exit the European Union, often referred to as Brexit. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the European Union and the United Kingdom.

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 United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, 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, or 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 United States 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 UK Bribery Act 2010, may apply to our operations.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, 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 United States, 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 United States, 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 Securities and Exchange Commission 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 production 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 President and Chief Executive Officer, Michael D. Taylor, Ph.D. retired from his positions with the Company, effective March 18, 2019. Our future operations will depend in large part on the efforts of our new 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. 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 potentially 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 and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters 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, 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 operations, 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 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.

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 control or significantly influence all matters submitted to stockholders for approval.

As of June 30, 2019, 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 54% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control 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 control 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.

We are also party to a loan agreement and a security agreement that includes covenants such as limitations on our ability to engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses.

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, or the Securities Act. 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 prices for our common stock may be adversely impacted by future events.

Our common stock is currently quoted on the Nasdaq Global Select Market under the symbol “DCPH.” 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;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

The price of our common stock may be volatile and fluctuate substantially, 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. 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 $45.61 per share through June 30, 2019. The market price for our common stock may be influenced by many factors, including:

- 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 United States 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;
- variations in our financial results or those of companies that are perceived to be similar to us;
- 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
- 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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. 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 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, 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, or 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, 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

Use of Proceeds from Initial Public Offering

On October 2, 2017, we completed the initial public offering of our common stock pursuant to which we issued and sold 7,500,000 shares of our common stock at a price to the public of $17.00 per share. In addition, on October 4, 2017, we issued and sold an additional 666,496 shares of common stock at the initial public offering price of $17.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock.

The offer and sale of all of the shares in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-220299), which was declared effective by the SEC on September 27, 2017, and a

registration statement on Form S-1MEF (File No. 333-220681), which was automatically effective upon filing with the SEC on September 27, 2017. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. J.P. Morgan Securities LLC and Piper Jaffray & Co. acted as joint book-running managers, JMP Securities LLC as lead manager and Nomura Securities International, Inc. as co-manager of our initial public offering.

We received aggregate gross proceeds from our initial public offering of $138.8 million, or aggregate net proceeds of approximately $124.6 million after deducting underwriting discounts and commissions and offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates, and we have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any such persons.

As of June 30, 2019, we estimate that we have used approximately $115 million of the net proceeds from our initial public offering for clinical development of our drug candidates and research activities and for working capital and other general corporate purposes. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 28, 2017.

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 Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

DECIPHERA PHARMACEUTICALS, INC.

Date: August 2, 2019

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	Third Amendment to Lease, dated April 29, 2019, by and between Deciphera Pharmaceuticals, Inc. and 200 Smith NWALP Property Owner LLC. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 3, 2019).
10.2*	License Agreement, made as of June 10, 2019, 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.

† Indicates management contract or compensation plan.

(1) Schedules and exhibits have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon its request; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit so furnished.

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

Exhibit 10.2

Execution Version

CERTAIN INFORMATION IDENTIFIED BY BRACKETED ASTERISKS ([* * *]) HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

LICENSE AGREEMENT

This **License Agreement** (this "**Agreement**") is made as of June 10, 2019 (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 500 Totten Pond Rd, 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**"). Deciphera and Zai are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Deciphera is a biopharmaceutical company specializing in the field of developing novel drug candidates to treat cancer, and Deciphera and its Affiliates own or control rights to the Compounds and Licensed Products (as defined herein);

WHEREAS, Zai is a pharmaceutical company having experience in the development and commercialization of pharmaceutical products in the Territory;

WHEREAS, Zai wishes to research, develop and commercialize the Licensed Products in the Territory; and

WHEREAS, Deciphera wishes to grant to Zai, and Zai wishes to be granted, the right to Develop and Commercialize (each as defined herein) Licensed Products in the Field in the Territory (each as defined herein) in accordance with the terms and conditions set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1. "**[***] GIST**" means, with respect to patients diagnosed with GIST, [***].

1.2. "**[***] GIST Regional Study**" shall have the meaning set forth in Section 5.4(b).

1.3. "**[***] GIST**" means, with respect to patients diagnosed with GIST, [***].

1.4. "**Acquirer**" shall have the meaning set forth in Section 2.6(b)(i).

1.5. "**Abandoned Development**" shall have the meaning set forth in Section 5.3.

1.6. **"Active Development Activities"** shall have the meaning set forth in Section 5.3.

1.7. "**Adverse Event**" means any unwanted or harmful medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to such Licensed Product, including any undesirable sign (including abnormal laboratory findings of clinical concern).

1.8. "**Affiliate**" means, with respect to a specified Person, any entity that directly or indirectly controls, is controlled by or is under common control with such Person. As used in this Section 1.7, "Control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means, in the case of a corporation, the ownership of fifty percent (50%) or more of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such party or the power to appoint fifty percent (50%) or more of the members of the governing body of the party or, where ownership of fifty percent (50%) or more of such securities or interest is prohibited by law, ownership of the maximum amount legally permitted. Notwithstanding the foregoing, Affiliates of a Party shall exclude Persons who are financial investors in such Person or under common control of such investors other than such Person and its parent and subsidiary entities.

1.9. "**Agreement**" shall have the meaning set forth in the introduction to this agreement.

1.10. "**Alliance Manager**" shall have the meaning set forth in Section 3.1.

1.11. "**Anti-Corruption Laws**" shall have the meaning set forth in Section 12.5(a)(i).

1.12. "**Applicable Laws**" means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the relevant activities contemplated by this Agreement.

1.13. "**Business Day**" means a day other than Saturday, Sunday or any day on which banks located in the United States or the PRC are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

1.14. "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31st, June 30th, September 30th and December 31st.

1.15. "**Calendar Year**" means each twelve (12) month period commencing on January 1st.

1.16. "**cGMP**" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country or region, each as may be amended and applicable from time to time.

1.17. "**Clinical Trial**" means any clinical testing of a Licensed Product in human subjects.

1.18. "**CMOs**" means Third Party contractor manufacture organizations.

1.19. "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which would result in shareholders or equity holders of such Party immediately prior to such transaction, no longer owning at least 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

1.20. "**Combination Product**" means [***].

1.21. "**Commercialization**" or "**Commercialize**" means all activities directed to marketing, distribution, promoting or selling of pharmaceutical products (including importing and exporting activities in connection therewith**)**.

1.22. "**Commercialization Plan**" means the written plan for the Commercialization of the Licensed Product in the Territory.

1.23. "**Commercially Reasonable Efforts**" means with respect to a Party, the use of diligent, good faith efforts and resources, in an active and ongoing program, as normally used by such Party for a product discovered or identified internally or in-licensed from a Third Party that is important to such Party's overall strategy or objectives, which product is at a similar stage in its development or product life and is of similar market potential and intellectual property protection but in the event such Party is Zai, not considering the obligations (including financial) to Deciphera or the rights of Deciphera hereunder; provided, *however*, that in no event shall such efforts and resources be less than those a similarly situated biopharmaceutical company would apply to the development, manufacture, or commercialization of a similarly situated product. Commercially Reasonable Efforts requires that a Party, at a minimum, (i) assign responsibility for such obligations to qualified employees, (ii) set annual goals and objectives for carrying out such obligations, and (iii) allocate adequate resources designed to meet such goals and objectives, in each case, in order to Develop and Commercialize the Licensed Product as an active and ongoing program, and obtain Regulatory Approval for the Licensed Product in the Territory in an expeditious manner and then exercise such efforts towards Commercialization.

1.24. "**Competing Activities**" shall have the meaning set forth in Section 2.6(b)(i).

1.25. "**Competing Product**" shall have the meaning set forth in Section 2.6(a).

1.26. "**Compound**" means (a) ripretinib (also known as DCC-2618), or (b) any Follow-on Compound, in each case, (a) and (b), includes any salt, metabolite, prodrugs, free-base, hydrate, solvate, polymorph, racemate, isotope, stereoisomer enantiomer thereof.

1.27. "**Confidential Information**" means all confidential information of the Disclosing Party or its Affiliates, regardless of its form or medium as provided to the Receiving Party or its Affiliates in connection with this Agreement; provided that, Confidential Information shall not include any information that the Receiving Party can show by competent written evidence: (a) was already known to the Receiving Party at the time it was disclosed to the Receiving Party by the Disclosing Party without an obligation of confidentiality and not through a prior disclosure by the Disclosing Party, (b) was or becomes generally known to the public through no act or omission of the Receiving Party in violation of the terms of this Agreement, (c) was lawfully received by the Receiving Party from a Third Party without restriction on its disclosure and without, to the reasonable knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party, or (d) was independently developed by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party. The terms of this Agreement that are not publicly disclosed through a press release or by filings to financial regulatory authorities shall be the Confidential Information of both Parties.

1.28. "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents or other intellectual property rights, that a party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.29. "**Deciphera**" shall have the meaning set forth in the preamble of this Agreement.

1.30. "**Deciphera Acquired Party**" shall have the meaning set forth in Section 2.6(b)(ii).

1.31. "**Deciphera Background Know-How**" means any and all Know-How Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of this Agreement that [***]. Schedule 1.31 contains a list of Deciphera Background Know-How as of the Effective Date. Deciphera Background Know-How shall include Deciphera's interest in any improvements to any Deciphera Background Know-How [***]. Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Know-How Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be Deciphera Background Know-How for the purposes of this Agreement unless [***].

1.32. "**Deciphera Indemnitee(s)**" shall have the meaning set forth in Section 13.1.

1.33. "**Deciphera IP**" means Deciphera Background Know-How and Deciphera Program IP.

1.34. "**Deciphera Know-How**" means Deciphera Background Know-How and Deciphera Program Know-How.

1.35. **"Deciphera Product Marks"** shall have the meaning set forth in Section 9.4.

1.36. "**Deciphera Program IP**" means the Deciphera Program Know-How and Deciphera Program Patents.

1.37. "**Deciphera Program Know-How**" means any and all Know-How Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of this Agreement that [***]. Schedule 1.37 contains a list of Deciphera Program Know-How as of the Effective Date. Deciphera Program Know-How (i) shall include Deciphera's interest in any improvements to any Deciphera Program Know-How [***] and (ii) all Know-How within the New Program IP. Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Know-How Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be Deciphera Program Know-How for the purposes of this Agreement unless [***].

1.38. "**Deciphera Program Patents**" means the Patents in the Territory Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of the Agreement that [***]. Schedule 1.38 contains a list of Deciphera Program Patents as of the Effective Date. Deciphera Program Patents shall include (i) Deciphera's interest in any improvements to any Deciphera Program Patents [***] and (ii) all Patents in the Territory claiming New Program IP. Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Patent Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be a Deciphera Program Patent for the purposes of this Agreement unless [***].

1.39. "**Deficient Site**" shall have the meaning set forth in Section 5.7(c).

1.40. "**Develop**" or "**Development**" or "**Developing**" means research, discovery, and preclinical and clinical drug or biological development activities, including test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, approval and registration.

1.41. "**Development Milestone Event**" shall have the meaning set forth in Section 10.2(a).

1.42. "**Development Milestone Payment**" shall have the meaning set forth in Section 10.2(a).

1.43. "**Development Plan**" shall have the meaning set forth in Section 5.2.

1.44. "**Development Technology Transfer**" shall have the meaning set forth in Section 4.1.

1.45. "**Disclosing Party**" shall have the meaning set forth in Section 11.1(a).

1.46. "**Dispute**" shall have the meaning set forth in Section 16.1.

1.47. "**DPI**" shall have the meaning set forth in Section 7.4.

1.48. "**Effective Date**" shall have the meaning set forth in the preamble in this Agreement.

1.49. "**Executive Officers**" shall have the meaning set forth in Section 3.2(f).

1.50. "**Expenses**" shall have the meaning set forth in Section 5.4(b).

1.51. "**Expiration Date**" shall have the meaning set forth in Section 15.1(a).

1.52. "**Field**" means the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans.

1.53. "**First Commercial Sale**" means, with respect to any Licensed Product, the first arm's length sale of such Licensed Product to a Third Party in a region of the Territory by Zai, its Affiliate(s) or Sublicensee(s) for use or consumption in such region following Regulatory Approval. Sales prior to receipt of marketing and pricing approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales" and any sales to any government, foreign or domestic, including purchases for immediate sale or stockpiling purposes, are not a First Commercial Sale in that region.

1.54. "**Follow-on Compound**" means a Compound other than ripretinib [***]

1.55. "**FTE**" means the equivalent of the work of a full-time individual for a twelve (12) month period.

1.56. "**FTE Rate**" means a rate of US$[***] per FTE per year, to be pro-rated on an hourly basis of US$[***] per FTE per hour, based on [***] hours per year for an FTE and is subject to adjustments on an annual basis as of January 1 of each year, beginning in [***], by factors which reflect (a) the increase in Deciphera's (or its Affiliate's) costs or (b) any change in the Consumer Price Index for All Urban Consumers (CPI-U) All Items (U.S. city average), as reported by the U.S. Bureau of Labor Statistics, for January 1 of such year when compared to the comparable statistics for January 1 of the preceding year.

1.57. "**Fully Burdened Manufacturing Costs**" means the cost of Manufacturing the Licensed Product. Fully Burdened Manufacturing Costs shall be a "standard cost" per unit (calculated annually), comprised of the following elements calculated in accordance with GAAP: [***]. To the extent that Licensed Products are sourced from one or more CMOs by Deciphera, Fully Burdened Manufacturing Costs shall be the actual invoiced price paid by Deciphera to such CMO(s) for the manufacture and supply of a Licensed Product.

1.58. "**GAAP**" means the United States generally accepted accounting principles, consistently applied.

1.59. "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.60. "**Generic Product**" shall have the meaning set forth in Section10.4(c)(ii).

1.61. "**GIST**" means Gastrointestinal Stromal Tumors as defined in the International Classification of Diseases, 10th Revision (ICD10) as code C49.A0-9.

1.62. "**Global Study**" means a clinical study designed to obtain Regulatory Approvals for the Licensed Products in multiple regions and countries through the conduct of a Clinical Trial in multiple medical institutions, countries, regions, territories and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.63. "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.64. "**Governmental Authority**" means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, region, state or local authority or any political subdivision thereof, or any association of countries.

1.65. "**GSP**" means all applicable Good Supply Practice standards, including, as applicable, as set forth in the then current good supply practice standards promulgated or endorsed by the FDA as defined in Good Supply Practice for Pharmaceutical Products or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.66. "**ICC Rules**" shall have the meaning set forth in Section 16.4(a).

1.67. "**IND**" means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence Clinical Trials in the applicable country.

1.68. "**Indemnifying Party**" shall have the meaning set forth in Section 13.3.

1.69. "**Indemnitee**" shall have the meaning set forth in Section 13.3.

1.70. "**Indication**" means a separate and distinct disease or condition, or sign or symptom of a disease or medical condition. For clarity, different lines of treatment or the treatment of separate stages or forms of the same diseases or medical condition shall not constitute separate Indications.

1.71. "**Initial Development Plan**" shall have the meaning set forth in Section 5.2.

1.72. **"Initiation"** means, with respect to a Clinical Trial, the administration of the first dose of the Licensed Product or comparator to the first patient or subject in such Clinical Trial.

1.73. "**INTRIGUE Study**" shall have the meaning set forth in Section 5.4(a).

1.74. "**Invention**" means any process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented as a result of a Party (or the Parties jointly) exercising its (their) rights or carrying out its obligations under this Agreement, including all rights, title and interest in and to the intellectual property rights therein.

1.75. "**IRB**" shall have the meaning set forth in Section 5.3.

1.76. "**Joint Steering Committee**" or "**JSC**" shall have the meaning set forth in Section 3.2(a).

1.77. "**Know-How**" means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.78. "**Knowledge**" means, with respect to [***].

1.79. "**Licensed Product**" means any pharmaceutical preparation containing the Compound.

1.80. "**Losses**" shall have the meaning set forth in Section 13.1.

1.81. "**Manufacture**" or "**Manufacturing**" or "**Manufactured**" means all operations involved in the manufacturing, filling and finishing, quality control testing (including in-process, release and stability testing, if applicable), storage, releasing and packaging.

1.82. "**Major Market**" shall have the meaning set forth in Section 15.1(c)

1.83. "**Medical Affairs**" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), publications, congress presentations and posters, published manuscripts, activities performed in connection with patient registries and post-approval trials, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product and are not conducted by a Party's medical affairs (or equivalent) departments, all of which shall be conducted in accordance with Applicable Law.

1.84. "**Medical Affairs Plan**" means an overall plan for the Medical Affairs activities for the Licensed Product to be conducted in the Territory prepared and updated by Zai as provided in Section 8.1, however Medical Affairs activities conducted outside the Territory with healthcare professionals resident in the Territory (e.g., meetings at congresses outside the Territory) may be included in this Medical Affairs Plan.

1.85. "**Milestone Events**" means Development Milestone Events and Net Sales Milestone Events.

1.86. "**Milestone Payments**" means Development Milestone Payments and Net Sales Milestone Payments.

1.87. "**Net Sales**" means the gross price billed or invoiced on sales of the Licensed Product by Zai, its Affiliates, or Sublicensees to a Third Party in the Territory, less (without duplication) usual and customary:

(a) [***] discounts actually granted and deducted solely on account of sales of the Licensed Product, but excluding early payment discounts;

(b) rebates actually paid [***] solely on account of the purchase of such Licensed Product;

(c) credits issued for the Licensed Product [***] actually granted and related to the Licensed Product;

(d) (i) freight expense (actual), including insurance, to the extent it is not charged to or reimbursed by the customer, (ii) [***], (iii) bad debt written off under GAAP, with reasonable collection efforts and added back if collected, [***]; and

(e) Taxes (including, but not limited to sales, value added, consumption and similar taxes; but excluding income taxes) actually incurred, paid or collected and remitted to the relevant tax authority for the sale of the Licensed Product; provided that any amount of such taxes refunded, recovered or credited back by the relevant tax authority shall be included in Net Sales.

Each of the amounts set forth above shall be determined from the books and records of Zai, its Affiliate or Sublicensee, maintained in accordance with GAAP or in the case of Sublicensees, such similar accounting principles, consistently applied, and any amounts that are deducted from Net Sales pursuant to one subsection may not be deducted pursuant to another subsection (i.e., a deduction may only be taken once).

The transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party (w) in connection with the Development or testing of a Licensed Product (including the conduct of clinical studies), (x) for purposes of distribution as promotional samples, (y) for indigent or similar public support or compassionate use programs, or (z) by and between Zai and its Affiliates or Sublicensees shall not, in any case, be considered a Net Sale of a Licensed Product under this Agreement. Subject to the foregoing, any sales income received by Zai, its Affiliates or Sublicensees for Licensed Products prior to Regulatory Approval shall be Net Sales and subject to the Royalty Payments under Section 10.4.

Net Sales shall also include and be deemed to have been made with respect to any Licensed Products used by Zai or any Affiliate, for its own commercial purposes, or transferred to any Third Party for less than the transferee is then charging in normal arms-length sales transactions; and Net Sales in all such cases shall be deemed to have been made at the prices therefor at which such Licensed Products are then being sold to the customers of such user or transferor (or of Zai, if an Affiliate is a user but not a seller) in arms-length sales transactions. For clarity, in the event the Licensed Product is sold in an arms-length transaction to a governmental agency, a group purchase entity or any other entity having the bargaining power to negotiate the purchase price below normal retail price in transactions of lesser volume, Net Sales shall be calculated based on the actual price negotiated and agreed to for such agency or entity and not be based on the price charged in other arms-length sales transactions.

To the extent that Zai or any of its Affiliates, or Sublicensees, provides to the purchasing Third Party discounts or allowances that are applicable to purchases of the Licensed Product and one or more other products (such as in a “bundled sale” arrangement), such discounts and allowances shall be allocated between the Licensed Product (for purposes of the deductions used in calculating Net Sales as above) and such other products in an equitable and commercially reasonable manner that does not unfairly or inappropriately bias the level of discounting against the Licensed Product (as compared to the other products).

If Zai or any of its Affiliates, or Sublicensees, sells a Licensed Product as a Licensed Component of a Combination Product in the Territory in any Calendar Quarter, then Net Sales shall be calculated by multiplying the Net Sales of the Combination Product during such Calendar Quarter by the fraction A/(A+B), where A is the average Net Sales per unit sold of the Licensed Component when sold separately in the Territory during such Calendar Year (calculated by determining the Net Sales of the Licensed Component during such Calendar Quarter in accordance with the definition of Net Sales set forth herein and dividing such Net Sales by the number of units of the Licensed Component during such Calendar Quarter) and B is the average Net Sales per unit sold of the Other Component(s) included in the Combination Product when sold separately during such Calendar Quarter (calculated by determining the Net Sales of such Other Component(s) sold during such Calendar Quarter by applying the definition of Net Sales set forth herein as if it applied to sales of such Other Component(s) and dividing such Net Sales by the number of units of such Other Component(s) sold during such Calendar Quarter).

For purposes of calculating the average Net Sales per unit sold of a Licensed Component and Other Component(s) of a Combination Product, any of the deductions described herein that apply to such Combination Product shall be allocated among sales of the Licensed Component and sales of the Other Component(s) included in such Combination Product as follows: (1) deductions that are attributable solely to the Licensed Component or one of the Other Component(s) shall be allocated solely to Net Sales of the Licensed Component or such Other Component, as applicable, and (2) all other deductions shall be allocated among sales of the Licensed Component and sales of the Other Component(s) in proportion to Zai's and Deciphera's mutual agreement of the fair market value of the Licensed Component and the Other Component(s).

In the event that no separate sales of the Licensed Component or any Other Component(s) included in a Combination Product are made by Zai or its Affiliates, or Sublicensees, during a Calendar Quarter in which such Combination Product is sold, the average Net Sales per unit sold in the above described equation shall be replaced with Zai's and Deciphera's mutual agreement of the fair market value of the Licensed Component and each of the Other Component(s) included in such Combination Product.

1.88. "**Net Sales Milestone Event**" shall have the meaning set forth in Section 10.3(a).

1.89. "**Net Sales Milestone Payment**" shall have the meaning set forth in Section 10.3(a).

1.90. "**New IP**" shall have the meaning set forth in Section 14.1(a).

1.91. "**New Program IP**" shall have the meaning set forth in Section 14.1(a).

1.92. "**NMPA**" means the National Medical Product Administration, formerly known as the China Food and Drug Administration, and local or provincial counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.93. **"Party"** or **"Parties"** shall have the meaning set forth in the preamble to this Agreement.

1.94. "**Patent Prosecution**" means the responsibility and authority for (a) preparing, filing and prosecuting applications (of all types) for any Patent, (b) managing any interference, opposition, re-issue, reexamination, invalidation proceedings, revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding to abandon Patent(s), (d) listing in regulatory publications (as applicable), (e) patent term extension, and (f) settling any interference, opposition, revocation, nullification or cancellation proceeding.

1.95. "**Patents**" means (a) all national, regional and international patents and patent applications, including any provisional patent application, (b) any patent application claiming priority from such patent application or provisional patent applications, including divisions, continuations, continuations-in-part, additions, (c) any patent that has issued or in the future issues from any of the foregoing patent applications, including any utility or design patent or certificate of invention, and (d) re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

1.96. "**Person**" means any individual, sole proprietorship, corporation, joint venture, limited liability company, partnership, limited partnership, limited liability partnership, trust or any other private, public or governmental entity.

1.97. "**Pharmacovigilance Agreement**" shall have the meaning set forth in Section 6.4(a).

1.98. "**Phase I Clinical Study**" means any Clinical Trial(s), the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirement of 21 C.F.R. § 312.21(a), or its foreign equivalent, as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws.

1.99. "**Phase III Clinical Study**" means any Clinical Trial(s), which Clinical Trial(s) is (are) designed to (a) establish that the Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) be a pivotal study for submission of an Regulatory Approval Application to obtain Regulatory Approval for such Licensed Product in any region or regulatory jurisdiction, as defined in 21 C.F.R. § 312.21(c), or its foreign equivalent, as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws.

1.100. "**PRC**" means the People's Republic of China, which for the purposes of this Agreement shall exclude Hong Kong, Macau, and Taiwan.

1.101. "**Prime Rate**" means for any day a per annum rate of interest equal to the "prime rate," as published in the "Money Rates" column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least percent (70%) of the ten largest U.S. banks.

1.102. "**Product Infringement**" shall have the meaning set forth in Section 14.4(a).

1.103. "**Product Marks**" shall have the meaning set forth in Section 9.4.

1.104. "**Product Specifications**" means the acceptance criteria agreed by the Parties, including numerical limits, ranges or other criteria for the Licensed Product.

1.105. "**Public Official**" shall have the meaning set forth in Section 12.5(d).

1.106. "**Quality Agreement**" shall have the meaning set forth in Section 7.2.

1.107. "**Receiving Party**" shall have the meaning set forth in Section 11.1(a).

1.108. "**Reduced Taxes**" shall have the meaning set forth in Section 10.8.

1.109. **"Regional Studies"** shall have the meaning set forth in Section 5.2(b).

1.110. "**Regulatory Approval**" means, with respect to a Licensed Product in a region or a country, the approvals from the necessary Governmental Authority or Regulatory Authority to import, market and sell such Licensed Product in such region, including pricing approvals (but excluding reimbursement approvals**)**.

1.111. "**Regulatory Approval Application**" means a New Drug Approval Application or Biologics License Application (each, as defined in the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time) in the U.S., or any corresponding application for approval to market or sell a product in any country, region or jurisdiction in the Territory outside the U.S.

1.112. "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting Regulatory Approvals for Licensed Products, including the NMPA, and any corresponding national or regional regulatory authorities.

1.113. "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Licensed Product.

1.114. "**Remedial Action**" shall have the meaning set forth in Section 6.8.

1.115. "**Replacement Site**" shall have the meaning set forth in Section 5.7(c).

1.116. "**Retained Rights**" shall have the meaning set forth in Section 2.2.

1.117. "**Royalty Payment**" shall have the meaning set forth in Section 10.4(a).

1.118. "**Royalty Term**" shall have the meaning set forth in Section 10.4(b).

1.119. [***]

1.120. "Sublicensee" means a Third Party, or Zai's Affiliates who was granted a sublicense by Zai under the licenses granted in Section 2.1. For clarity, a Third Party who was granted a sublicensee by a Sublicensee shall also be deemed a Sublicensee.

1.121. "**Supply Agreement**" shall have the meaning set forth in Section 7.2.

1.122. "**Supply Notice**" shall have the meaning set forth in Section 15.1(c).

1.123. "**Support Studies**" shall have the meaning set forth in Section 5.2(b).

1.124. [***]

1.125. [***]

1.126. "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon**)**. For the avoidance of doubt, Taxes includes VAT.

1.127. "**Term**" shall have the meaning set forth in Section 15.1.

1.128. "**Territory**" means the PRC, Hong Kong, Macau, and Taiwan (which for purposes of this Agreement shall each be deemed a region**)**.

1.129. [***]

1.130. "**Third Party**" means an entity other than (a) Zai and its Affiliates or (b) Deciphera and its Affiliates.

1.131. "**Transition Period**" shall have the meaning set forth in Section 15.8(b)(iv).

1.132. "**U.S. Dollars**" or "**$**" means United States dollars, the lawful currency of the United States.

1.133. "**Upfront Payment**" shall have the meaning set forth in Section 10.1.

1.134. "**Valid Claim**" means (a) a claim of an issued and unexpired Patent included within the Deciphera Program Patents that (i) covers the practice of the Licensed Product in the Territory that (ii) has not been permanently revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a claim of a pending patent application included within the Deciphera Program Patents in the Territory that (1) would cover the practice of the Licensed Product in the Territory if such claim was to issue, (2) has not been pending for more than [***] from its earliest priority date, and (3) (A) has not been cancelled, withdrawn or abandoned or (B) finally rejected by an administrative agency action from which no appeal can be taken or that has not been appealed within the time allowed for appeal.

1.135. "**VAT**" means value-added taxes or other similar taxes.

1.136. [***].

1.137. "**Zai**" shall have the meaning set forth in the preamble of this Agreement.

1.138. "**Zai Acquired Party**" shall have the meaning set forth in Section 2.6(b)(iii).

1.139. "**Zai Indemnitee(s)**" shall have the meaning set forth in Section 13.2.

1.140. "**Zai IP**" means any and all Know-How and Patents Controlled by Zai or its Affiliates as of the Effective Date or during the Term that are generated or used by Zai in the Development, packaging, having packaged, or Commercialization of a Licensed Product; provided that if any such Know-How or Patent is in-licensed by Zai from a Third Party, then such Know-How or Patent shall not be included in Zai IP unless Deciphera agrees in writing to comply (and does in fact comply) with the applicable terms and conditions of such Third Party license and to pay (and does in fact pay) any amount that Zai is obligated to pay such Third Party on account of Zai's grant and/or Deciphera's exercise of a sublicense under such Know-How or Patent.

ARTICLE 2

LICENSES; NON-COMPETE

2.1. License Grant to Zai.

(a) Subject to the terms and conditions of this Agreement, Deciphera hereby grants to Zai, during the Term, (i) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Program IP to Develop, package or have packaged, distribute, use, sell, offer for sale, import and otherwise Commercialize the Licensed Products in the Field in the Territory; (ii) a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Background Know-How to Develop, package or have packaged, distribute, use, sell, offer for sale, import and otherwise Commercialize the Licensed Products in the Field in the Territory; and (iii) a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Program IP and Deciphera Background Know-How to package or have packaged the Licensed Product in [***] for Development, distribution, use, sale and Commercialization in the Field in the Territory.

(b) For clarity, the licenses granted under this Section 2.1 (i) do not include the right to primary or secondary Manufacture or to have Manufactured the Compound, Licensed Products or drug substance of the Licensed Products in the Field in the Territory but (ii) include the right for Zai to package the Licensed Product in the Territory solely pursuant to Section 7.1.

2.2. Deciphera Retained Rights. Notwithstanding anything to the contrary in this Agreement, Deciphera hereby expressly retains, on behalf of itself (and its Affiliates, licensees, and sublicensees) (a) all rights under the Deciphera IP to fulfill, either itself, its Affiliates or

through subcontractors, Deciphera's obligations under this Agreement, (b) subject to Section 2.6 and subject to Zai's non-exclusive right to package or have packaged the Licensed Product in [***] in accordance with Section 2.1(a), the exclusive rights with respect to Deciphera IP to the extent relating to the Development, Manufacture and Commercialization of the Compound or Licensed Product outside the Territory, and (c) (i) the non-exclusive rights under the Deciphera IP to Develop or have Developed, and (ii) the exclusive the rights to Manufacture or have Manufactured, in each case of (i) and (ii) the Compound or Licensed Product in the Territory solely to support (1) the Development and Commercialization of the Licensed Product by Deciphera outside of the Territory or (2) the Development and Commercialization of the Licensed Product by Zai in the Territory (including through the conduct of Global Studies by Deciphera pursuant to Section 5.4) (the "**Retained Rights**"). In the event that Deciphera wishes to exercise its Retained Rights to Manufacture or have Manufactured the Licensed Product in the Territory, or to conduct the Global Studies in the Territory during the Term, Deciphera shall notify Zai in writing and the Parties shall discuss and coordinate regulatory activities relating to such Manufacture and Development activities in the Territory; provided that in no event such discussion and coordination shall diminish Deciphera's sole discretion and final decision-making authority with respect to any Global Study. Zai acknowledges and agrees that the Retained Rights includes the right for Deciphera to grant licenses under clause (a) or clause (c) of the Retained Rights to its Affiliates and Third Parties in the Field in the Territory; provided that, except for sales to Zai, subject to Section 15.1, during and after the expiration (but not early termination) of the Term, Deciphera shall not, and shall obligate its Affiliates, licensees, and sublicensees to not, sell or offer for sale in the Territory any Licensed Product Manufactured under the Retained Rights. For the avoidance of doubt, subject to Section 15.1, the Retained Rights shall exclude the right under the Deciphera IP to Commercialize the Compound or Licensed Product in the Field in the Territory during and after the expiration (but not early termination) of the Term, and Deciphera, its Affiliates and licensees shall not undertake such Commercialization in the Field in the Territory without Zai's express prior written consent.

2.3. Right to Sublicense.

(a) **General**. [***] Zai shall have the right to grant sublicenses to any Third Party as proposed in writing by Zai under the licenses granted in Section 2.1. Zai shall have the right to grant sublicenses to its Affiliates under the licenses granted in Section 2.1 [***]. Zai shall be liable for (i) its Sublicensee's conduct that is prohibited under this Agreement, and (ii) its Sublicensee's breach of this Agreement which shall be deemed a breach of this Agreement as if Zai had itself conducted the action or inaction attributed to the beach of this Agreement, provided that Zai shall have the right to cure, if curable, such breach on behalf of such Sublicensee within [***] days following the receipt of notice of such breach.

(b) **Restrictions**. Zai shall not grant a sublicense to any Third Party that has been debarred or disqualified by any Governmental Authority or is subject to any proceedings, sanctions or fines under any Anti-Corruption Law. Zai shall ensure that, prior to engaging any Third Party as a Sublicensee that such Third Party is subject to written agreements containing terms and conditions that: (i) require each such Sublicensee to protect and keep confidential any Confidential Information of the Parties, including in accordance with ARTICLE 11; (ii) provide Deciphera with the right to audit (either by itself or through Zai or Zai's designee) the books and records of each such Sublicensee in accordance with this Agreement (including pursuant to

Sections 5.7(b), 6.5, 9.6, 10.6(d), and 12.5(a)(iv)); (iii) do not impose any payment obligations or liability on Deciphera; and (iv) are otherwise consistent with the terms of this Agreement. Zai shall provide a copy of the complete executed agreement with each Sublicensee to Deciphera; provided that Zai shall be permitted to redact commercially sensitive economic terms of any such agreement which terms are not necessary for Deciphera to confirm its rights hereunder. Zai shall remain primarily responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any Sublicensee.

2.4. License Grant to Deciphera. Zai hereby grants to Deciphera a perpetual, non-exclusive, fully paid-up and royalty free, transferrable, unlimited, sublicenseable (in multiple tiers) license under Zai IP to (a) fulfill, either itself, its Affiliates or through subcontractors, its obligations under this Agreement, including its manufacturing and supply obligations under ARTICLE 7, (b) Develop or Manufacture the Compound and Licensed Product in the Territory solely for the purpose of the Development and Commercialization of the Compound and Licensed Product outside the Territory, and (c) Develop, Manufacture and Commercialize the Compound and Licensed Product outside the Territory.

2.5. No Implied Licenses; Negative Covenant. Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, trademarks, patents or patent applications of the other Party. Each Party shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Patent or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6. Exclusivity.

(a) **Non-Compete**. During the Term, except as provided in Section 2.6(b) below or otherwise expressly contemplated under this Agreement, neither Party shall, and each Party shall cause its Affiliates and Sublicensees to not, engage in (independently or for or with any Third Party) any Development, Manufacture or Commercialization in the Territory of any compound or product that is [***]; provided that in the event (i) [***]; and (ii) [***] then (iii) the Parties shall discuss in good faith whether such pharmaceutical product would not be deemed a Competing Product for the purposes of this Agreement and (iv) [***], shall such pharmaceutical product not be deemed a Competing Product.

(b) **Change of Control; Acquisition**.

(i) **Change of Control of a Party**. In the event that a Party or any of its Affiliates undergoes a Change of Control with a Third Party (a "**Acquirer**"), the restrictions set forth in Section 2.6(a) shall not apply to (1) any activities that would otherwise constitute a breach of Section 2.6(a), including a Competing Product that is being developed, manufactured or commercialized (collectively, "**Competing Activities**"), [***]

(ii) **Acquisition of a Third Party by Deciphera**. In the event that Deciphera or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transactions) (a "**Deciphera Acquired Party**"), the restrictions set forth in Section 2.6(a) shall not apply [***]

(iii) **Acquisition of a Third Party by Zai**. In the event that Zai or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transactions) (a "**Zai Acquired Party**"), that is performing any Competing Activities at the closing of such transaction, then [***]. Notwithstanding the foregoing, in the event [***], then [***] unless and until [***].

ARTICLE 3

GOVERNANCE

3.1. Alliance Managers. Within thirty (30) days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) to act as its alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall (a) facilitate the flow of information; (b) otherwise promote communication, coordination and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party or cross-functional disputes in a timely manner; and (c) manage the JSC meetings by (i) calling meetings of the JSC; (ii) preparing and issuing minutes of each such meeting within ten (10) Business Days thereafter; and (iii) preparing and circulating an agenda for the upcoming meeting, in each case at the direction of and in consultation with the then current chairperson. Each Party may replace its Alliance Manager by written notice to the other Party.

3.2. Joint Steering Committee.

(a) **Formation**. Within twenty (20) days after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**") to cooperate, coordinate, integrate, monitor and oversee the Development and Commercialization of the Licensed Products in the Field in the Territory under this Agreement. Each Party shall appoint three (3) representatives to the JSC, each of whom shall be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its JSC representatives upon written notice to the other Party. Upon the JSC's establishment, a representative from Zai shall act as the chairperson of the JSC. Once a year, the role of chairperson shall rotate between representatives of the Parties. The chairperson shall not have any greater authority than any other representative of the JSC.

(b) **Role**. The JSC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review, discuss and approve the overall strategy for the Development and Commercialization of the Licensed Product in the Field in the Territory; (iii)

review, discuss and approve the Development Plan and amendments thereto; (iv) review and discuss the Commercialization Plan and amendments thereto; (v) review, discuss and approve the Product Specifications; (vi) establish subcommittees as necessary or advisable to further the purpose of this Agreement; (vii) report safety issues of the Licensed Products to Regulatory Authorities; (viii) manage the supply chain; (ix) through a subcommittee solely consisting of medical affairs personnel, review, discuss, and approve the Medical Affairs Plan and oversee the Medical Affairs activities of the Parties in the Territory; and (x) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

(c) **Limitation of Authority**. The JSC shall only have the powers expressly assigned to it in this ARTICLE 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) make any decisions related to, or [***] other matters related to [***] or (v) impose any other obligations on either Party without the prior written consent of such Party. Notwithstanding anything to the contrary under this Agreement or in the Development Plan, [***].

(d) **Meetings**. The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every Calendar Quarter until the earlier of (i) one (1) year after the Effective Date, or (ii) Zai first receives a Regulatory Approval Application for the Licensed Product in the PRC. Thereafter, the JSC shall hold meeting no less frequently than once every six (6) months. Each Party may call additional ad hoc JSC meetings as the needs arise with reasonable advance notice to the other Party. Meetings of the JSC may be held in person, by audio or video teleconference; provided that at least one (1) meeting per Calendar Year of the JSC shall be held in person. In-person JSC meetings shall be held at locations selected alternately by the Parties. Each Party shall be responsible for such Party's expenses of participating in the JSC meetings. No action taken at any JSC meeting shall be effective unless at least two (2) representatives of each Party are participating in such JSC meeting.

(e) **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants relevant to items on the issued agenda, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making**. All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within [***] after such matter was brought to the JSC for resolution, such matter shall be referred by the Parties' Alliance Managers to the Chief Executive Officer of Deciphera (or a senior office designated by the Chief Executive Officer of Deciphera) and the Chief Executive Officer of Zai (or a senior office designated by the Chief Executive Officer of Zai) (the "**Executive Officers**") for resolution. [***]

(g) **Exchange of Information**. The Parties shall cooperate to exchange information with respect to Development, Commercialization and Medical Affairs activities conducted by each Party and their Affiliates, licensees and sublicensees. Such exchange shall include summaries of all Clinical Trials and other studies of the Licensed Product as reasonably requested by a Party. For Clinical Trials that may be used to support Regulatory Approval in the other Party's Territory (including Global Studies), such exchange shall also include all data, results and analyses as reasonably requested by a Party, and the other Party shall have the right to use such data and results for the purpose of obtaining and maintaining Regulatory Approval of the Licensed Product in its territory.

ARTICLE 4

DEVELOPMENT TECHNOLOGY TRANSFERS

4.1. Transfer of Deciphera Know-How. Deciphera shall transfer to Zai all Deciphera Know-How listed in Schedule 1.31 and Schedule 1.37 to the extent necessary or reasonably useful for Zai to perform its obligations under this Agreement, which transfer shall occur in a manner and following a reasonable schedule established by the JSC. During the Term, Deciphera shall provide Zai with additional Deciphera Know-How, to the extent such Deciphera Know-How comes to Deciphera's attention (or are reasonably requested by Zai) and have not previously been provided to Zai, to the extent necessary or reasonably useful for Zai to exercise its rights or perform its obligations under this Agreement.

4.2. Assistance by Deciphera. At Zai's reasonable request, Deciphera shall cooperate with Zai to provide such reasonable technical assistance as may be necessary in connection with (a) the transfer to Zai of the Development of Licensed Products in the Territory and (b) the seeking of Regulatory Approval for Licensed Products in the Territory, in each case as is consistent with the capacity and capabilities of Deciphera. Upon Zai's request for any reasonable technical assistance, Deciphera shall provide Zai with such reasonable technical assistance [***]. For clarity, [***] part of technical assistance provided to Zai by Deciphera to the extent [***].

4.3. No Manufacturing Technology Transfer. For the avoidance of doubt, Deciphera shall not be obligated to transfer any Know-How Controlled by Deciphera or its Affiliates or otherwise relating to the Manufacture of the Licensed Product to Zai.

ARTICLE 5

DEVELOPMENT

5.1. Diligence and Responsibilities.

(a) Zai shall be responsible for, and shall use Commercially Reasonable Efforts to, Develop the Licensed Product in the Field in the Territory in accordance with the Development Plan. For clarity, Zai shall use Commercially Reasonable Efforts to Develop the Licensed Products pursuant to the Development Plan [***].

(b) Zai shall use Commercially Reasonable Efforts to conduct its tasks pursuant to the Development Plan and to achieve the objectives of the Development Plan. Zai shall perform such obligations under the Development Plan in a professional manner, and in compliance in all respects with the Development Plan and the requirements of Applicable Laws, GCP and cGMP. Changes in the scope or direction of the Development work under this Agreement that would require a material deviation from the Development Plan must be approved by the JSC as set forth in Section 3.2(b).

(c) Zai shall use Commercially Reasonable Efforts to Develop the Licensed Product through the most expeditious available regulatory pathway in the Territory.

5.2. Development Plan. The Parties shall undertake the Development of the Licensed Product in a collaborative and efficient manner in accordance with this ARTICLE 5. The Development of the Licensed Product relating to the Territory under this Agreement shall be governed by a written Development Plan (the **"Development Plan"**), as such Development Plan may be revised from time to time in accordance with this Section 5.2. The Development Plan shall also include an outline of the Global Studies; provided that for clarity, such outline shall be for purposes of reference only [***]. Deciphera shall provide Zai with the protocol of the Global Studies upon request. The Development Plan shall contain in reasonable detail the major Development activities and the timelines for achieving such activities, including activities designed to achieve Regulatory Approvals for the Licensed Product in the Territory [***]. As of the Effective Date, the Parties have agreed to the initial Development Plan, which is attached hereto as Schedule 5.2 (the "**Initial Development Plan**"). From time to time, [***], Zai shall propose updates or amendments, if any, to the Development Plan in consultation with Deciphera and submit such proposed updated or amended plan to the JSC for review, discussion, and approval. In accordance with Section 3.2(b), the JSC shall review and approve any updates or amendments to the Development Plan.

(a) The Initial Development Plan shall list those activities that the Parties mutually agree that Zai shall undertake over a [***] period from the Effective Date for the purpose of coordinating and integrating the Development activities for the worldwide Development of the Licensed Products.

(b) The Initial Development Plan shall include (i) a list of any non-clinical studies or Clinical Trials in the Territory or outside the Territory (other than the Global Studies) that the Parties mutually agree would be required to support the regulatory activities in the Territory, such as drug interaction studies or comparability studies in connection with any manufacturing process changes (the "**Support Studies**"), or (ii) any country-specific development plans required to support registration of a Licensed Product in one or more regions in the Territory that are not covered under the Global Studies or Support Studies (the "**Regional Studies**").

5.3. Abandoned Development. If, prior to the First Commercial Sale of any Licensed Product Developed under the Development Plan, (a) no Active Development Activities (as defined below) have been conducted by Zai, its Affiliates or permitted Sublicensee for [***], (b) such inactivity was not caused by a Serious Adverse Event or Serious Adverse Drug Reaction reported pursuant to the Pharmacovigilance Agreement, Regulatory Authority or was not due to

a force majeure event or Deciphera's failure to supply sufficient quantities of the Licensed Product to Zai, and (c) Deciphera has complied with its obligations under this Agreement and the Supply Agreement during such time period, then Zai shall be deemed to have abandoned the Development under the applicable Development Plan for the Licensed Product therein ("**Abandoned Development**"). [***]. "**Active Development Activities**" exists if Zai has performed or is performing any of the following Development activities: [***].

5.4. Global Study.

(a) **General**. Deciphera (i) may initiate, suspend, or cease a Global Study for the Licensed Product for any Indication and (ii) shall [***] such Global Study or [***] such Global Study. The Parties acknowledge that Deciphera is currently conducting a Global Study for the Licensed Product for [***]. Notwithstanding anything to the contrary hereunder, (1) Deciphera shall be responsible for all Clinical Trial costs for any Global Study initiated and conducted by Deciphera [***] in the Territory, such costs to exclude all FTE costs and related expenses incurred by Zai in providing such assistance (referred to in the preceding sentence) in the Territory related to a Global Study, (2) [***] (3) Zai shall provide reasonable assistance [***] to Deciphera for any such Global Study in the Territory upon reasonable request of Deciphera, (4) Deciphera shall keep Zai reasonably informed of any material activities or progress of any such Global Study to the extent related to the Development of the Licensed Products in the Territory, and (5) Zai may provide recommendations or advice on Clinical Trial sites, and other Territory-specific matters in relation to any such Global Study, which Deciphera shall consider in good faith; provided, however, [***].

(b) [***].

5.5. Development Reports. The status, progress and results of Zai's Development activities under this Agreement shall be discussed at meetings of the JSC. At least [***] each regularly scheduled JSC meeting, Zai shall provide the JSC with a written report detailing its Development activities and the results thereof, covering subject matter at a level of detail reasonably required by Deciphera and sufficient to enable Deciphera to determine Zai's compliance with its diligence obligations pursuant to Section 5.1 and Section 5.3. Through the JSC, Deciphera shall keep Zai reasonably informed on the Development of the Licensed Product conducted by or on behalf of Deciphera, including the Global Studies and Support Studies. In addition, each Party shall make available to the other Party such additional information about its Development activities as may be reasonably requested by the other Party from time to time. All updates and reports provided by a Party pursuant to this Section 5.5 shall be the Confidential Information of such Party.

5.6. Development Costs. Zai shall be solely responsible for all expenses and costs incurred for all Development, packaging, having-packaged, and Commercialization of the Licensed Products in the Territory and packing and having-packaged in [***], including those incurred for the Regional Studies in the Territory but expressly excluding the cost of any Global Studies (which cost shall be borne solely by Deciphera unless otherwise agreed by the parties in writing) pursuant to Section 5.4, [***]. Zai shall be responsible for all expenses and costs incurred for the portion of the Support Studies that is conducted in the Territory and Deciphera shall be responsible for all expenses and costs incurred for the portion of such Support Studies that is conducted outside the Territory.

5.7. Clinical Trial Audit Rights.

(a) **Clinical Trials**. Each Party shall conduct all Clinical Trial of the Licensed Products in compliance with all Applicable Laws, including GCP and regulations promulgated by the NMPA and FDA.

(b) **Conduct of Audits**. [***] Deciphera or its representatives may conduct an audit of Zai, its Affiliates, or any Sublicensees, subcontractors, and all Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees, subcontractors to perform Zai's obligations under any Development Plan, in each case, to ensure that the applicable Clinical Trials are conducted in compliance with the Development Plan, GCP, and Applicable Laws; provided that in the event any such audit of Zai's subcontractors or Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees, subcontractor requires Zai's assistance, Zai shall provide Deciphera or its representatives with such assistance [***], to the extent reasonable, including providing personnel of Zai to be present for such audit and producing any documents or authorizations allowing Deciphera or its representatives to conduct such audit, to the extent reasonable. No later than thirty (30) days after the completion of such audit, Deciphera shall provide Zai with a written summary of Deciphera's findings of any deficiencies or other areas of remediation that Deciphera identifies during any such audit. Zai shall use Commercially Reasonable Efforts to respond or remediate any such deficiencies within thirty (30) days following Deciphera's receipt of such report. Without limiting the foregoing, Zai shall have the right to be present at any such audit conducted by Deciphera pursuant to this Section 5.7 of any Sublicensees, subcontractors, subcontractors or Clinical Trial sites. For the avoidance of doubt, [***].

(c) **Deficient Sites and Replacement**. With respect to any Clinical Trial in a Support Study or Regional Study, if the Parties acting reasonably and in good faith agree that any deficiencies with respect to a Clinical Trial site identified pursuant to Section 5.7(b) (each, a "**Deficient Site**") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the conduct of any such Clinical Trial at such Deficient Site, then Deciphera shall notify Zai of such Deficient Site and the Parties shall discuss and attempt to agree upon a remediation plan for such Deficient Site. If the Parties cannot agree to such a remediation plan for a Deficient Site, then Zai shall promptly remove such Deficient Site from such Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") in the Territory, and Zai shall be solely responsible for the costs of such replacement (unless not permitted by Applicable Law or for ethical reasons). Any such Replacement Site shall be compliant in all respects with Applicable Law.

5.8. Records. Each Party shall maintain appropriate records in either tangible or electronic form of (a) all significant Development, Manufacture, final packaging, and Commercialization events and activities conducted by it or on its behalf related to a Licensed Product; and (b) all significant information generated by it or on its behalf in connection with the Development, Manufacture, packaging, or Commercialization of a Licensed Product, in each case in accordance with its usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in a good scientific manner, all significant work

done, and the results of studies and trials undertaken and, further, shall be at a level of detail appropriate for patent and regulatory purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines. Upon a Party's reasonable request, the other Party shall, and shall cause its Affiliates and Sublicensees, to provide to the first Party copies of such records (including access to relevant databases, if any) of Development, packaging, and Commercialization activities to the extent necessary for the Development, packaging, and Commercialization of the Licensed Product in the other Party's territory, including for regulatory and patent purposes. All such records, reports, information and data provided shall be subject to the confidentiality provisions of ARTICLE 11.

ARTICLE 6

REGULATORY

6.1. Zai's Responsibilities. Zai shall use Commercially Reasonable Efforts to obtain Regulatory Approvals and pricing and reimbursement approvals for Licensed Products in the Territory in accordance with the Development Plan and Zai shall be solely responsible for all costs and expenses incurred in connection with performing such activities in the Territory. Zai shall be responsible for all regulatory activities leading up to and including the obtaining of the Regulatory Approvals for a Licensed Product from the Regulatory Authority on a region-by-region basis, at its sole cost and expense. Zai or its designee shall own, hold and maintain all Regulatory Approvals for a Licensed Product in the Territory; provided however that [***]; provided that in the event [***]. Zai shall keep Deciphera promptly informed of regulatory developments related to the Licensed Products in the Territory and shall promptly notify Deciphera in writing of any decision by any Regulatory Authority in the Territory regarding a Licensed Product.

(a) **Review of Regulatory Submissions**. Each Party shall provide to Deciphera for review and comment drafts of all Regulatory Submissions in the Territory for the Licensed Products no later than [***] prior to the planned submission. Each Party shall incorporate any comments received from the other Party on such Regulatory Submissions where required under any Applicable Law and shall consider in good faith any other comments received from the other Party on such Regulatory Submissions. In addition, each Party shall notify the other Party of any material Regulatory Submissions for the Licensed Products and any other material documents, comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and shall provide such other Party with copies thereof as soon as reasonably practicable, but in all events within [***] after submission or receipt thereof. If any such Regulatory Submission, comment, or correspondence is not in English, then, at the other Party's request and expense, the Party providing such copies shall also provide the other Party with a written English translation within the corresponding timelines as set forth in this ARTICLE 6.

(b) **Notice of Meetings**. Each Party shall provide the other Party with notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product no later than [***] after receiving notice thereof. The notifying Party shall lead any such meeting or discussion and the other Party or its designee shall have the right, but

not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. At the notifying Party's request, the other Party shall reasonably cooperate with the notifying Party in preparing for any such meeting or discussion. If the notified Party elects not to attend such meeting or discussion, then the notifying Party shall provide to the other Party a written summary thereof in English promptly following such meeting or discussion.

(c) **Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Zai relating to any Licensed Product, then Zai shall notify Deciphera of such contact, inspection, or notice or action within [***] after receipt of such notice (or, if action is taken without notice, within [***] of Zai becoming aware of such action). Deciphera shall have the right to review and comment on any other responses to Regulatory Authority that pertain to a Licensed Product in the Territory.

6.2. Deciphera's Responsibilities. Deciphera shall reasonably cooperate with Zai in obtaining any Regulatory Approvals for a Licensed Product in the Territory by providing, to the extent reasonably required by Zai, access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for the Licensed Product outside of the Territory pursuant to ARTICLE 4 if such information is required in furtherance of such Regulatory Approvals. In addition, upon Zai's reasonable request, Deciphera shall, and shall cause its Affiliates and sublicensees (to the extent permitted in such sublicensees' agreement with Deciphera), to provide to Zai copies of such records of Development, Manufacturing, and Commercialization activities to the extent necessary or reasonably useful to obtain Regulatory Approval of the Licensed Product in the Territory. [***].

6.3. Right of Reference. Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to the Licensed Product in the Field submitted by or on behalf of such Party. Zai may use such right of reference to Deciphera's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining Regulatory Approval of the Licensed Products in Field in the Territory. Deciphera may use the right of reference to Zai's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining Regulatory Approval of the Licensed Products outside the Territory.

6.4. Adverse Events Reporting.

(a) Promptly following the Effective Date, but in no event later than thirty (30) days thereafter, Zai and Deciphera shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Products, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the "**Pharmacovigilance Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The Pharmacovigilance Agreement shall be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 6.4, Section 6.5, or any related definitions and the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control with respect to safety matters and this Agreement shall control with respect to all other matters.

(b) Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Territory for all Clinical Trials performed by Zai and Deciphera shall be responsible for complying with all Applicable Laws covering Adverse Events (i) in the Territory for all Clinical Trials performed by Deciphera ([***]) and (ii) outside the Territory for all Clinical Trials.

6.5. Safety and Regulatory Audits. In addition to Deciphera's right to conduct Clinical Trial audits pursuant to Section 5.7, upon reasonable notification, Deciphera shall be entitled to conduct an audit of safety and regulatory systems, procedures and practices of Zai, including on-site evaluations to the extent permitting such on-site evaluations is in the control of Zai. With respect to any inspection of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to any Licensed Product, Zai shall notify Deciphera of such inspection (a) no later [***] after Zai receives notice of such inspection or (b) within [***] after the completion of any such inspection of which Zai did not receive prior notice. Zai shall promptly provide Deciphera with all information related to any such inspection. Zai shall also permit Governmental Authorities outside of the Territory to conduct inspections of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product, and shall ensure that all such Affiliates or Sublicensees permit such inspections. Deciphera shall have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection. Following any such regulatory inspection related to the Licensed Products, Zai shall provide Deciphera with (i) an unredacted copy of any finding, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Product) within [***] of Zai receiving the same, and (ii) in the event that such findings, notice, or report [***] such finding, notice, or report of a Governmental Authority related to such inspection (to the extent related to the Licensed Product) [***] receiving the same. Further details including notification, timing, response and scope of such audits shall be included in the Pharmacovigilance Agreement.

6.6. No Harmful Actions. If Deciphera believes that Zai is taking or intends to take any action with respect to a Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product outside the Territory, Deciphera shall have the right to bring the matter to the attention of the JSC and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Zai shall not communicate with any Regulatory Authority having jurisdiction outside the Territory, unless so ordered by such Regulatory Authority, in which case Zai shall immediately notify Deciphera of such order; and (b) Zai shall not submit any Regulatory Submissions or seek Regulatory Approvals for the Licensed Product outside the Territory.

6.7. Notification of Threatened Action. Each Party shall [***] the other Party of any information it receives regarding any threatened or pending action, inspection or communication by any Third Party, which would reasonably be expected to affect the safety or efficacy claims of any Licensed Product or the continued marketing of any Licensed Product (as to Deciphera's notification obligation, only to the extent it would reasonably be expected to affect the Territory). Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action with respect to the Territory.

6.8. Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (as to Deciphera's notification obligation, only to the extent it would reasonably be expected to affect the Territory) (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action with respect to the Territory. Zai shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action; provided that Deciphera shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory to the extent related to any Global Study. The cost and expenses of any Remedial Action in the Territory shall be borne solely by the Party with sole discretion, provided however that to the extent a Remedial Action in the Territory results primarily from the failure of the Licensed Product supplied by Deciphera to comply with the Product Specifications, product warranties (as set forth in the Supply Agreement) and Applicable Laws, including cGMP requirements, then Deciphera shall reimburse Zai for the reasonable cost and expense of such Remedial Action if this is required and after consultation with Deciphera. Each shall, and shall ensure that its Affiliates and sublicensees shall, maintain adequate records to permit the Parties to trace the distribution and use of the Licensed Product in the Territory.

ARTICLE 7

MANUFACTURING

7.1. Packaging. Zai shall (a) be responsible for, and use Commercially Reasonable Efforts to package or have packaged the Licensed Products, sufficient and solely to meet the Development and Commercialization requirements of a Licensed Product in the Territory, at its sole cost and expense, and (b) undertake such activities of the Licensed Products in accordance with the Product Specifications. Zai may not manufacture Licensed Products other than as otherwise specified in this Section 7.1.

7.2. Supply of Licensed Products. Customary terms of forecasting and ordering procedures, Product Specifications, and other operational matters relating to the supply of the Licensed Product under this Section 7.2 shall be set forth in a supply agreement to be mutually agreed upon by the Parties consistent with this ARTICLE 7 to be executed by the Parties within [***] following the Effective Date (the "**Supply Agreement**"). In connection with such Supply Agreement, the Parties shall enter into a quality agreement governing the agreed upon specifications and other technical aspects of the Licensed Product (the "**Quality Agreement**"). Subject to the terms of this ARTICLE 7, the Supply Agreement and Quality Agreement, Deciphera shall, itself or through one or more CMOs, (a) [***]. Zai or its Affiliates shall (i) obtain and maintain all required import licenses, and shall serve as importer of record for all Licensed Products delivered in or into any region in the Territory pursuant to this Agreement and the Supply Agreement; and (ii) be responsible for all customs' duties, import tariffs, taxes, freight, insurance, inspection costs and the like attributed to or for the transport and importation of the Licensed Product in or into any region in the Territory.

7.3. [***].

7.4. [***].

ARTICLE 8

MEDICAL AFFAIRS

8.1. Medical Affairs Plans. [***] the Effective Date, Zai shall develop and provide a preliminary draft of the Medical Affairs Plan for the Licensed Product to the JSC's subcommittee represented solely by medical affairs personnel for its review, discussion and approval. Upon approval and thereafter, Zai shall (a) undertake the major Medical Affairs activities for the Licensed Products in the Territory and the estimated timelines for performing such activities pursuant to the Medical Affairs Plan; and (b) from time to time but no less frequent than [***] propose updates or amendments to the Medical Affairs Plan for the JSC subcommittee's review, discussion and approval.

8.2. Medical Affairs Reports. For each Calendar Year following the first Regulatory Approval for a Licensed Product in the Territory, Zai shall provide to Deciphera a report (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities performed by or on behalf of Deciphera and its Affiliates and Sublicensees in the Territory for the Licensed Product in each region in the Territory since the prior report provided by Zai. Such reports shall be Confidential Information of Zai and subject to the terms of ARTICLE 11. Zai shall provide updates to any such report at each meeting of the subcommittee established by the JSC to oversee the Medical Affairs activities under this Agreement.

8.3. Coordination of Medical Affairs Activities. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the License Products inside and outside of the Territory. Accordingly, the Parties shall coordinate such activities through the subcommittee established by the JSC to oversee the Medical Affairs activities under this Agreement where appropriate.

ARTICLE 9

COMMERCIALIZATION

9.1. Commercialization Diligence. Zai shall be responsible for, and use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Commercialization Plan, at its sole cost and expense. Upon Zai's reasonable request, Deciphera shall reasonably assist Zai in such Commercialization of the Licensed Product [***].

9.2. Commercialization Plan. The Commercialization Plan shall contain in reasonable detail the major Commercialization activities and the timelines for achieving such activities, including [***] in the Territories. Zai shall deliver an initial Commercialization Plan

to the JSC for review and discussion no later than [***] of the first Regulatory Approval for a Licensed Product in the Territory. Thereafter, from time to time, but at least [***] Zai shall propose updates or amendments to the Commercialization Plan to reflect changes in such plans, including those in response to changes in the marketplace, relative success of the Licensed Product, and other relevant factors influencing such plan and activities, and submit such proposed updated or amended Commercialization Plan to the JSC. In preparing the initial Commercialization Plan and any updates or amendments thereto, Zai shall provide Deciphera with an opportunity to comment and Zai shall consider any Deciphera's comments in good faith in finalizing the initial Commercialization Plan and any updates or amendments thereto.

9.3. Commercialization Reports. Zai shall update the JSC at each regularly scheduled JSC meeting regarding Zai's Commercialization activities with respect to the Licensed Products in the Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Zai's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Licensed Products in the Territory, covering subject matter at a level of detail reasonably required by Deciphera and sufficient to enable Deciphera to determine Zai's compliance with its diligence obligations pursuant to Section 9.1. In addition, Zai shall make available to Deciphera such additional information about its Commercialization activities as may be reasonably requested by Deciphera from time to time. All updates and reports generated pursuant to this Section 9.3 shall be the Confidential Information of Zai.

9.4. Product Trademarks. Zai shall only use (pursuant to this Section 9.4) the trademarks Controlled by Deciphera in the Territory as Deciphera may provide to Zai in writing from time to time (the "**Deciphera Product Marks**") and shall use the English mark thereof with Chinese phonetic translation below. Deciphera hereby grants to Zai, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, exclusive license under Deciphera's rights to use such Deciphera Product Marks in connection with the Commercialization of the Licensed Products in the Field in the Territory in compliance with Applicable Laws. Zai may also brand the Licensed Products in the Territory using other trademarks, logos, and trade names specific for the Licensed Product; provided, *however*, that (a) prior to such use, Zai shall submit such trademarks, logos and trade names for Deciphera's prior written approval, (b) upon Deciphera's prior written approval, such trademarks, logos and trademarks shall be deemed owned by Zai (the "**Product Marks**"). Zai shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary. Upon Zai's request, Deciphera shall reasonably assist Zai in the selection and design of the Product Marks at Zai's cost. Zai shall comply with Deciphera's brand usage guidelines provided to Zai in its use of the Deciphera Product Marks. For the avoidance of doubt, Deciphera (i) has sole discretion regarding prosecution and maintenance of the Deciphera Product Marks, provided that, after Zai has initiated launch efforts to Commercialize the Licensed Product under any particular Deciphera Product Mark, Deciphera shall notify Zai in writing of any decision to modify or discontinue the application or registration of such Deciphera Product Mark in the Territory, and shall not carry out such modification or discontinuation without Zai's prior written consent (not to be unreasonably withheld), further provided that Deciphera shall not be required to obtain Zai's consent if such modification or discontinuation is required by the applicable Regulatory Authority in the Territory or is necessary to avoid any potential infringement of the rights of any Third Party, and (ii) has no obligation to ensure that, and provides no guarantee that, any applications included in the Deciphera Products Marks issues to a registered trademark in the Territory.

9.5. Commercialization Assistance. [***] provide assistance to Zai at Zai's request for the Commercialization activities, including assistance pursuant to Sections 9.1 and 9.4 as requested by Zai.

9.6. Compliance. Zai shall (a) comply, and shall cause its Affiliates and Sublicensees to comply, with all Applicable Laws and all applicable cGMP, GCP, GLP and GSP (or similar standards) in their conduct of the Development, packaging, and Commercialization activities under this Agreement and (b) ensure that its Affiliates and Sublicensees do not transfer or divert the Compound or Licensed Product to an entity other than Zai, or an entity approved by Zai, in each case in a manner that would cause the sale of such Compound or Licensed Product in the chain of distribution (from Zai or its Affiliates or Sublicensees to the end user) to be excluded (except as an exception provided in the Net Sales definition) in the calculation of Net Sales, provided that for each unit of the Compound or Licensed Product, the inclusion of such sales in the calculation of Net Sales shall occur only once. Upon reasonable notification, Deciphera shall have the right to conduct audits of Zai, and Zai shall procure such right for Deciphera to audit Zai's Affiliates and Sublicensees (either directly or through Zai and its designee), to ensure (i) compliance with applicable cGMP, GCP, GLP, and GSP standards, including on-site evaluations (to the extent permitting such evaluations is under the control of the audited Party), and (ii) compliance with this Section 9.6.

9.7. No Diversion. (a) Each of Deciphera and Zai hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, directly or indirectly, promote, market, distribute, import, sell or have sold the Licensed Products, including via internet or mail order, outside its territory; (b) With respect to any country or region outside its territory, each Party shall not, and shall ensure that its Affiliates and their respective sublicensees shall not: (i) unless otherwise agreed by the Parties in writing, establish or maintain any branch, warehouse or distribution facility for Licensed Products in such countries (except, in the event such Party is Zai, Zai shall have the right to [***] solely to support the packaging and having-packaged activities of the Licensed Product by Zai or its Affiliates in [***]), (ii) engage in any advertising or promotional activities relating to Licensed Products that are directed primarily to customers or other purchaser or users of Licensed Products located in such countries, (iii) solicit orders for Licensed Products from any prospective purchaser located in such countries, or (iv) sell or distribute Licensed Products to any person in such Party's territory who intends to sell or has in the past sold Licensed Products in such countries; (c) if a Party receives any order for any Licensed Product from a prospective purchaser reasonably believed to be located in a region or country outside its territory, such Party shall promptly refer that order to the other Party, and such Party shall not accept any such orders; (d) neither Party shall deliver or tender (or cause to be delivered or tendered) Licensed Products into a country or region outside its territory; and (e) each Party shall not, and shall ensure that its Affiliates and their respective sublicensees shall not, knowingly restrict or impede in any manner the other Party's exercise of its exclusive rights to Commercialize the Licensed Products in its territory. For the purpose of this Section 9.7, Zai's territory shall mean all countries and regions in the Territory and Deciphera's territory shall mean all countries and regions outside the Territory.

ARTICLE 10

PAYMENTS AND MILESTONES

10.1. Upfront Payment. In partial consideration of the rights granted by Deciphera to Zai hereunder, Zai shall pay to Deciphera an irrevocable, non-refundable, non-creditable amount of twenty million U.S. Dollars ($20,000,000) (the "**Upfront Payment**") within [***] of the Effective Date.

10.2. Development Milestones Payments to Deciphera.

(a) Subject to Section 5.4(b), in partial consideration of the rights granted herein, when each distinct Licensed Product first achieves the Milestone Events set forth below (each such event, a "**Development Milestone Event**") Zai shall pay to Deciphera the following irrevocable, non-refundable, non-creditable Development milestone payments (each such payment, a "**Development Milestone Payment**") within [***] of the achievement of the corresponding Milestone Events.

Development Milestone Event	Development Milestone Payment
The [***] in the INTRIGUE Study	Five Million U.S. Dollars ($5,000,000)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) For the avoidance of doubt, (i) each Development Milestone Payment shall be payable on the first occurrence of the corresponding Development Milestone Event for a distinct Licensed Product, and (ii) none of the Development Milestone Payments shall be

payable more than once for each distinct Licensed Product. For the purpose of this Section 10.2, a Licensed Product is distinct if [***] for which the applicable Development Milestone Payment was made. [***]. Notwithstanding the foregoing, in the event that Zai discontinues the Development of a Licensed Product, any Development Milestone Payment made with respect to such discontinued Licensed Product shall be credited against the corresponding Milestone Payments payable on another Licensed Product that achieves such milestones.

(c) If a Development Milestone Event described in the table above in this Section 10.2 is achieved for a Licensed Product before the achievement of a preceding Development Milestone Event listed in such table with respect to the same Indication, then all preceding Development Milestone Event(s) shall be deemed automatically achieved, and the corresponding Development Milestone Payment(s) shall be due and payable together with the payment of the Development Milestone Payment for the subsequent achieved Development Milestone Event. [***] in relation to a Licensed Product is achieved, both Development Milestone Events in relation to such Licensed Product for [***] shall be deemed automatically achieved, and the corresponding Development Milestone Payments for both Development Milestone Events in relation to such Licensed Product for [***] shall be due (if not already achieved and paid) immediately with the corresponding Development Milestone Payment for such Development Milestone Event in relation to a Licensed Product for [***].

10.3. Sales Milestones.

(a) In partial consideration of the rights granted herein, Zai shall pay to Deciphera the following milestone payments (each such payment, a "**Net Sales Milestone Payment"**) for the achievement of the corresponding Net Sales milestone events set forth below (each such event, a "**Net Sales Milestone Event**") within [***] after the end of the Calendar Quarter in which the Net Sales Milestone Event occurs.

Net Sales Milestone Event	Net Sales Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) For the avoidance of doubt (i) each Net Sales Milestone Payment shall be payable on the first occurrence of the corresponding Net Sales Milestone Event, and (ii) none of the Net Sales Milestone Payments shall be payable more than once.

10.4. Royalties.

(a) **Royalty Payment**. During the Royalty Term, Zai shall pay to Deciphera tiered royalties as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated Net Sales of all Licensed Product in the Territory in a Calendar Year (a "**Royalty Payment**"). The tiered royalty rates on Net Sales shall be as set forth below:

For that portion of annual Net Sales in a Calendar Year	Royalty%
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) **Royalty Term.** The Royalty Payments payable under this Section 10.4 shall be payable on a region-by-region and Licensed Product-by-Licensed Product basis from the First Commercial Sale of a Licensed Product in such region until the later of: (i) the abandonment, expiry or final determination of invalidity of the last Valid Claim within the Deciphera Program Patent in such region in the Territory; (ii) the expiry of the regulatory exclusivity for such Licensed Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the First Commercial Sale of such Licensed Product in such region (the "**Royalty Term**").

(c) **Royalty Reductions.**

(i) During the Royalty Term for a Licensed Product in a region in the Territory, subject to Section 10.4(c)(iv), the royalty rate applicable to Net Sales of such Licensed Product in such region shall be reduced by [***] after the expiration of the last Valid Claim that covers such Licensed Product in such region.

(ii) During the Royalty Term for a Licensed Product in a region in the Territory, subject to Section 10.4(c)(iv), the royalty rate applicable to Net Sales of such Licensed Product in such region shall be reduced by [***] after the first commercial sale of a Generic Product of such Licensed Product in such region, pursuant to Regulatory Approval. For the purpose of this Section 10.4, "**Generic Product**" means, with respect to a particular Licensed Product in a particular region, any pharmaceutical product that contains the same active ingredient as such Licensed Product and obtained regulatory approval in such region on an expedited or abbreviated basis in a manner relied on or incorporated data submitted by Deciphera, Zai, their Affiliates, licensees or sublicensees for such Licensed Product.

(iii) If Zai reasonably determines in good faith after advice of counsel that it is necessary for Zai to obtain a license under any Patents owned or controlled by a Third Party in order to Develop or Commercialize the Licensed Product in the Territory, subject to

Section 10.4(c)(iv), Zai shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 10.4, an amount equal to [***] of the royalties paid by Zai to such Third Party pursuant to such license on account of the sale of the Licensed Product in the Territory; provided that (1) prior to entering into such license, Zai shall [***]; and (2) in the event [***], (A) [***], (B) [***], and (C) if [***], then the Parties shall [***] (and, for clarity, [***]); further provided that if [***] for Zai to Develop or Commercialize the Licensed Product in the Territory, the royalty reduction mechanism described in this Section 10.4(c)(iii) shall [***]. Within [***] following the execution of any such Third Party license, Zai shall provide Deciphera with a true and complete copy of such Third Party license.

(iv) Notwithstanding the foregoing, in no event shall the operation of Section 10.4(c)(i) through (iii), individually or in combination, reduce the royalties paid to Deciphera with respect to the Net Sales of any Licensed Product in any region in the Territory in any Calendar Quarter to less than [***] of the amount that would otherwise have been due pursuant to Section 10.4(a) with respect to such Net Sales.

(d) **Royalty Estimate and Royalty Reports**. Following the First Commercial Sale of a Licensed Product for which royalties are due pursuant to this Section 10.4, and continuing for so long as royalties are due hereunder:

(i) Zai shall, within [***] Business Days after the end of each Calendar Quarter, provide Deciphera with a good faith estimate of the royalties due for such Calendar Quarter.

(ii) Zai shall, within [***] days after the end of each Calendar Quarter, provide Deciphera with a royalty report showing, on a region-by-region basis:

(1) the Net Sales of each Licensed Product sold by Zai, its Affiliates and Sublicensees during such Calendar Quarter reporting period;

(2) the Royalty Payments in United States dollars which shall have accrued hereunder with respect to such Net Sales, with supporting calculations showing the applicable royalty rate applied and any royalty reduction taken;

(3) the rate of exchange with supporting calculations, determined in accordance with Section 10.5(b), used by Zai in determining the amount of United States dollars payable hereunder.

(4) attaching a pro forma invoice in a form and with information acceptable to Zai which Deciphera can issue to Zai in relation to such Royalty Payment.

(e) **Royalty Payment**. After the receipt of each royalty report provided by Zai under Section 10.4(d) above, Deciphera shall submit to Zai an invoice for the amount of Royalty Payment set forth therein. Zai shall pay to Deciphera the royalties for each Calendar Quarter within [***] after the receipt of the invoice from Deciphera. If no royalty is due for any Calendar Quarter following commencement of the reporting obligation, Zai shall so report.

10.5. Payment.

(a) **Mode of Payment**. All payments to be made under this Agreement shall be made in U.S. Dollars and shall be paid by electronic transfer in immediately available funds to such bank account in the United States as is designated in writing by Deciphera. All payments shall be free and clear of any transfer fees or charges.

(b) **Currency Exchange Rate**. All payments under this Agreement shall be payable in U.S. Dollars. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars for calculating Net Sales in a Calendar Quarter (for purposes of both the royalty calculation and whether a Net Sales milestone has been achieved) shall be made at the average exchange rate as published by the Wall Street Journal for such Calendar Quarter, or such other source as the Parties may agree in writing.

(c) **Payment Timeline**. Except as otherwise provided in this Agreement, all payments to be made by one Party to the other Party under this Agreement shall be due within [***] following such Party's receipt of an invoice from the other Party.

10.6. Audits.

(a) Zai shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the GAAP, consistently applied), for a period not less [***] complete and accurate records in sufficient detail to properly reflect Net Sales and to enable any Milestone Payment payable hereunder to be determined.

(b) Upon the written request of Deciphera, Zai shall permit, and shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Deciphera and reasonably acceptable to Zai, at Deciphera's expense, to have access during normal business hours to such records of Zai or its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any Calendar Year ending not more [***]. These rights with respect to any Calendar Year shall [***] end of any such Calendar Year and shall be limited to once each Calendar Year (provided that the foregoing frequency limit shall not apply if Deciphera has cause). Deciphera shall provide Zai with a copy of the accounting firm's written report [***]. If such accounting firm correctly concludes that an underpayment was made, then Zai shall pay the amount due within [***] of the date Deciphera delivers to Zai such accounting firm's written report so correctly concluding. If such accounting firm concludes that an overpayment was made, then such over payment shall be credited against any future payment due to Deciphera hereunder (if there is no future payment due, then Deciphera shall promptly refund such overpayment to Zai). Deciphera shall bear the full cost of such audit unless such audit correctly discloses that the additional payment payable by Zai for the audited period is more [***] the amount otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

(c) Deciphera shall treat all financial information, subject to review under this Section 10.6 in accordance with the confidentiality provisions of ARTICLE 11, and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement

with Zai obligating it to treat all such financial information in confidence pursuant to such confidentiality provisions. Such accounting firm shall not disclose Zai's Confidential Information to Deciphera, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Zai or the amount of payments to or by Zai under this Agreement.

(d) Zai shall include in each relevant sublicense granted by it a provision requiring any Sublicensee to maintain records of sales of Licensed Products made pursuant to such sublicense, and to grant access to such records by an accounting firm to the same extent and under the same obligations as required of Zai under this Agreement. Deciphera shall advise Zai in advance of each audit of any such Sublicensee with respect to Licensed Product sales either by Deciphera or its designated auditor under the terms of such Sublicensee agreement. Deciphera shall provide Zai with a summary of the results received from the audit and, if Zai so requests, a copy of the audit report. Deciphera shall pay the full costs charged by the accounting firm, unless the audit discloses that the additional payments payable to Deciphera for the audited period is more than [***] from the amounts otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

10.7. Interest. Each Party shall pay interest on any amounts overdue under this Agreement [***] from the day payment was initially due; provided, however, that in no case shall such interest rate exceed the highest rate permitted by Applicable Laws. The payment of such interest shall not foreclose a Party from exercising any other rights it may have because any payment is overdue.

10.8. Taxes. Notwithstanding any other provision hereof, for any payment payable by Zai to Deciphera hereunder, [***]. Zai and Deciphera shall cooperate with respect to (i) any and all documentation required by any taxing authority or reasonably requested by Zai to secure a reduction in the rate of applicable Taxes and (ii) claiming refunds, credits or exemptions from such Tax deductions or withholdings under any relevant agreement or treaty, which is in effect. [***]. The Parties shall (1) discuss applicable reasonable mechanisms for minimizing such Taxes to the extent possible in compliance with Applicable Laws; and (2) use reasonable efforts, to the extent permitted by Applicable Laws, to minimize indirect Taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement; provided that in effectuating the foregoing sentences, [***]. In order to ensure all of the Territory Tax liabilities are duly withheld and settled in all regions of the Territory, each Party will, at the request of the other Party, provide such other Party promptly with an original or scanned copy of the relevant Tax filing form(s), Tax payment certificate and any other supporting documentation requested by the other Party, as applicable.

10.9. Blocked Currency. If by Applicable Law in a country or region in the Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Zai shall promptly notify Deciphera and, thereafter, amounts accrued in such country or region under this ARTICLE 10 shall be paid to Deciphera (or its designee) in such country or region in local currency by deposit to an escrow account in a local bank designated by Deciphera and to the credit of Deciphera, unless the Parties otherwise agree.

ARTICLE 11

CONFIDENTIALITY; PUBLICATION

11.1. Nondisclosure Obligation.

(a) For the Term of this Agreement [***], the Party receiving the Confidential Information of the other Party (such receiving Party, the "**Receiving Party**") shall keep confidential and not publish, make available or otherwise disclose any Confidential Information to any Third Party, without the express prior written consent of the Party that disclosed such Confidential Information (the "**Disclosing Party**"); provided however, the Receiving Party may disclose the Confidential Information to those of its Affiliates, officers, directors, employees, agents, consultants or independent contractors (including sublicensees) of such Receiving Party who need to know the Confidential Information in connection with this Agreement and are bound by confidentiality obligations with respect to such Confidential Information. The Receiving Party shall exercise at a minimum the same degree of care it would exercise to protect its own Confidential Information (and in no event less than a reasonable standard of care) to keep confidential the Confidential Information. The Receiving Party shall use the Confidential Information solely in connection with the purposes of this Agreement.

(b) It shall not be considered a breach of this Agreement if the Receiving Party discloses Confidential Information in order to comply with a lawfully issued court or governmental order or with a requirement of Applicable Laws or the rules of any internationally recognized stock exchange; provided that: (i) the Receiving Party gives prompt written notice of such disclosure requirement to the Disclosing Party and cooperates with the Disclosing Party's efforts to oppose such disclosure or obtain a protective order for such Confidential Information, and (ii) if such disclosure requirement is not quashed or a protective order is not obtained, the Receiving Party shall only disclose those portions of the Confidential Information that it is legally required to disclose and shall make a reasonable effort to obtain confidential treatment for the disclosed Confidential Information. To the extent there is any conflict between this ARTICLE 11 and any other agreement related to Confidential Information entered into between the Parties, including the Confidentiality Agreement executed by the Parties dated as of [***], the terms of this ARTICLE 11 shall control to the extent of such conflict.

11.2. Scientific Publication. The JSC shall discuss the publication strategy for the publication of scientific papers, abstracts, meeting presentations and other disclosure of the results of the Clinical Trials (other than the Global Studies and the Support Studies) carried out under this Agreement, taking into consideration the Parties' interest in publishing the results of the Development work in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, and the need to protect Confidential Information, intellectual property rights and other business interests of the Parties; provided that Zai's publication outside the Territory (including in any form or media that may be distributed outside the Territory) shall require Deciphera's prior written consent. Subject to the immediately preceding sentence, Zai shall provide Deciphera with the opportunity to review and comment on any proposed publication that pertains to the Licensed Products at [***] its intended submission for publication which shall only be permitted in the Territory and as to data, results and the like with respect to patients or subjects located in the Territory. Deciphera shall provide Zai with its

comments, if any, [***] the receipt of such proposed publication. Zai shall consider in good faith the comments provided by Deciphera and shall comply with Deciphera's request to: (a) remove any and all Confidential Information of Deciphera from such proposed publication; and (b) delay the submission for a period [***] as may be reasonably necessary to seek patent protection for the information disclosed in the proposed publication. Zai agrees to acknowledge the contribution of Deciphera and Deciphera's employees in all publication as scientifically appropriate. Zai shall have no right to publish outside the Territory without Deciphera's prior written consent.

11.3. Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party shall comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 11.3 shall be considered a publication for purposes of this Agreement and shall be subject to Section 11.2.

11.4. Publicity; Use of Names.

(a) Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to (i) advisors (including consultants, financial advisors, attorneys and accountants), (ii) bona fide potential and existing investors and acquirers on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof, (iii) to the extent necessary to comply with the terms of agreements with Third Parties, or (iv) to the extent required by Applicable Laws, including securities laws and regulations. Notwithstanding the foregoing, the Parties agree upon the initial press release(s) to announce the execution of this Agreement as contained in Schedule 11.4; thereafter, Deciphera and Zai may each disclose to Third Parties the information contained in such press release(s) without the need for further approval by the other.

(b) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding a Licensed Product for use in the Field in the Territory and other activities in connection with this Agreement, beyond what may be strictly required by Applicable Laws and the rules of a recognized stock exchange, and each Party may make such disclosures from time to time with respect to a Licensed Product with the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed. Such disclosures may include achievement of significant events in the Development (including regulatory process) or Commercialization of a Licensed Product for use in the Field in the Territory. Unless otherwise requested by the applicable Party, each Party shall indicate that Deciphera is the licensor of a Licensed Product and Deciphera IP, as applicable, in each public disclosure issued by such Party regarding a Licensed Product. When a Party elects to make any public disclosure under this Section 11.4(b), it shall give the other Party reasonable notice to review and comment on such statement, it being understood that (i) if the other Party does not notify such Party in writing [***] or such shorter period if required by Applicable Laws of any reasonable objections, as contemplated in this Section 11.4(b), such disclosure shall be

deemed approved, and (ii) if the other Party does notify such Party in writing within the time period set forth in clause (i) above, and reasonably determines that such public disclosure would entail the public disclosure of the other Party's Confidential Information or of patentable Inventions upon which patent applications should be filed prior to such public disclosure, such public disclosure shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party, or the drafting and filing of a patent application covering such Inventions, provided such additional period shall not [***] from the proposed date of the public disclosure, and, in any event, the other Party shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative reactions of applicable Regulatory Authorities.

(c) The Parties acknowledge the need to keep investors and others informed regarding such Party's business under this Agreement, including as required by the rules of a recognized stock exchange. To the extent a Party is publicly listed or becomes publicly listed, and subject to Sections 11.4(a) and 11.4(b), such Party may issue press releases or make disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with laws or regulations or for appropriate market disclosure; provided that each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

ARTICLE 12

REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1. Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement; and

(d) All consents, approvals and authorization from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

12.2. Additional Representations and Warranties of Deciphera. Deciphera represents and warrants to Zai that as the Effective Date:

(a) Deciphera is the sole owner of the Deciphera Program IP and it has the right under the Deciphera Program IP and Deciphera Background Know-How to grant the licenses to Zai as purported to be granted pursuant to this Agreement;

(b) Schedule 1.38 lists all Patents in the Territory Controlled by Deciphera that are necessary for the Development and Commercialization of the Licensed Product in the Territory;

(c) Deciphera has not granted (and shall not grant) any right to any Third Party under the Deciphera Program IP or Deciphera Background Know-How that would conflict with the rights granted to Zai hereunder;

(d) Deciphera and its Affiliates and their employees, consultants and contractors involved in the Development of the Compounds and Licensed Products are not, and have not been, debarred or disqualified by any Regulatory Authority as of the Effective Date, and have complied in all material respects with all Applicable Laws in connection with the Development of the Compounds and Licensed Product;

(e) [***];

(f) no claim or action has been brought against Deciphera or, to Deciphera's Knowledge, threatened in writing to Deciphera, by any Third Party alleging that (1) the Deciphera Program Patents are invalid or unenforceable, or (2) use of the Compound or Licensed Product infringes the Patents or misappropriates the Know-How of any Third Party; and, to Deciphera's Knowledge, no interference, opposition, cancellation or other protest proceeding has been filed against a Deciphera Program Patent owned by Deciphera; and

(g) [***].

12.3. Additional Representations, Warranties and Covenants of Zai. Zai represents, warrants and covenants to Deciphera that as of the Effective Date with respect to itself and its Affiliates:

(a) there are no legal claims, judgments or settlements against or owed by Zai or its Affiliates, or pending or, to Zai's or its Affiliates' actual knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations, including under any Anti-Corruption Laws;

(b) Zai and its Affiliates is not, and has not been, debarred or disqualified by any Regulatory Authority;

(c) [***];

(d) it shall comply with all Applicable Laws in connection with the Development, packaging, having packaging and Commercialization of the Licensed Product in the Territory and packaging and having packaging the Licensed Product in Singapore or the United States; and

(e) [***].

12.4. Covenants of Each Party. Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, it shall, and shall cause its Affiliates, Sublicensees to, comply with the Development Plan, all agreements referenced herein, all Applicable Laws, including as applicable, cGMP, GCP, GLP, and GSP standards, and shall not employ or engage any party who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

12.5. Compliance with Anti-Corruption Laws.

(a) Notwithstanding anything to the contrary in the Agreement, each Party hereby covenants to each other that:

(i) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (collectively "**Anti-Corruption Laws**", including the provisions of the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Law, and the Anti-Corruption Act of the PRC) that may be applicable to either or both Parties to the Agreement;

(ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it shall, on request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or shall provide details of any exception to the foregoing; and

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 12.5, and upon request of the other Party, upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this

Section 12.5. Acceptance of a proposed Third Party auditor may not be unreasonably withheld or delayed by either Party. It is expressly agreed that the costs related to the Third Party auditor shall be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

(b) To its knowledge as of the Effective Date and during the Term, neither Zai nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its subsidiaries or any of their Affiliates:

(i) has taken or shall take any action in violation of any applicable anticorruption law, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78 dd-1 et seq.); or

(ii) has corruptly, offered, paid, given, promised to pay or give, or authorized or shall corruptly, offer, pay give, promise to pay or give or authorize, the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 12.5(d) below), for the purposes of:

(iii) has influenced or shall influence any act or decision of any Public Official in his official capacity;

(iv) has induced or shall induce such Public Official to do or omit to do any act in violation of his lawful duty;

(v) has secured or shall secure any improper advantage; or

(vi) has induced or shall induce such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.

(c) As of the Effective Date, none of the officers, directors, employees, of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case that are employed or reside outside the United States, are themselves Public Officials.

(d) For purposes of this Section 12.5, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

12.6. NO OTHER REPRESENTATIONS OR WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 13

INDEMNIFICATION

13.1. By Zai. Zai shall indemnify and hold harmless Deciphera, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Deciphera Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") arising after the Effective Date to the extent arising from (a) the packaging, having packaged, Development, and Commercialization of the Licensed Product in the Territory, including the promotion of a Licensed Product and product liability claims relating to the Licensed Product, or any actions (or omissions) in the performance of its regulatory activities, in each case by Zai or any of its Affiliates or Sublicensees, (b) the packaging and having packaging of the Licensed Product [***] (including any and all activities relating to or support such packaging and having packaging); (c) the gross negligence, illegal conduct or willful misconduct of Zai or any of its Affiliates or Sublicensees, (d) Zai's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement or (e) [***] in accordance with [***], in each case of clauses (a) through (e) above except to the extent such Losses arise from, are based on, or result from any activity or occurrence for which Deciphera is obligated to indemnify the Zai Indemnitees under Section 13.2.

13.2. By Deciphera. Deciphera shall indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Zai Indemnitee(s)**") from and against all Losses to the extent arising from (a) Manufacture, Development and Commercialization of the Compounds and Licensed Products outside the Territory or in the Territory with respect to Global Studies or any Manufacturing activities in the Territory, in each such case by Deciphera or any of its Affiliates or licensees (other than Zai); (b) the gross negligence, illegal conduct or willful misconduct of Deciphera or any of its Affiliates or licensees (other than Zai), or (c) Deciphera's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, in each case of clauses (a) through (c) above, except to the extent Losses arise from, are based on, or result from any activity or occurrence for which Deciphera is obligated to indemnify the Zai Indemnitees under Section 13.1.

13.3. Defined Indemnification Terms. Either of the Zai Indemnitee or the Deciphera Indemnitee shall be an "**Indemnitee**" for the purpose of this ARTICLE 13, and the Party that is obligated to indemnify the Indemnitee under Section 13.1 or Section 13.2 shall be the "**Indemnifying Party**."

13.4. Defense. If any such claims or actions are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this ARTICLE 13.

13.5. Settlement. The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld or delayed.

13.6. Notice. The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Sections 13.1 or 13.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

13.7. Permission by Indemnifying Party. The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

13.8. Insurance. Zai shall procure and maintain for itself and its Affiliates during the Term and for a period [***] thereafter, insurance policies, including product liability and clinical trial insurance, adequate to cover its obligations hereunder with a company having a minimum of an A-rating by Best's rating; *provided*, *however*, that in no event shall such product liability insurance be written and in force in amounts not less than [***] per occurrence and [***] in the aggregate. Zai shall identify Deciphera as an additional insured and provide Deciphera with evidence of such insurance upon request and prior to expiration of any one coverage. Zai shall provide Deciphera with prompt written notice of cancellation, non-renewal or material change in such insurance, and shall provide such notice [***] any such cancellation, non-renewal or material change. Zai shall impose substantially identical obligations on its Affiliates (to the extent not named insureds under Zai's coverages) and Sublicensees. Such insurance shall not be construed to create a limit of the insured Party's liability with respect to its indemnification obligations under this ARTICLE 13.

13.9. LIMITATION OF LIABILITY. SUBJECT TO AND WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTIONS 13.1 OR 13.2 OR LIABILITY AS A RESULT OF A BREACH OF ARTICLE 11 [***], NO PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

ARTICLE 14

INTELLECTUAL PROPERTY

14.1. Inventions.

(a) **Ownership**. If any Inventions or intellectual property, including any Know-How generated for regulatory purposes relating to the Licensed Product, is created or generated by or on behalf of Zai as a result of Zai's Development or Commercialization activities in the Territory (the "**New IP**"), (i) Zai agrees and hereby assigns all such New IP (1) [***], or (2) [***] ("**New Program IP**") to Deciphera, and such New Program IP shall be (A) solely owned by Deciphera and (B) included in the Deciphera Program IP and licensed to Zai in the Field in the Territory under Section 2.1; (ii) Zai shall retain ownership of all other New IP, which shall be included in Zai IP and licensed to Deciphera under Section 2.4. In addition, Deciphera hereby grants to Zai a perpetual, irrevocable, non-exclusive, sublicenseable, fully-paid, royalty-free, worldwide license under the New Program IP described under Section 14.1(a)(i)(2) above (i.e., that constitutes an improvement to Deciphera IP) to research, develop, make, have made, use, sell, offer for sale, import, export, market and otherwise commercialize products other than Licensed Product.

(b) **Disclosure**. Zai shall promptly disclose to Deciphera all Inventions within the New IP, including all Invention disclosures or other similar documents submitted to Zai by its or its Affiliates' employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from Deciphera for additional information relating thereto.

(c) **Assignment of New Program IP.** Zai shall and hereby does assign to Deciphera all right, title and interest in and to all New Program IP. Zai shall take (and cause its Affiliates, sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by Deciphera to effectuate such assignment and to assist Deciphera in obtaining patent and other intellectual property rights protection for the New Program IP. Zai shall obligate its Affiliates, sublicensees and contractors to assign all New Program IP to Zai (or directly to Deciphera) so that Zai can comply with its obligations under this Section 14.1, and Zai shall promptly obtain such assignment.

14.2. Patent Prosecution of Deciphera Program Patents.

(a) As between the Parties, Deciphera shall have the first right to control the Patent Prosecution or maintenance of all Deciphera Program Patents and Patents claiming New Program IP at Deciphera's expense.

(b) Deciphera shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution or maintenance of the Deciphera Program Patents in the Territory and shall provide Zai with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, Deciphera shall provide Zai with drafts of all proposed

material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution or maintenance of the Deciphera Program Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence. Deciphera shall consider Zai's comments on Patent Prosecution or maintenance but shall have final decision-making authority under this Section 14.2(b). Further, Deciphera shall notify Zai of any decision to cease Patent Prosecution or maintenance of any Deciphera Program Patents in the Territory at [***] any due date for filing, payment or other action to avoid loss of rights, in which case Zai shall have the right to continue the Patent Prosecution or maintenance of such Deciphera Program Patents in the Territory at Zai's discretion and expense.

14.3. Patent and Trademark Prosecution Cooperation. With respect to all Patent Prosecution or maintenance and trademark prosecution or maintenance, each Party shall:

(a) execute any instruments to document their respective ownership consistent with this Agreement as reasonably requested by the other Party;

(b) make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the appropriate Party hereunder to undertake its Patent Prosecution or maintenance responsibilities;

(c) cooperate, if necessary, with the other Party in gaining Patent term extensions; and

(d) act in good faith to coordinate its efforts under this Agreement with the other Party to minimize or avoid interference with the Patent Prosecution or maintenance of the other Party's Patents to a Licensed Product or trademarks.

14.4. Patent Enforcement.

(a) **Notice.** Each Party shall notify the other [***] becoming aware of any alleged or threatened infringement by a Third Party of any of the Deciphera Program Patents in the Territory, and any related declaratory judgment or equivalent action, including the filing of any application, litigation, administration action or similar action alleging the invalidity, unenforceability or non-infringement of any Deciphera Program Patents (collectively "**Product Infringement**").

(b) **Enforcement Rights**. Zai shall have the first right to bring and control any legal action to enforce Deciphera Program Patents against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate, and Zai shall consider in good faith the interests of Deciphera in such enforcement of the Deciphera Program Patents; provided that Deciphera shall have the first right to control any proceedings as part of Patent Prosecution of Deciphera Program Patents in the Territory. If Zai or its designee fails to abate such Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory [***] a written request from Deciphera to do so, or if Zai discontinues the prosecution of any such action after filing without abating such infringement, then Deciphera shall have the right to enforce the Deciphera Program Patents against such Product Infringement in the Territory at its own expense as it reasonably determines appropriate; provided that neither Party shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Deciphera Program Patent without the prior written consent of the other Party (not to be unreasonably withheld, delayed or conditioned).

(c) **Cooperation**. At the request of the Party bringing an action related to Product Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action, at the enforcing Party's sole cost and expense.

(d) **Recoveries.** Any recoveries resulting from enforcement action under Section 14.4(b) relating to a Product Infringement shall be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall be retained by the enforcing Party; provided however [***].

14.5. Infringement of Third Party Rights. If any Licensed Product used or sold by either Party, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent or other intellectual property rights that are owned or controlled by such Third Party, such Party shall promptly notify the other Party [***] receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing along with an English summary of such summons or complaint. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

ARTICLE 15

TERMS AND TERMINATION

15.1. Term and Expiration.

(a) **Term**. This Agreement shall be effective as of the Effective Date, and shall continue, on a region-by-region and a Licensed Product-by-Licensed Product basis, in effect until the expiration of and payment by Zai of all Zai's payment obligations set forth in Section 10.4(b) applicable to such region (the "**Term**", and the date of such expiration with respect to such Licensed Product and such region, the "**Expiration Date**").

(b) **Expiration**. On a region-by-region and a Licensed Product-by-Licensed Product basis, upon the natural expiration of this Agreement as contemplated in this Section 15.1, the licenses granted by Deciphera to Zai under this Agreement in such region with respect to the Licensed Product in the Field shall become fully paid-up, perpetual and irrevocable.

(c) [***]:

(1) [***];

(2) [***];

(3) [***];

(4) [***].

[***].

15.2. Termination for Convenience. Zai shall have the right to terminate this Agreement in its entirety for any or no reason upon [***] written notice to Deciphera. Zai shall terminate this Agreement upon [***] written notice to Deciphera if it determines that it shall permanently discontinue all Development and Commercialization activities with respect to the Licensed Product under this Agreement.

15.3. Termination for Material Breach.

(a) This Agreement may be terminated in its entirety at any time during the Term upon [***] written notice by either Party if the other Party materially breaches a material term of the Agreement and, if such breach is curable, such breach has not been cured within [***] of such written notice; provided that the applicable material breach cure period [***] where Deciphera shall have the right to terminate this Agreement [***], subject to Section 15.3(c).

(b) For the avoidance of doubt, the Parties agree that [***].

(c) Notwithstanding the foregoing, if the alleged breaching Party disputes the existence or materiality of the alleged breach, the other Party shall not have the right to terminate this Agreement unless and until it is determined in accordance with ARTICLE 16 that the alleged breaching Party has materially breached this Agreement and fails to cure such breach within [***] after such determination.

15.4. Termination for Patent Challenge. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, Deciphera may terminate this Agreement in its entirety (a) immediately upon written notice to Zai if Zai or its Affiliates or Sublicensees, commences a legal, administrative or other action challenging the validity, enforceability or scope of any Patent in the Territory in Schedule 1.37 or (b) [***] written notice to Zai if Zai or its Affiliates or Sublicensees, commences a legal, administrative or other action challenging the validity, enforceability or scope of any Patent owned or Controlled by Deciphera or its Affiliates anywhere in the world, unless such action is withdrawn during [***] period. Notwithstanding the foregoing, if Zai promptly terminates the sublicense agreement of any Sublicensee that commences a legal action challenging the validity, enforceability or scope of any Deciphera Program Patents anywhere in the world, Deciphera shall not have the right to terminate this Agreement under this Section 15.4.

15.5. Termination for Insolvency. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization under the Chapter 7 of the United

States of Bankruptcy Code or other similar Applicable Law or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within ninety (90) days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

15.6. Termination by Deciphera [***]. Deciphera shall have the right to terminate this Agreement [***] to the extent permitted under and in accordance with [***].

15.7. Election to Terminate. If either Party has the right to terminate under Sections 15.2 through 15.5, it may at its sole option, elect either to (a) terminate this Agreement and pursue any legal or equitable remedy available to it or (b) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

15.8. Effect of Termination.

(a) Upon the termination of this Agreement for any reason, all rights and licenses (including the rights and licenses with respect to the Licensed Product) granted to a Party herein shall immediately terminate, and all sublicenses of such rights and licenses shall also terminate; provided that the licenses granted by Zai to Deciphera pursuant to Section 2.4 shall become perpetual and irrevocable to Develop, Manufacture and Commercialize Licensed Products worldwide, subject only to any terms and conditions of any upstream agreement(s) if such license includes a sublicense to intellectual property in-licensed by Zai from a Third Party. Upon termination of this Agreement, if a Sublicensee is then in good standing of its sublicense agreement with Zai, then at Deciphera's sole discretion, Deciphera may grant to such Sublicensee a direct license under the Deciphera IP that is the same scope as the sublicense granted by Zai on substantially the same terms and conditions set forth in this Agreement, and Section 15.8(b) below shall not apply to such Sublicensee. Termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

(b) Upon termination of this Agreement for any reason, the following additional provisions shall apply:

(i) **Reversion of Rights to Deciphera**. Any rights and licenses with respect to the Licensed Product granted to Zai under this Agreement shall immediately terminate, and all such rights shall revert back to Deciphera.

(ii) **Regulatory Materials; Data.** Zai shall, and shall cause its Affiliates and Sublicensees to, [***] to the maximum extent permitted by Applicable Laws at the time of any such termination to promptly (1) assign all Regulatory Submissions and Regulatory Approvals of Licensed Products to Deciphera, and (2) assign all data generated by or on behalf of Zai or its designee while conducting Development or Commercialization activities under the Agreement to Deciphera or its designee, including non-clinical and clinical studies conducted by or on behalf of Zai on Licensed Products and all pharmacovigilance data (including all Adverse Event database information) on Licensed Products.

(iii) **Trademarks.** Zai shall, and shall cause its Affiliates and Sublicensees, to promptly transfer and assign to Deciphera, [***], all Product Marks.

(iv) **Transition Assistance**. Zai shall, and shall cause its Affiliates and Sublicensees, to provide assistance, [***] as may be reasonably necessary or useful for Deciphera or its designee to commence or continue Developing or Commercializing Licensed Products in the Territory for a period of at least [***] after the effective date of such termination (the "**Transition Period**") to the extent Zai is then performing or having performed such activities, including transferring or amending as appropriate, upon request of Deciphera, any agreements or arrangements with Third Party to Develop and Commercialize the Licensed Products in the Territory. To the extent that any such contract between Zai and a Third Party is not assignable to Deciphera or its designee, then Zai shall reasonably cooperate with Deciphera to arrange to continue to and provide such services from such entity.

(v) **Ongoing Clinical Trial.** If at the time of such termination, any Clinical Trials for the Licensed Products are being conducted by or on behalf of Zai, then, at Deciphera's election on a Clinical Trial-by-Clinical Trial basis: (1) Zai shall, and shall cause its Affiliates and Sublicensees to, (A) continue to conduct such Clinical Trial during the Transition Period or another period of time as determined by Deciphera after the effective date of such termination at Deciphera's cost, and (B) after such period, to (y) fully cooperate with Deciphera to transfer the conduct of all such Clinical Trial to Deciphera or its designee or (z) continue to conduct such Clinical Trials, at Deciphera's cost, for so long as necessary to enable such transfer to be completed without interruption of any such Clinical Trials and (C) Deciphera shall assume any and all liability and costs for such Clinical Trial after the effective date of such termination, and (2) Zai shall, and shall cause its Affiliates and Sublicensees to, at Zai's sole cost and expense (but subject to Section 15.8(d) below), orderly wind down the conduct of any such Clinical Trial which is not assumed by Deciphera under clause (1).

(vi) **Inventory.** At Deciphera's election and request, Zai shall (1) transfer to Deciphera or its designee all inventory of the Licensed Product [***] then in possession or control of Zai, its Affiliates or Sublicensees; provided that Deciphera shall pay Zai a price equal to Zai's costs for such Licensed Products or (2) (A) continue to use Commercially Reasonable Efforts to Commercialize all inventory of the Licensed Products then in possession or control of Zai during the Transition Period and make the corresponding payments, including any milestone payments or royalties to Deciphera under this Agreement as though this Agreement had not been terminated and (B) after the Transition Period, transfer to Deciphera or its designee any remaining inventory of the Licensed Product to Deciphera or its designee at a price equal to Zai's costs for such Licensed Products.

(vii) **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party shall return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' or

Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); provided that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic.

(c) **Other Remedies**. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

(d) **Termination by Zai Due to Material Breach**. Notwithstanding anything to the contrary, upon the termination of this Agreement by Zai pursuant to Section 15.3, all of the provisions of Section 15.8(b) shall apply, except that [***].

15.9. Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. The following provisions shall survive the termination or expiration of this Agreement for any reason: Sections 1 (Definitions), 10 (Payments and Milestones) (solely to the extent payments have accrued prior to the effective date of termination), 11 (Confidentiality; Publication), 12.6 (No Other Representations or Warranties), 13 (Indemnification), 14.1 (Inventions), 15.1(b) (Expiration) (which shall survive only after the natural expiration (not early termination) of the Agreement), 15.1(c) ([***]) (which shall survive only after the natural expiration (not early termination) of the Agreement when all the conditions set forth in therein are met), 15.8 (Effect of Termination, to the extent applicable), 15.9 (Survival), 16 (Dispute Resolution), and 17 (Miscellaneous).

ARTICLE 16

DISPUTE RESOLUTION

16.1. General. The Parties recognize that a dispute may arise relating to this Agreement (a "**Dispute**"). Any Dispute, including Disputes that may involve the Affiliates of any Party, shall be resolved in accordance with this ARTICLE 16.

16.2. Continuance of Rights and Obligations during Pendency of Dispute Resolution. If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under ARTICLE 15, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this ARTICLE 16.

16.3. Escalation. Any claim, Dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to the Executive Officers set forth in

Section 3.2(f) for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [***] of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 16.4.

16.4. Arbitration.

(a) If the Parties fail to resolve the Dispute through escalation to the Executive Officers under Section 16.3, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for resolution in arbitration under the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"). There shall be three (3) arbitrators, the chairperson of whom shall be appointed by the two party arbitrators. The seat of arbitration shall be [***] and the language of the proceedings shall be English.

(b) The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction. The arbitral tribunal shall render its final award within nine months from the date on which the Request for Arbitration by one of the Parties wishing to have recourse to arbitration is received by the ICC Secretariat. The arbitral tribunal shall determine the dispute by applying the provisions of this Agreement and the governing law set forth in Section 17.5.

(c) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the Dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(d) EACH PARTY HERETO WAIVES: (I) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY, AND (II) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.

(e) Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrator; provided, however, that the arbitrator shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the administrator and the arbitrator.

(f) Notwithstanding anything in this Section 16.4, in the event of a Dispute with respect to (i) the validity, scope, enforceability or ownership of any Patent or other intellectual property rights, (ii) a matter for which this Agreement assigns decision-making to the Parties or to the JSC or requires the consent of one or both of the Parties, (iii) the necessity of

obtaining a Third Party license by Zai in the Territory in accordance with Section 10.4(c)(iii), or (iv) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, and such Dispute is not resolved in accordance with Section 16.3, such Dispute shall not be submitted to an arbitration proceeding in accordance with this Section 16.4, unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

ARTICLE 17

MISCELLANEOUS

17.1. Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God or any other deity, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

17.2. Assignment. Neither Party may assign this Agreement to a Third Party without the other Party's prior written consent (such consent not to be unreasonably withheld); except that (a) subject to Section 2.6, either Party may make such an assignment without the other Party's prior written consent to a successor to substantially all of the business of such Party to which this Agreement relates (whether by merger, sale of stock, sale of assets, exclusive license or other transaction), and (b) either Party may assign this Agreement to an Affiliate without the other Party's prior written consent for so long as such Affiliate remains an Affiliate of the Party making the assignment. For clarity, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assignees. Any assignment or transfer in violation of this Section 17.2 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

17.3. Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

17.4. Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Deciphera:

Deciphera Pharmaceuticals, LLC
Address: 500 Totten Pond Road, Waltham, MA 02451, USA
Attn: Chief Business Officer
cc: General Counsel

with a copy to:

Ropes & Gray, LLP
Address: 36/F, Park Place, Nanjing Road West, Shanghai 200040, China
Attn: Geoffrey Lin
Email: Geoffrey.Lin@ropesgray.com
Fax: +86 21 6157 5299

If to Zai:

Zai Lab (Shanghai) Co., Ltd.
Address: 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210
Attn: President

with a copy to:

Cooley, LLP
Address: 3175 Hanover Street, Palo Alto, CA 94304
Attn: Lila Hope, Ph.D.
Email: lhope@cooley.com
Fax: +1 650 849 7400

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith**.** Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

17.5. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without reference to any rules of conflict of laws.

17.6. Entire Agreement; Amendments. The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

17.7. Headings. The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Sections of this Agreement.

17.8. Independent Contractors. It is expressly agreed that Deciphera and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Deciphera will report any payments received under the Agreement as payments from Zai. Neither Deciphera nor Zai shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

17.9. Waiver. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

17.10. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

17.11. Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or” where applicable.

17.12. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

17.13. Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License 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 CEO	Title:
Date: 10 June 2019	Date: 10 June 2019

Schedule 1.26

Follow-On Compounds

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Schedule 1.31

Deciphera Background Know-How

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Schedule 1.37

Deciphera Program Know-How

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Schedule 1.38

Deciphera Program Patents

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Schedule 2.6

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Schedule 5.1(b)

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Exhibit 31.1

CERTIFICATIONS

I, Steven L. Hoerter, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 2, 2019

By: /s/ Steven L. Hoerter

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

Exhibit 31.2

CERTIFICATIONS

I, Thomas P. Kelly, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 2, 2019

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven L. Hoerter, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 2, 2019

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Deciphera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas P. Kelly, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 2, 2019

By: /s/ Thomas P. Kelly

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