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

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2018**

**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: 001-35403**

**Verastem, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**117 Kendrick Street, Suite 500**

**Needham, MA**

(Address of principal executive offices)

**27-3269467**

(I.R.S. Employer  
Identification Number)

**02494**

(Zip Code)

**(781) 292-4200**

(Registrant's telephone number, including area code)

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, 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 November 2, 2018, there were 73,740,167 shares of Common Stock, \$0.0001 par value per share, outstanding.

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements related to present facts or current conditions or historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. Such statements relate to, among other things, the development and activity of our lead product, COPIKTRA and our Phosphoinositide 3-kinase (PI3K) and Focal Adhesion Kinase (FAK) programs generally, our intent to commercialize COPIKTRA, the potential commercial success of COPIKTRA, the anticipated adoption of COPIKTRA by patients and physicians, the structure of our planned and pending clinical trials, and the timeline and indications for clinical development, regulatory submissions and commercialization of activities. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements we make. Applicable risks and uncertainties include the risks, among other things, uncertainties regarding the launch timing and commercial success of COPIKTRA in the United States; uncertainties regarding physician and patient adoption of COPIKTRA, including those related to the safety and efficacy of COPIKTRA; the uncertainties inherent in research and development of COPIKTRA, such as negative or unexpected results of clinical trials; whether and when any applications for COPIKTRA may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities in any other jurisdictions may approve any such other applications that may be filed for COPIKTRA, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether COPIKTRA will be commercially successful in such jurisdictions; our ability to obtain, maintain and enforce patent and other intellectual property protection for COPIKTRA and our other product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of COPIKTRA; that regulatory authorities in the U.S. or other jurisdictions, if approved, could withdraw approval; whether preclinical testing of our product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for our product candidates is uncertain; the risk that third-payors (including government agencies) will not reimburse for COPIKTRA; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that COPIKTRA or our other product candidates will cause unexpected safety events, experience manufacturing or supply interruptions or failures, or result in unmanageable safety profiles as compared to their levels of efficacy; that COPIKTRA will be ineffective at treating patients with lymphoid malignancies; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned; that we may not have sufficient cash to fund our contemplated operations; that we or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreement; that we may be unable to make additional draws under our debt facility or obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that we will not pursue or submit regulatory filings for our product candidates, including for duvelisib in patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) or indolent non-Hodgkin lymphoma (iNHL) in other jurisdictions; and that our product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients. Other risks and uncertainties include those identified under the heading “Risk Factors” in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (SEC) on March 13, 2018 and in any subsequent filings with the SEC.

As a result of these and other factors, we may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. The forward-looking statements contained in this Quarterly Report on Form 10-Q reflect our views as of the date hereof. We do not assume and specifically disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**PART I—FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (unaudited).**

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except per share amounts)

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 130,727	\$ 82,176
Short-term investments	14,912	4,496
Accounts receivable, net	10,562	—
Inventory	131	—
Prepaid expenses and other current assets	2,397	1,115
Total current assets	158,729	87,787
Property and equipment, net	1,210	861
Intangible assets, net	21,969	—
Restricted cash	242	162
Other assets	1,005	981
Total assets	<u>\$ 183,155</u>	<u>\$ 89,791</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 11,249	\$ 9,186
Accrued expenses	38,664	7,942
Current portion of long-term debt	3,528	—
Total current liabilities	53,441	17,128
Non-current liabilities:		
Long-term debt	21,535	14,828
Other non-current liabilities	566	151
Total liabilities	75,542	32,107
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 100,000 shares authorized, 73,703 and 50,801 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	7	5
Additional paid-in capital	471,831	360,823
Accumulated other comprehensive income (loss)	2	(2)
Accumulated deficit	(364,227)	(303,142)
Total stockholders' equity	107,613	57,684
Total liabilities and stockholders' equity	<u>\$ 183,155</u>	<u>\$ 89,791</u>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(unaudited)**  
**(in thousands, except per share amounts)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue:				
License revenue	\$ 15,000	\$ —	\$ 25,000	\$ —
Product revenue, net	508	—	508	—
<b>Total revenue</b>	<b>15,508</b>	<b>—</b>	<b>25,508</b>	<b>—</b>
Operating expenses:				
Costs of revenues, excluding amortization of acquired intangible assets	49	—	49	—
Research and development	11,571	17,743	34,886	35,170
Selling, general and administrative	25,426	5,394	51,066	14,582
Amortization of acquired intangible assets	31	—	31	—
<b>Total operating expenses</b>	<b>37,077</b>	<b>23,137</b>	<b>86,032</b>	<b>49,752</b>
Loss from operations	(21,569)	(23,137)	(60,524)	(49,752)
Interest income	763	121	1,297	416
Interest expense	(862)	(110)	(1,858)	(231)
<b>Net loss</b>	<b>\$ (21,668)</b>	<b>\$ (23,126)</b>	<b>\$ (61,085)</b>	<b>\$ (49,567)</b>
Net loss per share—basic and diluted	\$ (0.29)	\$ (0.61)	\$ (0.99)	\$ (1.33)
Weighted-average number of common shares used in net loss per share—basic and diluted				
	73,644	37,630	61,995	37,207
<b>Net loss</b>	<b>\$ (21,668)</b>	<b>\$ (23,126)</b>	<b>\$ (61,085)</b>	<b>\$ (49,567)</b>
Unrealized (loss) gain on available-for-sale securities	(2)	7	4	(27)
<b>Comprehensive loss</b>	<b>\$ (21,670)</b>	<b>\$ (23,119)</b>	<b>\$ (61,081)</b>	<b>\$ (49,594)</b>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<u>Nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
<b>Operating activities</b>		
Net loss	\$ (61,085)	\$ (49,567)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	892	428
Amortization of acquired intangible assets	31	—
Stock-based compensation expense	4,908	4,070
Amortization of deferred financing costs, debt discounts and premiums and discounts on available-for-sale marketable securities	335	170
Gain on sale of fixed assets	(79)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(10,562)	—
Inventory	(131)	—
Prepaid expenses, other current assets and other assets	(1,145)	(571)
Accounts payable	2,108	3,268
Accrued expenses and other liabilities	9,401	5,219
Net cash used in operating activities	<u>(55,327)</u>	<u>(36,983)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(1,244)	—
Sales of property and equipment	82	—
Purchases of investments	(14,912)	(6,461)
Maturities of investments	4,500	45,905
Net cash (used in) provided by investing activities	<u>(11,574)</u>	<u>39,444</u>
<b>Financing activities</b>		
Proceeds from long-term debt, net	9,900	2,386
Deferred debt financing costs	—	(138)
Proceeds from the exercise of stock options	637	91
Proceeds from the issuance of common stock, net	105,156	14,121
Net cash provided by financing activities	<u>115,693</u>	<u>16,460</u>
Increase in cash, cash equivalents and restricted cash	48,792	18,921
Cash, cash equivalents and restricted cash at beginning of period	82,338	32,511
Cash, cash equivalents and restricted cash at end of period	<u>\$ 131,130</u>	<u>\$ 51,432</u>
<b>Supplemental disclosure of non-cash investing activities</b>		
Acquired intangible assets included in intangible assets, net and accrued expenses	<u>\$ 22,000</u>	<u>\$ —</u>
<b>Supplemental disclosure of non-cash financing activities</b>		
Common stock issuance costs included in accounts payable and accrued expenses	<u>\$ 15</u>	<u>\$ —</u>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Nature of business**

Verastem, Inc. (the Company) is a biopharmaceutical company focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients. On September 24, 2018, the Company's first commercial product, COPIKTRA™ (duvelisib), was approved by the U.S. Food and Drug Administration (the FDA) for the treatment of patients with hematologic cancers including chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) and follicular lymphoma (FL). Both its marketed product, COPIKTRA, and most advanced product candidate, defactinib, utilize a multi-faceted approach designed to treat cancers originating either in the blood or major organ systems. The Company is currently developing its product candidates in both preclinical and clinical studies as potential therapies for certain cancers, including leukemia, lymphoma, lung cancer, ovarian cancer, mesothelioma, and pancreatic cancer. The Company believes that these compounds may be beneficial as therapeutics either as single agents or when used in combination with immuno-oncology agents or other current and emerging standard of care treatments in aggressive cancers that are poorly served by currently available therapies.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, possible failure of preclinical testing or clinical trials, competitors developing new technological innovations, market acceptance and the successful commercialization of COPIKTRA, or any of the Company's investigational product candidates following receipt of regulatory approval and protection of proprietary technology. If the Company does not successfully commercialize COPIKTRA or any of its other product candidates, it will be unable to generate product revenue or achieve profitability and may need to raise additional capital.

The Company has historical losses from operations and anticipates that it will continue to incur losses for the foreseeable future as it continues the commercialization of COPIKTRA and the research and development of its product candidates. As of September 30, 2018, the Company had cash, cash equivalents and investments of \$145.6 million and accumulated deficit of \$364.2 million. In October 2018, the Company closed a registered direct public offering of \$150.0 million aggregate principal amount of the Company's 5.00% Convertible Senior Notes due 2048 (the Notes), for net proceeds of approximately \$145.1 million. The Company expects that its cash, cash equivalents and investments will be sufficient to fund its obligations for at least twelve months from the date of issuance of these condensed consolidated financial statements.

**2. Summary of significant accounting policies**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2018. For further information, refer to the financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (SEC) on March 13, 2018.

## Significant Accounting Policies

The significant accounting policies identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 that require the Company to make estimates and assumptions include accrued research and development expenses and stock-based compensation. During the nine months ended September 30, 2018, there were no material changes to the significant accounting policies, except for the adoption of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, issued by the Financial Accounting Standards Board (the FASB), as well as significant accounting policies over revenue recognition, collaborative arrangements, accounts receivable, inventory and intangible assets, each of which is detailed below.

### Revenue Recognition

Effective January 1, 2018, the Company adopted ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five step assessment: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (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 it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception and once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines which goods and services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

*Product Revenue, Net* – The Company sells COPIKTRA to a limited number of specialty pharmacies and specialty distributors in the United States (collectively, Customers). These Customers subsequently resell COPIKTRA either directly to patients, or to community hospitals or oncology clinics with in-office dispensaries who in turn distribute COPIKTRA to patients. In addition to distribution agreements with Customers, the Company also enters into arrangements with (1) certain government agencies and various private organizations (Third-Party Payers), which may provide for chargebacks or discounts with respect to the purchase of COPIKTRA, and (2) Medicare and Medicaid, which may provide for certain rebates with respect to the purchase of COPIKTRA.

The Company recognizes revenue on sales of COPIKTRA when a Customer obtains control of the product, which occurs at a point in time (typically upon delivery). Product revenues are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, Third-Party Payer chargebacks and discounts, government rebates, other incentives, such as voluntary co-pay assistance, product returns, and other allowances that are offered within contracts between the Company and Customers, payors, and other indirect customers relating to the Company's sale of COPIKTRA. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable or a current liability. These estimates take into consideration a range of possible outcomes based upon relevant factors such as, Customer contract terms, information received from third parties regarding the anticipated payor mix for COPIKTRA, known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled with respect to sales made.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under contracts will not occur in a future period. The Company's analyses contemplate the application of the constraint in accordance with ASC 606. For the three and nine months ended September 30, 2018, the Company determined a material reversal of revenue would not occur in a future period for the estimates detailed



below and, therefore, the transaction price was not reduced further. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

**Trade Discounts and Allowances:** The Company generally provides Customers with invoice discounts on sales of COPIKTRA for prompt payment, which are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates its specialty distributor Customers for sales order management, data, and distribution services. The Company has determined such services are not distinct from the Company's sale of COPIKTRA to the specialty distributor Customers and, therefore, these payments have also been recorded as a reduction of revenue within the condensed consolidated statements of operations and comprehensive loss through September 30, 2018.

**Third-Party Payer Chargebacks, Discounts and Fees:** The Company executes contracts with Third-Party Payers which allow for eligible purchases of COPIKTRA at prices lower than the wholesale acquisition cost charged to Customers who directly purchase the product from the Company. In some cases, Customers charge the Company for the difference between what they pay for COPIKTRA and the ultimate selling price to the Third-Party Payers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable, net. Chargeback amounts are generally determined at the time of resale to the qualified Third-Party Payer by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at the end of each reporting period that the Company expects will be sold to Third-Party Payers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit. In addition, the Company compensates certain Third-Party Payers for administrative services, such as account management and data reporting. These administrative service fees have also been recorded as a reduction of product revenue within the condensed consolidated statements of operations and comprehensive loss through September 30, 2018.

**Government Rebates:** The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

**Other Incentives:** Other incentives which the Company offers include voluntary co-pay assistance programs, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses on the condensed consolidated balance sheets.

**Product Returns:** Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel.

The Company's limited return policy allows for eligible returns of COPIKTRA for credit under the following circumstances:

- Receipt of damaged product;
- Shipment errors that were a result of an error by the Company;
- Expired product that is returned during the period beginning three months prior to the product's expiration and ending six months after the expiration date;
- Product subject to a recall; and
- Product that the Company, at its sole discretion, has specified can be returned for credit.

The Company has not received any returns to date and believes that returns of its products will be minimal.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from product revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three and nine months ended September 30, 2018.

*Exclusive Licenses of Intellectual Property* - The Company may enter into collaboration and licensing arrangements for research and development, manufacturing, and commercialization activities with collaboration partners for the development and commercialization of its product candidates, which have components within the scope of ASC 606. The arrangements generally contain multiple elements or deliverables, which may include (1) licenses, or options to obtain licenses, to the Company's intellectual property, (2) research and development activities performed for the collaboration partner, (3) participation on joint steering committees, and (4) the manufacturing of commercial, clinical or preclinical material. Payments pursuant to these arrangements typically include non-refundable, upfront payments, milestone payments upon the achievement of significant development events, research and development reimbursements, sales milestones, and royalties on future product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which the Company enters generally do not include significant financing components.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its collaboration and license agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above; and d) the measure of progress in step (v) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below.

If a license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other elements, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of its associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining elements, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company

evaluates the measure of progress of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, is subject to estimates by management and may change over the course of the arrangement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

**Customer Options:** If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services such as research and development services or manufacturing services, the goods and services underlying the customer options are not considered to be performance obligations at the inception of the arrangement; rather, such goods and services are contingent on exercise of the option, and the associated option fees are not included in the transaction price. The Company evaluates customer options for material rights or options to acquire additional goods or services for free or at a discount. If a customer option is determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the estimated probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

**Milestone Payments:** At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved 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 control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

**Royalties:** For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

**Collaborative Arrangements:** Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808, *Collaborative Arrangements*: (i) the parties to the contract must actively participate in the joint operating activity and (ii) the joint operating activity must expose the parties to the possibility of significant risk and rewards, based on whether or not the activity is successful. Payments received from or made to a partner that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction or increase to research and development expense, respectively.

For a complete discussion of the Company's accounting for its license and collaboration agreements, see Note 14, *License and collaboration agreements*.

#### ***Accounts Receivable, Net***

Accounts receivable, net primarily relates to amounts due from Customers, net of applicable revenue reserves, or from the Company's license and collaboration partners. Accounts receivable are typically due within 31 days. The Company analyzes accounts that are past due for collectability and provides an allowance for receivables when collection becomes doubtful. Given the nature and limited history of collectability of the Company's accounts receivable, an allowance for doubtful accounts is not deemed necessary at September 30, 2018.

### ***Inventory***

The Company capitalizes inventories manufactured in preparation for initiating sales of a product candidate when the related product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, the Company evaluates risks associated with manufacturing the product candidate, including the ability of the Company's third-party suppliers to complete the validation batches and the remaining shelf life of the inventories. Costs associated with manufacturing product candidates prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenues. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required which would be recorded as a cost of product revenues in the condensed consolidated statements of operations and comprehensive loss.

Shipping and handling costs for product shipments are recorded as incurred in cost of product revenues along with costs associated with manufacturing the product, and any inventory write-downs.

### ***Intangible Assets***

The Company records finite-lived intangible assets related to certain capitalized milestone payments at their fair value. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining underlying patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated.

The Company assesses its finite-lived intangible assets for impairment at least annually, or if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each finite-lived intangible asset to its carrying value on the condensed consolidated balance sheets. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the finite-lived intangible asset and recognize an impairment loss if the carrying value of the finite-lived intangible asset exceeds its fair value.

### **Recently Issued Accounting Standards Updates**

In August 2018, the FASB issued Accounting Standards Update (ASU) 2018-15, *Intangibles-Goodwill and Other-Internal Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for annual and interim periods beginning after December 15, 2019, with early adoption permitted. The Company has not elected to early adopt this standard and is currently evaluating the impact the adoption of the standard will have on its condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. ASU 2018-13 is effective for all entities for annual and interim periods beginning after December 15, 2019. An entity is permitted to early adopt either the entire standard or only the provisions that eliminate or modify requirements. The Company has not elected to early adopt this standard and is currently evaluating the impact the adoption of the standard will have on its condensed consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include all share-based payment transactions for acquiring goods and services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract and services from nonemployees. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions accounted for under ASC 606. ASU 2018-07 is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted, but no earlier than the date on which ASC 606 is adopted. The Company has not elected to early adopt this standard and is currently evaluating the impact the adoption of the standard will have on its condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the guidance under FASB Accounting Standards Codification (ASC) Topic 840, *Leases*, resulting in the creation of FASB ASC Topic 842, *Leases*. ASU 2016-02 requires lessees to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases. The guidance also eliminates the current real estate-specific provisions for all entities. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities with relief from the costs of implementing certain aspects of the new leasing standard, ASU 2016-02. Under the amendments in ASU 2018-11, entities may elect not to restate the comparative periods presented when transitioning to ASC 842 (optional transition method) and lessors may elect not to separate lease and non-lease components when certain conditions are met (lessor relief practical expedient). The optional transition method applies to entities that have not yet adopted ASU 2016-02, which is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company has not elected to early adopt this standard and is currently evaluating the impact the adoption of the standard will have on its condensed consolidated financial statements and related disclosures. The Company's analysis includes, but is not limited to, reviewing existing leases, reviewing other service agreements for embedded leases, establishing policies and procedures, assessing potential disclosures and evaluating the impact of adoption on the Company's condensed consolidated financial statements.

**Recently Adopted Accounting Standards Updates**

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based award require an entity to apply modification accounting under Topic 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions and classification of the awards are the same immediately before and after a modification. ASU 2017-09 was effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard prospectively effective January 1, 2018. The adoption of this ASU did not have an effect on the Company's condensed consolidated financial statements or related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 was effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018. Upon adoption of ASU 2016-18, the Company applied the retrospective transition method for each period presented and included approximately \$162,000 of restricted cash in the beginning-of-period and end-of-period cash, cash equivalents and restricted cash balance reflected in the condensed consolidated statements of cash flows for the nine months ended September 30, 2017. A reconciliation of cash, cash equivalents and restricted cash for each period presented is provided in Note 3 to the condensed consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 adds or clarifies guidance on the classification of certain cash receipts and payments in the statement of cash flows. The standard was effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018. The adoption of this ASU did not have an effect on the Company's condensed consolidated financial statements or related disclosures.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606) which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*. In 2015 and 2016, the FASB issued additional ASUs related to ASC 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this new standard on January 1, 2018 using the full retrospective method. There was no change to the Company's condensed consolidated financial statements as a result of the adoption.

**3. Cash, cash equivalents and restricted cash**

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 130,727	\$ 82,176
Restricted cash (included in prepaid expenses and other current assets)	161	—
Restricted cash	242	162
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 131,130</b>	<b>\$ 82,338</b>

Amounts included in restricted cash represent cash held to collateralize outstanding letters of credit in the amount of approximately \$403,000 and \$162,000 as of September 30, 2018 and December 31, 2017, respectively, provided as a security deposit for the Company's office space located in Needham, Massachusetts.

#### 4. Fair value of financial instruments

The Company determines the fair value of its financial instruments based upon the fair value hierarchy, which prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs	Quoted prices in active markets for identical assets or liabilities that the Company can access at the measurement date.
Level 2 inputs	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
Level 3 inputs	Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

#### Items Measured at Fair Value on a Recurring Basis

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis (in thousands):

Description	September 30, 2018			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 129,309	\$ 100,006	\$ 29,303	\$ —
Short-term investments	14,912	—	14,912	—
<b>Total financial assets</b>	<b>\$ 144,221</b>	<b>\$ 100,006</b>	<b>\$ 44,215</b>	<b>\$ —</b>

Description	December 31, 2017			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 80,894	\$ 75,478	\$ 5,416	\$ —
Short-term investments	4,496	—	4,496	—
<b>Total financial assets</b>	<b>\$ 85,390</b>	<b>\$ 75,478</b>	<b>\$ 9,912</b>	<b>\$ —</b>

The Company's cash equivalents and investments are comprised of U.S. Government money market funds, government-sponsored enterprise securities, and corporate bonds and commercial paper of publicly traded companies. These investments and cash equivalents have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2018 and December 31, 2017.

### Fair Value of Financial Instruments

The fair value of the Company's long-term debt is determined using a discounted cash flow analysis using current applicable rates for similar instruments as of the condensed consolidated balance sheet dates. The carrying value of the Company's long-term debt, including the current portion, at September 30, 2018 and December 31, 2017 was approximately \$25.1 million and \$14.8 million, respectively. At September 30, 2018, the Company estimates that the fair value of its long-term debt, including the current portion, was approximately \$26.9 million. The fair value of the Company's long-term debt was determined using Level 3 inputs.

### 5. Investments

Cash, cash equivalents, and investments consist of the following (in thousands):

	<b>September 30, 2018</b>			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Cash and cash equivalents:				
Cash and money market accounts	\$ 101,424	\$ —	\$ —	\$ 101,424
Government-sponsored enterprise securities (due within 90 days)	9,987	—	—	9,987
Corporate bonds and commercial paper (due within 90 days)	19,318	—	(2)	19,316
<b>Total cash and cash equivalents</b>	<b>\$ 130,729</b>	<b>\$ —</b>	<b>\$ (2)</b>	<b>\$ 130,727</b>
Investments:				
Corporate bonds and commercial paper (due within 1 year)	\$ 14,908	\$ 4	\$ —	\$ 14,912
<b>Total investments</b>	<b>\$ 14,908</b>	<b>\$ 4</b>	<b>\$ —</b>	<b>\$ 14,912</b>
<b>Total cash, cash equivalents and investments</b>	<b>\$ 145,637</b>	<b>\$ 4</b>	<b>\$ (2)</b>	<b>\$ 145,639</b>

	<b>December 31, 2017</b>			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Cash and cash equivalents:				
Cash and money market accounts	\$ 76,760	\$ —	\$ —	\$ 76,760
Corporate bonds and commercial paper (due within 90 days)	5,418	\$ —	\$ (2)	\$ 5,416
<b>Total cash and cash equivalents</b>	<b>\$ 82,178</b>	<b>\$ —</b>	<b>\$ (2)</b>	<b>\$ 82,176</b>
Investments:				
Corporate bonds and commercial paper (due within 1 year)	\$ 4,496	\$ —	\$ —	\$ 4,496
<b>Total investments</b>	<b>\$ 4,496</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 4,496</b>
<b>Total cash, cash equivalents and investments</b>	<b>\$ 86,674</b>	<b>\$ —</b>	<b>\$ (2)</b>	<b>\$ 86,672</b>

There were no realized gains or losses on investments for the three and nine months ended September 30, 2018 or 2017, respectively. There were seven and five investments in an unrealized loss position as of September 30, 2018 and December 31, 2017, respectively. None of these investments had been in an unrealized loss position for more than 12 months as of September 30, 2018 and December 31, 2017, respectively. The aggregate unrealized loss on these securities as of September 30, 2018 and December 31, 2017 was approximately \$2,000 and \$2,000, respectively, and the fair value was \$18.3 million and \$9.9 million, respectively. The Company considered the decline in the market value for these investments to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these investments before the recovery of their amortized cost basis, which may be at maturity, the Company did not consider these investments to be other-than-temporarily impaired as of September 30, 2018 and December 31, 2017, respectively.



## 6. Inventory

During the third quarter of 2018, the Company began capitalizing inventory costs for COPIKTRA manufactured in preparation for its launch in the United States based on its evaluation of, among other factors, the status of the COPIKTRA New Drug Application (NDA) in the United States and the ability of its third-party suppliers to successfully manufacture commercial quantities of COPIKTRA, which provided the Company with reasonable assurance that the net realizable value of the inventory would be recoverable.

Inventory consists of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	\$ —	\$ —
Work in process	108	—
Finished goods	23	—
<b>Total inventories</b>	<b>\$ 131</b>	<b>\$ —</b>

Costs incurred prior to the quarter-ended September 30, 2018 to manufacture COPIKTRA were expensed as operating expenses as incurred.

## 7. Intangible assets

The Company's intangible assets consist of the following (in thousands):

	September 30, 2018	Estimated useful life
Acquired and in-licensed rights	\$ 22,000	14 years
Less: accumulated amortization	(31)	
<b>Total intangible assets, net</b>	<b>\$ 21,969</b>	

Acquired and in-licensed rights as of September 30, 2018, consist of a \$22.0 million milestone payment which became payable upon the FDA marketing approval on September 24, 2018 pursuant to the amended and restated license agreement with Infinity Pharmaceuticals, Inc. (Infinity). The Company made a milestone payment of \$22.0 million to Infinity in November 2018.

The Company recorded approximately \$31,000 in amortization expense related to finite-lived intangible assets during the three and nine months ended September 30, 2018 using the straight-line methodology. Estimated future amortization expense for finite-lived intangible assets as of September 30, 2018 is approximately \$392,000 for the remainder of 2018 and approximately \$1.6 million per year thereafter.

## 8. Accrued expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Infinity milestone	\$ 22,000	\$ —
Contract research organization costs	7,301	3,774
Compensation and related benefits	5,916	2,622
Commercialization costs	1,673	131
Professional fees	720	617
Consulting fees	519	448
Other	535	350
<b>Total accrued expenses</b>	<b>\$ 38,664</b>	<b>\$ 7,942</b>

## 9. Long-term debt

On March 21, 2017 (Closing Date), Verastem, Inc. (the Borrower) entered into a term loan facility of up to \$25.0 million with Hercules. The term loan facility is governed by a loan and security agreement, dated March 21, 2017 (the Original Loan Agreement), which was amended on January 4, 2018 and March 6, 2018 (the Amended Loan Agreement) to increase the total borrowing limit under the Original Loan Agreement from up to \$25.0 million to up to \$50.0 million (the Term Loan), pursuant to certain conditions of funding.

As of September 30, 2018, the Company has borrowed a total of \$25.0 million in term loans. The availability of the remaining \$25.0 million of borrowing capacity under the Amended Loan Agreement is subject to Hercules' sole discretion and may be drawn as term loans (each a Term F Loan Advance) in minimum increments of \$5.0 million.

The Term Loan will mature on December 1, 2020 (Loan Maturity Date). Each advance accrues interest at a floating per annum rate equal to the greater of either (a) 10.5% or (b) the lesser of (i) 12.75% and (ii) the sum of (x) 10.5% plus (y) (A) the prime rate minus (B) 4.5%. The Term Loan provided for interest-only payments until November 1, 2018, which was extended to May 1, 2019 pursuant to the Amended Loan Agreement upon the Borrower's receipt of a minimum of \$20.0 million in cash proceeds from a sale of equity securities in December 2017. Thereafter, amortization payments will be payable monthly in 20 installments of principal and interest (subject to recalculation upon a change in prime rates).

The Term Loan is secured by a lien on substantially all of the assets of the Borrower, other than intellectual property, and contains customary covenants and representations.

The Company assessed all terms and features of the Amended Loan Agreement in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of the Amended Loan Agreement, including put and call features. The Company determined that all features of the Amended Loan Agreement were clearly and closely associated with a debt host and did not require bifurcation as a derivative liability, or the fair value of the feature was immaterial to the Company's condensed consolidated financial statements. The Company reassesses the features on a quarterly basis to determine if they require separate accounting. There have been no changes to the Company's original assessment through September 30, 2018.

The future principal payments under the Amended Loan Agreement are as follows as of September 30, 2018 (in thousands):

Remainder of 2018	\$	—
2019		5,984
2020		19,016
<b>Total principal payments</b>	<b>\$</b>	<b>25,000</b>

## 10. Product revenue reserves and allowances

As of September 30, 2018, the Company's sole source of product revenue has been from sales of COPIKTRA in the United States, which it began shipping to Customers on September 25, 2018. The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2018 (in thousands):

	Trade discounts and allowances	Third-Party Payer chargebacks, discounts and fees	Government rebates and other incentives	Returns	Total
Beginning balance at December 31, 2017	\$ —	\$ —	\$ —	\$ —	\$ —
Provision related to sales in the current year	27	72	29	1	129
Adjustments related to prior period sales	—	—	—	—	—
Credits and payments made	—	—	—	—	—
<b>Ending balance at September 30, 2018</b>	<b>\$ 27</b>	<b>\$ 72</b>	<b>\$ 29</b>	<b>\$ 1</b>	<b>\$ 129</b>

Trade discounts and Third-Party Payer chargebacks and discounts are recorded as a reduction to accounts receivable, net on the condensed consolidated balance sheets. Trade allowances and Third-Party Payer fees, government rebates, other incentives and returns are recorded as a component of accrued expenses on the condensed consolidated balance sheets.

## 11. Net loss per share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company's potentially dilutive shares, which include outstanding stock options and restricted stock units (RSUs), are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2018	2017	2018	2017
Outstanding stock options	12,915,463	8,431,355	12,915,463	8,431,355
Outstanding restricted stock units	316,875	—	316,875	—
<b>Total potentially dilutive securities</b>	<b>13,232,338</b>	<b>8,431,355</b>	<b>13,232,338</b>	<b>8,431,355</b>

## 12. Stock-based compensation

### Stock options

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2018 is as follows:

	Shares	Weighted-average exercise price per share	Weighted-average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2017	8,719,978	\$ 5.19	7.9	\$ 6,150
Granted	5,250,121	\$ 5.29		
Exercised	(331,851)	\$ 2.09		
Forfeited/cancelled	(722,785)	\$ 5.43		
Outstanding at September 30, 2018	12,915,463	\$ 5.30	8.1	\$ 37,095
Vested at September 30, 2018	5,782,349	\$ 6.13	6.7	\$ 16,154
Vested and expected to vest at September 30, 2018(1)	12,472,463	\$ 5.32	8.0	\$ 35,661

(1) This represents the number of vested options as of September 30, 2018, plus the number of unvested options expected to vest as of September 30, 2018.

The fair value of each stock option granted during the nine months ended September 30, 2018 and 2017 was estimated on the grant date using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Nine months ended September 30,	
	2018	2017
Risk-free interest rate	2.63 %	1.98 %
Volatility	81 %	79 %
Dividend yield	—	—
Expected term (years)	6.0	5.9

During the first quarter of 2018, the Company granted stock options to purchase a total of 582,500 shares of common stock to certain executives that vest only upon the achievement of specified performance conditions. The Company determined that two of the performance conditions had been achieved as of September 30, 2018. As a result, the Company has recognized approximately \$161,000 and \$669,000 of stock-based compensation expense during the three and nine months ended September 30, 2018, respectively, related to awards that vest upon the achievement of performance conditions.

At September 30, 2018, there was \$21.0 million of total unrecognized compensation cost related to unvested stock options and the Company expects to recognize this cost over a remaining weighted-average period of approximately 4 years.

### Restricted stock units

The Company awards RSUs to employees under its 2012 Incentive Plan. Each RSU entitles the holder to receive one share of the Company's common stock when the RSU vests. The RSUs generally vest in either (i) four substantially equal installments on each of the first four anniversaries of the vesting commencement date, or (ii) 100 percent on the first anniversary of the vesting commencement date, subject to the employee's continued employment with, or service to, the Company on such vesting date. Compensation expense is recognized on a straight-line basis.

A summary of RSU activity during the nine months ended September 30, 2018 is as follows:

	Shares	Weighted- average grant date fair value per share
Outstanding at December 31, 2017	—	\$ —
Granted	336,000	\$ 5.51
Vested	—	\$ —
Forfeited	(19,125)	\$ 3.00
Outstanding at September 30, 2018	316,875	\$ 5.66

At September 30, 2018, there was approximately \$1.6 million of total unrecognized compensation cost related to unvested RSUs and the Company expects to recognize this cost over a remaining weighted-average period of approximately 2 years.

### 13. Common stock

#### *At-the-market equity offering programs*

In March 2017, the Company terminated the at-the-market equity offering program established in December 2013 and established a new at-the-market equity offering program pursuant to which it was able to offer and sell up to \$35.0 million of its common stock at then current market prices from time to time through Cantor Fitzgerald & Co. (Cantor) as sales agent. In August 2017, the Company amended its sales agreement with Cantor to increase the maximum aggregate offering price of shares of common stock that can be sold under the at-the-market equity offering program to \$75.0 million.

During the three months ended September 30, 2018, there were no sales under the at-the-market equity program. During the nine months ended September 30, 2018, the Company sold 6,481,475 shares under this program for net proceeds of approximately \$24.3 million (after deducting commissions and other offering expenses). Through September 30, 2018, the Company has sold a total of 11,518,354 shares under this program for net proceeds of approximately \$47.3 million (after deducting commissions and other offering expenses).

#### *Equity offerings*

On May 16, 2018, the Company entered into an underwriting agreement with Cantor relating to the underwritten offering of 7,777,778 shares (the Shares) of the Company's common stock (Underwriting Agreement). Cantor agreed to purchase the Shares pursuant to the Underwriting Agreement at a price of \$4.31 per share. In addition, the Company granted Cantor an option to purchase, at the public offering price less any underwriting discounts and commissions, an additional 1,166,666 shares of the Company's common stock, exercisable for 30 days from the date of the prospectus supplement. The option was exercised by Cantor in full on May 23, 2018. The aggregate proceeds from Cantor, net of underwriting discounts and offering costs, were approximately \$38.3 million.

On June 14, 2018, the Company entered into a purchase agreement with Consonance Capital Master Account L.P. and P Consonance Opportunities Ltd. (collectively, Consonance) relating to the registered offering of 7,166,666 shares of its common stock at a price of \$6.00 per share. The aggregate proceeds from Consonance, net of offering costs, were approximately \$42.8 million.

## 14. License and collaboration agreements

### *Yakult Honsha Co., Ltd. (Yakult)*

On June 5, 2018, the Company entered into a license and collaboration agreement (the Agreement) with Yakult, under which the Company granted exclusive rights to Yakult to develop and commercialize products containing duvelisib in Japan for the treatment, prevention, palliation or diagnosis of all oncology indications in humans or animals.

Under the terms of the Agreement, Yakult received an exclusive right to develop and commercialize products containing duvelisib in Japan under mutually agreed upon development and commercialization plans at its own cost and expense. Yakult also received certain limited manufacturing rights in the event that the Company is unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to Yakult during the term of the Agreement. The Company retained all rights to duvelisib outside of Japan.

Yakult paid the Company an upfront, non-refundable payment of \$10.0 million in June 2018. The Company is also entitled to receive aggregate payments of up to \$90.0 million if certain development, regulatory and commercial milestones are successfully achieved. Yakult is obligated to pay the Company a double-digit royalty on net sales of products containing duvelisib in Japan, subject to reduction in certain circumstances, and to fund certain global development costs related to worldwide clinical trials conducted by the Company in which Yakult has opted to participate (Global Clinical Trials) on a pro-rata basis.

Unless earlier terminated by either party, the Agreement will expire upon the fulfillment of Yakult's royalty obligations to the Company for the sale of any products containing duvelisib in Japan, which royalty obligations expire, on a product-by-product basis, upon the last to occur of (a) expiration of valid claims covering such product, (b) expiration of regulatory exclusivity for such product or (c) 10 years from first commercial sale of such product. Yakult may terminate the Agreement in its entirety at any time with 180 days' written notice. Either party may terminate the Agreement in its entirety with 60 days' written notice for the other party's material breach if such party fails to cure the breach. The Company may terminate the Agreement if (i) Yakult fails to use commercially reasonable efforts to develop and commercialize products containing duvelisib in Japan or (ii) Yakult challenges any patent licensed by the Company to Yakult under the Agreement. Either party may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

The Company first assessed the Agreement under ASC 808 to determine whether the Agreement (or part of the Agreement) represents a collaborative arrangement based on the risks and rewards and activities of the parties pursuant to the Agreement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC 606. For a component of the Agreement, the Company concluded that both the Company and Yakult are exposed to significant risks while developing duvelisib and ultimately would share in the reward upon successful commercialization of duvelisib. The Company then considered each remaining component in the Agreement to determine if ASC 606 should be applied to those components. Generally, the components in the Agreement fall under one of two potential research and development activities: (i) the parties' joint participation in Global Clinical Trials and (ii) the territory-specific development of duvelisib.

For the parties' participation in the Global Clinical Trials, the Company concluded that the research and development activities and payments related to such activities are not within the scope of ASC 606 as Yakult is not a customer of the Company with regards to these activities in the context of the Agreement. As such, costs incurred to execute the Global Clinical Trials will be recorded as research and development expense and payments received from Yakult related to such will be recorded as a reduction of research and development expense.

For Territory-specific activities, the Company concluded that Yakult is a customer with regard to this component in the context of the Agreement. As such, the Territory-specific component and all related payments are within the scope of ASC 606.

The Company determined that there were two material promises associated with the territory-specific activities: (i) an exclusive license to develop and commercialize duvelisib in the territory and (ii) the initial technology transfer. The Company determined that the exclusive license and initial technology transfer were not distinct from another, as the license has limited value without the initial technology. Therefore, the exclusive license and initial technology transfer are combined as a single performance obligation. The Company evaluated the option rights for manufacturing and supply services to determine whether they represent material rights to Yakult and concluded that the options were not issued at a significant and incremental discount and therefore do not represent material rights. As such, they are not performance obligations at the outset of the arrangement. Based on this assessment, the Company concluded one performance obligation exists at the outset of the Agreement: the exclusive license combined with the initial technology transfer.

The Company determined that the upfront payment of \$10.0 million constitutes the transaction price as of the outset of the Agreement. Future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved. The achievement of the future potential milestones is not within the Company's control and is subject to certain research and development success or regulatory approvals and therefore carry significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. As all performance obligations have been satisfied, if the risk of significant revenue reversal is resolved, any future milestone revenue from the arrangement will be added to the transaction price (and thereby recognized as revenue) in the period the risk is relieved.

The Company satisfied the performance obligation upon delivery of the license and initial technology transfer and recognized the upfront payment of \$10.0 million as license revenue during the three months ended June 30, 2018.

#### ***CSPC Pharmaceutical Group Limited (CSPC)***

On July 26, 2018, the Company and CSPC entered into an Exclusivity Agreement which granted CSPC the exclusive right to negotiate a licensing agreement with the Company for duvelisib in China. CSPC paid the Company a non-refundable exclusivity fee of \$5.0 million in August 2018 (Exclusivity Fee) which was creditable against any payments agreed to under the terms of a potential definitive license agreement.

On September 25, 2018, the Company entered into a license and collaboration agreement with CSPC (the CSPC Agreement), under which the Company granted exclusive rights to CSPC to develop and commercialize products containing duvelisib in the People's Republic of China (China), Hong Kong, Macau and Taiwan (collectively, the CSPC Territory) for the treatment, prevention, palliation or diagnosis of all oncology indications in humans.

Under the terms of the CSPC Agreement, CSPC received an exclusive right to develop and commercialize products containing duvelisib in the CSPC Territory under mutually agreed upon development and commercialization plans at its own cost and expense. CSPC also received certain limited manufacturing rights in the event that the Company is unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to CSPC during the term of the CSPC Agreement. The Company retained all rights to duvelisib outside of the CSPC Territory.

As of September 30, 2018, CSPC became obligated to pay the Company an aggregate upfront, non-refundable payment of \$15.0 million, less the previously paid \$5.0 million Exclusivity Fee, resulting in an outstanding payment due of \$10.0 million, which is included in accounts receivable, net within the condensed consolidated balance sheets. The remaining \$10.0 million upfront payment was paid in full in November 2018. The Company is also entitled to receive aggregate payments of up to \$160.0 million if certain development, regulatory and commercial milestones are successfully achieved. CSPC is obligated to pay the Company a double-digit royalty on net sales of products containing duvelisib in the CSPC Territory, subject to reduction in certain circumstances, and to fund certain global development costs related to worldwide clinical trials conducted by the Company in which CSPC has opted to participate (Global Clinical Trials) on a pro-rata basis.

Unless earlier terminated by either party, the CSPC Agreement will expire upon the fulfillment of CSPC's royalty obligations to the Company for the sale of any products containing duvelisib in the CSPC Territory, which

royalty obligations expire, on a product-by-product basis, upon the last to occur of (a) expiration of valid claims covering such product, (b) expiration of regulatory exclusivity for such product or (c) 10 years from first commercial sale of such product. CSPC may terminate the CSPC Agreement in its entirety at any time with 180 days' written notice. Either party may terminate the CSPC Agreement in its entirety with 60 days' written notice for the other party's material breach if such party fails to cure the breach. The Company may terminate the CSPC Agreement if (i) CSPC fails to use commercially reasonable efforts to develop and commercialize products containing duvelisib in the CSPC Territory or (ii) CSPC challenges any patent licensed by the Company to CSPC under the CSPC Agreement. Either party may terminate the CSPC Agreement in its entirety upon certain insolvency events involving the other party.

The Company first assessed the CSPC Agreement under ASC 808 to determine whether the CSPC Agreement (or part of the CSPC Agreement) represents a collaborative arrangement based on the risks and rewards and activities of the parties pursuant to the CSPC Agreement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC 606. For a component of the CSPC Agreement, the Company concluded that both the Company and CSPC are exposed to significant risks while developing duvelisib and ultimately would share in the reward upon successful commercialization of duvelisib. The Company then considered each remaining component in the CSPC Agreement to determine if ASC 606 should be applied to those components. Generally, the components in the CSPC Agreement fall under one of two potential research and development activities: (i) the parties' joint participation in Global Clinical Trials and (ii) the territory-specific development of duvelisib.

For the parties' participation in the Global Clinical Trials, the Company concluded that the research and development activities and payments related to such activities are not within the scope of ASC 606 as CSPC is not a customer of the Company with regards to these activities in the context of the CSPC Agreement. As such, costs incurred to execute the Global Clinical Trials will be recorded as research and development expense and payments received from CSPC related to such will be recorded as a reduction of research and development expense.

For CSPC Territory-specific activities, the Company concluded that CSPC is a customer with regard to this component in the context of the CSPC Agreement. As such, the CSPC Territory-specific component and all related payments are within the scope of ASC 606.

The Company determined that there were two material promises associated with the territory-specific activities: (i) an exclusive license to develop and commercialize duvelisib in the territory and (ii) the initial technology transfer. The Company determined that the exclusive license and initial technology transfer were not distinct from another, as the license has limited value without the initial technology. Therefore, the exclusive license and initial technology transfer are combined as a single performance obligation. The Company evaluated the option rights for manufacturing and supply services to determine whether they represent material rights to CSPC and concluded that the options were not issued at a significant and incremental discount and therefore do not represent material rights. As such, they are not performance obligations at the outset of the arrangement. Based on this assessment, the Company concluded one performance obligation exists at the outset of the CSPC Agreement: the exclusive license combined with the initial technology transfer.

The Company determined that the upfront payment of \$15.0 million constitutes the transaction price as of the outset of the CSPC Agreement. Future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved. The achievement of the future potential milestones is not within the Company's control and is subject to certain research and development success or regulatory approvals and therefore carry significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. As all performance obligations have been satisfied, if the risk of significant revenue reversal is resolved, any future milestone revenue from the arrangement will be added to the transaction price (and thereby recognized as revenue) in the period the risk is relieved.

The Company satisfied the performance obligation upon delivery of the license and initial technology transfer and recognized the upfront payment of \$15.0 million as license revenue during the three months ended September 30, 2018.



**15. Income taxes**

The Company did not record a federal or state income tax provision or benefit for the three and nine months ended September 30, 2018 and 2017 due to the expected loss before income taxes to be incurred for the years ended December 31, 2018 and 2017, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

**16. Commitments and contingencies**

On April 15, 2014, the Company entered into a lease agreement for approximately 15,197 square feet of office and laboratory space in Needham, Massachusetts. Effective February 15, 2018, the Company amended its lease agreement to relocate within the facility to another location consisting of 27,810 square feet of office space (the Amended Lease Agreement). The Amended Lease Agreement extends the expiration date of the lease from September 2019 through May 2025. Pursuant to the Amended Lease Agreement, the initial annual base rent amount is approximately \$660,000, which increases during the lease term to \$1.1 million for the last twelve-month period. The deferred rent obligation is included in accrued expenses (current portion) and other liabilities (noncurrent portion) in the condensed consolidated balance sheets. The Company has also agreed to pay its proportionate share of increases in operating expenses and property taxes for the building in which the leased space is located.

The minimum aggregate future lease commitments as of September 30, 2018 are as follows (in thousands):

Remainder of 2018	\$ 165
2019	716
2020	971
2021	1,020
2022	1,041
Thereafter	2,600
<b>Total</b>	<b>\$ 6,513</b>

In conjunction with the execution of the Amended Lease Agreement, the Company increased its security deposit by increasing its existing letter of credit to approximately \$403,000. The amount is included in prepaid expenses and other current assets and restricted cash on the condensed consolidated balance sheets as of September 30, 2018.

**17. Subsequent events**

The Company reviews all activity subsequent to the end of the quarter but prior to issuance of the condensed consolidated financial statements for events that could require disclosure or that could impact the carrying value of assets or liabilities as of the balance sheet date. The Company is not aware of any material subsequent events other than the following:

***Hercules Amendment***

On October 11, 2018, the Company entered into Amendment No. 3 to the Amended Loan Agreement (the Third Amendment). The Third Amendment permits the Company to issue convertible notes in an aggregate principal amount of not more than \$175.0 million, provided that such convertible notes meet certain stipulations.

***5.00% Convertible Senior Notes Due 2048***

On October 17, 2018, the Company closed a registered direct public offering of \$150.0 million aggregate principal amount of the Company's 5.00% Convertible Senior Notes due 2048 (the Notes), for net proceeds of approximately \$145.1 million. The Notes are governed by the terms of a base indenture for senior debt securities (the Base Indenture), as supplemented by the first supplemental indenture thereto (the Supplemental Indenture and together with the Base Indenture, the Indenture), each dated October 17, 2018, by and between the Company and Wilmington

Trust, National Association, as trustee. The Notes are senior unsecured obligations of the Company and bear interest at a rate of 5.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year, beginning on May 1, 2019. The Notes will mature on November 1, 2048, unless earlier repurchased, redeemed or converted in accordance with their terms.

The Notes are convertible into shares of the Company's common stock, par value \$0.0001 per share (the Common Stock), together, if applicable, with cash in lieu of any fractional share, at an initial conversion rate of 139.5771 shares of Common Stock per \$1,000 principal amount of the Notes, which corresponds to an initial conversion price of approximately \$7.16 per share of Common Stock and represents a conversion premium of approximately 15.0% above the last reported sale price of the Common Stock of \$6.23 per share on October 11, 2018. Upon conversion, converting noteholders will be entitled to receive accrued interest on their converted Notes. To the extent the Company has insufficient authorized but unissued shares to settle conversions in shares of Common Stock, the Company would be required to settle the deficiency in cash.

The Company will have the right, exercisable at its option, to cause all Notes then outstanding to be converted automatically if the "Daily VWAP" (as defined in the Indenture) per share of the Common Stock equals or exceeds 130% of the conversion price on each of at least 20 VWAP Trading Days (as defined in the Indenture), whether or not consecutive, during any 30 consecutive VWAP Trading Day period commencing on or after the date the Company first issued the Notes.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends, but will not be adjusted for any accrued and unpaid interest.

The Notes are the Company's senior, unsecured obligations and are senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the Notes; equal in right of payment with the Company's existing and future indebtedness that is not so subordinated, and effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing such indebtedness. The Notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

The Indenture includes customary covenants and set forth certain events of default after which the Notes may be declared immediately due and payable and set forth certain types of bankruptcy or insolvency events of default involving the Company or certain of its subsidiaries after which the Notes become automatically due and payable.

## Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for our fiscal year ended December 31, 2017. Please also refer to the sections under headings “Forward-Looking Statements” and “Risk Factors” in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for our fiscal year ended December 31, 2017.*

### OVERVIEW

We are a biopharmaceutical company focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients. Both our marketed product, COPIKTRA™ (duvelisib) capsules, and most advanced product candidate, defactinib, utilize a multi-faceted approach designed to treat cancers originating either in the blood or major organ systems. We are currently developing our product candidates in both preclinical and clinical studies as potential therapies for certain cancers, including leukemia, lymphoma, lung cancer, ovarian cancer, mesothelioma, and pancreatic cancer. We believe that these compounds may be beneficial as therapeutics either as single agents or when used in combination with immuno-oncology agents or other current and emerging standard of care treatments in aggressive cancers that are poorly served by currently available therapies.

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K) and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant B-cells and T-cells. PI3K signaling may lead to the proliferation of malignant B-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment. COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL), after at least two prior systemic therapies. The indication in FL is approved under accelerated approval based on overall response rate and continued approval for this indication may be contingent upon verification and description of clinical benefits in confirmatory trials. Subsequently, on November 2, 2018, the U.S. Food and Drug Administration (FDA) confirmed that as the first sponsor to obtain marketing approval for COPIKTRA (duvelisib) for the above-referenced indications, we are entitled to seven years of orphan-drug exclusive approval pursuant to section 527 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360cc).

COPIKTRA is also being developed by us for the treatment of peripheral T-cell lymphoma (PTCL), which has Fast Track status with the FDA, and is being investigated in combination with other agents through investigator-sponsored studies (ISTs). During 2019, we plan to continue to advance our development of COPIKTRA through the initiation of a confirmatory study of patients with FL and other sponsored trials, and the expansion of our study in patients with PTCL. Furthermore, we plan to report interim data for several ongoing ISTs and to enter into additional partnerships or collaborations for the potential commercialization of COPIKTRA outside of the United States.

We have entered into license and collaboration agreements with Yakult Honsha Co., Ltd. (Yakult) and CSPC Pharmaceutical Group Limited (CSPC), under which we granted Yakult and CSPC exclusive rights to develop and commercialize products containing duvelisib in specified territories including Japan and China, respectively, for the treatment, prevention, palliation or diagnosis of cell oncology indications in humans and animals, and we intend to enter into additional partnerships or collaborations for the potential commercialization of duvelisib outside of the United States.

Defactinib is a targeted inhibitor of the Focal Adhesion Kinase (FAK) signaling pathway. FAK is a non-receptor tyrosine kinase encoded by the Protein Tyrosine Kinase-2 (PTK-2) gene that is involved in cellular adhesion and, in cancer, metastatic capability. Similar to COPIKTRA, defactinib is also delivered orally and designed to be a potential therapy for patients to take at home under the advice of their physician. Defactinib is currently being investigated in

combination with immunotherapeutic and other agents through ISTs. During 2019, we plan to report the results from several ongoing dose escalation combination studies.

Our operations to date have consisted of organizing and staffing our company, business planning, raising capital, identifying and acquiring potential product candidates and undertaking preclinical studies and clinical trials for our product candidates. We have financed our operations to date primarily through public offerings of our common stock, sales of common stock under our at-the-market equity offering programs, our loan and security agreement executed with Hercules Capital, Inc. (Hercules) in March 2017, as amended, the upfront payments under our license and collaboration agreements with Yakult and CSPC, and the issuance of \$150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2048 in October 2018. Following our U.S. commercial launch of COPIKTRA on September 24, 2018, we have recently begun financing a portion of our operations through product revenue.

As of September 30, 2018, we had an accumulated deficit of \$364.2 million. Our net loss was \$21.7 million, \$61.1 million, \$23.1 million and \$49.6 million for the three and nine months ended September 30, 2018 and 2017, respectively. We expect to incur significant expenses for the foreseeable future as a result of our commercialization of COPIKTRA and the continued research and development of all of our product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so.

## **CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES**

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as “critical” because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2017 related to accrued research and development expenses and stock-based compensation. During the nine months ended September 30, 2018, there were no material changes to the significant accounting policies, except for the adoption of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, issued by the Financial Accounting Standards Board (the FASB), as well as significant accounting policies over revenue recognition, collaborative arrangements, accounts receivable, inventory and intangible assets, each of which is detailed below.

### ***Revenue Recognition***

Effective January 1, 2018, we adopted ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are 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; (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. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations; and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

*Product Revenue, Net* – We sell COPIKTRA to a limited number of specialty pharmacies and specialty distributors in the United States (collectively, Customers). Customers subsequently resell COPIKTRA either directly to patients, or to community hospitals or oncology clinics with in-office dispensaries who in turn distribute COPIKTRA to patients. In addition to distribution agreements with Customers, we also enter into arrangements with (1) certain

government agencies and various private organizations (Third-Party Payers), which may provide for chargebacks or discounts with respect to the purchase of COPIKTRA, and (2) Medicare and Medicaid, which may provide for certain rebates with respect to the purchase of COPIKTRA.

We recognize revenue on sales of COPIKTRA when a Customer obtains control of the product, which occurs at a point in time (typically upon delivery). Product revenues are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, Third-Party Payer chargebacks and discounts, government rebates, other incentives, such as voluntary co-pay assistance, product returns, and other allowances that are offered within contracts between us and Customers, payors, and other indirect customers relating to our sale of COPIKTRA. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable or a current liability. These estimates take into consideration a range of possible outcomes based upon relevant factors such as, Customer contract terms, information received from third-parties regarding the anticipated payor mix for COPIKTRA, known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled with respect to sale made.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under contracts will not occur in a future period. Our analyses contemplate the application of the constraint in accordance with ASC 606. For the three and nine months ended September 30, 2018, we determined a material reversal of revenue would not occur in a future period for the estimates detailed below and, therefore, the transaction price was not reduced further. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

**Trade Discounts and Allowances:** We generally provide Customers with invoice discounts on sales of COPIKTRA for prompt payment, which are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate our specialty distributor Customers for sales order management, data, and distribution services. We have determined such services are not distinct from our sale of COPIKTRA to the specialty distributor Customers and, therefore, these payments have also been recorded as a reduction of revenue within the condensed consolidated statements of operations and comprehensive loss through September 30, 2018.

**Third-Party Payer Chargebacks, Discounts and Fees:** We execute contracts with Third-Party Payers which allow for eligible purchases of COPIKTRA at prices lower than the wholesale acquisition cost charged to Customers who directly purchase the product from us. In some cases, Customers charge us for the difference between what they pay for COPIKTRA and the ultimate selling price to the Third-Party Payers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable, net. Chargeback amounts are generally determined at the time of resale to the qualified Third-Party Payer by Customers, and we generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at the end of each reporting period that we expect will be sold to Third-Party Payers, and chargebacks that Customers have claimed, but for which we have not yet issued a credit. In addition, we compensate certain Third-Party Payers for administrative services, such as account management and data reporting. These administrative services have also been recorded as a reduction of product revenue within the condensed consolidated statements of operations and comprehensive loss through September 30, 2018.

**Government Rebates:** We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the condensed consolidated balance sheets. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received,

estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

**Other Incentives:** Other incentives which we offer include voluntary co-pay assistance programs, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses on the condensed consolidated balance sheets.

**Product Returns:** Consistent with industry practice, we generally offer Customers a limited right of return for product that has been purchased from us. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We estimate product return liabilities using available industry data and our own sales information, including our visibility into the inventory remaining in the distribution channel.

Our limited return policy allows for eligible returns of COPIKTRA for credit under the following circumstances:

- Receipt of damaged product;
- Shipment errors that were a result of an error by us;
- Expired product that is returned during the period beginning three months prior to the product's expiration and ending six months after the expiration date;
- Product subject to a recall; and
- Product that we, at our sole discretion, have specified can be returned for credit.

We have not received any returns to date and believes that returns of our product will be minimal.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from product revenue. We expense incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that we would have recognized is one year or less. However, no such costs were incurred during the three and nine months ended September 30, 2018.

*Exclusive Licenses of Intellectual Property* - We may enter into collaboration and licensing arrangements for research and development, manufacturing, and commercialization activities with collaboration partners for the development and commercialization of our product candidates, which have components within the scope of ASC 606. The arrangements generally contain multiple elements or deliverables, which may include (1) licenses, or options to obtain licenses, to our intellectual property, (2) research and development activities performed for the collaboration partner, (3) participation on joint steering committees, and (4) the manufacturing of commercial, clinical or preclinical material. Payments pursuant to these arrangements typically include non-refundable, upfront payments, milestone payments upon the achievement of significant development events, research and development reimbursements, sales milestones, and royalties on future product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which we enter generally do not include significant financing components.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our collaboration and license agreements, we perform the following steps: (i) identification of the promised goods or services in the contract within the scope of ASC 606; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; c) the stand-

alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above; and d) the measure of progress in step (v) above. We use judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below.

If a license to our intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other elements, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of its associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining elements, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, is subject to estimates by management and may change over the course of the arrangement. Such a change could have a material impact on the amount of revenue we record in future periods.

**Customer Options:** If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services such as research and development services or manufacturing services, the goods and services underlying the customer options are not considered to be performance obligations at the inception of the arrangement; rather, such goods and services are contingent on exercise of the option, and the associated option fees are not included in the transaction price. We evaluate customer options for material rights or options to acquire additional goods or services for free or at a discount. If a customer option is determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the estimated probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

**Milestone Payments:** At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved 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 control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

**Royalties:** For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

**Collaborative Arrangements:** Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808, *Collaborative Arrangements*: (i) the parties to the contract must actively participate in the joint operating activity and (ii) the joint operating activity must expose the parties to the possibility of significant risk and rewards, based on whether or not the activity is successful. Payments received from or made to a

partner that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction or increase to research and development expense, respectively.

### ***Accounts Receivable, Net***

Accounts receivable, net primarily relates to amounts due from Customers, net of applicable revenue reserves, or from our license and collaboration partners. Accounts receivable are typically due within 31 days. We analyze accounts that are past due for collectability and provide an allowance for receivables when collection becomes doubtful. Given the nature and limited history of collectability of our accounts receivable, an allowance for doubtful accounts is not deemed necessary at September 30, 2018.

### ***Inventory***

We capitalize inventories manufactured in preparation for initiating sales of a product candidate when the related product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, we evaluate, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, we evaluate risks associated with manufacturing the product candidate, including the ability of our third-party suppliers to complete the validation batches, and the remaining shelf life of the inventories. Costs associated with manufacturing product candidates prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

We value our inventories at the lower of cost or estimated net realizable value. We determine the cost of our inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. We perform an assessment of the recoverability of capitalized inventory during each reporting period, and we write down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenues. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required which would be recorded as a cost of product sales in the condensed consolidated statements of operations and comprehensive loss.

Shipping and handling costs for product shipments are recorded as incurred in cost of product revenues along with costs associated with manufacturing the product, and any inventory write-downs.

### ***Intangible Assets***

We record finite-lived intangible assets related to certain capitalized milestone payments at their fair value. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining underlying patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated.

We assess our finite-lived intangible assets for impairment at least annually, or if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of our drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, we perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each finite-lived intangible asset to its carrying value on the condensed consolidated balance sheets. If the undiscounted cash flows used in the recoverability test are less than the carrying value, we would determine the fair value of the finite-lived intangible asset and recognize an impairment loss if the carrying value of the finite-lived intangible asset exceeds its fair value.



**RESULTS OF OPERATIONS****Comparison of the three months ended September 30, 2018 and 2017**

	<b>Three months ended September 30,</b>			
	<b>2018</b>	<b>2017</b>	<b>Change</b>	<b>% Change</b>
<b>Revenue:</b>				
License revenue	\$ 15,000	\$ —	\$ 15,000	100%
Product revenue, net	508	—	508	100%
<b>Total revenue</b>	<b>15,508</b>	<b>—</b>	<b>15,508</b>	<b>100%</b>
<b>Operating expenses:</b>				
Costs of revenues, excluding amortization of acquired intangible assets	49	—	49	100%
Research and development	11,571	17,743	(6,172)	-35%
Selling, general and administrative	25,426	5,394	20,032	371%
Amortization of acquired intangible assets	31	—	31	100%
<b>Total operating expenses</b>	<b>37,077</b>	<b>23,137</b>	<b>13,940</b>	<b>60%</b>
Loss from operations	(21,569)	(23,137)	1,568	-7%
Interest income	763	121	642	531%
Interest expense	(862)	(110)	(752)	684%
<b>Net loss</b>	<b>\$ (21,668)</b>	<b>\$ (23,126)</b>	<b>\$ 1,458</b>	<b>-6%</b>

*License revenue.* Revenue for the three months ended September 30, 2018 (2018 Quarter) was \$15.0 million and was related to an upfront payment pursuant to the license and collaboration agreement executed between ourselves and CSPC in September 2018. We had no license revenue during the three months ended September 30, 2017 (2017 Quarter).

*Product revenue, net.* We began commercial sales of COPIKTRA within the United States in September 2018, following receipt of FDA marketing approval on September 24, 2018. For the 2018 Quarter we recorded approximately \$508,000 of net product revenue. We had no product revenue during the 2017 Quarter.

*Costs of revenues, excluding amortization of acquired intangible assets.* Costs of revenues, excluding amortization of acquired intangible assets (cost of revenues) of approximately \$49,000 for the 2018 Quarter, consisted of costs associated with the manufacturing of COPIKTRA, royalties owed to Infinity Pharmaceuticals, Inc. (Infinity) on such sales, and certain period costs. We expensed the manufacturing costs of COPIKTRA as operating expenses in the periods prior to July 1, 2018. In the 2018 Quarter, we began capitalizing inventory costs for COPIKTRA manufactured in preparation for our launch in the United States based on our evaluation of, among other factors, the status of the COPIKTRA New Drug Application in the United States and the ability of our third-party suppliers to successfully manufacture commercial quantities of COPIKTRA. Certain of the costs of COPIKTRA units recognized as revenue during the 2018 Quarter were expensed prior to the September 2018 FDA marketing approval and, therefore, are not included in cost of sales during the 2018 Quarter. We expect cost of revenues to increase in relation to product revenues as we deplete these inventories. We had no cost of revenues during the 2017 Quarter.

*Research and development expense.* Research and development expense for the 2018 Quarter was \$11.6 million compared to \$17.7 million for the 2017 Quarter. The \$6.1 million decrease from the 2017 Quarter to the 2018 Quarter was primarily related to a decrease of \$6.0 million in license fees related to a one-time milestone payment pursuant to the Infinity license agreement that was recognized in the 2017 Quarter and a decrease of \$1.2 million in consulting fees and other costs. These decreases were offset by an increase of \$1.1 million in personnel related costs, including non-cash stock-based compensation.

We allocate the expenses related to external research and development services, such as contract research organizations (CROs), clinical sites, manufacturing organizations and consultants by project. The table below summarizes our allocation of research and development expenses to our clinical programs, including COPIKTRA and defactinib, for the 2018 Quarter and the 2017 Quarter. We use our employee and infrastructure resources across multiple research and development projects. Our project costing methodology does not allocate personnel and other indirect costs to specific clinical programs. These unallocated research and development expenses are summarized in the table below and include approximate personnel related costs of \$2.3 million and \$1.2 million for the 2018 Quarter and the 2017 Quarter, respectively.

	<b>Three months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(in thousands)</b>	
COPIKTRA	\$ 6,703	\$ 13,600
Defactinib	375	807
Unallocated and other research and development expense	3,874	2,676
Unallocated stock-based compensation expense	619	660
<b>Total research and development expense</b>	<b>\$ 11,571</b>	<b>\$ 17,743</b>

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2018 Quarter was \$25.4 million compared to \$5.4 million for the 2017 Quarter. The increase of \$20.0 million from the 2017 Quarter to the 2018 Quarter primarily resulted from increases in personnel related costs, including non-cash stock-based compensation, of \$9.7 million, primarily related to the hiring and staffing of our sales and commercial teams, consulting and professional fees of \$9.1 million, primarily related to the support of commercial launch preparation activities, and travel and other costs of \$1.2 million.

*Amortization of acquired intangible assets.* Amortization of acquired intangible assets for the 2018 Quarter of approximately \$31,000 was related to the COPIKTRA finite-lived intangible asset which we recognized and began amortizing in September 2018. There was no amortization of acquired intangible assets in the 2017 Quarter.

*Interest income.* Interest income increased to approximately \$763,000 for the 2018 Quarter from approximately \$121,000 for the 2017 Quarter. This increase was primarily due to higher investment cost basis and higher interest rates on investments.

*Interest expense.* Interest expense related to our loan and security agreement executed with Hercules in March 2017 was approximately \$862,000 for the 2018 Quarter compared to approximately \$110,000 for the 2017 Quarter. The increase was due to a higher principal balance and interest rates in the 2018 Quarter compared to the 2017 Quarter.

#### Comparison of the nine months ended September 30, 2018 and 2017

	<b>Nine months ended September 30,</b>			
	<b>2018</b>	<b>2017</b>	<b>Change</b>	<b>% Change</b>
<b>Revenue:</b>				
License revenue	\$ 25,000	\$ —	\$ 25,000	100%
Product revenue, net	508	—	508	100%
<b>Total revenue</b>	<b>25,508</b>	<b>—</b>	<b>25,508</b>	<b>100%</b>
<b>Operating expenses:</b>				
Costs of revenues, excluding amortization of acquired intangible assets	49	—	49	100%
Research and development	34,886	35,170	(284)	-1%
Selling, general and administrative	51,066	14,582	36,484	250%
Amortization of acquired intangible assets	31	—	31	100%
<b>Total operating expenses</b>	<b>86,032</b>	<b>49,752</b>	<b>36,280</b>	<b>73%</b>
Loss from operations	(60,524)	(49,752)	(10,772)	22%
Interest income	1,297	416	881	212%
Interest expense	(1,858)	(231)	(1,627)	704%
<b>Net loss</b>	<b>\$ (61,085)</b>	<b>\$ (49,567)</b>	<b>\$ (11,518)</b>	<b>23%</b>

*License revenue.* Revenue for the nine months ended September 30, 2018 (2018 Period) was \$25.0 million and was related to upfront payments pursuant to the license and collaboration agreements executed between ourselves and Yakult and CSPC. We had no license revenue in the nine months ended September 30, 2017 (2017 Period).

*Product revenue, net.* We began commercial sales of COPIKTRA within the United States in September 2018, following receipt of FDA marketing approval on September 24, 2018. For the 2018 Period we recorded approximately \$508,000 of net product revenue. We had no product revenue during the 2017 Period.

*Costs of revenues, excluding amortization of acquired intangible assets.* Costs of revenues, excluding amortization of acquired intangible assets (cost of revenues) of approximately \$49,000 for the 2018 Period, consisted of costs associated with the manufacturing of COPIKTRA, royalties owed to Infinity on such sales, and certain period costs. We expensed the manufacturing costs of COPIKTRA as operating expenses in the periods prior to July 1, 2018. In the third quarter of 2018, we began capitalizing inventory costs for COPIKTRA manufactured in preparation for our launch in the United States based on our evaluation of, among other factors, the status of the COPIKTRA New Drug Application in the United States and the ability of our third-party suppliers to successfully manufacture commercial quantities of COPIKTRA. Certain of the costs of COPIKTRA units recognized as revenue during the 2018 Period were expensed prior to the September 2018 FDA marketing approval and, therefore, are not included in cost of sales during this period. We expect cost of revenues to increase in relation to product revenues as we deplete these inventories. We expect cost of revenues to increase in relation to product revenues as we deplete these inventories. We had no cost of revenues during the 2017 Period.

*Research and development expense.* Research and development expense for the 2018 Period was \$34.9 million compared to \$35.2 million for the 2017 Period. The approximately \$284,000 decrease from the 2017 Period to the 2018 Period was primarily related to a decrease of \$6.0 million in license fees related to a one-time milestone payment pursuant to the Infinity license agreement that was recognized in the 2017 Period and a decrease of approximately \$975,000 in consulting fees, partially offset by increases of \$3.6 million in personnel related costs, including non-cash stock-based compensation, and \$2.7 million in CRO expense for outsourced biology, development and clinical services, which includes our clinical trial costs, and approximately \$443,000 in other costs.

We allocate the expenses related to external research and development services, such as CROs, clinical sites, manufacturing organizations and consultants by project. The table below summarizes our allocation of research and development expenses to our clinical programs, including COPIKTRA and defactinib, for the 2018 Period and the 2017 Period. We use our employee and infrastructure resources across multiple research and development projects. Our project costing methodology does not allocate personnel and other indirect costs to specific clinical programs. These unallocated research and development expenses are summarized in the table below and include approximate personnel related costs of \$6.9 million and \$3.9 million for the 2018 Period and the 2017 Period, respectively.

	<b>Nine months ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(in thousands)</b>	
COPIKTRA	\$ 20,187	\$ 23,125
Defactinib	1,691	2,326
Unallocated and other research and development expense	11,317	8,578
Unallocated stock-based compensation expense	1,691	1,141
Total research and development expense	<u>\$ 34,886</u>	<u>\$ 35,170</u>

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2018 Period was \$51.1 million compared to \$14.6 million for the 2017 Period. The increase of \$36.5 million from the 2017 Period to the 2018 Period primarily resulted from an increase in consulting and professional fees of \$17.4 million, primarily related to the support of the commercial launch preparation activities, an increase in personnel related costs, including non-cash stock-based compensation, of \$16.1 million, primarily related to the hiring and staffing of our sales and commercial teams, and an increase in travel and other costs of \$3.0 million.

*Amortization of acquired intangible assets.* Amortization of acquired intangible assets for the 2018 Period of approximately \$31,000 was related to the COPIKTRA finite-lived intangible asset which we recognized and began amortizing in September 2018. There was no amortization of acquired intangible assets in the 2017 Period.

*Interest income.* Interest income increased to approximately \$1.3 million for the 2018 Period from approximately \$416,000 for the 2017 Period. This increase was primarily due to higher investment cost basis and higher interest rates on investments.

*Interest expense.* Interest expense related to our loan and security agreement executed with Hercules in March 2017 was approximately \$1.9 million for the 2018 Period compared to approximately \$231,000 for the 2017 Period. The increase was due to a higher principal balance, higher interest rates, and an increase in the number of days outstanding in the 2018 Period compared to the 2017 Period.

## LIQUIDITY AND CAPITAL RESOURCES

### Sources of liquidity

We have financed our operations to date primarily through public offerings of our common stock, sales of common stock under our at-the market equity offering programs, our loan and security agreement executed with Hercules in March 2017, as amended, the upfront payments under our license and collaboration agreements with Yakult and CSPC and the issuance of \$150.0 million aggregate principal amount of 5.00% Convertible Senior Notes due 2048 in October 2018. Following the commercial launch of COPIKTRA in the United States in September 2018, we have recently begun financing a portion of our operations through product revenue.

As of September 30, 2018, we had \$145.6 million in cash, cash equivalents and investments.

COPIKTRA is our only approved product and our business currently depends heavily on its successful commercialization. Successful commercialization of an approved product is an expensive and uncertain process. Risks and uncertainties include those identified under Item 1A. *Risk Factors*, in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (SEC) on March 13, 2018 and in any subsequent filings with the SEC.

### Cash flows

The following table sets forth the primary sources and uses of cash for the 2018 Period and the 2017 Period (in thousands):

	Nine months ended September 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$ (55,327)	\$ (36,983)
Investing activities	(11,574)	39,444
Financing activities	115,693	16,460
<b>Increase in cash, cash equivalents and restricted cash</b>	<b>\$ 48,792</b>	<b>\$ 18,921</b>

*Operating activities.* The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital.

*Investing activities.* The cash used in investing activities for the 2018 Period relates to the net purchases of investments of \$10.4 million and net purchases of property and equipment approximately \$1.2 million. The cash provided by investing activities for the 2017 Period reflects the net maturities of investments of \$39.4 million.

*Financing activities.* The cash provided by financing activities for the 2018 Period primarily represents \$81.2 million in net proceeds from the sales of our common stock under the Underwriting Agreement and Purchase Agreement described below, \$24.3 million in net proceeds received under our at-the-market equity offering program (ATM), \$9.9 million in net proceeds received from our loan and security agreement executed with Hercules, and approximately

\$637,000 related to stock option exercises, offset by the payment of approximately \$324,000 of issuance costs related to a sale of our common stock during December 2017. The cash provided by financing activities for the 2017 Period primarily represents \$14.1 million in net proceeds received under our ATM, \$2.4 million in net proceeds received from our loan and security agreement executed with Hercules, and approximately \$91,000 received from the exercise of stock options, offset by approximately \$138,000 of deferred financing costs.

In March 2017, we terminated the ATM established in December 2013 and established a new ATM pursuant to which we were able to offer and sell up to \$35.0 million of our common stock at then current market prices from time to time through Cantor Fitzgerald & Co. (Cantor), as sales agent. In August 2017, we amended our sales agreement with Cantor to increase the maximum aggregate offering price of shares of common stock that can be sold under the ATM to \$75.0 million.

During the three months ended September 30, 2018, there were no sales under the at-the-market equity offering program. During the nine months ended September 30, 2018, we sold 6,481,475 shares under this program for net proceeds of approximately \$24.3 million (after deducting commissions and other offering expenses). Through September 30, 2018, we have sold a total of 11,518,354 shares under this program for net proceeds of approximately \$47.3 million (after deducting commissions and other offering expenses).

On May 16, 2018, we entered into an underwriting agreement with Cantor relating to the underwritten offering of 7,777,778 shares of our common stock (Underwriting Agreement). Cantor agreed to purchase the shares of our common stock pursuant to the Underwriting Agreement at a price of \$4.31 per share (Underwriting Agreement). In addition, we granted Cantor an option to purchase, at the public offering price less any underwriting discounts and commissions, an additional 1,166,666 shares of our common stock, exercisable for 30 days from the date of the prospectus supplement. The option was exercised by Cantor on May 23, 2018. The aggregate proceeds from Cantor, net of underwriting discounts and offering costs, were approximately \$38.3 million.

On June 14, 2018, we entered into a purchase agreement with Consonance Capital Master Account L.P. and P Consonance Opportunities Ltd. (collectively, Consonance) relating to the registered offering of 7,166,666 shares of our common stock at a price of \$6.00 per share (Purchase Agreement). The aggregate proceeds from Consonance, net of offering costs, were approximately \$42.8 million.

On October 17, 2018, we closed a registered direct public offering of \$150.0 million aggregate principal amount of our 5.00% Convertible Senior Notes due 2048 (the Notes), for net proceeds of \$145.1 million. The Notes are the senior unsecured obligations and bear interest at a rate of 5.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year, beginning on May 1, 2019. The Notes will mature on November 1, 2048, unless earlier repurchased, redeemed or converted in accordance with their terms.

The Notes are convertible into shares of our common stock, par value \$0.0001 per share (the Common Stock), together, if applicable, with cash in lieu of any fractional share, at an initial conversion rate of 139.5771 shares of Common Stock per \$1,000 principal amount of the Notes, which corresponds to an initial conversion price of approximately \$7.16 per share of Common Stock and represents a conversion premium of approximately 15.0% above the last reported sale price of the Common Stock of \$6.23 per share on October 11, 2018. Upon conversion, converting noteholders will be entitled to receive accrued interest on their converted Notes. To the extent we have insufficient authorized but unissued shares to settle conversions in shares of Common Stock, we would be required to settle the deficiency in cash.

We will have the right, exercisable at our option, to cause all Notes then outstanding to be converted automatically if the "Daily VWAP" (as defined in the supplemental indenture governing the Notes) per share of the Common Stock equals or exceeds 130% of the conversion price on each of at least 20 trading days, whether or not consecutive, during any 30 day consecutive period commencing on or after the date the first Notes were issued.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends, but will not be adjusted for any accrued and unpaid interest.

## License and collaboration agreements

### *Yakult*

On June 5, 2018, we entered into a license and collaboration agreement (the Agreement) with Yakult, under which we granted exclusive rights to Yakult to develop and commercialize products containing duvelisib in Japan for the treatment, prevention, palliation or diagnosis of all oncology indications in humans or animals.

Under the terms of the Agreement, Yakult received an exclusive right to develop and commercialize products containing duvelisib in Japan under mutually agreed upon development and commercialization plans at its own cost and expense. Yakult also received certain limited manufacturing rights in the event that we are unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to Yakult during the term of the Agreement. We retained all rights to duvelisib outside of Japan.

Yakult paid us an upfront, non-refundable payment of \$10.0 million in June 2018. We are also entitled to receive aggregate payments of up to \$90.0 million if certain development, regulatory and commercial milestones are successfully achieved. Yakult is obligated to pay us a double-digit royalty on net sales of products containing duvelisib in Japan, subject to reduction in certain circumstances, and to fund certain global development costs related to worldwide clinical trials conducted by us in which Yakult has opted to participate (Global Clinical Trials) on a pro-rata basis.

Unless earlier terminated by either party, the Agreement will expire upon the fulfillment of Yakult's royalty obligations to us for the sale of any products containing duvelisib in Japan, which royalty obligations expire, on a product-by-product basis, upon the last to occur of (a) expiration of valid claims covering such product, (b) expiration of regulatory exclusivity for such product or (c) 10 years from first commercial sale of such product. Yakult may terminate the Agreement in its entirety at any time with 180 days' written notice. Either party may terminate the Agreement in its entirety with 60 days' written notice for the other party's material breach if such party fails to cure the breach. We may terminate the Agreement if (i) Yakult fails to use commercially reasonable efforts to develop and commercialize products containing duvelisib in Japan or (ii) Yakult challenges any patent licensed by us to Yakult under the Agreement. Either party may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

We recognized the upfront payment of \$10.0 million as license revenue upon execution of the Agreement in June 2018.

### *CSPC*

On July 26, 2018, we entered into an Exclusivity Agreement with CSPC which granted CSPC the exclusive right to negotiate a licensing agreement with us for duvelisib in China. CSPC paid us a non-refundable exclusivity fee of \$5.0 million in August 2018 (Exclusivity Fee) which was creditable against any payments agreed to under the terms of a potential definitive license agreement.

On September 25, 2018, we entered into a license and collaboration agreement with CSPC (the CSPC Agreement), under which we granted exclusive rights to CSPC to develop and commercialize products containing duvelisib in the People's Republic of China (China), Hong Kong, Macau and Taiwan (collectively, the CSPC Territory) for the treatment, prevention, palliation or diagnosis of all oncology indications in humans.

Under the terms of the CSPC Agreement, CSPC received an exclusive right to develop and commercialize products containing duvelisib in the CSPC Territory under mutually agreed development and commercialization plans at its own cost and expense. CSPC also received certain limited manufacturing rights in the event that we are unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to CSPC during the term of the CSPC Agreement. We retained all rights to duvelisib outside of the CSPC Territory.

As of September 30, 2018, CSPC is obligated to pay us an upfront, non-refundable payment of \$15.0 million, less the initial \$5.0 million Exclusivity Fee, resulting in an outstanding payment due of \$10.0 million, which is included in accounts receivable, net on the condensed consolidated balance sheets. The remaining \$10.0 million upfront payment was paid in full in November 2018. We are also entitled to receive aggregate payments of up to \$160.0 million if certain development, regulatory and commercial milestones are successfully achieved. CSPC is obligated to pay us a double-digit royalty on net sales of products containing duvelisib in the CSPC Territory, subject to reduction in certain circumstances, and to fund certain global development costs related to worldwide clinical trials conducted by us in which CSPC has opted to participate (Global Clinical Trials) on a pro-rata basis.

Unless earlier terminated by either party, the CSPC Agreement will expire upon the fulfillment of CSPC's royalty obligations to us for the sale of any products containing duvelisib in the CSPC Territory, which royalty obligations expire, on a product-by-product basis, upon the last to occur of (a) expiration of valid claims covering such product, (b) expiration of regulatory exclusivity for such product or (c) 10 years from first commercial sale of such product. CSPC may terminate the CSPC Agreement in its entirety at any time with 180 days' written notice. Either party may terminate the CSPC Agreement in its entirety with 60 days' written notice for the other party's material breach if such party fails to cure the breach. We may terminate the CSPC Agreement if (i) CSPC fails to use commercially reasonable efforts to develop and commercialize products containing duvelisib in the CSPC Territory or (ii) CSPC challenges any patent licensed by us to CSPC under the CSPC Agreement. Either party may terminate the CSPC Agreement in its entirety upon certain insolvency events involving the other party.

We recognized the upfront payment of \$15.0 million as license revenue upon execution of the CSPC Agreement during the three months ended September 30, 2018.

### **Funding requirements**

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses and operating losses will increase substantially if and as we:

- commercialize COPIKTRA;
- continue our ongoing clinical trials, including with COPIKTRA and defactinib;
- initiate additional clinical trials for our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other products and technologies;
- hire additional clinical, development and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- establish and maintain a sales, marketing and distribution infrastructure to commercialize COPIKTRA or any products for which we may obtain marketing approval.

We expect our existing cash, cash equivalents and investments will be sufficient to fund our obligations for at least the next twelve months from the date of filing of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the costs and timing of commercialization activities for COPIKTRA and the product candidates for which we expect to receive marketing approval;
- the scope, progress and results of our ongoing and potential future clinical trials;

- the extent to which we acquire or in-license other product candidates and technologies;
- the costs, timing and outcome of regulatory review of our product candidates (including our efforts to seek approval and fund the preparation and filing of regulatory submissions);
- revenue received from commercial sales of COPIKTRA and our product candidates, should any of our other product candidates also receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property related claims; and
- our ability to establish collaborations or partnerships on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product 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 when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The disclosure of our contractual obligations and commitments was reported in our Annual Report on Form 10-K for the year ended December 31, 2017. There have not been any material changes from the contractual obligations and commitments previously disclosed in such report other than (i) a change in estimated obligations due to our landlord under the terms of our operating lease, entered into in April 2014, and amended effective February 2018, for our office space located in Needham, Massachusetts and (ii) our borrowing of an additional \$10.0 million from Hercules Capital, Inc. in June 2018. These changes are more fully described in Note 16, *Commitments and contingencies* and Note 9, *Long-term debt*, respectively, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

## 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 under SEC rules.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and investments of \$145.6 million as of September 30, 2018, consisting of cash, U.S. Government money market funds, government-sponsored enterprise securities, and corporate bonds and commercial paper of publicly traded companies. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because most of our investments are interest bearing. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and contract manufacturers globally which may be denominated in foreign currencies. We may be subject to fluctuations in foreign currency rates in connection with these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of September 30, 2018, an immaterial amount of our total liabilities was denominated in currencies other than the functional currency.



As of September 30, 2018, we have borrowed \$25.0 million under the Amended Loan Agreement. The Amended Loan Agreement bears interest per annum equal to the greater of either (a) 10.5% or (b) the lesser of (i) 12.75% and (ii) the sum of (x) 10.5% plus (y) (A) the prime rate minus (B) 4.5%. Changes in interest rates can cause interest charges to fluctuate under the Amended Loan Agreement. A 10% increase in current interest rates would have resulted in an immaterial increase in the amount of cash interest expense for the three and nine months ended September 30, 2018.

#### **Item 4. Controls and Procedures.**

##### **Evaluation of disclosure controls and procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934 (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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and our 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**

During the quarter ended September 30, 2018, we began generating product revenue from the sale of COPIKTRA in the United States. We consider the accounting for our net product revenue to be material to the results of operations for the three and nine months ended September 30, 2018, and believe that the additional internal controls and procedures relating to the accounting for net product revenues, as well as adoption of ASC Topic 606, *Revenue from Contracts with Customers* in connection therewith, and related commercial inventory, have a material effect on our internal control over financial reporting. During the three and nine months ended September 30, 2018, there were no further changes in our internal controls over financial reporting. See Note 2, *Summary of significant accounting policies*, to our unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for further details.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### Item 1A. Risk Factors.

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as filed with the SEC on March 13, 2018. There have been no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as noted below.

#### **Risks Related to the Commercialization of COPIKTRA and Development of Our Product Candidates**

##### ***We are dependent on the commercial success of COPIKTRA.***

A majority of our time, resources and effort are focused on the commercialization of COPIKTRA in the United States. While we expect to continue to expend significant time, resources and effort on the development of our other product candidates, they are in earlier stages of development and subject to the risks of failure inherent in developing drug products.

Our ability to successfully commercialize COPIKTRA will depend on, among other things, our ability to:

- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, through a validated process, sufficiently large quantities and inventory of COPIKTRA to meet demand;
- build and maintain internal sales, distribution and marketing capabilities sufficient to generate commercial sales of COPIKTRA;
- secure widespread acceptance of our product from physicians, health care payors, patients and the medical community;
- properly price and obtain coverage and adequate reimbursement of COPIKTRA by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements;
- manage our growth and spending as costs and expenses increase due to commercialization; and
- establish and maintain collaborations with third parties for the commercialization of COPIKTRA in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries.

There are no guarantees that we will be successful in completing these tasks. In addition, we have begun, and will need to continue investing substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of our sales of COPIKTRA.

##### ***Sales of COPIKTRA may be slow or limited for a variety of reasons including competing therapies or safety issues. If COPIKTRA is not successful in gaining broad commercial acceptance, our business would be harmed.***

Any sales of COPIKTRA will be dependent on several factors including our ability to educate and increase physician awareness of the benefits and cost-effectiveness of COPIKTRA relative to competing therapies. The degree of market acceptance of COPIKTRA among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- effectiveness of our sales and marketing capability and strategies;
- ability to obtain sufficient third-party coverage and reimbursement;
- changes in the standard of care for the targeted indications for COPIKTRA;
- warnings and limitations, including the boxed warning related to the risks of infections, diarrhea or colitis, cutaneous reactions, and pneumonitis, contained in the approved labeling for COPIKTRA;
- safety concerns with similar products marketed by others;
- the prevalence and severity of any side effects as a result of treatment with COPIKTRA;
- our ability to comply with FDA post-marketing requirements imposed upon COPIKTRA, including conducting and completing a confirmatory clinical trial in patients with relapsed or refractory follicular lymphoma that verifies and isolates the benefits of COPIKTRA; and
- the actual market-size for COPIKTRA, which may be larger or smaller than expected.

In addition, COPIKTRA will be subject to continual review by the FDA, and we cannot assure you that newly discovered or developed safety issues will not arise. With the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us to suspend or cease marketing COPIKTRA, cause us to modify how we market COPIKTRA, subject us to substantial liabilities and adversely affect our revenues and financial condition. In the event of a withdrawal of COPIKTRA from the market, our revenues would decline significantly and our business would be seriously harmed and could fail. We additionally may experience significant fluctuations in sales of COPIKTRA from period to period and, ultimately, we may never generate sufficient revenues from COPIKTRA to reach or maintain profitability or sustain our anticipated operations.

***Preclinical testing and clinical trials of our product candidates may not be successful. In the near term, we are dependent on the success of our PI3K inhibitor program, including COPIKTRA. If we are unable to obtain marketing approval for or successfully commercialize any of our other product candidates, or if we experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the research and development of our product candidates, including COPIKTRA, for which we are conducting clinical trials in multiple indications. We received FDA approval for COPIKTRA for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and were granted accelerated approval of COPIKTRA for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Our ability to generate product revenues will depend heavily on the successful commercialization of COPIKTRA and development of our other product candidates. The success of our product candidates will depend on several factors, including the following:

- initiation and successful enrollment and completion of our clinical trials;
- receipt of marketing approvals from the FDA and other regulatory authorities for our future product candidates, including pricing approvals where required;
- establishing and maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing and maintaining commercial capabilities, including hiring and training a sales force, and launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;

- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- securing and maintaining coverage and adequate reimbursement for our products from third party payors;
- effectively competing with other therapies; and
- a continued acceptable safety and efficacy profile of the products following approval.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any collaborator. 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 product candidates, which would materially harm our business.

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to 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 results of a clinical trial do not necessarily predict final results. For example, a further review and analysis of this data may change the conclusions drawn from this unaudited data indicating less promising results than we currently anticipate.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. There also may be significant variability in the safety results obtained through the long-term follow-up of patients from ongoing studies. We do not know whether any clinical trial we may conduct or follow-up data we collect will demonstrate consistent or adequate efficacy and/or safety sufficient to obtain regulatory approval to market our product candidates.

In addition, the design of a clinical trial may determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

A failure of one or more clinical trials could indicate a higher likelihood that subsequent clinical trials of the same product candidate in the same or other indications or subsequent clinical trials of other related product candidates will be unsuccessful for the same reasons as the unsuccessful clinical trials.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate our participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining or not obtain marketing approval for our product candidates;
- 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 including imposition of a Risk Evaluation and Mitigation Strategy (REMS), or safety warnings, including boxed warnings;
- be subject to additional post marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

The FDA and foreign regulatory authorities may determine that the results from our ongoing and future trials do not support regulatory approval and may require us to conduct an additional clinical trial or trials. If these agencies take such a position, the costs of development of our product candidates could increase materially and their potential market introduction could be delayed. The regulatory agencies could also require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will consider an NDA. Our product development costs will also increase if we experience delays in clinical testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, there are a number of ongoing clinical trials being conducted by other companies for product candidates treating cancer. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates, particularly if they view such treatments to be more conventional and established.

Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- severity of the disease under investigation;
- eligibility criteria for the study in question;

- perceived risks and benefits of the product candidate under study in relation to other available treatments including any new treatments that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

- the inclusion of a placebo arm in a trial;
- possible inactivity or low activity of the product candidate being tested at one or more of the dose levels being tested;
- the occurrence of adverse side effects, whether or not related to the product candidate; and
- the availability of numerous alternative treatment options, including clinical trials evaluating competing product candidates, that may induce patients to discontinue their participation in the trial.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

***If serious adverse or unexpected side effects are identified during the commercialization of COPIKTRA or development of our other product candidates, we may need to abandon or limit the commercialization of COPIKTRA and abandon or limit our development of some of our other product candidates.***

The FDA approved COPIKTRA with labeling that includes a boxed warning for four fatal and/or serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis. As a requirement of the FDA's approval, we are implementing an informational REMS to provide appropriate dosing and safety information to better support physicians in managing their patients on COPIKTRA. In addition to the boxed warning, use of COPIKTRA is also associated with adverse reactions, which may require dose reduction, treatment delay or discontinuation of COPIKTRA. Warnings and precautions are provided for infections, diarrhea or colitis, cutaneous reactions, pneumonitis, hepatotoxicity, neutropenia, and embryo-fetal toxicity. The most common adverse reactions (reported in  $\geq 20\%$  of patients) were diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia.

Our other product candidates are in various stages of clinical development and their risk of failure is high. It is impossible to predict when or if our other product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk benefit perspective. Patients in our clinical trials have experienced serious adverse events, deemed by us and the clinical investigator to be related to our product candidates. Serious adverse events generally refer to adverse events, that result in death, are life threatening, require hospitalization or prolonging of hospitalization, or cause a significant and permanent disruption of normal life functions, congenital anomalies or birth defects, or require intervention to prevent such outcomes.

Defactinib is in our Phase 1 and Phase 2 clinical trials and the development program continues to progress. The toxicities reported thus far are consistent with other drugs in this class.

As a result of adverse events observed to date, or further safety or toxicity issues that we may experience in our clinical trials in the future, we may not receive approval to market any product candidates, which could prevent us from ever generating revenue from the sale of products or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. In addition, while we and our clinical trial investigators currently determine if serious adverse or unacceptable side effects are drug related, the FDA or other non-U.S. regulatory authorities may disagree with our or our clinical trial investigators' interpretation of data from clinical trials and the conclusion that a serious adverse effect or unacceptable side effect was not drug related.

For COPIKTRA, if we or others identify previously unknown side effects or if known side effects are more frequent or severe than in the past, then:

- sales of COPIKTRA may be modest;
- regulatory approvals for COPIKTRA may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;
- additional non-clinical or clinical studies, changes in labeling or changes to manufacturing processes, specifications and/or facilities may be required; and
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of COPIKTRA, increase our expenses and impair our ability to successfully commercialize COPIKTRA. Furthermore, as COPIKTRA is commercially available, it may be used in a wider population and in a less rigorously controlled environment than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third-party payors or patients may perceive or conclude that the use of COPIKTRA is associated with previously unknown serious adverse effects, undermining our commercialization efforts.

***Preclinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or later clinical trials of our product candidates. If we cannot replicate the results from our preclinical studies and clinical trials of our product candidates, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.***

Preclinical studies and any positive preliminary and interim data from our clinical trials of our product candidates may not necessarily be predictive of the results of ongoing or later clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, the positive results from clinical trials of our product candidates may not be replicated in subsequent clinical trial results. Also, our later stage clinical trials could differ in significant ways from earlier stage clinical trials, which could cause the outcome of the later stage trials to differ from our earlier stage clinical trials. For example, these differences may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. Many companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late stage clinical trials after achieving positive results in an earlier stage of development. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

***Our approach to the treatment of cancer through the killing of cancer cells and disruption of the tumor microenvironment is relatively unproven, and we do not know whether we will be able to develop any products of significant commercial value.***

We are commercializing COPIKTRA and developing duvelisib in other indications and other product candidates to treat cancer by using targeted agents to kill cancer cells or disrupt the tumor microenvironment and thereby thwart their growth and proliferation of cancer cells.

Research on the use of small molecules to inhibit PI3K and FAK signaling pathways and disrupt the tumor microenvironment is an emerging field and, consequently, there is still uncertainty about whether COPIKTRA and defactinib are effective in improving outcomes for patients with cancer. With respect to our FAK inhibition program, there is some debate in the scientific community regarding cancer stem cells (CSCs), the existence of these cells, the defining characteristics of these cells, as well as whether targeting such cells is an effective approach to treating cancer. Some believe that targeting CSCs as part of our multi-faceted approach should be sufficient for a positive clinical outcome, while others believe that, at times or always, the use of FAK inhibitors that reduce CSCs should be coupled with conventional chemotherapies for a positive clinical outcome.

Any products that we develop may not effectively target cancer cells, enhance anti-tumor immunity, or modulate the local tumor microenvironment. While we are currently commercializing COPIKTRA and conducting clinical trials for other product candidates that we believe will attack cancer cells through the inhibition of the PI3K or FAK signaling pathways and potentially disrupt the tumor microenvironment, we may not ultimately be successful in demonstrating their efficacy, alone or in combination with other treatments.

***The approval of our product candidates as part of a combination therapy for the treatment of certain cancers may be more costly than our prior clinical trials, may take longer to achieve regulatory approval, may be associated with new, more severe or serious and unanticipated adverse events, and may have a smaller market opportunity.***

Part of our current business model involves conducting clinical trials to study the effects of combining our product candidates with other approved and investigational targeted therapies, chemotherapies, and immunotherapies to treat patients with cancer. Regulatory approval for a combination treatment generally requires clinical trials to evaluate the activity of each component of the combination treatment. As a result, it may be more difficult and costly to obtain regulatory approval of our product candidates for use as part of a combination treatment than obtaining regulatory approval of our product candidates alone. In addition, we also risk losing the supply of any approved or investigational product being combined with our product candidate in these clinical trials. Furthermore, the potential market opportunity for our product candidates is difficult to estimate precisely. For instance, if one of our product candidates receives regulatory approval from a combination study, it may be approved solely for use in combination with the approved or investigational product in a particular indication and the market opportunity our product candidate would be dependent upon the continued use and availability of the approved or investigational product. In addition, because physicians, patients and third-party payors may be sensitive to the addition of the cost of our product candidates to the cost of treatment with the other products, we may experience downward pressure on the price that we can charge for our product candidates if they receive regulatory approval. Further, we cannot be sure that physicians will view our product candidates, if approved as part of a combination treatment, as sufficiently superior to a treatment regimen consisting of only the approved or investigational product. Additionally, the adverse side effects of our product candidates may be enhanced when combined with other products. If such adverse side effects are experienced, we could be required to conduct additional pre-clinical and clinical studies and if such adverse side effects are severe, we may not be able to continue the clinical trials of the combination therapy because the risks may outweigh the therapeutic benefit of the combination.

***We may not be successful in obtaining necessary rights to compounds and product candidates for our development pipeline through acquisitions and in-licenses.***

We may seek to acquire new compounds and product candidates from other pharmaceutical and biotechnology companies, academic scientists and other researchers, such as our exclusive in-license from Infinity Pharmaceuticals, Inc. (Infinity), to research, develop, commercialize, and manufacture products in oncology indications containing duvelisib. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including



some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We also may be unable to license or acquire the relevant compound or product candidate on terms that would allow us to make an appropriate return on our investment. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including manufacturing, pre-clinical testing, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development.

In addition, future product or business acquisitions 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 to develop acquired products, product candidates or technologies;
- higher than expected acquisition and integration costs;
- increased amortization expenses; and
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions.

Future business acquisitions may also entail certain additional risks, such as:

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

***If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.***

We intend to seek regulatory approval for our product candidates, including COPIKTRA, in a number of countries outside of the United States and expect that these countries will be important markets for our products, if approved. Marketing our products in these countries will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The regulations that apply to the conduct of clinical trials and approval procedures vary from country to country and may require additional testing. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Failure to obtain regulatory approval in one country may have a negative effect on the regulatory approval process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product 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 product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product 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 product candidates for specific indications may not yield any commercially viable products.

***We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to COPIKTRA and our other product candidates and will face competition with respect to any product 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 COPIKTRA and our product candidates, including Gilead Sciences, Inc., Abbvie, Pharmacyclics LLC, Roche, Celgene Corporation, AstraZeneca, Incyte Corporation, TG Therapeutics, Inc., Novartis and others. Some of these competitive products and therapies are based on scientific approaches that are the same as or 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.

We are commercializing COPIKTRA and developing our other product candidates for the treatment of cancer. There are a variety of available therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that COPIKTRA and our other product candidates, if approved, will be priced at a significant premium over competitive generic products.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing 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 and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In addition, to the extent that products or product candidates of our competitors demonstrate serious adverse side effects or are determined to be ineffective in clinical trials, the commercialization of COPIKTRA and the development of our other product candidates could be negatively impacted.

***COPIKTRA and any future product candidates that we commercialize may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

In both domestic and foreign markets, sales of COPIKTRA and any product candidates that may receive marketing approval in the future will depend, in part, on favorable pricing as well as the availability of coverage and amount of reimbursement by third party payors, including governments and private health plans. Substantial uncertainty exists regarding coverage and reimbursement by third party payors of newly approved health care products.

Outside the United States, some countries require approval of the sale price of a drug before the product can be marketed. In many such 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 revenues 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 COPIKTRA and other product candidates, even if those product candidates obtain marketing approval.

Cost containment is a key trend in the United States and elsewhere. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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 coverage and reimbursement will be available for COPIKTRA or any other product that we commercialize and, if reimbursement is available, the level of reimbursement. Coverage and reimbursement may impact the demand for, or the price of, COPIKTRA or any other product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize COPIKTRA or any other product candidate for which we may obtain marketing approval.

***If we participate in and then fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

With the approval of COPIKTRA, we anticipate that we will need to participate in the Medicaid Drug Rebate Program, Medicare Coverage Gap Discount Program and a number of other federal and state government pricing programs in the U.S. in order to obtain coverage for the product by certain government healthcare programs. These programs would generally require us to pay rebates or provide discounts to certain private purchasers or government payors in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

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

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

- decreased demand for COPIKTRA or any other product 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; 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, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our

insurance coverage as we commercialize COPIKTRA and any future product candidates or if we initiate additional clinical trials in the United States and around the world. 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.

***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 have a material adverse effect on the success of our business.***

We are subject to numerous 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

#### **Risks Related to Our License Agreement with Infinity**

***If we do not realize the anticipated benefits of our license agreement with Infinity for the COPIKTRA program, our business could be adversely affected.***

Our license agreement with Infinity for COPIKTRA may fail to further our business strategy as anticipated or to achieve anticipated benefits and success. We may make or have made assumptions relating to the impact of the acquisition of COPIKTRA on our financial results relating to numerous matters, including:

- the cost of development and commercialization of COPIKTRA; and
- other financial and strategic risks related to the license agreement with Infinity.

Further, we may incur higher than expected operating and transaction costs, and we may encounter general economic and business conditions that adversely affect us relating to our license agreement with Infinity. If one or more of these assumptions are incorrect, it could have an adverse effect on our business and operating results, and the benefits from our license agreement with Infinity for COPIKTRA may not be realized or be of the magnitude expected.

#### **Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.***

Since inception, we have incurred significant operating losses. As of September 30, 2018, we had an accumulated deficit of \$364.2 million. To date, we have generated minimal product revenues and have financed our operations primarily through public offerings of our common stock, sales of our common stock pursuant to our at-the-market equity offering programs, and our loan and security agreement with Hercules Capital Inc. (Hercules). As of

September 30, 2018, there was \$25.0 million available to borrow under the amended term loan facility with Hercules, subject to certain conditions of funding. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- commercialize COPIKTRA;
- continue our ongoing clinical trials with our product candidates, including with COPIKTRA and defactinib;
- initiate additional clinical trials for our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other products and technologies;
- hire additional clinical, development and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- establish and maintain a sales, marketing and distribution infrastructure to commercialize COPIKTRA or any products for which we obtain marketing approval.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential, such as COPIKTRA. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. 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 decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or 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 continue to need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts, including for COPIKTRA.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we commercialize COPIKTRA and continue the clinical development of our other product candidates. We expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of COPIKTRA. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, including for our clinical development programs and any commercialization efforts for COPIKTRA.

We expect our cash, cash equivalents and investments at September 30, 2018 will be sufficient to fund our current operating plan and capital expenditure requirements beyond the next twelve months. Our future capital requirements will depend on many factors, including:

- the costs and timing of commercialization activities for COPIKTRA and the product candidates for which we expect to receive marketing approval;
- the scope, progress and results of our ongoing and potential future clinical trials;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs, timing and outcome of regulatory review of our product candidates (including our efforts to seek approval and fund the preparation and filing of regulatory submissions);
- revenue received from commercial sales of COPIKTRA and our product candidates, should any of our other product candidates also receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property related claims; and
- our ability to establish collaborations or partnerships on favorable terms, if at all.

Conducting 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 of any of our other product candidates. Even though the FDA approved COPIKTRA, it may not achieve commercial success. Our commercial revenues will be derived from sales of products, such as COPIKTRA. Accordingly, even though we received regulatory approval for COPIKTRA, it will take several years to achieve peak sales, and we will need to continue to rely on additional financing to further our clinical development objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

***Raising additional capital or entering into certain licensing arrangements may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to COPIKTRA and our other product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, grants and government funding, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. To the extent that we enter into certain licensing arrangements, the ownership interest of our existing stockholders may be diluted if we elect to make certain payments in shares of our common stock. For example, pursuant to the terms of our license agreement with Infinity, we may elect to make certain milestone payments in shares of common stock in lieu of cash, according to a formula set forth in the license agreement. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, see our risk factors under the heading "Risks Related to Our Indebtedness."

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish future revenue streams or valuable rights to COPIKTRA or other product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market COPIKTRA and other product candidates that we would otherwise prefer to develop and market ourselves.

#### **Risks Related to Our Indebtedness**

***Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.***

In March 2017, we entered into a Loan and Security Agreement with Hercules, which was subsequently amended in January, March and October 2018. Under the Loan and Security Agreement, as amended (the Amended Loan Agreement), Hercules will provide access to term loans with an aggregate principal amount of up to \$50.0 million. As of September 30, 2018, there was \$25.0 million available to borrow under the Amended Loan Agreement, subject to certain conditions of financing.

All obligations under the Amended Loan Agreement are secured by substantially all of our existing property and assets, excluding our intellectual property. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the restrictive covenants in the Amended Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce their security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

***We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.***

Failure to satisfy our current and future debt obligations under the Amended Loan Agreement, or breaching any covenants under the Amended Loan Agreement, subject to specified cure periods with respect to certain breaches, could result in an event of default and, as a result, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Amended Loan Agreement as a result of an event of default, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our COPIKTRA commercialization efforts, other product candidate development or grant to others the rights to develop and market COPIKTRA and our other product candidates that we would otherwise prefer to develop and market internally. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the term loans for its benefit, which collateral includes substantially all of our property other than our intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events. We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

The Amended Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- dispose of certain assets;
- change our lines of business;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make distributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

**Risks Related to Our Dependence on Third Parties**

***We rely in part on third parties to conduct our clinical trials and preclinical testing, and if they do not properly and successfully perform their obligations to us, we may not be able to commercialize COPIKTRA or obtain regulatory approvals for and commercialize any of our other product candidates.***

We rely on third parties, such as contract research organizations (CROs), clinical data management organizations, medical institutions and clinical investigators, to conduct, provide monitors for and manage data from all of our clinical trials. We compete with many other companies for the resources of these third parties.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and ultimately the commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other regulatory agencies require us to comply with standards, commonly referred to as Good Clinical Practices (GCP) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for some of our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize COPIKTRA and our other product candidates.

***We intend to rely on third parties to conduct investigator sponsored clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.***

We intend to rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will provide us certain information rights with respect to the investigator sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator sponsored trials. However, we do not have control over the timing and reporting of the data from investigator sponsored trials, nor do we own the data from the investigator sponsored trials. If we are unable to confirm or replicate the results from the investigator sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

***We contract with third parties for the manufacture of our product candidates, including COPIKTRA, and for compound formulation research, and these third parties may not perform satisfactorily.***

We do not have any manufacturing facilities or personnel. We currently obtain all of our supply of COPIKTRA and our other product candidates for clinical development from third-party manufacturers or third-party collaborators,



and we expect to continue to rely on third parties for the manufacture of clinical quantities of our product candidates and commercial quantities of COPIKTRA. In addition, we currently rely on third parties for the development of various formulations of COPIKTRA and our other product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of COPIKTRA or our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties may terminate their engagement with us at any time. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. 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, including the misappropriation of our proprietary information, trade secrets and know how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- disruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers or suppliers.

Third-party manufacturers may not be able to comply with current good manufacturing practices (cGMP) regulations or similar regulatory requirements outside 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 fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any interruption of the development or operation of the manufacturing facilities due to, among other reasons, events such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility by natural disasters, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available COPIKTRA, other product candidates or materials.

If our current contract manufacturers cannot perform as agreed or these parties cease to provide quality manufacturing and related services to us, we may be required to replace that manufacturer. If we are not able to engage appropriate replacements in a timely manner, our ability to manufacture COPIKTRA or our other product candidates in sufficient quality and quantity required for commercial use of COPIKTRA and/or for planned pre-clinical testing, clinical trials and potential commercial use of our product candidates would be adversely affected. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement, as well as producing the drug product and obtaining regulatory approvals for the new manufacturer. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time consuming and may result in delays. In light of the lead time needed to manufacture COPIKTRA and our other product candidates, and the availability of underlying materials, we may not be able to, in a timely manner or at all, establish or maintain sufficient commercial manufacturing arrangements on commercially reasonable terms necessary to provide adequate supply of COPIKTRA to meet demands that exceed our commercial assumptions or to provide adequate supply of our other product candidates to meet demands that exceed our clinical assumptions. Furthermore, we may not be able to obtain the significant financial capital that may be required in connection with such arrangements. Even after successfully engaging third parties to execute the manufacturing process for COPIKTRA and our other product candidates, such parties may not comply with the terms and timelines they have agreed to for various reasons, some of which may be out of their or our control, which

could impact our ability to execute our business plans on expected or required timelines in connection with the commercialization of COPIKTRA and the continued development of our other product candidates. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties, which could have a material adverse effect on our business prior to and after commercialization.

Our current and anticipated future dependence upon others for the manufacture of our other product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

***If we are not able to establish collaborations, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, 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 collaborator may also consider alternative product 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 product candidate. 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 collaborators.

We may not be able to negotiate 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 certain product candidates, reduce or delay our development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development 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 product candidates or bring them to market and generate product revenue.

***We may depend on collaborations with third parties for the commercialization of COPIKTRA and the development and commercialization of our other product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of COPIKTRA or any other product candidates.***

We may seek third-party collaborators for the development and commercialization of our product candidates. For instance, we have entered into agreements for the development and commercialization of COPIKTRA in China, Hong Kong, Macau and Taiwan with CSPC Pharmaceutical Group Limited and in Japan with Yakult Honsha Co., Ltd. We anticipate that we may seek to enter into a collaboration for marketing and commercialization of our product candidates in certain territories worldwide at the appropriate time in the future. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a future 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 we are unable to maintain our agreements with third parties to distribute COPIKTRA to patients, our results of operations and business could be adversely affected.***

We will rely on third parties to commercially distribute COPIKTRA to patients. We have contracted with a third-party logistics company to warehouse COPIKTRA and to process and ship customer orders, and with specialty pharmacies and specialty distributors to sell and distribute COPIKTRA. The specialty pharmacies sell COPIKTRA directly to patients and provide patient education and ongoing management. The specialty distributors sell COPIKTRA to community oncologists with in-office dispensaries, hospital-owned practices, local offices with onsite pharmacies, retail pharmacies, and other institutional customers. We have also contracted with a third-party patient services hub to help us with some or all of the following: reimbursement adjudication, patient financial support, patient assistance programs and ongoing compliance support. This distribution network will require significant coordination with our sales and marketing and finance organizations. In addition, failure to coordinate financial systems could negatively impact our ability to accurately report product revenue from COPIKTRA. If we are unable to effectively manage the distribution process, the commercial launch and sales of COPIKTRA, as well as any future products we may commercialize, sales could be delayed or severely compromised and our results of operations may be harmed.

In addition, the use of specialty pharmacies, specialty distributors and a call center involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using COPIKTRA or serious adverse reactions, events and/or product complaints regarding COPIKTRA;

- not effectively sell or support COPIKTRA, or communicate publicly concerning COPIKTRA in a manner that is contrary to FDA rules and regulations;
- reduce or discontinue their efforts to sell or support COPIKTRA;
- not devote the resources necessary to sell COPIKTRA in the volumes and within the time frame we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Any such events may result in decreased product sales and lower product revenue, which would harm our results of operations and business.

### **Risks Related to Our Intellectual Property**

***If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are a party to a number of intellectual property license agreements with third parties, including Infinity and Pfizer Inc., or Pfizer, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, under our license agreements with Infinity and Pfizer, we are required to use diligent or commercially reasonable efforts to develop and commercialize licensed products under the agreement and to satisfy other specified obligations. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or to convert the exclusive licenses to non-exclusive licenses, which could materially adversely affect the value of COPIKTRA or the product candidate being developed under these license agreements. Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which may not be possible. If Pfizer were to terminate its license agreement with us for any reason, we would lose our rights to defactinib. If Infinity were to terminate its license agreement with us for any reason, we would lose our rights to COPIKTRA.

***If we are unable to obtain and maintain patent protection for our products, or if our licensors are unable to obtain and maintain patent protection for the products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.***

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our products. We and our licensors seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. We cannot be certain that any patents will issue with claims that cover COPIKTRA or our other product candidates.

The patent prosecution process is expensive and time consuming, and 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 will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering products that we license from third parties and are reliant on our licensors. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and

our licensors' pending and future patent applications may not result in patents being issued which protect our products 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.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, in the United States, for patents that have an effective filing date prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States transitioned to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed 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. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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 this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we are reliant on them.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability and the ability of our collaborators to commercialize, develop, manufacture, market and sell COPIKTRA and our other product candidates without infringing the proprietary rights of third parties. We have yet to conduct comprehensive freedom to operate searches to determine whether our use of certain of the patent rights owned by or licensed to us would infringe patents issued to third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products. 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. We could be forced, including by court order, to cease commercializing the infringing product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing COPIKTRA and our other product 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.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our products, we also rely on trade secrets, including unpatented know how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements 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, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

**Risks Related to Maintaining and Expanding COPIKTRA'S Regulatory Approval, Achieving Regulatory Approval of Our Other Product Candidates and Other Legal Compliance Matters**

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize such candidates, and our ability to generate revenue will be materially impaired.***

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. The activities associated with a product candidate's development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for product candidates will prevent us from commercializing such product candidates. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction, except for COPIKTRA in the United States. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. A product candidate 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 product candidates involved. 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. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be subject to more limited indications than those we propose 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 a product candidate, its commercial prospects may be harmed and our ability to generate revenues will be materially impaired.

***We have received orphan drug designation for COPIKTRA and certain of our product candidates, but there can be no assurance that we will be able to prevent third parties from developing and commercializing products that are competitive to COPIKTRA or these product candidates.***

We received orphan drug designation in the United States and the European Union for the use of COPIKTRA in CLL/SLL and FL, in the United States and European Union for the use of defactinib in ovarian cancer, and in the United States, the European Union, and Australia for the use of defactinib in mesothelioma. Orphan drug exclusivity grants seven years of marketing exclusivity under the Federal Food, Drug and Cosmetic Act (FDCA), up to ten years of marketing exclusivity in Europe, and five years of marketing exclusivity in Australia. Other companies have received orphan drug designations for compounds other than COPIKTRA or defactinib for the same indications for which we may

have received orphan drug designation in corresponding territories. While orphan drug exclusivity for COPIKTRA or defactinib provides market exclusivity against the same active ingredient for the same indication, we would not be able to exclude other companies from manufacturing and/or selling drugs using the same active ingredient for the same indication beyond that timeframe on the basis of orphan drug exclusivity. Furthermore, the marketing exclusivity in Europe can be reduced from ten years to six years if the orphan designation criteria are no longer met or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which the FDA may approve a competing product for the same indication during the seven-year period of marketing exclusivity, such as if the later product is the same compound as our product but is shown to be clinically superior to our product, or if the later product is a different drug than our product candidate. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same compound for other indications or of another compound for the same use as the orphan drug.

***We may seek fast track designation for COPIKTRA in additional indications, or for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process, and it does not ensure that we will receive marketing approval.***

The FDA has granted fast track designation for COPIKTRA for the treatment of patients with peripheral T-cell lymphoma who have received at least one prior therapy. Any sponsor may seek fast track designation for a drug if it is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a drug sponsor may apply for FDA fast track designation. If we seek fast track designation for a product candidate, we may not receive it from the FDA. However, even if we receive fast track designation, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

***COPIKTRA and any other product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.***

COPIKTRA and any other product candidate for which we obtain marketing approval, along with the manufacturing processes, post approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post marketing testing and surveillance to monitor the safety or efficacy of the product, including the imposition of a REMS.

With respect to COPIKTRA, the indication in FL is approved by the FDA under accelerated approval based on overall response rate observed in clinical trials. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The FDA is requiring that we conduct a clinical trial in patients with relapsed or refractory FL that verifies and isolates the benefits of COPIKTRA. Additionally, as a requirement of the FDA's approval, we are implementing an informational REMS that entails a communication plan to provide appropriate dosing and safety information to better support physicians in managing their patients on COPIKTRA.

The FDA closely regulates the post approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes



stringent restrictions on manufacturers' communications regarding off label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- 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 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;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may fail to obtain any marketing approvals, lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

Healthcare providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of COPIKTRA and any other product candidates for which we obtain marketing approval. Our arrangements with healthcare providers, third-party payors and other parties within the healthcare industry 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 COPIKTRA and any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare and regulatory laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the anti-kickback statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act (FCA), which imposes criminal and civil penalties on individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government and actions under the FCA may be brought by private whistleblowers as well as the government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also establishes requirements related to the privacy, security and transmission of individually identifiable health information which apply to many healthcare providers, physicians and third-party payors with whom we interact;
- 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 FDCA, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under governmental healthcare programs;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the so-called federal "sunshine law" or Open Payments requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests; and analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws regulate interactions between pharmaceutical companies and healthcare providers and require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information. State 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.

Similar healthcare laws and regulations exist in the European Union and other foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

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, including arrangements we may have with physicians and other healthcare providers, or patient assistance programs, 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, 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, and the curtailment or restructuring of our operations. If any of the physicians or other 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. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraud or other misconduct, including intentional failures to: comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***Recently enacted and future legislation may increase the difficulty and cost for us to commercialize COPIKTRA, obtain marketing approval of and commercialize our other product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities and affect our ability to profitably sell COPIKTRA and any other product candidates for which we obtain marketing approval.

The U.S. healthcare industry generally and U.S. government healthcare programs in particular are highly regulated and subject to frequent and substantial changes. The U.S. government and individual states have been aggressively pursuing healthcare reform. For example, in March 2010, President Obama signed into law the Health Care Reform Act, 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 healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law, for example, increased drug rebates under state Medicaid programs for brand name prescription drugs and extended those rebates to Medicaid managed care and assessed a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid.

Since its enactment, there have been ongoing judicial, legislative and administrative efforts to modify, repeal or prevent implementation of various provisions of the Health Care Reform Act. We cannot predict the ultimate content, timing or effect of any federal or state healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the U.S. since the Health Care Reform Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to the Bipartisan Budget Act of 2015, will remain in effect through 2027 unless additional action is taken by Congress. Tax reform legislation enacted at the end of 2017 eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called "individual mandate").

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price constraints, restrictions on copayment assistance by pharmaceutical manufacturers, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition,

individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We cannot be sure whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on COPIKTRA or the marketing approvals of our product candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post marketing testing and other requirements.

#### **Risks Related to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Robert Forrester, our President and Chief Executive Officer, Daniel Paterson, our Chief Operating Officer, Robert Gagnon, our Chief Financial Officer, and Joseph Lobacki, our Chief Commercial Officer, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with Robert Forrester, Daniel Paterson, Robert Gagnon and Joseph Lobacki, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies, universities and research institutions for similar personnel. Although we have implemented a retention plan for certain key employees, our retention plan may not be successful in incentivizing these employees to continue their employment with us. 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, including our scientific co-founders, 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.

***We may expand our development, regulatory and sales and marketing capabilities over time, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We may experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we may 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, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel when we expand. The physical 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 the execution of our business plans or disrupt our operations.

***Our business and operations may be materially adversely affected in the event of computer system breaches or failures.***

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our key business

processes and clinical development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials 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 results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be exposed to liability, which could have a material adverse effect on our operating results and financial condition and possibly delay the further development and commercialization of COPIKTRA and our other product candidates.

### **Risks Related to Our Common Stock**

***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, 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 corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us 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 not all members of the board are elected at one time;
- 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 the board;
- 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 certain 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.

***The market price of our common stock has been, and may continue to be, highly volatile.***

Our stock price has been volatile. Since January 27, 2012, when we became a public company, the price for one share of our common stock has reached a high of \$18.82 and a low of \$1.05 through September 30, 2018. We cannot predict whether the price of our common stock will rise or fall. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors; the success of commercializing COPIKTRA;

- regulatory or legal developments in the United States and other countries;
- 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 product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- 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;
- 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.

In addition, the stock market in general and the market for small pharmaceutical companies and biotechnology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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

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

***We have limited experience in marketing and commercializing product candidates. If we are unable to successfully maintain and further develop internal commercialization capabilities, establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, sales of COPIKTRA may be negatively impacted and we may not be successful in commercializing our other product candidates if and when they are approved.***

We have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties.

We have hired a commercial team and implemented the organizational infrastructure we believe we need for a successful commercial launch of COPIKTRA. We will need to commit significant time and financial and managerial resources to maintain and further develop our marketing and sales force to ensure they have the technical expertise required to address any challenges we may face with the commercialization of COPIKTRA. Factors that may inhibit our efforts to maintain and develop our commercialization capabilities include:

- an inability to retain an adequate number of effective commercial personnel;
- an inability to train sales personnel, who may have limited experience with our company or COPIKTRA, to deliver a consistent message regarding COPIKTRA and be effective in persuading physicians to prescribe COPIKTRA;
- an inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe COPIKTRA or any other product candidates;

- an inability of third-parties to manufacture COPIKTRA consistently in commercial quantities, at acceptable costs and on expected timelines;
- a 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;
- an inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding COPIKTRA; and
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization.

If we are not successful in establishing and maintaining an effective sales and marketing infrastructure, we will have difficulty commercializing COPIKTRA, which would adversely affect our business and financial condition.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us 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 sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to 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 our product candidates.

### **Risks Related to the Notes**

***Servicing our debt, including the Notes, requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.***

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on the timing of regulatory reviews and approvals and our future performance, which is subject to regulatory, economic, financial, competitive and other factors beyond our control. We are a clinical stage biopharmaceutical company and we have not yet generated any profit from product sales. We expect to continue to incur losses as we continue our clinical development of, and seek regulatory approvals for, our product candidates, prepare to commercialize any approved products and add infrastructure and personnel to support our product development efforts and operations. Accordingly, our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

***The Notes are effectively subordinated to our secured indebtedness and structurally subordinated to any liabilities of our subsidiaries.***

The Notes are our senior, unsecured obligations and are senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the Notes; equal in right of payment with our existing and future indebtedness that is not so subordinated, and effectively subordinated to our existing and future secured indebtedness, to the extent of the value of the collateral securing such indebtedness. The Notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent we are not a holder thereof) preferred equity, if any, of our subsidiaries. In the event of our bankruptcy, liquidation, reorganization or other winding up, our assets that secure debt will be available to pay obligations on the Notes only after the secured debt has been repaid in full from these assets, and the assets of our subsidiaries will be available to pay obligations on the Notes only after all claims of such subsidiaries' creditors, including trade creditors and preferred equity holders have been repaid in full. There may not be sufficient assets remaining to pay amounts due on any or all of the Notes then outstanding. The indenture and supplemental indenture governing the Notes do not prohibit us from incurring additional senior debt or secured debt, nor do they prohibit any of our subsidiaries from incurring additional liabilities.

***Despite our current debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.***

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt agreements, some of which may be secured debt. We are not restricted under the terms of the indenture or the supplemental indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture or the supplemental indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. While the Amended Loan Agreement, as amended by the Third Amendment, restricts our ability and the ability of our subsidiaries to issue or incur additional indebtedness, including secured indebtedness, if our loans under the Amended Loan Agreement, as amended by the Third Amendment, mature or are repaid, we may not be subject to such restrictions under the terms of any subsequent indebtedness.

***We may not have the ability to raise the funds necessary to repurchase the Notes upon a fundamental change, and our existing or future debt may contain limitations on our ability to repurchase the Notes.***

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor. In addition, our ability to repurchase the Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness that exist at the time of the repurchase. The Amended Loan Agreement, as amended by the Third Amendment, currently limits our ability to repurchase the Notes. Our failure to repurchase Notes at a time when the repurchase is required by the indenture and supplemental indenture governing the Notes would constitute a default under the indenture and supplemental indenture. A default under the indenture or the supplemental indenture or the fundamental change itself could also lead to a default under the Amended Loan Agreement, as amended by the Third Amendment, and/or agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

In addition, our borrowings under the Amended Loan Agreement, as amended by the Third Amendment, are, and are expected to continue to be, at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remained the same, and our net income would decrease.



***The Amended Loan Agreement, as amended by the Third Amendment, limits our ability to pay any cash amount upon repurchase of the Notes.***

The Amended Loan Agreement, as amended by the Third Amendment, prohibits us from making any cash payments to repurchase the Notes upon a fundamental change. Any new credit facility that we may enter into may have similar restrictions.

Our failure to repurchase the Notes as required under the terms of the Notes would constitute a default under the indenture and the supplemental indenture governing the Notes and would permit holders of the Notes to accelerate our obligations under the Notes. A default under the indenture or the supplemental indenture or the fundamental change itself could also lead to a default under the Amended Loan Agreement, as amended by the Third Amendment, or agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

***Future sales of our common stock or equity-linked securities in the public market could lower the market price for our common stock.***

In the future, we may sell additional shares of our common stock or equity-linked securities to raise capital. In addition, a substantial number of shares of our common stock are reserved for issuance upon the exercise of stock options and upon conversion of the Notes. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance and sale of substantial amounts of common stock or equity-linked securities, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-linked securities.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

**RECENT SALES OF UNREGISTERED SECURITIES**

None.

**PURCHASE OF EQUITY SECURITIES**

We did not purchase any of our equity securities during the period covered by this Quarterly Report on Form 10-Q.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

The following disclosure is provided in accordance with and in satisfaction of the requirements of Item 2.02 “*Results of Operations and Financial Condition*” of Form 8-K:

On November 7, 2018, Verastem, Inc. announced its financial results for the quarter ended September 30, 2018 and commented on certain corporate accomplishments and plans. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 hereto.

The information furnished in Item 5 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

**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.

**EXHIBIT INDEX**

- 4.1 [Indenture, dated as of October 17, 2018, by and between the Company and Wilmington Trust, National Association \(incorporated by reference to Exhibit 4.1 to Form 8-K filed by the Registrant on October 17, 2018\).](#)
- 4.2 [First Supplemental Indenture, dated as of October 17, 2018, by and between the Company and Wilmington Trust, National Association \(incorporated by reference to Exhibit 4.2 to Form 8-K filed by the Registrant on October 17, 2018\).](#)
- 4.3\* [Form of Inducement Award Restricted Stock Unit Agreement.](#)
- 10.1\*† [License and Collaboration Agreement, dated September 25, 2018, between Verastem, Inc. and CSPC Pharmaceutical Group Limited.](#)
- 10.2\* [Consulting Agreement, dated October 3, 2018, between Verastem, Inc. and Louise Phanstiel.](#)
- 10.3 [Amendment No. 3 to Loan and Security Agreement, as amended, with Hercules Capital, Inc., as administrative agent, and the Lenders from time to time party thereto \(incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Registrant on October 11, 2018\).](#)
- 31.1\* [Certification of Chief Executive Officer pursuant to Rules 13a-14\(a\) or 15d-14\(a\) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2\* [Certification of Chief Financial Officer pursuant to Rules 13a-14\(a\) or 15d-14\(a\) of the Securities Exchange Act of 1934, as adopted 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.](#)
- 99.1\* [Press Release issued by Verastem, Inc. on November 7, 2018.](#)
- 101.INS\* XBRL Instance Document
- 101.SCH\* XBRL Taxonomy Extension Schema Document
- 101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB\* XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document

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\* Filed or furnished herewith.

† Confidential treatment requested under 17 C.F.R. §200.80(c) and Rule 24b-2. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.



**VERASTEM, INC.**  
Restricted Stock Unit Agreement  
Inducement Award

**NOTICE OF GRANT**

This Restricted Stock Unit Agreement (this "Agreement") is made as of the Agreement Date between Verastem, Inc. (the "Company"), a Delaware corporation, and the Participant.

**I. Agreement Date**

Date: [ ]

**II. Participant Information**

Participant: [ ]

Participant Address: [ ]

**III. Grant Information**

Grant Date: [ ]

Restricted Stock Units: [ ]

**IV. Vesting**

Up to [ ]% of the Participant's Restricted Stock Units shall vest on [ ], provided that the Participant continues to serve as an employee, consultant and/or director of the Company on each such vesting date.

This Agreement includes this Notice of Grant and the following General Terms and Conditions (attached as Exhibit A), which are expressly incorporated by reference in their entirety herein.

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

VERASTEM, INC.

PARTICIPANT

By:

Name: [ ]

Name: [ ]

Title: [ ]

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# Restricted Stock Unit Agreement

## EXHIBIT A

### **GENERAL TERMS AND CONDITIONS**

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Grant of RSUs; Condition of Grant. This Agreement evidences an inducement award granted by the Company to the Participant, of an award of Restricted Stock Units (the "RSUs"), representing an award of the number of RSUs (the "Share Number") set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 3 below), one share of common stock, \$0.0001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to in this Agreement as the "Shares." The RSUs are granted to the Participant in connection with the Participant's entering into employment with the Company and is regarded by the parties as an inducement material to the Participant's entering into employment within the meaning of NASDAQ Listing Rule 5635(c)(4).

2. Relationship to and Incorporation of the 2012 Incentive Plan.

The RSUs shall be subject to and governed by, and shall be construed and administered in accordance with, the terms and conditions of the Company's 2012 Incentive Plan, as amended from time to time (the "Plan"), which terms and conditions are incorporated herein by reference, except for those terms and conditions contained in Sections 3(c), 4(a), 4(b), 5, 6, 7(c) and 8 of the Plan and any amendments to such sections of the Plan. Notwithstanding the foregoing, the RSUs are not awarded under the Plan and the grant of the RSUs and issuance of any Shares pursuant to settlement of the RSUs shall not reduce the number of shares of Common Stock available for issuance under awards pursuant to the Plan. Capitalized terms in this Agreement have the meanings specified in the Plan, unless a different meaning is specified in this Agreement.

By accepting all or any part of the RSUs, the Participant agrees to be bound by the terms and conditions set forth in this Agreement and incorporated herein by reference to the Plan, a copy of which has been furnished to the Participant.

3. Vesting of the RSUs; Issuance of Shares.

a. Vesting of the RSUs. Subject to the other provisions of this Section 3, the RSUs shall vest in accordance with the vesting schedule set forth in the Notice of Grant (the "Vesting Schedule"). Any fractional RSU resulting from the application of the percentages in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs. Within thirty days of each vesting date shown in the Vesting Schedule (the "Vesting Dates"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date and shall deliver such Shares to the Participant, or to the broker designated by the Participant.

b. Termination of Relationship with the Company. Except to the extent specifically otherwise provided herein, in the Plan or in another agreement between the Company and the Participant, if the Participant ceases to be an Eligible Participant for any reason, all RSUs that have not

vested pursuant to Section 3(a) shall be automatically forfeited as of such termination. For purposes of this agreement, an “Eligible Participant” is an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive RSU grants under the Plan (an “Eligible Participant”).

#### 4. Change of Control.

If within 90 days prior to a Change of Control or within 18 months following a Change of Control, the Company or any successor thereto terminates the Participant’s employment other than for Cause, or the Participant terminates his or her employment for Good Reason (as defined below), then, each RSU will become exercisable (“vest”) as to 100% of the Shares on the date the Participant’s employment terminates.

For purposes of this Agreement, “Change of Control” shall mean (i) the acquisition of beneficial ownership (as defined in Rule 13d-3 under the Exchange Act) directly or indirectly by any “person” (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) of securities of the Company representing a majority or more of the combined voting power of the Company’s then outstanding securities, other than an acquisition of securities for investment purposes pursuant to a bona fide financing of the Company; (ii) a merger or consolidation of the Company with any other corporation in which the holders of the voting securities of the Company prior to the merger or consolidation do not own more than 50% of the total voting securities of the surviving corporation; or (iii) the sale or disposition by the Company of all or substantially all of the Company’s assets other than a sale or disposition of assets to an affiliate of the Company or a holder of securities of the Company; notwithstanding the foregoing, no transaction or series of transactions shall constitute a Change of Control unless such transaction or series of transactions constitutes a “change in control event” within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i).

If the Participant is party to an employment, consulting or severance agreement with the Company that contains a definition of “cause” for termination of employment or other service relationship, “Cause” shall have the meaning ascribed to such term in such agreement. Otherwise, “Cause” shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant’s employment or other service relationship shall be considered to have been terminated for “Cause” if the Company determines, within 30 days after the Participant’s resignation, that termination for Cause was warranted.

If the Participant is party to an employment, consulting or severance agreement with the Company that contains a definition of “good reason” for termination of employment or other service relationship, “Good Reason” shall have the meaning ascribed to such term in such agreement. Otherwise, “Good Reason” shall mean, without the Participant’s consent, the occurrence of any one or more of the following events: (i) material diminution in the nature or scope of the Participant’s responsibilities, duties or authority, provided that neither (x) the Company’s failure to continue the Participant’s appointment or election as a director or officer of any of its Affiliates nor (y) any diminution in the nature or scope of the Participant’s responsibilities, duties or authority that is reasonably related to a diminution of the business of the Company or any of its affiliates shall constitute “Good Reason”; (ii) a material reduction in the Participant’s base salary other than one temporary reduction of not more than 120 days and not in excess of 20% of the Participant’s base salary in connection with and in proportion to a general reduction of the base salaries of the Company’s executive



officers; (iii) failure of the Company to provide the Participant the base salary or benefits owed to the Participant in accordance with his or her employment agreement with the Company, if any, after 30 days' notice during which the Company does not cure such failure; or (iv) relocation of the Participant's principal place of business more than forty (40) miles from the then current location of the Participant's principal place of business.

5. Dividends. The RSUs shall have no rights with respect to dividends declared by the Company with respect to its capital stock, provided that the foregoing shall not prohibit or otherwise limit the adjustment of the terms of this Agreement in accordance with Section 9 of the Plan.

6. Withholding Taxes.

a. Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the grant of the RSUs and the Shares upon vesting thereof and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs or Shares. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs and the Shares underlying the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code, as amended, is available with respect to the issuance of the RSUs and the Shares underlying the RSUs.

b. Withholding. As a condition to the granting of the RSUs and the vesting thereof, the Participant acknowledges and agrees that he or she is responsible for the payment of income and employment taxes (and any other taxes required to be withheld) payable in connection with the grant or vesting of, or otherwise in connection with, the RSUs. Accordingly, the Participant agrees to remit to the Company or any applicable subsidiary an amount sufficient to pay such taxes. Such payment shall be made to the Company or the applicable subsidiary of the Company in a form that is reasonably acceptable to the Company, as the Company may determine in its discretion. The Company in its discretion may permit such payment to be made by "net settlement" through which the Company retains and withholds from delivery at the time of vesting that number of shares of Common Stock having a fair market value sufficient to satisfy the applicable tax withholding requirements (but not in excess of the maximum withholding amount consistent with the award being subject to equity accounting treatment under the applicable accounting rules). Alternatively, the Company may require the Participant to provide a designated broker with irrevocable instructions directing the designated broker to, on the date of the designated broker's receipt of any shares of Common Stock in accordance with Section 3, sell in accordance with ordinary principles of best execution that number of such shares of Common Stock as is necessary to yield net proceeds to the Participant equal to the amount of withholding taxes with respect to the income recognized by the Participant as a result of the vesting of the RSUs (but not in excess of the maximum withholding amount consistent with the award being subject to equity accounting treatment under the applicable accounting rules) and remit such proceeds to the Company in satisfaction of such tax withholding obligations of the Company.

7. Transferability. The Participant shall not sell, assign, transfer, pledge, hypothecate or otherwise encumber, by operation of law or otherwise, any RSUs, or any interest therein, until such RSUs have vested and the Shares underlying the RSUs have been issued.

8. Miscellaneous.

a. No Rights to Employment. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 3 do not constitute an express or implied promise of continued employment for any period.

b. Section 409A. This Agreement is intended to comply with or be exempt from the requirements of Section 409A and shall be construed consistently therewith. In any event, the Company makes no representations or warranties and will have no liability to the Participant or to any other person, if any of the provisions of or payments under this Agreement are determined to constitute nonqualified deferred compensation subject to Section 409A but that do not satisfy the requirements of that Section.

c. Entire Agreement. This Agreement and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this Agreement; provided that any separate employment or severance agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by this Agreement. Other than as provided in Section 2 of this Agreement, in the event of a conflict between the terms and provisions of the Plan and the terms and provisions of this Agreement, the Plan terms and provisions shall prevail.

d. Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware, without regard to any applicable conflict of law principles.

e. Authority of Compensation Committee. In making any decisions or taking any actions with respect to the matters covered by this Agreement, the Compensation Committee shall have all of the authority and discretion, and shall be subject to all of the protections, provided for in the Plan. All decisions and actions by the Compensation Committee with respect to this Agreement shall be made in the Compensation Committee's discretion and shall be final and binding on the Participant.

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT  
REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION ("SEC"). REDACTED  
MATERIAL IS MARKED  
WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

**LICENSE AND COLLABORATION AGREEMENT**

**between**

**VERASTEM, INC.**

**and**

**CSPC PHARMACEUTICAL GROUP LIMITED**

**DATED**

**September 25, 2018**

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## LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this “*Agreement*”) is made as of \_\_\_\_\_, 2018 (the “*Effective Date*”), by and between VERASTEM, INC., a Delaware corporation (“*Verastem*”), having a place of business at 117 Kendrick Street, #500, Needham, MA 02494, USA, and CSPC PHARMACEUTICAL GROUP LIMITED, a Chinese corporation (“*Licensee*”), having a place of business at Suite 3206, 32/F, Central Plaza, Wanchai, Hong Kong. Verastem and Licensee are referred to in this Agreement individually as a “*Party*” and collectively as the “*Parties*.”

### RECITALS

WHEREAS, Licensee has extensive experience and expertise in, the research, development and commercialization of pharmaceutical products in China;

WHEREAS, Verastem is a biopharmaceutical company that Controls (as defined below) certain intellectual property rights related to the pharmaceutical compound known as Duvelisib; and

WHEREAS, Licensee is interested in obtaining a license under such intellectual property rights to Develop and Commercialize Licensed Product in the Field in the Territory (each capitalized term as defined below), and Verastem is willing to grant such a license to Licensee, all subject to the terms and conditions set forth herein.

### AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the covenants contained herein, the receipt and sufficiency of which are 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 “*Affiliate*” means, with respect to an Entity, any Entity that controls, is controlled by, or is under common control with such Entity. For the purpose of this definition only, “control” (including, with correlative meaning, the terms “controlled by” and “under the common control”) means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of an Entity, whether by the ownership of more than fifty percent (50%) of the voting stocking of such Entity, by contract or otherwise.

1.2 “*Alliance Manager*” has the meaning set forth in Section 3.1.

1.3 “**Anti-Corruption Laws**” means the United States Foreign Corrupt Practices Act of 1977, as amended, the Criminal Law of the People’s Republic of China, as amended, the Anti-Unfair Competition Law of the People’s Republic of China, as amended, and any other applicable anti-corruption or anti-bribery laws or regulations.

1.4 “**Applicable Laws**” means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing) and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party’s activities in connection with this Agreement.

1.5 “**Arbitration Notice**” has the meaning set forth in Section 13.3(a).

1.6 “**Arbitrators**” has the meaning set forth in Section 13.3(b).

1.7 “**Bankruptcy Code**” has the meaning set forth in Section 12.4.

1.8 “**Business Day**” means a day other than a Saturday, Sunday or a day on which banking institutions in New York, New York or Beijing, China are required by Applicable Laws to remain closed.

1.9 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.10 “**Calendar Year**” means each twelve (12) month period commencing on January 1.

1.11 “**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 of ICH Guidelines, and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

1.12 “**Change of Control**” means, with respect to a Party, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Party or its direct or indirect controlling Affiliate to a Third Party, other than to an Entity of which more than fifty percent (50%) of the voting capital stock are owned after such sale or disposition by the Persons that were shareholders of such Party or its direct or indirect controlling Affiliate (in either case, whether directly or indirectly through any parent Entity) immediately prior to such transaction; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates, of more than fifty percent (50%) of the outstanding shares of voting capital stock of such Party or its direct or indirect controlling Affiliate, or (ii) the acquisition, merger or consolidation of such Party or its direct or indirect controlling Affiliate with or into another Person, other than, in the case of this clause (b), an acquisition or a merger or consolidation of such Party or its controlling Affiliate in which the holders of shares of voting capital stock of such Party or its controlling Affiliate, as



the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation.

**1.13** “*Clinical Trial*” means any human clinical trial of a Licensed Product.

**1.14** “*CNDA*” means the China National Drug Administration, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

**1.15** “*Co-Formulation*” has the meaning set forth in Section 1.16.

**1.16** “*Combination Product*” means a pharmaceutical product that contains both the Licensed Compound and one (1) or more other active pharmaceutical ingredients whether in a single pharmaceutical product (a “*Co-Formulation*”) or a co-packaged product. For the avoidance of doubt, Single API Product will not constitute a Combination Product, even if it is co-administered with a pharmaceutical product containing one or more active pharmaceutical ingredients that are not the Licensed Compound.

**1.17** “*Commercialization*” or “*Commercialize*” means all activities directed to marketing, promoting, advertising, exhibiting, distributing (including storage for distribution or inventory), detailing, selling (and offering for sale or contracting to sell) or otherwise commercially exploiting (including pricing and reimbursement activities) a Licensed Product in the Field (including importing and exporting activities in connection therewith).

**1.18** “*Commercialization Plan*” has the meaning set forth in Section 6.3.

**1.19** “*Commercially Reasonable Efforts*” means, with respect to a Party’s obligations or activities under this Agreement, [\* \* \*] Commercially Reasonable Efforts of a Party shall require that such Party (on its own or acting through its Affiliates, Sublicensees or, Subcontractors), at a minimum, and without in any way limiting the foregoing: [\* \* \*].

**1.20** “*Conditional Approval*” means, with respect to a Licensed Product in a Region, a Regulatory Approval that requires, as a condition of such approval, additional (or a continuation of) Clinical Trials for such Licensed Product to obtain further safety or efficacy data.

**1.21** “*Confidential Information*” of a Party means, subject to Section 8.2, (a) all Know-How, unpublished patent applications and other non-public information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, in each case in connection with this Agreement or the Confidentiality Agreement, whether made available orally, visually, in writing or in electronic form, and (b) any information that was disclosed by Verastem to Licensee or any Affiliate of Licensee prior to the Effective Date pursuant to the confidentiality agreement between Verastem and Licensee, [\* \* \*] (the “*Existing*”

*Confidentiality Agreement*”), which shall be treated as Verastem’s Confidential Information, with Verastem considered the Disclosing Party and Licensee considered the Receiving Party. For the avoidance of doubt, the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties.

**1.22** “*Control*” or “*Controlled*” means the possession by a Party (whether by ownership, license or otherwise) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms and conditions set forth herein, or (b) with respect to Patent Rights, intangible Know-How or other intellectual property rights, the legal authority or right to grant a license, sublicense, access or right to use (as applicable) under such Patent Rights, intangible Know-How or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case of (a) and (b), without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

**1.23** “*CRO*” means a contract research organization.

**1.24** “*Develop*” or “*Development*” or “*Developing*” means all development activities for any Licensed Compound or Licensed Product that are directed to obtaining Regulatory Approval(s) of such Licensed Product and to support appropriate usage for such Licensed Product, including: all research, non-clinical, preclinical and clinical activities, testing and studies of such Licensed Compound or Licensed Product; toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies of such Licensed Compound or Licensed Product; sourcing and distribution of such Licensed Product for use in Clinical Trials (including placebos and comparators); statistical analyses; the preparation, filing and prosecution of Regulatory Documents for such Licensed Compound or Licensed Product; with respect to Development conducted by Verastem pursuant to the Global Strategy, or by Licensee under the Development Plan, development activities directed to label expansion (including prescribing information) or obtaining Regulatory Approval for one (1) or more additional Indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining or maintaining a Regulatory Approval; and pharmaco-economic studies relating to the Indication for which the applicable Licensed Product is being developed; in each case above, including investigator- or institution-sponsored studies for which a Party is providing material or assistance or otherwise has written obligations to such investigator or institution; and all regulatory activities related to any of the foregoing; provided, however, that Development shall exclude Commercialization and Manufacturing (including Manufacturing related to Development).

**1.25** “*Development Data*” shall mean written reports of pre-clinical studies and Clinical Trials primarily containing non-clinical, clinical or CMC data relating to the Licensed Compound or the Licensed Products in the Field, and supporting documentation (e.g., protocols, format of case report forms, analysis plans) for such reports. Notwithstanding any provision of this

Agreement to the contrary, Development Data that Verastem is required to deliver to Licensee under this Agreement shall be limited to Development Data that is Controlled by Verastem and is necessary or useful to support the Development, Regulatory Approval or Commercialization of a Licensed Product in the Territory. Licensee’s use of such Development Data in connection with applications for Regulatory Approval shall be subject to Licensee’s payment obligations under Section 5.3(a).

**1.26** “*Development Plan*” has the meaning set forth in Section 4.2.

**1.27** “*Disclosing Party*” has the meaning set forth in Section 8.1(a).

**1.28** “*Dispute*” has the meaning set forth in Section 13.1.

**1.29** “*Dollar*” or “\$” means the U.S. dollar, and “\$” shall be interpreted accordingly.

**1.30** “*Entity*” means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

**1.31** “*Executive Officers*” has the meaning set forth in Section 3.2(e).

**1.32** “*Existing Confidentiality Agreement*” has the meaning set forth in Section 1.21.

**1.33** “*Exploit*” or “*Exploiting*” means to (a) Develop, (b) obtain, hold and maintain Regulatory Approvals, and any pricing or reimbursement approvals, as applicable, (c) Manufacture, or (d) Commercialize Licensed Products.

**1.34** “*Field*” means the treatment, prevention, palliation or diagnosis of any oncology Indication in humans.

**1.35** “*Final Approval*” means, with respect to a Licensed Product in a Region, (a) a further Regulatory Approval for such Licensed Product that was previously granted Conditional Approval following the completion of all requirements of such Conditional Approval, or (b) a Regulatory Approval that is granted, in the first instance, without any additional Clinical Trial requirements.

**1.36** “*First Commercial Sale*” means, with respect to a given Licensed Product in a given Region in the Territory, the first sale of such Licensed Product by Licensee or its Affiliates or Sublicensees to a Third Party (excluding Sublicensees) in such Region after the receipt of a Regulatory Approval for such Licensed Product in such Region (to the extent such Regulatory Approval is required for such sale of such Licensed Product in such Region).

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

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**1.38** “*FTE Rate*” means a rate of [\* \* \*] per FTE per year, to be pro-rated on an hourly basis of [\* \* \*] per FTE per hour, assuming [\* \* \*] hours per year for an FTE. Verastem may increase the FTE Rate on January 1 of each Calendar Year, provided that any such increase will not exceed the increase in the Consumer Price Index for All Urban Consumers (CPI-U) for the U.S. City Average, 1982-84 = 100, calculated by the Bureau of Labor Statistics during the immediately preceding Calendar Year.

**1.39** “*Fully Burdened Manufacturing Cost*” means, with respect to any Licensed Product supplied by or on behalf of Verastem to Licensee hereunder:

(a) to the extent that such Licensed Product (or any precursor or intermediate thereof) is Manufactured by a Third Party manufacturer, [\* \* \*]; plus, if applicable,

(b) to the extent that such Licensed Product (or any precursor or intermediate thereof) is Manufactured by Verastem or its Affiliates, [\* \* \*] Such fully burdened costs shall be calculated in accordance with GAAP.

**1.40** “*GAAP*” means generally accepted accounting principles in the United States, consistently applied.

**1.41** “*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 ICH E6 of the ICH Guideline and any other guidelines for good clinical practice for Clinical 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), and (d) the equivalent Applicable Laws 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.

**1.42** “*Generic Product*” means, with respect to a Licensed Product in the Territory, a pharmaceutical product that (a) contains the same active pharmaceutical ingredients (and no other active pharmaceutical ingredients) as such Licensed Product, (b) is approved by a Regulatory Authority in the Territory based on reference to data contained in an earlier Regulatory Approval for such Licensed Product, and (c) is sold by a Third Party that is not a Sublicensee and did not purchase such product or its active pharmaceutical ingredients from Licensee or its Affiliates or Sublicensees.

**1.43** “*Global Clinical Trial*” means a Clinical Trial conducted by Verastem (or any of its Affiliates, Third Party Licensees or Subcontractors) in cooperation with Licensee both inside and outside the Territory under the Global Strategy, which Global Clinical Trial shall be governed by the following:

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(a) if Verastem plans to conduct a multi-national Clinical Trial, the JSC shall discuss and agree upon whether such multi-national Clinical Trial should include the Territory, [\* \* \*]; and

(b) in the event that the JSC agrees to include the Territory, or a Region in the Territory, in such multi-national Clinical Trial, such Clinical Trial shall be regarded as a Global Clinical Trial (and if the JSC determines that such multi-national Clinical Trial will not include any Region in the Territory, such multi-national Clinical Trial shall be regarded as a Verastem New Clinical Trial).

**1.44 “Global Strategy”** means Verastem’s worldwide Development, regulatory and Commercialization strategy with respect to the Licensed Compound and Licensed Products, including the designation of Indications for which to seek Regulatory Approval and Verastem’s global publication strategy.

**1.45 “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, and the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

**1.46 “Governmental Authority”** means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any state-owned or state-controlled enterprise or other entity owned or controlled by any of the forgoing governments, entities, organizations or authorities, or any court or tribunal (or any department, bureau, division or instrumentality thereof, or any governmental arbitrator or arbitral body).

**1.47 “ICH Guidelines”** mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline.

**1.48 “Indemnified Party”** has the meaning set forth in Section 10.3.

**1.49 “Indemnifying Party”** has the meaning set forth in Section 10.3.

**1.50 “Indication”** means a disease, condition, disorder or syndrome.

**1.51 “Infinity”** has the meaning set forth in Section 2.4(a)(i).

**1.52 “Infinity Agreement”** has the meaning set forth in Section 2.4(a)(i).

**1.53 “Infringed Patent Right”** has the meaning set forth in Section 7.4(b).

1.54 “*Initial Tech Transfer*” has the meaning set forth in Section 2.5.

1.55 “*INK*” has the meaning set forth in Section 2.4(a)(i).

1.56 “*INK Agreement*” has the meaning set forth in Section 2.4(a)(i).

1.57 “*Invention*” means any information, discovery, improvement, modification, process, method, assay, design, protocol (including any Clinical Trial protocol), formula, data, invention, algorithm, forecast, profile, strategy, plan, result, Know-How or trade secret (in each case, whether or not patentable), that is discovered, generated, conceived or reduced to practice by or on behalf a Party (including by its Affiliates, licensees, Sublicensees, Subcontractors or their respective employees, agents), in the course of the performance of this Agreement, including all rights, title and interest in and to the intellectual property rights therein and thereto.

1.58 “*JPT*” has the meaning set forth in Section 3.2(f).

1.59 “*JSC*” has the meaning set forth in Section 3.2(a).

1.60 “*Knowledge*” means, with respect to Verastem, [\* \* \*].

1.61 “*Know-How*” means any information and materials, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols (including Clinical Trial protocols), formulas, data, inventions, algorithms, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, regardless of whether patentable, copyrightable or otherwise), but excluding any Patent Rights and any information that is not Confidential Information. For the avoidance of doubt, “*Know-How*” shall include the Development Data (subject to Section 5.3), the manufacturing data that is necessary or reasonably useful to Manufacture the Licensed Compound or Licensed Product (subject to Section 2.2, Section 5.3 and Section 6.1) and the Regulatory Documents.

1.62 “*License*” means the licenses granted by Verastem to Licensee pursuant to Section 2.1 and Section 2.2.

1.63 “*Licensed Compound*” means the compound known by the names INK1197, IPI-145 or Duvelisib (INN; International Nonproprietary Names), as described on **Exhibit B**, or any of its various chemical forms, including acids, bases, salts, metabolites, esters, isomers, enantiomers, pro-drug forms, hydrates, solvates, polymorphs and degradants thereof, in each case that has substantially the same pharmacological effect, in crystal, powder or other form.

1.64 “*Licensed Product*” means (a) Single API Product in [\* \* \*] Each Licensed Product shall be distinguished by dosage form, and for the avoidance of doubt, Single API Product and each Combination Product shall constitute separate and distinct Licensed Products under this Agreement.

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1.65 “*Licensed Trademarks*” means the trademarks set forth on **Exhibit D**, to the extent Controlled by Verastem in the Territory.

1.66 “*Licensee Indemnitees*” has the meaning set forth in Section 10.2.

1.67 “*Licensee IP*” means Licensee Know-How and Licensee Patents, in each case, solely to the extent arising from the activities under, and during the Term of, this Agreement. For clarity, Inventions owned by Licensee pursuant to Section 11.1(b) shall be included within the Licensee IP.

1.68 “*Licensee Know-How*” means all Know-How Controlled by Licensee or its Affiliates during, but not prior to, the Term (including any and all data, Clinical Trial data, results, Development Data and Regulatory Documents generated by or on behalf of Licensee, its Affiliates, Sublicensees or Subcontractors) relating to the Licensed Compound or Licensed Product that is necessary or reasonably useful for Exploiting the Licensed Products in the Field.

1.69 “*Licensee Patents*” means all Patent Rights Controlled by Licensee or its Affiliates during, but not prior to, the Term that cover the Licensed Compound or Licensed Product (including composition of matter and methods of using, making or detecting the Licensed Compound or the Licensed Products).

1.70 “*Losses*” has the meaning set forth in Section 10.1.

1.71 “*Manufacture*” or “*Manufacturing*” means any activities directed to producing, manufacturing, scaling up, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping, and storage at manufacturing facilities of any Licensed Compound or Licensed Product or component thereof (including production of drug substance and drug product, in bulk form, for Development and Commercialization).

1.72 “*Net Sales*” means, (i) with respect to a Licensed Product (subject to clause (ii) below, for a Combination Product) in a particular period, the [\* \* \*] by Licensee, its Affiliates or its Sublicensees on sales or other dispositions (excluding sales or dispositions for use in Clinical Trials or other scientific testing, in either case for which Licensees, its Affiliates or its Sublicensees receive no revenue) of such Licensed Product to Third Parties during such period, less the following deductions (to the extent included in the gross amount invoiced or otherwise directly paid or incurred by Licensee, its Affiliates or its Sublicensees):

[\* \* \*]

Such amounts shall be determined from the books and records of Licensee, its Affiliates and its Sublicensees, in each case maintained in accordance with GAAP or International Financial Reporting Standards, consistently applied.

**1.73** “*Patent Prosecution*” means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent Right, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing Patent Rights, (c) maintaining issued Patent Right(s), (d) listing in regulatory publications (as applicable), (e) patent term extension for issued Patent Right(s) and maintenance thereof, and (f) managing, including settling, any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding relating to issued Patent Right(s).

**1.74** “*Patent Right*” means all issued patents and pending patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any confirmation patent or registration patent or patent of addition based on any such patent, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing.

**1.75** “*Person*” means any individual, unincorporated organization or association, Entity, Governmental Authority or governmental agency.

**1.76** “*Pharmacovigilance Agreement*” has the meaning set forth in [Section 5.4](#).

**1.77** “*Product Infringement*” has the meaning set forth in [Section 11.3\(a\)](#).

**1.78** “*Product Marks*” has the meaning set forth in [Section 11.6\(b\)](#).

**1.79** “*Public Official*” has the meaning set forth in [Section 9.5\(d\)](#).

**1.80** “*Publication*” has the meaning set forth in [Section 8.4](#).

**1.81** “*Quality Agreement*” has the meaning set forth in [Section 6.1\(b\)](#).

**1.82** “*Receiving Party*” has the meaning set forth in [Section 8.1\(a\)](#).

**1.83** “*Region*” means the People’s Republic of China, Hong Kong, Macau, and Taiwan, each of which constitutes a separate Region under this Agreement.

**1.84** “*Regulatory Approval*” means, with respect to a Licensed Product in a Region, all regulatory approvals granted by the applicable Regulatory Authority that are necessary for the Commercialization of such Licensed Product in such Region, excluding any pricing and reimbursement approvals in connection therewith. For the avoidance of doubt, a Conditional Approval and Final Approval shall each be considered a "Regulatory Approval" for purposes hereunder.



**1.85** “*Regulatory Authority*” means any applicable Governmental Authority responsible for granting approvals for the Manufacture, Development, Commercialization, reimbursement or pricing, as applicable, for the Licensed Compound or the Licensed Product, including the Regulatory Approvals. “Regulatory Authority” includes the USFDA, CNDA and any corresponding national or Regional regulatory authorities, and any successor agency of the foregoing.

**1.86** “*Regulatory Documents*” means any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals and any pricing or reimbursement approvals, as applicable, and all written correspondence or written 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 the Licensed Compound or the Licensed Product.

**1.87** “*Regulatory Exclusivity*” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical product, including any such right that may become available following the Effective Date, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, pediatric exclusivity, rights conferred in the United States under the Hatch-Waxman Act or the USFDA Modernization Act of 1997 (but excluding any patent term extension mechanism), or rights similar thereto outside the United States, but in all cases excluding Patent Rights and patent term extensions based on such rights.

**1.88** “*Royalty Term*” means, with respect to a given Licensed Product in a given Region in the Territory, the period commencing on the First Commercial Sale of such Licensed Product in such Region and ending on the last to occur of (a) the date on which all Verastem Patents containing a Valid Claim [\* \* \*] have expired, (b) the date on which all Verastem Patents containing a Valid Claim [\* \* \*] have expired, (c) the expiration of Regulatory Exclusivity with respect to such Licensed Product in such Region, or (d) the tenth (10<sup>th</sup>) anniversary of the First Commercial Sale of such Licensed Product in such Region.

**1.89** “*Rules*” has the meaning set forth in Section 13.3(a).

**1.90** “*Sales Milestone Event*” has the meaning set forth in Section 7.3.

**1.91** “*Sales Milestone Payment*” has the meaning set forth in Section 7.3.

**1.92** “*SEC*” has the meaning set forth in Section 8.6(c).

**1.93** “*Single API Product*” means a pharmaceutical product that contains the Licensed Compound as its sole active pharmaceutical ingredient.

**1.94** “*Subcontractor*” has the meaning set forth in Section 4.8(a).

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION (“SEC”). REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

**1.95** “*Sublicensee*” means any Entity to whom Licensee grants a sublicense of its rights under this Agreement pursuant to Section 2.3.

**1.96** “*Supply Agreement*” has the meaning set forth in Section 6.1(a).

**1.97** “*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 include VAT.

**1.98** “*Term*” has the meaning set forth in Section 12.1.

**1.99** “*Territory*” means the People’s Republic of China, Hong Kong, Macau, and Taiwan (each of which, for purposes of this Agreement shall each be deemed a “*Region*”).

**1.100** “*Third Party*” means any Person other than a Party or an Affiliate of a Party.

**1.101** “*Third Party Licensee*” means any Third Party holding a license (whether exclusive or non-exclusive) under the Verastem IP in the Field outside of the Territory.

**1.102** “*TP-IP Sublicense Payments*” has the meaning set forth in Section 2.9.

**1.103** “*United States*” means the United States of America.

**1.104** “*Upstream License Agreement*” has the meaning set forth in Section 2.4(a)(i).

**1.105** “*Upstream Licensors*” has the meaning set forth in Section 2.4(a)(i).

**1.106** “*Usage Guidelines*” has the meaning set forth in Section 11.6(d)(i).

**1.107** “*USFDA*” means the United States Food and Drug Administration or any successor Entity thereto.

**1.108** “*Valid Claim*” means a claim of any (a) issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a pending patent application that is being prosecuted in good faith, that to Verastem’s Knowledge is patentable, and that has not been finally abandoned, finally rejected or expired (after exhaustion of all appeals); provided, however, that if a claim of a pending patent application shall not have issued within [\* \* \*] years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a patent issues with such claim.

**1.109** “*VAT*” means the value added taxes.

1.110 “*Verastem Indemnitees*” has the meaning set forth in Section 10.1.

1.111 “*Verastem IP*” means Verastem Know-How, Verastem Patents, and the Licensed Trademarks. For clarity, Inventions owned by Verastem in accordance with Section 11.1(a) shall be included in the Verastem IP.

1.112 “*Verastem Know-How*” means all Know-How Controlled by Verastem or its Affiliates as of the Effective Date or at any time during the Term (subject to the provisions of Section 2.10) that is necessary or reasonably useful for the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory; provided, however, that Verastem Know-How shall exclude all Know-How that comes into Verastem’s Control as a result of a Change of Control of Verastem.

1.113 “*Verastem New Clinical Trial*” means any Clinical Trial in which the first patient is enrolled after the Effective Date, or any ongoing trial that Licensee chooses to join within [\* \* \*] days of the Effective Date, and that is conducted by Verastem or any of its Affiliates, Third Party Licensees or Subcontractors outside the Territory.

1.114 “*Verastem Patents*” means all Patent Rights Controlled by Verastem or its Affiliates as of the Effective Date or at any time during the Term (subject to the provisions of Section 2.10) that cover Licensed Compound or Licensed Product in the Territory (including composition of matter and methods of using, making or detecting the Licensed Compound or the Licensed Products); provided, however, that Verastem Patents shall exclude all Patent Rights that come into Verastem’s Control as a result of a Change of Control of Verastem. Verastem’s Patents existing in the Territory, including pending PCT applications, as of the Effective Date are set forth on **Exhibit A**.

1.115 “*Working Group*” has the meaning set forth in Section 3.2(g).

## ARTICLE 2 LICENSE

2.1 **Exclusive License Grant to Licensee.** Subject to the terms and conditions of this Agreement, Verastem hereby grants to Licensee an exclusive (subject to Verastem’s retained rights as set forth in Section 2.6), royalty-bearing, non-transferable (except in accordance with Section 14.1) license, with the right to grant sublicenses (solely in accordance with Section 2.3), under the Verastem IP to (a) Develop (subject to Section 4.2) Licensed Compound or Licensed Products and Commercialize Licensed Products in the Field in the Territory, and (b) obtain, own if applicable, hold and maintain the Regulatory Approvals and any pricing or reimbursement approvals for the Licensed Products in the Field in the Territory.

2.2 **Non-Exclusive License Grant to Licensee.** Verastem hereby grants to Licensee a non-exclusive, royalty-bearing, non-transferable (except in accordance with Section 14.1) license with the right to grant sublicenses (solely in accordance with Section 2.3), under the Verastem IP

to, subject to the requirements set forth in this Section 2.2 and Section 6.1, Manufacture the Licensed Compound and the Licensed Products inside the Territory, solely for purposes of Exploitation of the Licensed Product in the Field in the Territory. For the avoidance of doubt, Licensee shall have no right to practice the license granted by Verastem in this Section 2.2, except to the extent expressly set forth in the Supply Agreement with respect to the limited Manufacturing license granted by Verastem to Licensee to fill, finish, package, and label the Licensed Product (as provided in the Supply Agreement), unless and until (a) the occurrence of a Supply Failure by Verastem (as defined in the Supply Agreement), or (b) the Parties otherwise mutually agree in writing.

### **2.3 Right to Sublicense.**

(a) Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant sublicenses of the License: (i) to its Affiliates, provided that such sublicense shall automatically terminate if such Sublicensee ceases to be an Affiliate of Licensee; and (ii) subject to Section 4.8, to CROs, distributors and other Third Party Subcontractors for the sole purpose of performing Licensee’s obligations with respect to the Development and Commercialization of Licensed Products in the Field in the Territory. Notwithstanding the foregoing, Licensee shall obtain Verastem’s prior written consent if Licensee wishes to sublicense to a Third Party all or substantially all of Licensee’s rights or obligations under this Agreement with respect to any Region within the Territory.

(b) Each sublicense shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement, and Licensee shall ensure that its Sublicensees comply with the terms and conditions of this Agreement. Licensee may fulfill any of its obligations under this Agreement itself or through its Affiliates and Sublicensees, provided however that Licensee will remain directly responsible for all its obligations under this Agreement, regardless of whether any such obligation is delegated, subcontracted or sublicensed to any of its Affiliates or Sublicensees. Any breach of the terms or conditions of this Agreement by any Affiliate or Sublicensee of Licensee shall be deemed a direct breach by Licensee of such terms or conditions. Licensee shall provide Verastem with a true and complete copy of each sublicense agreement and a certified English translation thereof within [\* \* \*] days after the execution of such sublicense agreement.

(c) Licensee shall provide Verastem with copies of any quality oversight or audit reports, including certified English translations thereof, from audits that Licensee has conducted on any Sublicensees or Subcontractors that Licensee engages to fulfill its obligations under this Agreement to the extent such reports are relevant to such Sublicensees’ or Subcontractors’ conduct of such obligations no later than [\* \* \*] Business Days after receiving or preparing, as applicable, any such report.

### **2.4 Upstream Licenses.**

(a) Licensee acknowledges and agrees that:

(i) (1) Verastem obtained the rights to certain Verastem IP from Infinity Pharmaceuticals, Inc. (“*Infinity*”) under that certain Amended and Restated License Agreement, dated November 1, 2016, by and between Infinity and Verastem (the “*Infinity Agreement*”); (2) Infinity obtained certain of such rights from Intellikine LLC (“*INK*”) under that certain Amended and Restated Development and License Agreement, dated December 24, 2012, as amended, by and between Infinity and INK (the “*INK Agreement*”) (each of Infinity and INK, an “*Upstream Licensor*”, and each of the *Infinity Agreement* and the *INK Agreement*, an “*Upstream License Agreement*”); (3) the License constitutes a sublicense under each applicable Upstream License Agreement; and (4) each such sublicense is subject to the terms and conditions of the applicable Upstream License Agreement;

(ii) it has received a redacted copy of the *INK Agreement* and a copy of the *Infinity Agreement* existing as of the Effective Date;

(iii) Licensee shall, and shall cause its Affiliates and Sublicensees to, comply in all material respects with the Upstream License Agreements and take any action reasonably requested by Verastem to prevent any potential material breach by Licensee, its Affiliates or Sublicensees of any applicable term of any Upstream License Agreements; and

(iv) notwithstanding any provision of this Agreement to the contrary, (1) Verastem may provide a copy of this Agreement, and any amendment to this Agreement, to any Upstream Licensor, and (2) Verastem may provide to any Upstream Licensor any information required to be provided to such Upstream Licensor in accordance with the applicable Upstream License Agreement.

(b) [\* \* \*]

**2.5 Disclosure of the Verastem IP.** Verastem shall, at its cost and expense, within [\* \* \*] days after the Effective Date, furnish to Licensee a then-current data/information package that includes true, complete and correct copies of existing Regulatory Documents and existing Development Data that are necessary or reasonably useful to Develop and seek Regulatory Approval for the Licensed Compound and Licensed Product in the Territory (the “*Initial Tech Transfer*”).

**2.6 Verastem Retained Rights.** Notwithstanding the exclusive nature of the License, Verastem expressly retains the rights to use the Verastem IP in the Field in the Territory to the extent necessary to perform its obligations under this Agreement and to Develop and Manufacture Licensed Compound and Licensed Products in the Territory (solely for Commercialization of Licensed Products outside the Territory), in each case whether directly or through its Affiliates, Third Party Licensees or Subcontractors. For clarity, and without limiting the foregoing, Verastem retains the exclusive right to practice, license and otherwise Exploit the Verastem IP outside the scope of the License (*e.g.*, outside the Field or outside the Territory).

**2.7 License Grant to Verastem.** Licensee hereby grants to Verastem a non-exclusive, fully-paid, royalty-free, perpetual, irrevocable and sublicenseable (through multiple tiers) license under the Licensee IP, to the extent necessary or useful, to Exploit the Licensed Compound and the Licensed Products in the Field outside the Territory, provided that, in the event of a termination of this Agreement pursuant to Section 12.2, the foregoing license shall apply on a worldwide basis.

**2.8 No Implied Licenses; Negative Covenant.** Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Patent Rights, Know-How, trademarks, or other intellectual property rights of the other Party. Licensee shall not, and shall not permit any of its Affiliates, Sublicensees or Subcontractors to, practice any Verastem IP outside the scope of the License.

**2.9 Reimbursement for Third Party IP Sublicense.** If, during the Term, Verastem obtains Control of any intellectual property rights from a Third Party (other than as a result of a Change of Control of Verastem), which intellectual property rights are useful for the Development or Commercialization of Licensed Products in the Field in the Territory (excluding, for the avoidance of doubt, Infringed Patent Rights which are subject to the provisions of Section 7.4(b)), then Verastem shall so notify Licensee in writing of such intellectual property rights, including a description thereof and any payments that Verastem is obligated to pay in connection with the grant, maintenance or exercise of a sublicense to Licensee in the Territory (the “*TP-IP Sublicense Payments*”), and Licensee shall have the right to elect to take such a sublicense under such intellectual property rights. If Licensee so elects, then such intellectual property rights shall be included in the Verastem IP and sublicensed to Licensee hereunder, subject to the terms and conditions of this Agreement and the agreement between Verastem and such Third Party (which Third Party shall be deemed an Upstream Licensor hereunder, and any such Agreements shall be deemed Upstream License Agreements), and Licensee shall [\* \* \*].

**2.10 Non-Compete.** During the Term, Licensee shall not, and shall ensure that its Affiliates and Sublicensees do not, [\* \* \*], without the prior written consent of Verastem.

### ARTICLE 3 GOVERNANCE

**3.1 Alliance Managers.** Each Party shall appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each Party’s appointed individual, its “*Alliance Manager*”). Each Alliance Manager shall have the ability to speak English sufficient for purposes of business communication. The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party’s activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, provided that all communications between the Parties shall be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC meetings (as a non-voting participant) and JPT meetings. An Alliance Manager may also bring any matter to the attention of the JSC, JPT or applicable Working Group if such Alliance Manager

reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon [\* \* \*] days prior written notice to the other Party.

### **3.2 Joint Steering Committee.**

**(a) Formation.** No later than [\* \* \*] days following the Effective Date, the Parties shall establish a joint steering committee (the “*JSC*”) to monitor and coordinate the Development and Commercialization of Licensed Products in the Field in the Territory, as set forth in Section 3.2(b) below. The JSC will be comprised of an equal number of representatives from each Party and a minimum of three (3) representatives of each Party, each with the requisite experience and seniority to enable them to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one or more of its representatives to the JSC upon written notice to the other Party.

**(b) Role and Purpose.** The JSC shall (i) provide a forum for the discussion of the Parties’ activities under this Agreement and for sharing with Verastem the progress, results and other relevant information with respect to the Development and Commercialization by Licensee in the Field in the Territory; (ii) draft, review and approve the Development Plan and any amendments thereto pursuant to Section 4.2, (iii) review, discuss and approve the overall strategy for the Exploitation of Licensed Products in the Field in the Territory; (iv) review, discuss and approve the Commercialization Plan and amendments thereto; (v) establish and oversee the JPT and Working Groups as necessary or advisable to further the purpose of this Agreement; (vi) approve the Clinical Trial design of Clinical Trials to be conducted in the Territory, in accordance with Verastem’s Global Clinical Trial program, and serve as a forum for Verastem to share the Global Strategy, the study plans and details for the Global Clinical Trials, and status, results and other relevant information in connection with the Global Clinical Trials and Verastem’s Exploitation of the Licensed Product in the Field outside the Territory; and (vii) perform such other functions as expressly set forth in this Agreement or allocated to the JSC 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 (except for amendments to the Development Plan pursuant to Section 4.2); (ii) waive either Party’s compliance with the terms and conditions of this Agreement; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

**(d) Meetings.** The JSC shall hold meetings on a regular basis, but no less frequently than [\* \* \*] per Calendar Year, or with such other frequency as the Parties may agree. The JSC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communication method; provided that all such meetings shall be conducted in English; and provided further, that at least [\* \* \*] during the period commencing on the Effective Date and ending on the date the JSC is disbanded pursuant to Section 3.2(h), such meetings will be conducted in person at locations selected alternatively by Verastem and Licensee or at such

other location as the Parties may agree. Each Party shall bear its own expenses related to participation in and attendance at such meetings by its respective JSC representatives. The Alliance Manager of Verastem shall prepare minutes for each JSC meeting and provide such minutes to the Alliance Manager of Licensee within [\* \* \*] days of each such meeting, and the Alliance Managers shall ensure that such minutes are reviewed and approved by their respective Parties within [\* \* \*] days thereafter. For the avoidance of doubt, the meetings of the JSC and the JPT shall be conducted in English, and any materials provided to the JSC in connection with such discussions shall be provided in English.

(e) **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 unanimous decision as to such matter within [\* \* \*] days after such matter was brought to the JSC for resolution, then such matter shall be referred to the Chief Executive Officer of Verastem (or an executive officer of Verastem designated by the Chief Executive Officer of Verastem who has the power and authority to resolve such matter) and the Head of Pharmaceutical Division of Licensee (collectively, the “*Executive Officers*”) for resolution. If the Executive Officers cannot resolve such matter within [\* \* \*] Business Days after such matter has been referred to them, then [\* \* \*], provided that Licensee shall not make any decision or take any action that (i) could reasonably be expected to adversely impact the Licensed Product outside of the Territory, including the Licensed Product brand as established under the Global Strategy, (ii) requires Verastem to perform or refrain from performing any activity except as expressly required under this Agreement, or (iii) requires Verastem to provide any resources or bear any costs except as expressly required under this Agreement, in each case ((i) through (iii)), without first obtaining Verastem’s prior written consent, which consent may be withheld in Verastem’s sole discretion. Notwithstanding the foregoing, for so long as Verastem owns the Regulatory Approvals in the Territory, Verastem will have final decision-making authority over all regulatory matters relating to the Exploitation of Licensed Products in the Territory, including with respect to the applicable regulatory strategies, all activities associated with seeking and maintaining Regulatory Approvals, all communications with Regulatory Authorities regarding the Licensed Compounds or Licensed Products, and all Regulatory Documents.

(f) **Joint Project Team.** No later than [\* \* \*] days following the Effective Date, the JSC will form a joint project team (the “*JPT*”) to coordinate and oversee the day-to-day performance of the activities and obligations of the Parties under this Agreement. The JPT will be composed of representatives from each Party who have direct knowledge and expertise in each of the following functional areas: clinical, clinical operations, pharmaceutical development, regulatory, safety, manufacturing, intellectual property, marketing and commercial, in each case, as such functional areas relate to products similar to the Licensed Compound or the Licensed Products. The JPT shall meet at least once per [\* \* \*], or such other frequency as the JSC may determine. The JPT may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications method. The JPT and its activities shall be subject to the oversight of, and shall report to, the JSC and the JSC shall resolve all disputes that



arise within the JPT within [\* \* \*] days after any such matter is brought to the JSC for resolution. In no event shall the authority of the JPT exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in the JPT.

(g) **Working Groups.** From time to time, the JSC may establish joint working groups (each, a “*Working Group*”) on an “as-needed” basis to oversee specific functional areas or activities and coordinate the day-to-day performance of such activities under this Agreement, which establishment of Working Groups shall be reflected in the minutes of the meetings of the JSC. Each such Working Group shall be constituted, shall meet as frequently as and shall operate as the JSC may determine. Working Groups may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications method. Each Working Group and its activities shall be subject to the oversight of, and shall report to, the JSC, and the JSC shall resolve all disputes that arise within a Working Group within [\* \* \*] days after any such matter is brought to the JSC for resolution. In no event shall the authority of any Working Group exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in any Working Group.

(h) **Discontinuation of JSC.** The JSC shall continue to exist until the Parties’ mutual written agreement to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement and decisions formerly decided by the JSC shall be decided between the Parties, subject to the other terms and conditions of this Agreement (including the dispute resolution mechanisms set forth in Article 13).

(i) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of the JSC (in a non-voting capacity), JPT or any Working Group in the event that the planned agenda for such JSC, JPT or Working Group meeting would require such participants’ expertise; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide [\* \* \*] days prior written notice to the other Party and shall ensure that such Third Party is bound by a written confidentiality and non-use agreement consistent with the terms of this Agreement.

## **ARTICLE 4 DEVELOPMENT**

### **4.1 Diligence and Responsibilities.**

(a) Licensee shall be responsible for and use Commercially Reasonable Efforts to Develop Licensed Products in the Field in each Region in the Territory, in a timely manner, including the timely completion of all activities set forth in the Development Plan. Licensee shall, and shall cause its Affiliates, Sublicensees and its Subcontractors to, conduct all Development under this Agreement in a professional manner and in compliance with all Applicable Laws in the Territory, including applicable GLP, cGMP and GCP.

(b) Without limiting the foregoing, with respect to the Global Clinical Trials, Licensee shall have a right to elect, at its sole discretion, to perform certain Development activities such as monitoring and site management in the Territory by using its internal clinical research associates. If Licensee elects (i) to perform such Development activities of a Global Clinical Trial in the Territory, Licensee shall, in collaboration with any global CRO engaged by Verastem to conduct such Global Clinical Trial (including any local Affiliate of a global CRO or global service provider), use Commercially Reasonable Efforts to perform the Development activities in the Territory that are assigned to Licensee for purposes of contributing to such Global Clinical Trial, or (ii) not to perform such Development activities of a Global Clinical Trial in the Territory by using its internal clinical research associates, such Development activities shall be performed by a global CRO engaged by Verastem instead.

**4.2 Development Plan.** All Development by Licensee in the Field in the Territory under this Agreement shall be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 4.2 and Section 3.2, the “*Development Plan*”) which Development Plan shall be created by the Parties through the JSC promptly following the Effective Date (but in any event with [\* \* \*] days following the Effective Date). The Development Plan will include a timeline for submission of applicable Regulatory Documents to the CNDA and from time to time following the Effective Date, Licensee shall have the right to propose amendments or modifications to the Development Plan in consultation with Verastem, and shall submit such proposed amended or modified Development Plan to the JSC for review and comment. If such proposed amended or modified Development Plan is approved by the JSC, then such amended or updated Development Plan shall become effective and binding upon the Parties. Licensee shall only conduct Development to the extent such Development is expressly contemplated by the then-current Development Plan.

**4.3 Development Costs.**

(a) Licensee shall bear all costs and expenses of the Development activities conducted solely by Licensee, its Affiliates its Sublicensees or its Subcontractors (whether inside or outside of the Territory) hereunder.

(b) Notwithstanding Section 4.3(a) above, with respect to a Global Clinical Trial, Licensee shall bear (i) all costs incurred by Licensee, its Affiliates, its Sublicensees or its Subcontractors to the extent Licensee, its Affiliates, its Sublicensees, or its Subcontractors perform Development activities in connection with such portion of Global Clinical Trial conducted within the Territory; (ii) all costs incurred by Verastem, its Affiliates, its Third Party Licensees or its Subcontractors to the extent Verastem, its Affiliates, its Third Party Licensees or its Subcontractors perform Development activities in connection with such Global Clinical Trial in the Territory, to the extent Licensee does not perform Development activities of such Global Clinical Trial in the Territory; and (iii) to the extent Licensee desires a right to use and reference Development Data obtained outside of the Territory, a pro rata portion of the common expenses (e.g., study management cost and data management cost) [\* \* \*], and Licensee shall pay the amount invoiced within [\* \* \*] Business Days after the receipt of any such invoice. Licensee shall be entitled to

receive copies of any and all Development Data generated by Verastem in the conduct of Clinical Trial activities in the Territory that are paid for by Licensee pursuant to the foregoing (i) and (ii) at no additional cost.

**4.4 Development Records.** Licensee shall maintain complete, current and accurate records of all Development activities conducted by or on behalf of Licensee or its Affiliates Sublicensees, or Subcontractors pursuant to this Agreement and all data and other information resulting from such activities consistent with its standard practices in accordance with all Applicable Laws, and in validated computer systems that are compliant with 21 C.F.R. §11 (with respect to Global Clinical Trials). Licensee will obtain Verastem’s written consent prior to destroying any records relating to the Development of Licensed Products. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Licensee shall document all non-clinical studies and Clinical Trials in formal written study reports in accordance with Applicable Laws and applicable guidelines (*e.g.*, GCP, GLP and GMP).

**4.5 Clinical Trial Audit Rights.**

(a) Upon reasonable notification by Verastem and at Verastem’s cost and expense, Verastem or its representatives shall be entitled to conduct an audit of any Clinical Trial sites engaged by Licensee or its Affiliates or Sublicensees to conduct Development activities under the Development Plan, subject to any applicable restrictions contained in Licensee’s contracts with such Clinical Trial sites, to ensure that such Clinical Trials; (i) are conducted in compliance with applicable GCP, and (ii) meet Verastem’s standards for the Global Clinical Trial as well in case of such Clinical Trial sites are engaged in the Global Clinical Trials. No later than [\* \* \*] days following the completion of any such audit, Verastem shall provide Licensee with a written summary of Verastem’s findings, including any potential deficiencies or other areas of remediation that Verastem identifies during such audit, and the Parties shall discuss in good faith such potential deficiencies and other areas of remediation. Licensee will remediate any such deficiencies and any other areas of remediation confirmed by both Parties within [\* \* \*] days following such confirmation, at Licensee’s cost and expense.

(b) Licensee will provide Verastem with copies of all quality oversight or audit reports prepared in connection with any audit that Licensee, its Affiliates or Sublicensees conduct of any Clinical Trial site that Licensee, its Affiliates or Sublicensees have engaged, or are evaluating to potentially engage, to fulfill Licensee’s Development obligations under the Development Plan no later than [\* \* \*] days after receiving or finalizing, as applicable, any such report.

**4.6 Development Reports.** No less frequently than [\* \* \*], Licensee shall provide Verastem with written reports summarizing its, its Affiliates’, its Sublicensees’ and its Subcontractors’ Development of Licensed Products, including a summary of the data, timelines and results of such Development, and an overview of future Development activities reasonably contemplated by Licensee, which reports shall be provided in English. Licensee shall also establish

a secure link that includes adequate encryption safeguards to provide Verastem with electronic access to such information. Without limiting the foregoing, such reports shall contain sufficient detail to enable Verastem to assess Licensee’s compliance with Licensee’s Development obligations hereunder. [\* \* \*]. Licensee shall promptly respond to Verastem’s reasonable requests for additional information regarding significant Development activities, as Verastem may request from time to time. The Parties shall discuss the status, progress and results of Development activities at JSC meetings.

#### **4.7 Data Exchange and Use.**

(a) In addition to its adverse event and safety data reporting obligations pursuant to Section 5.4 each Party shall promptly, but in no event later than [\* \* \*] days, provide the other Party with copies of all Development Data Controlled by such Party that are generated and finalized by or on behalf of such Party or its Affiliates, Third Party Licensees (with respect to Verastem), Sublicensees (with respect to Licensee) or its Subcontractors, if applicable, in the Development in the Field, provided that Verastem’s obligation to provide such Development Data shall be limited to such Development Data as is necessary or useful for the Development, Regulatory Approval or Commercialization of Licensed Products in the Territory, and Licensee’s use of such Development Data in applications for Regulatory Approval shall be subject to Licensee’s payment obligations under Section 5.3(a). Such copies of Development Data shall include a written English summary in the event that such Development Data is generated in a language other than English.

(b) Upon Verastem’s reasonable request, Licensee shall allow Verastem to access, review and copy records relating to the Development activities (including access to relevant databases), to the extent that such records are Controlled by Licensee. Upon Licensee’s reasonable request, Verastem shall allow Licensee to access, review and copy records relating to the Development activities (including access to relevant databases), to the extent that such records are Controlled by Verastem, provided that Licensee’s right to access, review and copy such records shall be limited to such records that are necessary or useful for the Development, Regulatory Approval or Commercialization of Licensed Products in the Territory, and Licensee’s use of such records in connection with applications for Regulatory Approval shall be subject to Licensee’s payment obligations under Section 5.3(a).

(c) Notwithstanding anything herein to the contrary, Licensee’s use of the Development Data from any Verastem New Clinical Trial shall be subject to Section 5.3(a).

#### **4.8 Subcontractors.**

(a) Licensee shall have the right to engage subcontractors for purposes of conducting activities assigned to it under this Agreement or for which it is responsible under this Agreement (each, a “**Subcontractor**”); provided that Licensee shall cause any Subcontractor engaged by it to be bound by written obligations of confidentiality and non-use consistent with this Agreement prior to performing any activities. Licensee shall cause its Subcontractors to assign

to Licensee all intellectual property made, discovered, developed or otherwise created by such Subcontractor in the course of performing such subcontracted work, which intellectual property will be owned in accordance with Section 11.1. Licensee shall cause its Subcontractors to implement and maintain inventor reward and remuneration policies and agreements, as required by Applicable Law, sufficient to supersede any inventor claim that such inventor is entitled to any reward or remuneration for any such intellectual property. Licensee shall remain directly responsible for any obligations under this Agreement that have been delegated or subcontracted to any Subcontractor and shall be directly responsible for the performance of its Subcontractors. Any breach of the terms or conditions of this Agreement by any Subcontractor of Licensee shall be deemed a direct breach by Licensee of such terms or conditions.

(b) Notwithstanding any provision of this Agreement to the contrary, Verastem shall have the right to engage its Affiliates, licensees, sublicensees, contractors or subcontractors to perform all or any portion of its obligations under this Agreement.

## **ARTICLE 5 REGULATORY**

### **5.1 Licensee’s Responsibilities.**

(a) Licensee shall use Commercially Reasonable Efforts to seek and maintain Regulatory Approval for Licensed Products in the Field in each Region in the Territory, and shall be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the obtaining, owning if applicable, holding and maintaining of Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products from Regulatory Authorities in the Territory, in each case, in accordance with this Section 5.1. Unless and until Verastem transfers ownership of the Regulatory Approvals to Licensee pursuant to Section 2.2 and Section 6.1(c), Licensee shall conduct such regulatory activities (and any and all regulatory activities delegated to Licensee hereunder) (i) as the express and authorized regulatory agent of record for Verastem in the Territory, with Verastem retaining ownership of such Regulatory Approvals and the applicable product importation licenses, (ii) on behalf of Verastem and for the benefit of Verastem in the Territory, (iii) solely within the scope of Verastem’s express authorization with respect to such activities, and (iv) in accordance with the applicable regulatory strategy approved by the JSC. Promptly after the Effective Date, the Parties shall execute such documents as are required for Licensee to act as Verastem’s express and authorized regulatory agent of record in the Territory. Without limiting the foregoing, Licensee shall keep Verastem informed of regulatory status related to Licensed Products in the Territory and shall promptly notify Verastem in writing of any decision by any Regulatory Authority in the Territory regarding any Licensed Product.

(b) Licensee shall provide to Verastem for review and comment drafts of all Regulatory Documents which Licensee plans to submit to a Regulatory Authority, and any Regulatory Documents that could reasonably be expected to have an impact on the further Development or Regulatory Approval in the Field in the Territory, together with a written English

summary thereof, reasonably (but in no event later than [\* \* \*] Business Days or, if Licensee has fewer than [\* \* \*] Business Days to prepare a submission, as soon as reasonably practicable) prior to submission, and shall incorporate any comments from Verastem that are provided to Licensee before the date of such submission. In addition, Licensee shall notify Verastem of any Regulatory Documents submitted to or received from any Regulatory Authority in the Territory and shall provide Verastem with copies thereof within [\* \* \*] Business Days after submission or receipt of such Regulatory Documents.

(c) Licensee shall provide Verastem with notice no later than [\* \* \*] Business Days after receiving notice of any meeting or discussion with any Regulatory Authority in the Territory related to any the Licensed Compound or the Licensed Product. Licensee shall lead such meeting or discussion, provided, however, that Verastem shall have the right, but not the obligation, to attend and participate in such meeting or discussion in its sole discretion. In addition, for so long as Verastem owns the Regulatory Approvals in the Territory, Licensee shall lead such any meeting or discussion in accordance with Verastem’s instructions and Verastem shall have the right, but not the obligation, to assume leadership of such meeting or discussion in its sole discretion. If Verastem elects not to attend such meeting or discussion, Licensee shall provide Verastem with a written summary thereof in English promptly, but in no event later than [\* \* \*] days, following such meeting or discussion.

**5.2 Verastem’s Responsibilities.** Subject to the requirements set forth in Section 5.1, Verastem agrees to engage Licensee as its agent to seek and maintain Regulatory Approvals. Verastem shall reasonably cooperate with Licensee in obtaining, holding and maintaining any Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for a Licensed Product in the Territory by providing, to the extent Controlled by Verastem and subject to Section 5.3(a), access to Regulatory Approvals, Regulatory Documents and the Development Data (including raw data and records to the extent expressly required by Regulatory Authorities) for the Licensed Compound and Licensed Products inside and outside of the Territory, in each case, to the extent applicable to and solely for the purposes of seeking, obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory. [\* \* \*].

**5.3 Right of Reference and Use.**

(a) **General Right of Reference.** Each Party hereby grants to the other Party the right of reference to all Regulatory Documents pertaining to Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates, provided that Licensee’s right of reference to Regulatory Documents Controlled by Verastem or its Affiliates shall be (i) subject to this Section 5.3, (ii) limited to Regulatory Documents Controlled by Verastem or its Affiliates, and (iii) solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory. Each Party shall bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 5.3.

**(b) Global Clinical Trial.** With respect to any Global Clinical Trial, Licensee shall be entitled to use and make reference to any and all data arising from such Global Clinical Trial, subject to Licensee’s payment of any amounts owed under Section 4.3(b)(i) – (iii) for such Global Clinical Trial.

**(c) Verastem New Clinical Trial.** With respect to any Verastem New Clinical Trial, Licensee shall be entitled to include any Development Data arising from such Verastem New Clinical Trial in any application for Regulatory Approval in any Region in the Territory for the purpose of supporting efficacy of any Licensed Product (excluding, for the avoidance of doubt, inclusion of Development Data in supplemental documents for purposes that are unrelated to efficacy, such as mandatory inclusion in the Licensed Product’s safety database), subject to Licensee’s payment of a portion of the costs of such Verastem New Clinical Trial as follows:

**(i)** In the event that Licensee notifies Verastem in writing before enrollment of the first patient in such Verastem New Clinical Trial, Licensee shall be responsible for [\* \* \*] of the costs incurred by Verastem in the conduct of such Verastem New Clinical Trial. Verastem shall invoice Licensee on a [\* \* \*] basis for the amount of foregoing Licensee’s cost burden, and Licensee shall pay the amount invoiced within [\* \* \*] Business Days after the receipt of such invoice.

**(ii)** In the event that Licensee notifies Verastem in writing after the enrollment of the first patient in such Verastem New Clinical Trial, but before Verastem’s final data becomes available, Licensee shall be responsible for [\* \* \*] of the costs incurred by Verastem in the conduct of such Verastem New Clinical Trial. Verastem shall invoice Licensee [\* \* \*] of the costs actually incurred by Verastem up to that point and Licensee shall pay the amount invoiced within [\* \* \*] Business Days after the receipt of any such invoice. Thereafter, Verastem shall invoice Licensee on a [\* \* \*] basis for the amount of foregoing Licensee’s cost burden, and Licensee shall pay the amount invoiced within [\* \* \*] Business Days after the receipt of such invoice.

**(iii)** In the event that Licensee notifies Verastem in writing after the final data of such Verastem New Clinical Trial is available, Licensee shall be responsible for [\* \* \*] of the costs incurred by Verastem in the conduct of such Verastem New Clinical Trial. Verastem shall invoice Licensee for the amount of foregoing Licensee’s cost burden, and Licensee shall pay the amount invoiced within [\* \* \*] Business Days after the receipt of such invoice.

For the avoidance of doubt, the foregoing cost sharing percentages are subject to change following the Effective Date in the event that the aggregate sales of oncology therapeutics in the Territory increase relative to the aggregate sales of oncology therapeutics outside of the Territory during the Term, in which case, the Parties shall discuss and agree upon, through the JSC, a proportionate increase in the cost sharing percentages set forth in Section 5.3(c)(i) – (iii).

#### 5.4 Adverse Events Reporting.

(a) Promptly following the Effective Date, but in no event later than [\* \* \*] days thereafter, Licensee and Verastem shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the “**Pharmacovigilance Agreement**”). Such Pharmacovigilance Agreement shall describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting and exchange of information between the Parties concerning adverse events or any other safety issue of any significance and product quality and product complaints involving adverse events, in each case with respect to Licensed Products and sufficient to permit each Party and its Affiliates, Third Party Licensees and Sublicensees to comply with its legal obligations with respect thereto. The Pharmacovigilance Agreement shall be promptly updated if required by changes in Applicable Law. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, Third Party Licensees and Sublicensees to comply with such obligations.

(b) Licensee shall maintain an adverse event database for Clinical Trials conducted in the Territory under the Development Plan, at its sole cost and expense. Licensee shall be responsible for reporting to the applicable Regulatory Authorities in the Territory all quality complaints, adverse events and safety data related to Licensed Products for all Clinical Trials conducted in the Territory under the Development Plan, as well as responding to safety issues and to all requests of Regulatory Authorities related to Licensed Products in the Territory. Verastem shall maintain a global adverse event database for the completed Clinical Trials and any future Global Clinical Trials or Verastem New Clinical Trials at Verastem’s cost and expense, except for any costs allocated to Licensee pursuant to Section 4.3.

#### 5.5 Safety and Regulatory Audits.

(a) If a Regulatory Authority desires to conduct an inspection or audit of Licensee, its Affiliates, Sublicensees or Subcontractors (including Clinical Trial sites) relating to the Licensed Compound or the Licensed Products, Licensee shall promptly notify Verastem thereof. Verastem shall have the right, but not the obligation, to be present at any such inspection. Licensee shall permit Regulatory Authorities to conduct inspections or audit of Licensee, its Affiliates, Sublicensees or Subcontractors (including Clinical Trial sites) relating to the Licensed Compound or the Licensed Products, and shall ensure that such Affiliates, Sublicensees and Subcontractors permit such inspections or audit. Licensee will provide Verastem with a written summary in English of any findings of a Regulatory Authority following a regulatory audit within [\* \* \*] days following any such inspection or audit, and will provide Verastem with an unredacted copy of any report issued by such Regulatory Authority following such audit.

(b) If a Regulatory Authority desires to conduct an inspection or audit of Verastem, its Affiliates, Third Party Licensees or Subcontractors (including Clinical Trial sites) relating to the Licensed Compound or the Licensed Products for the Territory, Verastem shall



promptly notify Licensee thereof. Licensee shall have the right to request to be present at any such inspection, and Verastem shall consider Licensee’s request in good faith. Verastem shall permit Regulatory Authorities to conduct inspections or audit of Verastem, its Affiliates, Third Party Licensees or Subcontractors (including Clinical Trial sites) relating to the Licensed Compound and/or the Licensed Products, and shall ensure that such Affiliates, Third Party Licensees and Subcontractors permit such inspections or audit. Verastem will provide Licensee with a written summary in English of any findings of a Regulatory Authority following a regulatory audit within [\* \* \*] days following any such inspection or audit, and will provide Licensee with an unredacted copy of any report issued by such Regulatory Authority following such audit.

**5.6 No Harmful Actions.** Licensee shall not, and shall not permit its Affiliates, Sublicensees or Subcontractors to, take any action with respect to a Licensed Product that could reasonably be expected to have an adverse impact upon the regulatory status of any Licensed Product inside or outside the Territory. If Verastem believes that Licensee is (or any of its Affiliates, Sublicensees or Subcontractors are) taking or intends to take any action with respect to a Licensed Product that could have an adverse impact upon the regulatory status of any Licensed Product, then Verastem 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) Licensee shall not, and shall not permit its Affiliates, Sublicensees or Subcontractors to, communicate with any Regulatory Authority having jurisdiction outside the Territory with respect to any Licensed Product, unless so ordered by such Regulatory Authority, in which case Licensee shall immediately, but in any event within [\* \* \*], notify Verastem of such order; and (b) Licensee shall not, and shall not permit its Affiliates, Sublicensees or Subcontractors to, submit any Regulatory Documents or seek regulatory approvals for any Licensed Product outside the Territory.

**5.7 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 Licensee or its Affiliates, Sublicensees or Subcontractors relating to any Licensed Compound or Licensed Product, then Licensee shall notify Verastem of such contact, inspection or notice or action within [\* \* \*] hours after receipt of any such notice or conduct of any such action. Verastem shall have the right to review and comment on any responses to Regulatory Authorities that pertain to a Licensed Compound or Licensed Product and Licensee shall incorporate any reasonable comments received from Verastem. The costs and expenses of any regulatory action in any Region in the Territory shall be borne solely by Licensee. Licensee shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors, maintain adequate records to permit the Parties to trace the distribution, sale and use of Licensed Products in the Territory. In addition, each Party shall promptly, but in any event within [\* \* \*] hours, notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party, including a Regulatory Authority, that would reasonably be expected to materially adversely affect the Exploitation of the Licensed Compounds or Licensed Products in the Territory.

ARTICLE 6  
SUPPLY AND COMMERCIALIZATION

6.1 Supply.

(a) **Supply by Verastem.** Subject to Section 2.2, Section 6.1(a), and the terms and conditions of the Supply Agreement, Verastem shall supply to Licensee, and Licensee hereby agrees to purchase from Verastem, any and all requirements of Licensed Product for Commercialization in the Territory during the Term, limited solely to Licensed Compound in the same bulk drug substance form, and the formulation of Licensed Product (including co-administered formulations), in each case that Verastem or its Affiliates is at the applicable time of such supply, Manufacturing or having Manufactured for Development and Commercialization purposes, by Verastem, its Affiliates or Third Party Licensees (as applicable). Subject to the foregoing, Verastem shall supply Licensed Compound or Single API Product in [\* \* \*], at a transfer price equal to Verastem’s Fully Burdened Manufacturing Costs plus a fixed handling amount of [\* \* \*]. Within [\* \* \*] months following the Effective Date, the Parties will execute a separate supply agreement containing supply and quality terms and conditions (the “**Supply Agreement**”). Verastem shall invoice Licensee for the Licensed Compound and Licensed Product upon delivery and Licensee shall pay the amount invoiced within [\* \* \*] days after its receipt of the invoice.

(b) **Responsibilities of each Party.** Within [\* \* \*] months following the Effective Date, the Parties shall enter into a separate quality agreement that describes the responsibilities of each Party in the area of technical cooperation and quality assurance with respect to the supply of the Licensed Product in the Territory and containing terms and conditions typical for such agreements (the “**Quality Agreement**”).

(c) **Technology Transfer and Cooperation.** In connection with the negotiation of the Supply Agreement, the Parties will discuss in good faith (a) the possibility of Licensee Manufacturing and supplying Licensed Product inside the Territory with respect to Licensee, and outside of the Territory with respect to Verastem and Third Party Licensees (each on a non-exclusive basis), and (b) in the event of a Supply Failure (as such term is defined in the Supply Agreement), the terms and conditions of a technology transfer of the Verastem Know-How necessary to Manufacture Licensed Products to a Licensee facility (or its designee) in accordance with a technology transfer plan to be agreed upon by the Parties. In the event that a technology transfer to Licensee is completed, the Parties shall use Commercially Reasonable Efforts to promptly enable Licensee to hold the Regulatory Approvals for Licensed Products in the Territory. Notwithstanding any provision of this Agreement to the contrary, nothing in this Agreement shall be deemed to require Verastem to take, or refrain from taking, any action that, on the advice of legal counsel, would require Verastem or its Affiliates to violate any Applicable Law, whether inside or outside of the Territory.

6.2 **Commercialization Diligence.** Licensee shall be responsible for, and shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in the Field in each

Region in the Territory, including the timely performance of all activities set forth in the Commercialization Plan for such Licensed Product, at its sole cost and expense.

**6.3 Commercialization Plan.** The Commercialization activities with respect to a Licensed Product shall be set forth in a written plan that contains, in reasonable detail, the major Commercialization activities, including revenue targets and unit forecasts, planned for such Licensed Product in the Territory and the timelines for achieving such activities (the “*Commercialization Plan*”). Licensee shall deliver an initial draft of the Commercialization Plan to Verastem for Verastem’s review no later than the earlier of [\* \* \*] months prior to the anticipated date of (i) the first Regulatory Approval for a Licensed Product in the Territory, or (ii) the First Commercial Sale of a Licensed Product in the Territory. Verastem shall have the right to review and comment on such Commercialization Plan and Licensee shall consider incorporating any reasonable comments received from Verastem prior to finalizing such Commercialization Plan. Licensee shall submit a draft of updated or amended Commercialization Plan to Verastem for review and comment during Verastem’s brand planning process in the [\* \* \*] of each Calendar Year (and at such other times during the Calendar Year as the Parties may agree), and Licensee shall consider in good faith any reasonable comments received from Verastem into such update or amendment.

**6.4 Commercialization Reports.** For each Calendar Year following the first Regulatory Approval for any Licensed Product in the Territory, Licensee shall provide to Verastem annually within [\* \* \*] days after the end of such Calendar Year a written report that summarizes the Commercialization activities on a Licensed Product-by-Licensed Product and Region-by-Region basis performed by or on behalf of Licensee, its Affiliates and Sublicensees in the Territory during such Calendar Year. Such report shall contain sufficient detail to enable Verastem to assess Licensee’s compliance with its Commercialization obligations in Section 6.2, [\* \* \*]. Licensee shall provide updates to any such report at each meeting of the JSC, JPT and any Working Group established by the JSC to oversee Commercialization-related activities under this Agreement.

**6.5 Commercial Forecast.** Within [\* \* \*] Business Days after the First Commercial Sale of a Licensed Product by Licensee or any of its Affiliates or Sublicensees, and on a [\* \* \*] basis thereafter, Licensee shall provide to Verastem a forward-looking, non-binding forecast, for the then-current Calendar Year (or, with respect to the first such forecast, the remainder of the current Calendar Year), of anticipated annual Net Sales of Licensed Products in the Territory; provided, however, that if the First Commercial Sale of the Licensed Product by Licensee or any of its Affiliates or Sublicensees occurs [\* \* \*], the first such forecast shall cover the remainder of the current Calendar Year (if applicable) and the next Calendar Year, and no forecast shall be due by [\* \* \*] in such next Calendar Year.

**6.6 Coordination of Commercialization Activities.**

(a) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of Licensed Products in and outside the Territory in furtherance of the Global Strategy. As such, the Parties shall coordinate such activities where

appropriate, which may include scientific and medical communication and Licensed Product positioning.

(b) Licensee shall keep Verastem informed on the status of any application for pricing or reimbursement approval for Licensed Products in the Territory, including any discussion with Regulatory Authorities with respect thereto, and shall notify Verastem within [\* \* \*] Business Days of any such status update or discussion. Each Party shall have the right to determine the price of Licensed Products sold in its territory and neither Party shall have the right to direct, control or approve the pricing of Licensed Products in the other Party’s territory.

(c) At the reasonable request of Licensee, Verastem shall, at its cost and expense, provide samples to Licensee of the marketing materials used by Verastem in the United States at the time of such request, including advertising materials, flyers, and brochures; provided that, Licensee shall be solely responsible for conforming and translating any such materials provided by Verastem for use in the Territory in accordance with Applicable Laws.

**6.7 Diversion.** Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates, Third Party Licensees (with respect to Verastem) and Sublicensees (with respect to Licensee) shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party’s territory; provided that each Party shall have the right to attend conferences and meetings of congresses in the other Party’s territory and to promote and market, for their respective territory, Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 6.7. Neither Party shall engage, nor permit its Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee) to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of Licensed Products located in any country, jurisdiction or Region in the other Party’s territory, or solicit orders from any prospective purchaser located in any country, jurisdiction or Region in the other Party’s territory. If a Party, its Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee) receive any order for Licensed Products for use from a prospective purchaser located in a country, jurisdiction or Region in the other Party’s territory, then such Party shall immediately, but in any event within [\* \* \*], refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee) to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use in the other Party’s territory.

## **ARTICLE 7 PAYMENTS**

**7.1 Upfront Payment.** Licensee shall pay to Verastem a one-time, non-refundable, non-creditable upfront payment of Fifteen Million Dollars (\$15,000,000) within [\* \* \*] days after the Effective Date, for which payment Verastem shall issue an invoice to Licensee on or following the Effective Date.

**7.2 Development Milestone Payments.** Licensee shall pay to Verastem the non-refundable, non-creditable milestone payments as set forth in this Section 7.2. Licensee shall notify Verastem in writing of the achievement by or on behalf of Licensee, its Affiliates or Sublicensees of any and each milestone event set forth in the table below promptly following the occurrence thereof, but in no event later than [\* \* \*] days following the occurrence thereof. Verastem shall issue an invoice to Licensee for the amount of the milestone payment corresponding to such achieved milestone event, and Licensee shall pay to Verastem such invoiced amount within [\* \* \*] days after the occurrence of the applicable milestone event.

Development Milestone Event	Milestone Payment
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

If Conditional Approval of a Licensed Product in a particular Indication is not achieved because Development activities transpired such that achievement of such Conditional Approval was unnecessary or did not otherwise occur, then upon achievement of Final Approval for such Licensed Product for such Indication, the milestone event payment applicable to the Conditional Approval milestone event will also be due. For the avoidance of doubt, the milestone event payment applicable to the Final Approval milestone shall be due only once upon the first Final Approval of a Licensed Product for any Indication in any Region in the Territory, regardless of the number of Licensed Products (or Indications) that receive Final Approval.

**7.3 Sales Milestone Payments.** Subject to the terms and conditions of this Agreement, Licensee shall pay to Verastem the following non-refundable, non-creditable one-time sales milestone payments (each, a “**Sales Milestone Payment**”) following the achievement of each event described in the below table (each, a “**Sales Milestone Event**”). Licensee shall notify Verastem in writing of the achievement of each Sales Milestone Event within [\* \* \*], and Verastem shall promptly issue an invoice to Licensee for the amount of the corresponding Sales Milestone Payment. Licensee shall pay to Verastem such invoiced amount within [\* \* \*] days after achievement of the applicable Sales Milestone Event.

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

Each Sales Milestone Payment will be payable only one-time and only upon the first achievement of the applicable Sales Milestone Event in the Territory, and no amounts would be due for subsequent or repeated achievements.

**7.4 Royalty Payments to Verastem.**

**(a) Royalty Payments and Rates.** Licensee shall, on a Licensed Product-by-Licensed Product and [\* \* \*] basis during the applicable Royalty Term, make non-refundable, non-creditable royalty payments to Verastem based on [\* \* \*] in accordance with the following:

Net Sales Threshold	Royalty %
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

**(b) Royalty Reductions**

**(i) Third Party Payments.** If Licensee (i) reasonably determines in good faith that it is required to obtain a license from a Third Party to any intellectual property right that, in the absence of such license, would be infringed by the Commercialization in any Region in the Territory of the Licensed Product, which intellectual property right (A) is not licensed or

sublicensed hereunder, (B) claims the composition of matter of the Licensed Compound or Licensed Product, or the method of use of such composition of matter in the Field, and (C) is necessary (and not just useful) to Commercialize the Licensed Product (the relevant “*Infringed Patent Right*”), or (ii) shall be subject to a final court or other binding order or ruling that such Commercialization of the Licensed Product infringed an Infringed Patent Right requiring any payments, including a payment of a royalty to the applicable Third Party intellectual property right holder in respect of future sales of the Licensed Product in a Region in the Territory, then the amount of Licensee’s royalty payments to Verastem under Section 7.4(a) shall be reduced by [\* \* \*] of the royalty amounts actually paid by Licensee to such Third Party with respect to such Infringed Patent Right in each applicable [\* \* \*] that is reasonably and appropriately allocable to the Licensed Product in the Territory in each [\* \* \*], subject to Section 7.4(b)(iii). The royalty reductions set forth in this Section 7.4(b)(i) shall not apply to any amounts payable by Licensee under Section 2.9.

**(ii) Generic Entry.** If, in any Region in the Territory during the Royalty Term for a Licensed Product, the sales of all Generic Products in a [\* \* \*] exceed [\* \* \*], then the amount of Licensee’s royalty payments to Verastem under Section 7.4(a) with respect to such [\* \* \*] shall be reduced to [\* \* \*].

**(iii) Cumulative Deductions.** With respect to a Licensed Product in the Territory, in no event shall a deduction or cumulative deductions under Section 7.4(b)(i) or Section 7.4(b)(ii) reduce the royalty payment made by Licensee in respect of Net Sales of such Licensed Product in the Territory in any [\* \* \*] by more than [\* \* \*] of the royalties otherwise payable by Licensee to Verastem under Section 7.4(a) with respect to such Licensed Product.

**(c) Payments to Third Parties.** Each Party shall be solely responsible for making all payments owed by it to Third Parties, including, with respect to Verastem, the Upstream Licensors (in accordance with the terms of the Upstream License Agreements), and neither Party shall have any obligation to make any such payments on behalf of the other Party.

**(d) Royalty Reports and Payments.** Within [\* \* \*], commencing with [\* \* \*], Licensee shall provide Verastem with a report that contains the following information for the applicable [\* \* \*], on a Licensed Product-by-Licensed Product and Region-by-Region basis: [\* \* \*]. Concurrent with the delivery of the applicable quarterly report, Licensee shall, but in no event later than [\* \* \*] Business Days following the end of each [\* \* \*], pay in Dollars all royalties due to Verastem with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such [\* \* \*].

**(e) Payment Method, Currency, and Exchange Rate.** All payments to be made by Licensee to Verastem under this Agreement shall be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Verastem. For the purposes of calculating any sums due under this Agreement, Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents, calculated using the applicable currency conversion rate as published in [\* \* \*], (a) for sales, on [\* \* \*] in which the relevant sales were

made or (b) for calculations of all other payments payable under this Agreement, [\* \* \*]. In the event that the “applicable currency conversion rate” set forth in [\* \* \*], is discontinued or no longer available, then the Parties shall mutually agree upon an alternate currency conversion index to be used for purposes of this Section 7.4.

**7.5 Late Payments.** Without limiting any other rights or remedies available to Verastem hereunder, interest shall be payable by Licensee on any amounts payable to Verastem under this Agreement which are not paid by the due date for payment. All interest shall accrue and be calculated on a daily basis (both before and after any judgment) at a rate per annum equal to [\* \* \*] percentage points above the then current “prime rate” in effect published in [\* \* \*] (but in no event in excess of the maximum rate permissible under Applicable Law), for the period from the due date for payment until the date of actual payment. In the event that the “prime rate” set forth in [\* \* \*], is discontinued or no longer available, then the Parties shall mutually agree upon an alternate prime rate index to be used for purposes of this Section 7.5.

**7.6 Financial Records and Audits.**

**(a)** Licensee shall maintain, and shall cause its Affiliates and Sublicensees to maintain, complete and accurate records in sufficient detail to permit Verastem to confirm the accuracy of the amount of royalty payments and other amounts payable under this Agreement, in accordance with GAAP. Upon reasonable prior notice, such records shall be open during regular business hours for a period of [\* \* \*] years from the creation of individual records for examination by an independent certified public accountant selected by Verastem and reasonably acceptable to Licensee for the purpose of verifying for Verastem the accuracy of the financial reports furnished by Licensee pursuant to this Agreement or of any payments made, or required to be made by Licensee, pursuant to this Agreement. Such audits shall not occur more often than once each [\* \* \*]. Such accountant shall execute a suitable confidentiality agreement reasonably acceptable to Licensee prior to conducting such audit, and shall not disclose Licensee’s Confidential Information to Verastem, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Licensee or the amount of payments by Licensee under this Agreement. Licensee will pay any amounts shown to be owed to Verastem but unpaid within [\* \* \*] days after the accountant’s report, plus interest (as set forth in Section 7.5) from the original due date. Verastem shall bear the full cost of such audit unless such audit reveals an underpayment by Licensee of more than [\* \* \*] of the amount actually due for the time period being audited, in which case Licensee shall [\* \* \*].

**(b) Upstream Licensor Audit Right.** For the purpose of verifying amounts payable by Verastem under the Upstream License Agreements, Infinity shall have the right, no more than [\* \* \*], at Infinity’s expense (except as set forth below), to retain an independent certified public accountant selected by Infinity, to review the records set forth in Section 7.6 above in the location(s) where such records are maintained by Licensee upon reasonable notice and during regular business hours. Such representatives shall execute a suitable confidentiality agreement reasonably acceptable to Licensee prior to conducting such audit. Such representatives shall disclose to each of Infinity, Verastem and Licensee only their conclusions regarding the



accuracy of payments hereunder and of records related thereto. The right to audit any records underlying any royalty report shall extend for [\* \* \*] years from the end of the Calendar Year in which a royalty report was delivered.

**7.7 Taxes.**

(a) **Responsibility.** Any Taxes imposed on Licensee or with respect to Licensee’s business operations or activities hereunder, including any VAT, consumption, transfer, sales, use or other such Taxes relating to the transactions contemplated herein, shall be borne by Licensee (excluding national, state or local Taxes based on income to Verastem), and Licensee shall timely pay, and indemnify and hold harmless, Verastem from and against all such Taxes, including any penalties or interest associated therewith.

(b) **Withholding Tax.** All payments due and payable hereunder shall be made without any deduction or withholding for or on account of any Tax except to the extent otherwise required by Applicable Laws. If Licensee is so required to withhold, Licensee will (a) promptly notify Verastem of such requirement; (b) make such deduction and withholding and pay such additional amounts to Verastem as may be necessary to ensure that Verastem receives the amount it would have otherwise received had no such withholding applied (including any withholding imposed in respect of such additional amounts), (c) pay to the relevant Governmental Authority the full amount required to be withheld promptly upon the earlier of (i) determining that such withholding is required or (ii) receiving notice that such amount has been assessed against Verastem; and (d) promptly forward to Verastem an official receipt (or certified copy) or other documentation reasonably acceptable to Verastem evidencing such payment to such authorities. Notwithstanding the foregoing, [\* \* \*].

(c) **Cooperation.** The Parties acknowledge and agree that it is mutual objective and intent to minimize, to the extent feasible under the Applicable Laws, any Taxes payable in connection with this Agreement, and shall reasonably cooperate each other in good faith in accordance with Applicable Laws to minimize any Taxes in connection with this Agreement.

**ARTICLE 8  
CONFIDENTIALITY; PUBLICATION**

**8.1 Duty of Confidence.** Subject to the other provisions of this Article 8:

(a) Except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the “**Disclosing Party**”) shall be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the “**Receiving Party**”) and its Affiliates for the Term and [\* \* \*] years thereafter;

(b) the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement; and

(c) a Receiving Party may disclose Confidential Information of the Disclosing Party to: (i) such Receiving Party’s Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee); and (ii) employees, directors, agents, contractors, consultants and advisors of the Receiving Party and its Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee), in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such Persons are bound by legally enforceable obligations to maintain the confidentiality of the Disclosing Party’s Confidential Information in a manner consistent with the confidentiality provisions of this Agreement; and provided further that each Party shall remain responsible for any failure by its Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee), and its and its Affiliates’, Third Party Licensees’ (with respect to Verastem) or Sublicensees’ (with respect to Licensee) respective employees, directors, agents, consultants, advisors, and contractors, to treat such Confidential Information as required under this Section 8.1 as if such Affiliates, Third Party Licensees (with respect to Verastem) or Sublicensees (with respect to Licensee) employees, directors, agents, consultants, advisors and contractors were Parties directly bound to the requirements of this Section 8.1.

**8.2 Exemptions.** Information of a Disclosing Party will not be deemed to be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

(a) is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party’s business records;

(b) is generally available to the public before its receipt from the Disclosing Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party (or any Person to whom the Receiving Party disclosed such Confidential Information) in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

(e) is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party’s business records.

No combination of features or disclosures shall be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful

possession of the Receiving Party, unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

**8.3 Authorized Disclosures.** Notwithstanding the obligations set forth in Sections 8.1 and 8.4, a Party may disclose the other Party’s Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) (i) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Development and Commercialization (and, subject to Section 2.2, Manufacturing) of the Licensed Compound or Licensed Product; or (ii) subject to Section 8.6, complying with Applicable Laws, including regulations promulgated by securities exchanges;

(b) disclosure of this Agreement, its terms and the status and results of Development or Commercialization activities to actual or *bona fide* potential investors, acquirors, (sub)licensees, lenders and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction or collaboration; provided that in each such case on the condition that such Persons are bound by written, binding obligations of confidentiality and non-use consistent with this Agreement;

(c) such disclosure is required by judicial or administrative process, provided that in such event such Party shall promptly notify the other Party in writing of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 8, and the Party disclosing Confidential Information pursuant to Applicable Laws or court order shall (i) take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information (ii) limit disclosure of such Confidential Information only to that which is required to be disclosed by the applicable Governmental Authority;

(d) such disclosure is by Verastem and is required to comply with its obligations to one or more Upstream Licensors; or

(e) disclosure pursuant to Sections 8.4 and 8.6.

Notwithstanding the foregoing, in the event a Party is required or permitted to make a disclosure of the other Party’s Confidential Information pursuant to Section 8.3(a), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use Commercially Reasonable Efforts to secure confidential treatment of such information. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

Nothing in Sections 8.1 or 8.3 shall limit either Party in any way from disclosing to any Third Party such Party’s U.S. or foreign income tax treatment and the U.S. or foreign income tax structure of the transactions relating to such Party that are based on or derived from this Agreement, as well as all materials of any kind (including opinions or other tax analyses) relating to such tax treatment or tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

**8.4 Publications.** Verastem shall have the right to publicly present or publish any Clinical Trial data, non-clinical data or any associated results or conclusions generated pursuant to this Agreement (each such presentation or publication, a “**Publication**”), provided that such presentation or publication shall not include any Confidential Information of Licensee without Licensee’s prior written consent. Licensee shall not have the right to issue any Publication except with the prior written approval of Verastem and in accordance with Verastem’s Global Strategy. If Licensee desires to publicly present or publish a Publication in accordance with the foregoing sentence, then Licensee shall provide Verastem (including the Alliance Manager and all Verastem members of the JSC) with a copy of such proposed Publication at least [\* \* \*] days prior to the earlier of its presentation or intended submission for publication. Licensee agrees that it will not submit or present any Publication until Verastem has approved such Publication in writing. Licensee shall incorporate any reasonable written comments received from Verastem, including (i) the deletion of any Confidential Information of Verastem that Verastem identifies for deletion in Verastem’s written comments, and (ii) the deletion of any Clinical Trial data, results, conclusions or other related information which Verastem determines, in its sole discretion, to conflict with Verastem’s Global Strategy with respect to the Licensed Product. If permitted to publish or present any Publication pursuant to this Section 8.4 Licensee shall provide Verastem a copy of the Publication at the time of the submission for publication or presentation. Licensee agrees to acknowledge the contributions of Verastem, and the employees of Verastem, in all Publications as scientifically appropriate. Licensee shall require its Affiliates, Sublicensees and Subcontractors to comply with the obligations of this Section 8.4 as if they were Licensee, and shall be liable for their non-compliance.

**8.5 Publication and Listing of Clinical Trials.** Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, 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; provided that any listings or publications made pursuant to this Section 8.5 shall be considered a Publication hereunder and shall be subject to Section 8.4.

**8.6 Publicity; Use of Names.**

(a) The Parties agree that the terms and conditions of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 8.3 and this Section 8.6. The Parties have agreed on a press release announcing

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION (“SEC”). REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

this Agreement, which is attached hereto as **Exhibit C**, to be issued by the Parties on such date and time as may be agreed by the Parties. No other disclosure of the existence or the terms of this Agreement may be made by either Party or its Affiliates except as provided in Section 8.3 and this Section 8.6. Except as may be required by Applicable Laws, Licensee shall not use the name, trademark, trade name or logo of Verastem, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as provided in this Section 8.6 or with the prior express written permission of Verastem. Licensee shall use Verastem’s corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases, and accompanied explanatory text such as “Licensed from Verastem, Inc.”; provided that Licensee will use Verastem’s corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of Verastem shall not be impaired, in a manner consistent with best practices used by Licensee with respect to its other collaborators, and in a manner consistent with Verastem’s brand usage policies. Except as may be required by Applicable Laws, Verastem shall not use the name, trademark, trade name or logo of Licensee, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as provided in this Section 8.6 or with the prior express written permission of Licensee.

**(b)** Each party has the right to publicly disclose (i) the achievement of milestones under this Agreement; (ii) the amount of related milestone payments if and to the extent required by Applicable Laws (including the rules and regulations promulgated by any applicable securities exchange, the U.S. Securities and Exchange Commission, or any foreign counterparts thereto); and (iii) the commencement, completion, material data and key results of Clinical Trials conducted by it or its Affiliates under this Agreement. After a Publication has been made available to the public by a Party, the other Party may post such Publication or a link to it on its corporate web site without the prior written consent of the other Party.

**(c)** A Party may disclose this Agreement in securities filings with the Securities and Exchange Commission (the “**SEC**”) or equivalent foreign agency to the extent required by Applicable Laws. In such event, the Party seeking such disclosure shall prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no more than [\* \* \*] Business Days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by Applicable Laws. The Party seeking such disclosure shall reasonably consider any comments thereto provided by the other Party within such [\* \* \*] Business-Day period.

**(d)** Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with Governmental Authorities) of certain terms of or material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Applicable Laws, provided that the Party

seeking such disclosure (i) receives advice from counsel that it is legally required to make such public disclosure and (ii) if practicable and permitted by Applicable Laws, first provides the other Party a copy of the proposed disclosure, and reasonably considers any comments thereto provided by the other Party within [\* \* \*] Business Days after the receipt of such proposed disclosure.

(e) Other than the press release set forth in **Exhibit C** and the public disclosures permitted by Section 8.6(b), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain, shall first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld or delayed), except as required by Applicable Laws.

(f) The Parties agree that after a disclosure pursuant to Section 8.6(d) or issuance of a press release (including the initial press release) or other public announcement pursuant to Section 8.6(a) or Section 8.6(b) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party’s prior consent and approval.

(g) Each Party shall have the right to use the other Party’s name and logo in presentations, its website, collateral materials and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 8.6; provided that each Party will use the other Party’s corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of the other Party shall not be impaired, in a manner consistent with best practices used by the Party for its other collaborators, and in a manner consistent with the other Party’s brand usage policies.

**ARTICLE 9  
REPRESENTATIONS, WARRANTIES, AND COVENANTS**

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

(a) it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder;

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Laws or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(c) there are no legal claims, judgments or settlements against or owed by it or any of its Affiliates, or pending or, to its present knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations.

**9.2 Representations and Warranties of Verastem.** Verastem represents and warrants to Licensee that as of the Effective Date:

(a) subject to Section 2.4, it has the right under the Verastem IP to grant the License to Licensee, and it has not granted any license or other right under the Verastem IP that is inconsistent with the License;

(b) to Verastem’s Knowledge, the Verastem Patents are (i) subsisting and in good standing, and (ii) being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Laws;

(c) to Verastem’s Knowledge, all Know-How being used by Verastem to Develop, Manufacture and Commercialize the Licensed Compound and Single API Product as of the Effective Date (a) constitutes Verastem Know-How and is being licensed to Licensee hereunder or (b) is generally known to the public;

(d) Verastem and its Affiliates are not, and have not been, debarred or disqualified by any Regulatory Authority;

(e) Neither it nor its Affiliates (i) Manufacture Licensed Compound or Licensed Products in the Territory or (ii) have engaged any Third Party to Manufacture Licensed Compound or Licensed Products on behalf of Verastem or its Affiliates in the Territory;

(f) it has not received any written notice from any Third Party asserting or alleging or, to Verastem’s Knowledge, threatening that the Exploitation of the Licensed Compound or Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(g) to Verastem’s Knowledge, there are no claims, judgments, or settlements against, or amounts with respect thereto, owed by Verastem or any of its Affiliates relating to the Verastem IP existing as of the Effective Date; and no claim or litigation has been brought or, to Verastem’s Knowledge, threatened by any Person (i) alleging that any Verastem Patents are invalid or unenforceable, (ii) asserting the misuse or non-infringement of any of the Verastem Patents, (iii) challenging Verastem’s Control of the Verastem Patents or (iv) alleging misappropriation of the Verastem Know-How;

(h) to Verastem’s Knowledge, except as set forth in the Upstream License Agreements, the Verastem Patents are free and clear of any liens, charges, encumbrances or, to Verastem’s Knowledge, claims of ownership by an Third Party, other than (i) non-exclusive licenses granted by Verastem or an Upstream Licensor to Third Parties, which grants are not in conflict with, or do not preclude Licensee from exercising the License, or are of the nature of material transfer agreements, clinical trial agreements and Manufacturing agreements, which will not adversely affect Licensee’s ability to Exploit Licensed Products in accordance with this Agreement, and (ii) the rights of the relevant Third Party grantor and their licensees;

(i) to Verastem’s Knowledge, there are no judgments or settlements against or owed by Verastem, and no pending or threatened (in writing), adverse actions, suits or proceedings involving the Licensed Compound or Licensed Product;

(j) [\* \* \*];

(k) to Verastem’s Knowledge, Verastem and its Affiliates have generated, prepared, maintained, and retained all Regulatory Documents existing as of the Effective Date that are relevant to the Territory in material compliance with Applicable Laws;

(l) to Verastem’s Knowledge, no material breach of confidentiality has been committed by any Third Party with respect to Verastem Know-How and Verastem has used commercially reasonable measures to protect the confidentiality thereof; and

(m) to Verastem’s Knowledge, there are no material safety issues with respect to the Licensed Compound or Licensed Product in the Field.

**9.3 Representations and Warranties of Licensee.** Licensee represents and warrants to Verastem that as of the Effective Date:

(a) Licensee and its Affiliates are not, and have not been, debarred or disqualified by any Regulatory Authority;

(b) Licensee has sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business;

(c) Licensee has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to the Exploitation of Licensed Products in the Field in the Territory; and

(d) Licensee has, and has caused its Affiliates to have, implemented and maintained inventor reward and remuneration policies or agreements compliant with Applicable Law sufficient to supersede any inventor claim that such inventor is entitled to any reward or remuneration (outside of the reward or remuneration set in such policies or agreement) for any Inventions made solely by Licensee.

**9.4 Covenants of Both Parties.** Either Party covenants to the other Party that:

(a) in the course of performing its obligations and exercising its rights under this Agreement, it shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards, and shall not knowingly employ or engage any Person who has been debarred by any Regulatory Authority, or, to its knowledge, is the subject of debarment proceedings by a Regulatory Authority;



(b) it will conduct its Clinical Trials under the Development Plan in strict adherence with the study design set forth in the protocol for such Clinical Trial, as may be amended from time to time, and will comply with the statistical analysis plan implemented in connection therewith; and

(c) it will only engage Clinical Trial sites that conduct all Clinical Trials in compliance with Applicable Laws in the Territory, including GCP and the ICH Guidelines as applicable.

#### **9.5 Compliance with Anti-Corruption Laws.**

(a) Notwithstanding anything to the contrary in this Agreement, Licensee agrees that:

(i) it shall not, in the performance of this Agreement, perform any actions, or permit its Affiliates, Sublicensees or Subcontractors to perform any actions, that are prohibited by the Anti-Corruption Laws that may be applicable to one or both Parties;

(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 Governmental Authority, 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 will, no later than [\* \* \*] days following the end of each Calendar Year, verify in writing that to the best of Licensee’s knowledge, there have been no violations of Anti-Corruption Laws by Licensee, its Affiliates, Sublicensees, or Subcontractors or any Persons employed or engaged by any of the foregoing in the performance of this 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 this Agreement in order to document or verify compliance with the provisions of this Section 9.5, and upon request of Verastem, up to once per year and upon reasonable advance notice, shall provide Verastem or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 9.5.

(b) Licensee represents and warrants that, to its knowledge, neither Licensee nor any of its Affiliates, or its or their respective directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties (including any Subcontractors) acting on behalf of Licensee or any of its Affiliates:

(i) has taken any action in violation of any applicable Anti-Corruption Laws; or

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION (“SEC”). REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

(ii) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 9.5(d)), for the purposes of:

- (1) influencing any act or decision of any Public Official in his or her official capacity;
- (2) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;
- (3) securing any improper advantage; or
- (4) inducing such Public Official to use his or her influence with a government, Governmental Authority, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

(c) Licensee further represents and warrants that, as of the Effective Date, none of the officers, directors or employees of Licensee or of any of its Affiliates or agents acting on behalf of Licensee or any of its Affiliates, in each case that are employed or reside outside the United States, is a Public Official.

(d) For purposes of this Section 9.5, “**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, laboratory 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 Governmental Authority, enterprise or organization identified above.

**9.6 NO OTHER WARRANTIES.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF VERASTEM OR LICENSEE; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED (INCLUDING TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, ANY WARRANTY THAT THE VERASTEM IP, LICENSED COMPOUND OR ANY LICENSE PRODUCT IS COMPLETE OR CAPABLE OF ACHIEVING A SPECIFIED GOAL OR VERASTEM OBLIGATION TO BE RESPONSIBLE FOR ANY INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS), INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

ARTICLE 10  
INDEMNIFICATION

**10.1 By Licensee.** Licensee shall indemnify and hold harmless Verastem, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the “*Verastem 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*”) to the extent arising from (a) the Exploitation of the Licensed Compound or Licensed Products by or on behalf of Licensee or any of its Affiliates, Sublicensees or Subcontractors, including product liability claims (other than product liability claims resulting from Verastem’s breach of its obligations under the Supply Agreement), (b) actions taken by Licensee in Licensee’s capacity as Verastem’s regulatory agent under Section 5.1, (c) the gross negligence or willful misconduct of Licensee or its Affiliates, Sublicensees or Subcontractors, (d) Licensee’s breach of any of its representations or warranties made in or pursuant to this Agreement or any Licensee covenants or obligations set forth in or entered into pursuant to this Agreement, or (e) failure of Licensee or its Affiliates, Sublicensees or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (e) above, except to the extent such Losses arise out of a Verastem Indemnitee’s gross negligence or willful misconduct or material failure to abide by any Applicable Laws.

**10.2 By Verastem.** Verastem shall indemnify and hold harmless Licensee, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the “*Licensee Indemnitee(s)*”) from and against all Losses to the extent arising from (a) the Exploitation of the Licensed Compound or Licensed Products by or on behalf of Verastem or any of its Affiliates or Subcontractors (other than the Manufacture or Commercialization of Licensed Compound or Licensed Products supplied to Licensee or its designees under the Supply Agreement), (b) the gross negligence or willful misconduct of Verastem or its Affiliates or Subcontractors, (c) Verastem’s breach of any of its representations or warranties made in or pursuant to this Agreement or any Verastem covenants or obligations set forth in or entered into pursuant to this Agreement, or (d) failure of Verastem or its Affiliates or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (d) above, except to the extent such Losses arise out of any of a Licensee Indemnitee’s gross negligence or willful misconduct or material failure to abide by any Applicable Laws.

**10.3 Indemnification Procedure.** If either Party is seeking indemnification under Sections 10.1 or 10.2 (the “*Indemnified Party*”), it shall inform in writing the other Party (the “*Indemnifying Party*”) of the claim giving rise to the obligation to indemnify pursuant to such Section within [\* \* \*] Business Days after receiving written notice of the claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate

with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party’s written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Parties cannot agree as to the application of Sections 10.1 or 10.2 as to any claim, pending resolution of the dispute pursuant to Article 13, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Sections 10.1 or 10.2 upon resolution of the underlying claim.

**10.4 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 10. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

**10.5 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER [\* \* \*].

**10.6 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder [\* \* \*]. Licensee shall provide Verastem with evidence of such insurance upon request and shall provide Verastem with written notice at least [\* \* \*] days prior to the cancellation, non-renewal or material changes in such insurance. Such insurance shall not be construed to create a limit of Each Party’s liability with respect to its indemnification obligations under this Article 10.

## **ARTICLE 11 INTELLECTUAL PROPERTY**

### **11.1 Ownership.**

(a) **Verastem.** As between the Parties, Verastem shall retain ownership of (i) all Verastem IP, (ii) all Inventions made solely by employees or representatives of Verastem, and (iii) all Inventions made jointly by the employees or representatives of both Parties. Further, Verastem shall retain ownership of all Inventions generated in connection with any Global Clinical Trial. For clarity, all Inventions under the foregoing subsections (ii) and (iii) of this Section 11.1(a) are part of the Verastem IP and licensed to Licensee in the Field in the Territory under Section 2.1.

**(b) Licensee.** As between the Parties, Licensee shall retain ownership of (i) all Licensee IP, and (ii) all Inventions made solely by the employees or representatives of Licensee. With respect to all Inventions under the foregoing subsection (ii) of this Section 11.1(b), to the extent they solely relate to the Licensed Compound or Licensed Products, Licensee hereby grants to Verastem a perpetual, irrevocable, royalty-free, sublicenseable (through multiple tiers) (A) non-exclusive license outside the Territory for any and all purposes related to the Licensed Compound and Licensed Products (including to Exploit the Licensed Compound and Licensed Products in the Field); provided that, with respect to the foregoing non-exclusive license, Verastem shall have the right to request that such license be converted to an exclusive license at any time, in which case the Parties shall negotiate in good faith the terms and conditions of such exclusive license (including commercially reasonable economic terms), and (B) a non-exclusive license in the Territory for any and all purposes related to the Licensed Compound and Licensed Products (including to the extent necessary or useful for Verastem to perform its obligations under this Agreement); provided that, (1) during the Term, the foregoing license under subsection (B) of this Section 11.1(b) shall exclude the right to Commercialize Licensed Compound and Licensed Products in the Field inside the Territory and (2) in the event of a termination of this Agreement pursuant to Section 12.2, the foregoing license under subsection (B) of this Section 11.1(b) shall be deemed exclusive.

**(c) Assignment.** Licensee shall and hereby does assign to Verastem all right, title and interest in and to any Inventions developed jointly by the Parties pursuant to Section 11.1(a)(iii) above. Licensee shall take (and cause its Affiliates, Sublicensees, and Subcontractors, including their respective employees, agents, and contractors to take) such further actions reasonably requested by Verastem to evidence such assignment and to assist Verastem in obtaining patent and other intellectual property rights protection for such Inventions. Licensee shall obligate its Affiliates, Sublicensees and Subcontractors to assign all such jointly-invented Inventions to Licensee (or directly to Verastem) so that Licensee can comply with its obligations under this Section 11.1(c), and Licensee shall promptly obtain such assignment.

## **11.2 Patent Prosecution.**

### **(a) Verastem Patents.**

**(i)** As between the Parties, Verastem shall have the right to control the Patent Prosecution of all Verastem Patents (including Patent Rights within the Inventions that are solely owned by Verastem pursuant to Section 11.1(a)) in the Territory [\* \* \*]. Verastem shall have the sole right to control the Patent Prosecution of all of Verastem’s Patent Rights outside the Territory, at Verastem’s own cost and expense.

**(ii)** Verastem shall consult with Licensee and keep Licensee reasonably informed of the Patent Prosecution of the Verastem Patents in the Territory and shall provide Licensee with copies of all material correspondence received from any patent authority in the Territory in connection therewith. In addition, Verastem shall provide Licensee with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection

with the Patent Prosecution of the Verastem Patents for Licensee’s review and comment prior to the submission of such proposed filings and correspondence.

**(iii)** [\* \* \*]

**(b) Licensee Patents.** As between the Parties, Licensee shall have the sole right to control the Patent Prosecution of all Licensee Patents (including Patent Rights within the Inventions that are solely owned by Licensee pursuant to Section 11.1(b)) throughout the world, at Licensee’s own cost and expense.

**(c) Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 11.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

### **11.3 Patent Enforcement.**

**(a) Notice.** Each Party shall notify the other within [\* \* \*] Business Days of becoming aware of any alleged or threatened infringement by a Third Party of (i) any of the Verastem Patents in the Territory or (ii) any of the Licensee Patents in the Territory, which infringement of such Licensee Patents adversely affects or is expected to adversely affect any Licensed Product in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Verastem Patents and Licensee Patents (collectively “**Product Infringement**”). For clarity, Product Infringement excludes any adversarial Patent Prosecution proceedings.

**(b) Enforcement Right.**

**(i)** Verastem shall have the first right, in its sole discretion, to bring and control any legal action to enforce Verastem Patents against any Product Infringement in the Territory at its own expense as it determines appropriate, provided that Verastem notifies Licensee of any such legal action reasonably in advance, and reasonably considers Licensee’s comments with respect thereto. In the event Verastem is unable or unwilling to bring or control such legal action against such Product Infringement in the Territory within [\* \* \*] months after the date of notice of such Product Infringement, Licensee, subject to any applicable restrictions under the Upstream License Agreements, shall have the right, but not the obligation to, take any legal action, at Licensee’s own cost and expense, as Licensee deems appropriate to prevent or enjoin such Product Infringement in the Territory.

**(ii)** Licensee shall have the first right to bring and control any legal action to enforce Licensee Patents against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate, and in the event Licensee is unable or unwilling to bring or control the legal action against such Product Infringement in the Territory within [\* \* \*] months after the date of notice of such Product Infringement, Verastem may, but not be

obligated to, take any legal action, at Verastem’s own expense, as Verastem deems appropriate to prevent or enjoin such Product Infringement in the Territory.

(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 each such Party’s sole cost and expense.

(d) **Recoveries.** Any recoveries resulting from enforcement action relating to a claim of Product Infringement in the Territory shall be first applied against payment of each Party’s costs and expenses in connection therewith. [\* \* \*].

#### **11.4 Infringement of Third Party Rights.**

(a) **Notice.** If any Licensed Compound or Licensed Product used or sold by Licensee, its Affiliates or Sublicensees in the Territory becomes the subject of a Third Party’s claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or Controlled by such Third Party, then the Party becoming aware of such claim or assertion shall promptly notify the other Party within [\* \* \*] days after 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. 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.

(b) **Defense.** Licensee shall be solely responsible for the defense of any such infringement claims brought against Licensee, at Licensee’s cost and expense, using counsel mutually agreed upon by the Parties; provided that Licensee shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Verastem’s consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (1) result in the admission of any liability or fault on behalf of Verastem, (2) result in or impose any payment obligations upon Verastem, or (3) subject Verastem to an injunction or otherwise limit Verastem’s ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. Licensee shall keep Verastem informed on the status of such defense action, and Verastem shall, at its own expense, (i) provide reasonable support to Licensee upon Licensee’s reasonable request; and (ii) have the right, but not the obligation, to participate or be separately represented in such defense action at its sole option using counsel of its choosing.

**11.5 Patents Licensed From Third Parties.** Notwithstanding any provision of this Agreement to the contrary, each Party’s rights under this Article 11 with respect to the prosecution and enforcement of any Verastem Patent that is licensed from an Upstream Licensor to Verastem shall be subject to the prosecution and enforcement rights of such Upstream Licensor under the corresponding Upstream License Agreement.

**11.6 Product Trademarks.**

(a) **Ownership of the Licensed Trademarks.** Licensee acknowledges that, as between the Parties, Verastem is the sole and exclusive owner of all rights, title, and interests in and to the Licensed Trademarks, including all goodwill associated therewith, throughout the world. Licensee shall not, and shall cause its Affiliates and Sublicensees not to, register or seek to register any trademark that is substantially the same as or deceptively or confusingly similar to any Licensed Trademark.

(b) **Product Marks.** Subject to Section 11.6(a), Licensee shall have the right to brand Licensed Products in the Territory using trademarks, logos, and trade names it determines appropriate for such Licensed Products, including the Licensed Trademarks (the “**Product Marks**”); provided, however, that Licensee shall (i) provide Verastem with a reasonable opportunity to review and approve each proposed Product Mark and use thereof, and (ii) not use any trademark (other than Licensed Trademarks) Controlled by Verastem or its Affiliates (including Verastem’s corporate name) without Verastem’s prior written consent. Subject to Section 11.6(a), Licensee shall own all rights in the Product Marks (other than the Licensed Trademarks) in the Territory and shall register and maintain such Product Marks in the Territory that it determines reasonably necessary, at Licensee’s cost and expense.

(c) **Trademark License.** Subject to the terms and conditions of this Agreement, including Section 11.6(a), Section 11.6(b) and Section 11.6(d), Verastem hereby grants to Licensee an exclusive right and license to use the Licensed Trademarks in the Territory solely during the Term and solely for the purpose of Commercializing Licensed Products in the Territory hereunder.

(d) **Trademark Usage Guidelines and Requirements for the Licensed Trademark.**

(i) Licensee shall, and shall cause its Affiliates, Sublicensees and Subcontractors to comply with all quality standards, quality control requirements, and style or usage guidelines (collectively, the “**Usage Guidelines**”) provided by Verastem to Licensee with respect to use of the Licensed Trademarks stipulated in this Section 11.6(d)(i). Licensee acknowledges and agrees that no ownership rights are vested or created by the trademark license granted pursuant to Section 2.1, and that all goodwill developed by virtue of the use of the Licensed Trademarks in accordance with this Section 11.6(d)(i) inures to the benefit of Verastem. Upon Verastem’s request, Licensee shall submit to Verastem representative samples of materials bearing the Licensed Trademarks for Verastem’s review. Licensee shall not change, modify, alter, create,



combine with other trademarks or use the Licensed Trademarks in any manner that would reasonably be expected to result in, or does result in (i) a material adverse impact on such Licensed Trademarks or the goodwill associated therewith in any country, or (ii) a material negative reputational impact on Verastem’s or any of its Affiliates’ business in any country, or (iii) the creation of material adverse publicity in any country for Verastem or any of its Affiliates. Licensee shall, and shall cause its Affiliates, Sublicensees and Subcontractors to, use the Licensed Trademarks in accordance with (A) sound trademark usage principles, (B) all Applicable Laws, and (C) all Usage Guidelines. Upon receipt by Licensee of any notice from Verastem that Licensee or its Affiliates, Sublicensees or Subcontractors have failed to comply with any of the terms or conditions of this Section 11.6, Licensee shall, and shall cause its Affiliates, Sublicensees and Subcontractors to, immediately remedy such failure.

(ii) Licensee shall execute any documents required in the reasonable opinion of Verastem to be entered as a “registered user” or recorded licensee of Verastem’s Licensed Trademarks or to be removed as registered user or licensee thereof.

(iii) Licensee agrees to indemnify and to hold Verastem harmless in the event that Verastem incurs liability as a result of Licensee’s use of the Licensed Trademarks in the Territory, unless such liability is due to the fault of Verastem.

**11.7 Patent Marking.** Licensee shall mark all Licensed Products in accordance with the applicable patent marking laws, and shall require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Laws and deemed to be standard in the pharmaceutical industry in the Territory, Licensee shall indicate on the product packaging, advertisement and promotional materials that such Licensed Product is in-licensed from Verastem.

## **ARTICLE 12 TERMS AND TERMINATION**

**12.1 Term.** This Agreement shall be effective as of the Effective Date, and shall continue on a Licensed Product-by-Licensed Product and Region-by-Region basis until the expiration of the last-to-expire Royalty Term in a Region, unless terminated earlier in accordance with this Article 12 (the “*Term*”).

### **12.2 Termination**

(a) **Termination by Licensee for Convenience.** At any time, Licensee may terminate this Agreement by providing written notice of termination to Verastem, which notice includes an effective date of termination at least one hundred and eighty (180) days after the date of the notice.

**(b) Termination for Material Breach.**

**(i)** If either Party believes in good faith that the other is in material breach of its obligations hereunder, then the non-breaching Party may deliver written notice of such breach to the other Party, and the allegedly breaching Party shall have [\* \* \*] Business Days from receipt of such notice to dispute the validity of such breach. For all breaches of this Agreement, the allegedly breaching Party shall have sixty (60) days [\* \* \*] from the receipt of the initial notice to cure such breach. If the Party receiving notice of breach fails to cure the breach within such sixty (60) [\* \* \*] day period, then the non-breaching Party may terminate this Agreement in its entirety effective on written notice of termination to the other Party. Notwithstanding the foregoing, (a) if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the sixty (60) day, then such period shall be extended if the breaching Party provides a written plan for curing such breach to the non-breaching Party and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan; provided, that no such extension shall exceed [\* \* \*] days without the consent of the non-breaching Party.

**(ii)** Without limiting the provisions of Section 12.2(b)(i) and subject to the provisions of this Section 12.2(b)(ii), Verastem may immediately, and in any event within twenty-four (24) hours, terminate this Agreement in its entirety if Licensee breaches Section 2.9, Section 9.3, Section 9.4 or Section 9.5 hereof. Further, without limiting the provisions of Section 12.2(b)(i) and subject to the provisions of this Section 12.2(b)(ii), Verastem shall have the right to terminate this Agreement in its entirety if Licensee is in material breach of its obligations under Section 4.1, Section 5.1(a), or Section 6.2; provided, however, this Agreement shall not so terminate unless (i) Verastem provides Licensee with written notice of Verastem’s intent to terminate, stating the reasons and justification for such termination and recommending steps which Verastem believes Licensee should take to cure such alleged breach, and (ii) Licensee, or its Affiliates or Sublicensee, has not (A) during the [\* \* \*] day period immediately following such notice, provided Verastem with a plan for curing such breach and (B) during the sixty (60) day period immediately following such notice carried out such plan and cured such breach.

**(c) Termination for Patent Challenge.** [\* \* \*] Verastem may immediately terminate this Agreement in its entirety if Licensee or its Affiliates or Sublicensees, individually or in association with any other Person, commences a legal action challenging the validity, enforceability or scope of any Verastem Patent that is or was included in the License at any time during the Term anywhere in the world.

**(d) 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 (i) 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 or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) 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 [\* \* \*] days of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(e) **Full Force and Effect During Notice Period.** This Agreement shall remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if any milestone event is achieved during the termination notice period, then the corresponding milestone payment is accrued and Licensee shall remain responsible for the payment of such milestone payment even if the due date of such milestone payment may come after the effective date of the termination.

**12.3 Effect of Termination.** Upon the termination of this Agreement, the following provisions shall apply (except with respect to a termination by Licensee pursuant to Section 12.2(d), in which case only Section 12.3(a) below shall apply):

(a) **License.** The License and all other rights granted by Verastem to Licensee under this Agreement shall terminate and all sublicenses granted by Licensee shall also terminate except as otherwise expressly set forth herein; provided that, in the event of a termination by Licensee pursuant to Section 12.2(d), the License, and Licensee’s obligation to pay Verastem all amounts payable thereunder shall survive subject to the provisions of Section 12.4.

(b) **Regulatory Approval.** If at the time of expiration or termination of this Agreement, Licensee holds or has rights in or to any Regulatory Approvals for the Licensed Products in the Territory, Licensee shall assign to Verastem or a Third Party designated by Verastem all Regulatory Approvals for the Licensed Products in the Territory, at Licensee’s cost and expense. If at the time of expiration or termination of this Agreement Verastem holds the Regulatory Approvals for Licensed Products in the Territory, Licensee shall assist Verastem in designating a replacement agent of record for Verastem in the Territory, including by filing and executing all necessary documents to give effect thereto. In addition, upon Verastem’s written request, Licensee shall, at its cost and expense, provide to Verastem copies of all tangible Development Data and Regulatory Documents Controlled by Licensee. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange, provided that Verastem will assume all safety and safety database activities no later than [\* \* \*] months after the termination hereof.

(c) **Product Marks.** Except with respect to the Licensed Trademarks, which, for the avoidance of doubt, shall remain solely owned by Verastem during and following the Term, Licensee shall transfer and assign, and shall ensure that its Affiliates and Sublicensees transfer and assign, to Verastem, at no cost to Verastem, all Product Marks relating to any Licensed Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logos of Licensee or its Affiliates or Sublicensees). Verastem and its Affiliates and licensees shall have the right to use other identifiers specific to any Licensed Product (e.g., Licensee compound identifiers). Licensee shall also transfer to Verastem any in-process applications for trademarks for any Licensed Product.

**(d) Inventory.** At Verastem’s election and request, Licensee shall transfer to Verastem or a Third Party designated by Verastem some or all inventory of the Licensed Compound and the Licensed Products [\* \* \*] then in the possession or control of Licensee, its Affiliates or Sublicensees, and copies of all Development Data and Regulatory Documents related to such inventory; provided that Verastem shall [\* \* \*].

**(e) Wind Down and Transition.** Licensee shall be responsible, at its own cost and expense, for the wind-down of Licensee’s, its Affiliates’ and its Sublicensees’ Development and Commercialization activities for the Licensed Compound and Licensed Products. Licensee shall, and shall cause its Affiliates and Sublicensees to, reasonably cooperate with Verastem to facilitate orderly and prompt transition of the Development and Commercialization of the Licensed Compound and Licensed Products to Verastem or its designee, including (i) assigning or amending as appropriate, upon request of Verastem, any agreements or arrangements with Third Party vendors (including distributors) to Develop, promote, distribute, sell or otherwise Commercialize the Licensed Compound or Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to Verastem, reasonably cooperating with Verastem to arrange to continue to provide such services for a reasonable time after termination; and (ii) to the extent that Licensee or its Affiliate is performing any activities described above in (i), reasonably cooperating with Verastem to transfer such activities to Verastem or its designee and continuing to perform such activities on Verastem’s behalf for a reasonable time after termination until such transfer is completed. Further, Licensee shall not take any action (including through the use of pricing strategies) that could reasonably be expected to interfere with Verastem’s ability to continue to Exploit the product in the Territory during such period of transition contemplated by this Section 12.3(e).

**(f) Ongoing Clinical Trial.** If, at the time of such termination, Licensee or its Affiliates are conducting any Clinical Trials, then, on a Clinical Trial-by-Clinical Trial basis, and in Verastem’s sole discretion:

**(i)** If Verastem elects to have such Clinical Trial transferred to Verastem, then Licensee shall fully cooperate, and shall ensure that its Affiliates fully cooperate, with Verastem to transfer the conduct of such Clinical Trial to Verastem or its designees [\* \* \*] after the termination effective date, and Verastem shall assume responsibility for the conduct of such transferred Clinical Trial after the effective date of such transfer; provided that Licensee shall bear the cost and expense of such Clinical Trial until the effective date of such transfer; or

**(ii)** If Verastem elects not to have such Clinical Trial transferred to Verastem, then Licensee shall, at its sole cost and expense, orderly wind-down the conduct of any such Clinical Trial that is not assumed by Verastem under clause (i) above.

**(g) Return of Confidential Information.** At Verastem’s election, Licensee shall return (at Verastem’s expense) or destroy all tangible materials comprising, bearing or containing any Confidential Information of Verastem that are in Licensee’s or its Affiliates’ or Sublicensees’ possession or control and provide written certification of such destruction; provided

that, Licensee may retain one (1) copy of such Confidential Information for its legal archives, and provided further, that Licensee 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 record retention and destruction practices that apply to its own general electronic files and information. Any Confidential Information retained by Licensee pursuant to this Section 12.3(g) shall remain subject to Licensee’s confidentiality obligations in accordance with Article 8.

**12.4 Bankruptcy Code § 365(n) Election.** All rights and licenses now or hereafter granted by Verastem to Licensee under or pursuant to this Agreement, are rights to “intellectual property” (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the “**Bankruptcy Code**”). Licensee will retain and may fully exercise all of its rights under the United States Bankruptcy Code. In the event of the commencement of a bankruptcy or insolvency proceeding (including similar proceedings) by or against Verastem under the Bankruptcy Code, Licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to it under this Agreement (including rights of reference with respect to Regulatory Approvals), if not already in its possession, unless Verastem continues to perform all of its obligations under this Agreement.

**12.5 Accrued Rights.** Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement shall not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination.

**12.6 Survival.** The provisions of Article 1, Article 7 (except with respect to Section 7.6, and solely with respect to any amounts that have accrued prior to the effective date of expiration or termination of this Agreement), Article 8, Article 13 (with respect to any disputes arising during the Term), Article 10 (solely with respect to indemnifiable events that occur prior to the effective date of expiration or termination of this Agreement), and Article 14 (as applicable), and Sections 2.6, 2.7, 2.8, 2.9 (solely with respect to amounts that accrue prior to the effective date of expiration or termination of this Agreement), 4.4 (as required by Licensee’s standard practices and in accordance with Applicable Laws), 5.3(a) (solely with respect to rights of reference granted by Licensee to Verastem), 5.4, 9.6, 11.1, 11.2(b), 11.6(a), 12.3, 12.4, 12.5, 12.6, and 12.7, shall survive the expiration or termination of this Agreement.

**12.7 Termination Not Sole Remedy.** Termination shall not be the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as otherwise expressly agreed herein.

ARTICLE 13  
DISPUTE RESOLUTION

**13.1 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 13.

**13.2 Negotiation; Escalation.** The Parties shall negotiate in good faith and use Commercially Reasonable Efforts to settle any Dispute under this Agreement. Any Dispute as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to the Executive Officers for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [\* \* \*] days 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 13.3.

**13.3 Arbitration.**

(a) In the event of a Dispute that cannot be resolved between the Parties or the Executive Officers as set forth in Section 13.2, either Party shall be free to institute binding arbitration with respect to such dispute in accordance with this Section 13.3 upon written notice to the other Party (an “*Arbitration Notice*”) and seek any and all remedies available under Applicable Law. Subject to the provisions of Section 13.3(h), any Dispute to be resolved under this Section 13.3 shall be settled by binding arbitration administered by JAMS (or any successor Entity thereto) and in accordance with the Comprehensive Arbitration Rules and Procedures then in effect and the Expedited Procedures contained therein, as modified in this Section 13.3 (the “*Rules*”), except to the extent such rules are inconsistent with this Section 13.3, in which case this Section 13.3 shall control. The proceedings and decisions of the arbitrators shall be confidential, final and binding on the Parties, and judgment upon the award of such arbitrators may be entered in any court having jurisdiction thereof.

(b) Upon receipt of an Arbitration Notice by a Party, the applicable dispute shall be resolved by final and binding arbitration before a panel of three (3) arbitrators (the “*Arbitrators*”), with each arbitrator having not less than fifteen (15) years of experience in the biotechnology or pharmaceutical industry and subject matter expertise with respect to the matter subject to arbitration. Any Arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the particular dispute. Each Party shall promptly select one (1) Arbitrator each, which selections shall in no event be made later than [\* \* \*] days after receipt of the Arbitration Notice. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrators chosen by the Parties, but in no event later than [\* \* \*] days after the date that the last of such Arbitrators was appointed.

(c) The Arbitrators’ decision and award shall be made within [\* \* \*] days of the filing of the arbitration demand, and the Arbitrators shall agree to comply with this schedule

before accepting appointment. However, this time limit may be extended by agreement of the Parties or by the Arbitrators. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement. The Arbitrators shall, within [\* \* \*] days after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The decision of the Arbitrators shall be final, conclusive and binding on the Parties and enforceable by any court of competent jurisdiction.

(d) Each Party shall bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the Arbitrators and other related costs of the arbitration shall be shared equally by the Parties, unless the Arbitrators determine that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the Arbitrators may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred.

(e) The Arbitrators shall be required to render the decision in writing and to comply with, and the award shall be limited by, any express provisions of this Agreement relating to damages or the limitation thereof. No Arbitrator shall have the power to award punitive damages under this Agreement regardless of whether any such damages are contained in a proposal, and such award is expressly prohibited.

(f) Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.

(g) All arbitration proceedings and decisions of the Arbitrators under this Section 13.3 shall be deemed Confidential Information of both Parties under Article 8. The arbitration proceedings shall take place in [\* \* \*]. The language of the arbitration proceeding shall be in English.

(h) Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Rights or trademark rights shall be submitted to a court of competent jurisdiction in the country in which such Patent Rights or trademark rights were granted or arose. Nothing in this Section 13.3 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

ARTICLE 14  
MISCELLANEOUS

**14.1 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), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except for a strike, lockout or labor disturbance with respect to the non-performing Party's respective employees or agents), fire, floods, earthquakes or other acts of God, or any generally applicable action or inaction by any Governmental Authority (but excluding any government action or inaction that is specific to such Party, its Affiliates or sublicensees, such as revocation or non-renewal of such Party's license to conduct business), or omissions or delays in acting by the other Party. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations despite the ongoing circumstances.

**14.2 Assignment.** This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; except that either Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates, provided, that the assigning Party shall remain jointly and severally liable with such Affiliate in respect of all obligations so assigned; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its assets to which this Agreement relates, provided, that such successor agrees in writing to be bound by the terms of this Agreement as if it were the assigning party. Any attempted assignment not in accordance with this Section 14.1 shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

**14.3 Severability.** If any one (1) 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) that, insofar as practical, implement the purposes of this Agreement.

**14.4 Notices.** All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or electronic mail (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 Verastem:

**Verastem, Inc.**  
117 Kendrick Street, #500,  
Needham, MA 02494  
USA  
Attn: President and CEO

with a copy to:

**Verastem, Inc.**  
117 Kendrick Street, #500,  
Needham, MA 02494  
USA  
Attn: COO

If to Licensee:

**CSPC Pharmaceutical Group Limited**  
302 Carnegie Center Blvd, Suite 100  
Princeton, NJ 08540  
Attn: President, International Division

with a copy to:

**CSPC Pharmaceutical Group Limited**  
226 Huanghe Avenue,  
Shijiazhuang, Hebei, The People’s Republic of China  
Attn: Executive assistant, Chairman’s Office

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 electronic mail or facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next 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.

**14.5 Governing Law.** This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations.

**14.6 Entire Agreement; Amendments.** This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties. The Parties agree that, effective as of the Effective Date, that the Existing Confidentiality Agreement shall be superseded by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Confidentiality Agreement shall be subject to the confidentiality and non-use provisions of this Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party’s or its Affiliate’s obligations pursuant to the Confidentiality Agreement.

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

**14.8 Independent Contractors.** It is expressly agreed that Verastem and Licensee shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture or agency. Neither Verastem nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

**14.9 Waiver.** Any waiver of any provision of this Agreement shall be effective only if in writing and signed by Verastem and Licensee. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

**14.10 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.

**14.11 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Laws.

**14.12 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business

Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

**14.13 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**14.14 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.”

**14.15 Counterparts.** This Agreement may be executed in two (2) 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.

**14.16 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.

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT  
REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION (“SEC”). REDACTED  
MATERIAL IS MARKED  
WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

*{Signature Page Follows}*

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION (“SEC”). REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED SEPARATELY WITH THE SEC.**

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

**VERASTEM, INC.**

**CSPC PHARMACEUTICAL GROUP LIMITED**

By: /s/ Robert Forrester

By: /s/ Dongchen Cai

Name: Robert Forrester

Name: Dongchen Cai

Title: President and CEO

Title: Chairman

## List of Exhibits

<b>Exhibit A:</b>	<b>Verastem Patents</b>
<b>Exhibit B:</b>	<b>Structure of Licensed Compound</b>
<b>Exhibit C:</b>	<b>Joint Press Release</b>
<b>Exhibit D:</b>	<b>Licensed Trademarks</b>

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**Exhibit B**  
**Structure of Licensed Compound**

[\* \* \*]

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**Exhibit C**  
**Joint Press Release**

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## CONSULTING AGREEMENT

This Consulting Agreement (together with its attachments, this “Agreement”) made as of October 16th, 2018 (the “Effective Date”) is between **Verastem, Inc.** a Delaware corporation having headquarters located at 117 Kendrick Street, Suite 500, Needham, MA 02494 (the “Company”), and **Louise Phanstiel**, residing at 123 Miankoma Lane, Amagansett, NY 11930 (“Consultant”). The Company desires to have the benefit of Consultant’s knowledge and experience, and Consultant desires to provide Consulting Services (defined below) to the Company, all as provided in this Agreement.

**1. Consulting Services.** The Company hereby retains Consultant and Consultant agrees to provide Consulting Services to the Company as it may from time to time reasonably request (the “Consulting Services”). Any changes to the Consulting Services (and any related compensation adjustments) must be agreed upon in writing between Consultant and the Company prior to implementation of such changes.

**1.1 Performance.** Consultant agrees to render the Consulting Services to the Company, or to its designee, (a) at such reasonably convenient times and places as the Company may direct, (b) under the general supervision of the Company, and (c) on a best efforts basis. Consultant will comply with all rules, procedures and standards promulgated from time to time by the Company with regard to Consultant’s access to and use of the Company’s property, information, equipment and facilities. Consultant agrees to furnish the Company with written reports with respect to the Consulting Services if and when requested by the Company.

**1.2 Third Party Confidential Information.** Consultant agrees not to use or disclose any trade secrets or other confidential information of any other person, firm, corporation, institution or other entity in connection with any of the Consulting Services without such third party’s express written consent.

**1.3 Consultant Personnel.** In the event that others are, or may hereafter become, associated with Consultant or are used by Consultant in connection with the Consulting Services (“Consultant Personnel”), Consultant agrees to procure from them agreements containing obligations substantially identical in form and content to those contained in this Agreement, and Consultant agrees to cooperate with the Company in procuring execution by them of such assignments and other papers as may be required by the terms of this Agreement.

**1.4 Compensation.** In consideration for the Consulting Services rendered by Consultant to the Company, the Company agrees to pay Consultant the sum of \$45,000 payable in three equal quarterly installments over the Term of the Agreement. Payments will be made by the Company within thirty (30) days after the end of each of the Company’s fiscal quarters during the term of the Agreement. All fees will be payable in U.S. Dollars in accordance with the terms of this Agreement. The Company will reimburse Consultant for reasonable and pre-approved business expenses incurred by Consultant in the performance of the Consulting Services under this Agreement.

(i) **Stock Vesting.** Any unvested stock options, which were issued to Consultant during her previous term of service on the Company’s Board of Directors will continue to vest during

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the Term (as defined in Section 6.1) of this Agreement. Additionally, the parties agree that Consultant will be free to exercise any and all vested stock options issued to her by the Company for a period of ninety (90) days following the termination of this Agreement. For the avoidance of doubt, the parties agree that as of the effective date of this Agreement, Consultant will no longer serve as a member of the Verastem Board of Directors. As such, and pursuant to the Company's Insider Trading Policy, Consultant's purchase, sale or other trading in the Company's common stock will not be subject to public disclosure obligations on SEC Form 4. Additionally, pursuant to the Company's Insider Trading Policy Consultant will not be subject to the restrictions imposed on company employees and Directors during regular « blackout » periods. Consultant acknowledges that she is precluded by law from trading in Company stock while in possession of material non-public information concerning the Company.

## 2. **Inventions.**

**2.1 Definition.** "Inventions" means all inventions, discoveries, improvements, ideas, designs, processes, products, computer programs, works of authorship, databases, gene sequences, cell lines, samples, chemical compounds, assays, biological materials, mask works, trade secrets, know-how, research and creations (whether or not patentable or subject to copyright or trade secret protection) that Consultant makes, conceives or reduces to practice, either alone or jointly with others, and that (a) result from the performance of the Consulting Services, and/or (b) result from use of facilities, equipment, supplies, Research Materials (defined below), or Confidential Information (defined below) of the Company.

**2.2 Ownership.** Consultant will promptly disclose all Inventions in confidence to the Company. Consultant agrees to irrevocably transfer and assign and hereby does irrevocably transfer and assign to the Company or its successors or designees the entire right, title and interest now existing or that may exist in the future to all Inventions and any and all related patents, patent applications, copyrights, copyright applications, trademarks, trade names, trade secrets and other proprietary and moral rights in the United States and throughout the world ("Work Product"). All Work Product will be the exclusive property of the Company. For purposes of the copyright laws of the United States, all Work Product will constitute "works made for hire," except to the extent such Inventions cannot by law be "works made for hire." Consultant agrees to execute, at the Company's request and expense, all documents and other instruments necessary or desirable to confirm such assignment. In the event that Consultant does not, for any reason, execute such documents within a reasonable time of the Company's request, Consultant hereby irrevocably appoints the Company as Consultant's attorney-in-fact for the purpose of executing such documents on Consultant's behalf, which appointment is coupled with an interest. Consultant shall not attempt to register any works created by Consultant pursuant to this Agreement at the U.S. Copyright Office, the U.S. Patent & Trademark Office, or any foreign copyright, patent, or trademark registry. Consultant retains no rights in the Work Product and agrees not to challenge the Company's ownership of the rights embodied in the Work Product. Consultant further agrees to assist the Company in every proper way to enforce the Company's rights relating to the Work Product in any and all countries, including, but not limited to, executing, verifying and delivering such documents and performing such other acts (including appearing as a witness) as the Company may reasonably request for use in obtaining, perfecting, evidencing, sustaining and enforcing the Company's rights relating to the Work Product.

**2.3 Moral Rights.** If Consultant has any rights, including without limitation "artist's rights" or "moral rights" in the Work Product which cannot be assigned (the "Non-Assignable Rights"), Consultant agrees to waive enforcement worldwide of such rights against the Company. In the event that Consultant has any such rights that cannot be assigned or waived, Consultant hereby grants to the Company a royalty-free, paid-up, exclusive, worldwide, irrevocable, perpetual license under the Non-Assignable Rights to (i) use, make, sell, offer to sell, have made,

commercialize, and further sublicense the Work Product, and (ii) reproduce, distribute, create derivative works of, publicly perform and publicly display the Work Product in any medium or format, whether now known or later developed.

- 2.4 Research Materials.** For Consulting Services which involve laboratory work or experiments, “Research Materials” means all materials (a) furnished by the Company, (b) developed by Consultant in connection with the Consulting Services, or (c) the cost of which are reimbursed to Consultant by the Company. Research Materials include, in the case of biological materials, all progeny and unmodified derivatives of those materials, and in the case of chemical materials, all analogs, formulations, mixtures and compositions of those materials. Research Materials are the sole property of the Company. Consultant agrees not to use or evaluate Research Materials for any purpose other than as directed by the Company, and not to transfer the Research Materials to any third party without the prior written consent of the Company. Consultant will use the Research Materials in strict compliance with all laws and regulations.
- 2.5 Records.** Consultant shall make and maintain adequate and current written records of all Inventions, which records shall be available to and remain the property of the Company at all times.
- 2.6 Work at Third Party Facilities.** Consultant agrees not to make use of any funds, space, personnel, facilities, equipment or other resources of a third party in performing the Consulting Services, and further agrees not to take any other action that would result in a third party owning or having a right in any Inventions, unless agreed upon in writing in advance by the Company.

**3. Confidential Information.**

- 3.1 Definition.** “Confidential Information” means information with respect to the facilities and methods of the Company, Research Materials, trade secrets, Inventions, systems, patents and patent applications, procedures, manuals, confidential reports, financial or legal information, business plans, prospects, or opportunities, personnel information, lists of customers and suppliers, and information of third parties provided by the Company to Consultant. Confidential Information does not include information which (i) is in the public domain or which becomes part of the public domain through no wrongful act on Consultant’s part but only after it becomes so publicly known, (ii) is already in Consultant’s possession at the time of disclosure by the Company, other than by previous disclosure by the Company, as evidenced by written or electronic records, or (iii) that becomes known to Consultant through disclosure by a third party having the right to disclose the information, as evidenced by written or electronic records.
- 3.2 Obligations of Confidentiality.** Consultant will not directly or indirectly publish, disseminate or otherwise disclose, use for Consultant’s own benefit or for the benefit of a third party, deliver or make available to any third party, any Confidential Information, other than in furtherance of the purposes of this Agreement, and only then with the prior written consent of the Company, and it is agreed and understood that all Confidential Information shall remain the sole property of the Company. Without the Company’s prior written approval, Consultant will not directly or indirectly disclose to anyone the existence or terms of this Agreement or the fact that Consultant has this arrangement with the Company. If required, Consultant may disclose the Confidential Information to a governmental authority or by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice of such compulsory disclosure is given to the Company. Consultant will exercise all reasonable precautions to protect the physical integrity and confidentiality of the Confidential Information, and will not remove any Confidential Information or copies or derivations thereof from the Company’s premises except to the extent necessary to fulfill the Consulting Services, and then only with

the Company's prior consent. Consultant may disseminate or permit access to Confidential Information only to Consultant Personnel who have a need to know such Confidential Information in the course of the performance of their duties under this Agreement and who are bound to protect the confidentiality of the Confidential Information consistent with the terms of this Agreement. Consultant agrees to be responsible for any breach of this Agreement by any of the Consultant Personnel. The Company will be entitled to injunctive relief as a remedy for any breach of the terms of this Section 4.

**3.3 Third Party Confidential Information.** Consultant recognizes that the Company has received and in the future will receive from third parties confidential and proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that Consultant owes the Company and such third parties, during the term of this Agreement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence in accordance with the Company's obligations to such third party, and agrees not to disclose it to any person, firm or corporation or use it except in carrying out the Consulting Services for the Company consistent with the Company's agreement with such third party.

**4. Restrictions.** While Consultant is engaged by the Company and for a period of twelve (12) months after the termination or cessation of such engagement for any reason, Consultant will not:

(i) provide consulting services to, or become a member of the Board of Directors of any company, business or entity developing or commercializing a product or sponsoring a project which competes with a product being developed or project being sponsored by the Company targeting the tumor microenvironment and for which Consultant is providing Consulting Services. It will not, without more, be considered a competitive activity for Consultant to be a member of the faculty or staff of a university, college or other educational or non-profit research institution; or

(ii) recruit, solicit or hire any consultants of the Company or any person who was a consultant of the Company during the twelve (12) month period prior to the termination of Consultant's engagement by the Company, or induce or attempt to induce any of the Company's employees to terminate their employment with, or otherwise cease or diminish their relationship with, the Company or accept employment with anyone else.

**5. Representations and Warranties.**

**5.1 No Conflicts.** Consultant is under no contractual or other obligation or restriction which is inconsistent with Consultant's execution of this Agreement or the performance of the Consulting Services. During the Term (as defined below), Consultant will not enter into any agreement, either written or oral, in conflict with Consultant's obligations under this Agreement. Consultant will arrange to provide the Consulting Services in such manner and at such times that the Consulting Services will not conflict with Consultant's responsibilities under any other agreement, arrangement or understanding or pursuant to any employment relationship Consultant has at any time with any third party.

**5.2 Absence of Debarment.** Consultant represents that (a) neither Consultant nor any Consultant Personnel has been debarred, and to the best of Consultant's knowledge is not under consideration to be debarred, by the U.S. Food and Drug Administration ("FDA") from working in or providing consulting services to any pharmaceutical or biotechnology company under Section 306(a) or 306(b) of the federal Food, Drug and Cosmetic Act (codified at 21 U.S.C. §§ 335a(a) and 335a(b)); (b) no debarred person will in the future be employed by Consultant to perform any services hereunder in connection with any application for approval

of a drug by the FDA; and (c) neither Consultant nor any Consultant Personnel has a conviction on their record for which a person can be debarred as described in Sections 306(a) or 306(b) of the federal Food, Drug and Cosmetic Act. Consultant further represents and warrants that should Consultant or any Consultant Personnel be convicted in the future of any act for which a person can be debarred as described in Sections 306(a) or 306(b) of the federal Food, Drug and Cosmetic Act, Consultant shall immediately notify Company of such conviction in writing.

- 5.3 Assignment of Ownership in Work Product.** Consultant represents and warrants that (i) Consultant has the right and unrestricted ability to assign the Work Product to the Company as set forth in Section 3 (including without limitation the right to assign any Work Product created by Consultant's employees or contractors); (ii) the Work Product has not heretofore been published in whole or in part; and (iii) the Work Product will not infringe upon any copyright, patent, trademark, right of publicity or privacy, or any other proprietary or intellectual property right of any person, whether contractual, statutory or common law.
- 5.4 Compliance with Law.** Consultant covenants that the services to be provided hereunder shall be in compliance with all applicable laws, rules and regulations. Consultant acknowledges that Consultant is subject to the Company's insider trading policy, a copy of which can be found on the Company's website at [www.verastem.com](http://www.verastem.com).
- 5.5 No Conflicting Agreements.** Consultant represents that Consultant's performance of all the terms of this Agreement and as a provider of services to the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by Consultant in confidence or in trust prior to or during this Agreement, and Consultant has not and will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employers or other third parties. When performing the Consulting Services, Consultant agrees to use only such materials and information of any kind that Consultant has rightfully obtained and that are not considered proprietary or confidential by any third party unless agreed to otherwise by the Company in writing. For the avoidance of doubt, Consultant is not precluded by the terms of this Agreement from serving on the Board of Directors of another company or entity so long as that company or entity is not deemed to be a direct competitor of the Company in the Company's reasonable determination.

## **6. Term and Termination.**

- 6.1 Term.** This Agreement will commence on the Effective Date and continue through September 30, 2019 (the "Term"), unless sooner terminated pursuant to the express terms of this Section 6 or extended by mutual agreement of the parties.
- 6.2 Termination for Breach.** If either party breaches in any material respect any of its obligations under this Agreement, in addition to any other right or remedy, the non-breaching party may terminate this Agreement in the event that the breach is not cured within ten (10) days after receipt by that party of written notice of the breach.
- 6.3 Effect of Expiration/Termination.** Upon expiration or termination of this Agreement, neither the Company nor Consultant will have any further obligations under this Agreement, except (a) for liabilities accrued through the date of termination, and (b) the obligations under Sections 3, 4, 5, 7 and 8 hereof will survive. Upon expiration or termination, and in any case upon the Company's request, Consultant will return immediately to the Company all tangible Confidential Information, including all copies, reproductions and derivations thereof, and shall delete any such Company Confidential Information from Consultant's computer storage or any other media (including, but not limited to, online and off-line libraries).

7. **Miscellaneous.**

- 7.1 Independent Contractor.** All Consulting Services will be rendered by Consultant as an independent contractor, and this Agreement does not create an employer-employee, partnership, agency or joint venture relationship between the Company and Consultant. Consultant will have no rights to receive any employee benefits, such as health and accident insurance, sick leave or vacation which are accorded to regular Company employees. Consultant will not in any way represent herself to be an employee, partner, joint venturer, or agent of the Company. Consultant is not authorized to make any representation, contract, or commitment on behalf of the Company or incur any liabilities or obligations of any kind in the name of or on behalf of the Company. Consultant shall work independently, without day-to-day direction from the Company, and may adopt such arrangements as Consultant desires with regard to the details of the Consulting Services performed under this Agreement, the hours during which the Consulting Services will be provided, and the place or places where the Consulting Services are to be furnished; provided that: (a) such arrangements, details, hours and location of services shall be consistent with the proper accomplishment of the agreed objectives of the Company; and (b) such services by Consultant shall be performed in a manner calculated to obtain the most satisfactory results for the Company.
- 7.2 Taxes.** Consultant and the Company agree that the Company will treat Consultant as an independent contractor for purposes of all tax laws (local, state and federal) and file income reporting and other forms consistent with such status. Consultant agrees that, as an independent contractor, neither Consultant nor Consultant's employees are entitled to unemployment benefits in the event this Agreement terminates, or to workers' compensation benefits in the event that Consultant, or any employee of Consultant, is injured in any manner while performing obligations under this Agreement. Consultant will be solely responsible to pay any and all local, state, and/or federal income, social security and unemployment taxes for Consultant and Consultant's employees. The Company will not withhold any taxes or prepare W-2 Forms for Consultant, but will provide Consultant with a Form 1099 if and to the extent required by law. Consultant is solely responsible for, and will timely file, all tax returns and payments required to be filed with, or made to, any federal, state or local tax authority with respect to the performance of services and receipt of fees under this Agreement. Consultant is solely responsible for, and must maintain adequate records of, expenses incurred in the course of performing services under this Agreement, except as provided herein. The Company will regularly report amounts paid to Consultant with the appropriate taxing authorities, as required by law. Consultant will provide the Company with Consultant's taxpayer identification number or social security number, as applicable. Consultant agrees to indemnify the Company and its affiliates and hold them harmless from and against any loss, cost, liability or expense (including attorney's fees) incurred by the Company or any of its affiliates on account of any breach of Consultant's obligations under this Section 9, or on account of any tax treatment of Consultant by taxing authorities inconsistent with the terms hereof.
- 7.3 Use of Name.** Consultant consents to the use by the Company of Consultant's name and likeness in written materials and oral presentations to current or prospective customers, partners, investors or others, provided that such materials or presentations accurately describe the nature of Consultant's relationship with and contributions to the Company.
- 7.4 Disclosure.** Consultant acknowledges that pursuant to certain federal and/or state laws and regulations, Company may be required to disclose the nature, value and purpose of this Agreement to certain government agencies, which may result in such information becoming available to the general public.



- 7.5 **Indemnification.** Both parties agree to continue to be bound by the terms and conditions of the Indemnification Agreement by and between the parties dated June 13, 2017 for the Term of this Agreement.
- 7.6 **Assignability and Binding Effect.** The Consulting Services to be rendered by Consultant are personal in nature. Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations hereunder except to a corporation of which Consultant is the sole stockholder. In no event will Consultant assign or delegate responsibility for actual performance of the Consulting Services to any other natural person except to Consultant Personnel as provided for under this Agreement. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns. The Company may assign this Agreement to any other corporation or entity which acquires (whether by purchase, merger, consolidation or otherwise) all or substantially all of the business and/or assets of the Company.
- 7.7 **Headings.** The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement.
- 7.8 **Notices.** Any notices or other communications from one party to the other will be in writing and will be given by addressing the same to the other at the address or facsimile number set forth in this Agreement. Notices to the Company will be marked "Attention: General Counsel." Notice will be deemed to have been duly given when (a) deposited in the United States mail with proper postage for first class Registered or Certified Mail prepaid, return receipt requested, (b) sent by any reputable commercial courier, delivery confirmation requested, (c) delivered personally, or (d) if promptly confirmed by mail or commercial courier as provided above, when dispatched by facsimile.
- 7.9 **Amendment.** This Agreement may be amended or modified only by a writing signed by authorized representatives of both parties.
- 7.10 **No Waiver.** No waiver of any term or condition of this Agreement shall be valid or binding on either party unless the same shall be been mutually assented to in writing by both parties. The failure of either party to enforce at any time any of the provisions of this Agreement, or the failure to require at any time performance by the other party of any of the provisions of this Agreement, shall in no way be construed to be a present or future waiver of such provisions, nor in any way affect the right of either party to enforce each and every such provision thereafter. The express waiver by either party of any provision, condition or requirement of this Agreement shall not constitute a waiver of any future obligation to comply with such provision, condition or requirement.
- 7.11 **Severability.** In the event that any one or more of the provisions contained in this Agreement is, for any reason, held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.
- 7.12 **Entire Agreement.** This Agreement constitutes the entire agreement of the parties with regard to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between the parties.
- 7.13 **Governing Law/Jurisdiction.** All disputes related to or arising out of this Agreement shall be resolved in the state or federal courts of the Commonwealth of Massachusetts, to whose

exclusive jurisdiction each party hereby consents. This Agreement will be governed by, construed and enforced in accordance with the laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws.

**7.14 Remedies.** Consultant's obligations under this Agreement are of a unique character that gives them particular value; breach of any of such obligations will result in irreparable and continuing damage to the Company for which there will be no adequate remedy at law; and, in the event of such breach or threatened breach, the Company will be entitled to injunctive relief and/or a decree for specific performance, an award of its attorney's fees incurred, and such other and further relief as may be proper. Consultant and the Company further agree that no bond or other security shall be required in obtaining such equitable relief.

**7.15 Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement under seal as of the Effective Date.

**VERASTEM, INC.**

**CONSULTANT**

By: /s/ SEAN C. FLYNN

By: /s/ S. LOUISE PHANSTIEL

Name: Sean C. Flynn

Name: Louise Phanstiel

Title: VP, General Counsel  
duly authorized

## CERTIFICATIONS

I, Robert Forrester, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verastem, 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.

/s/ ROBERT FORRESTER

Robert Forrester  
*President and Chief Executive Officer*

Date: November 7, 2018

## CERTIFICATIONS

I, Robert Gagnon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verastem, 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.

/s/ ROBERT GAGNON

Robert Gagnon  
Chief Financial Officer

Date: November 7, 2018

**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 Verastem, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Forrester, 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 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.

/s/ ROBERT FORRESTER

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Robert Forrester  
*President and Chief Executive Officer*

Date: November 7, 2018

**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 Verastem, Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Gagnon, 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 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.

/s/ ROBERT GAGNON

Robert Gagnon  
*Chief Financial Officer*

Date: November 7, 2018



## Verastem Oncology Reports Third Quarter 2018 Financial Results

*Quarter Highlighted by FDA Approval of COPIKTRA™ (duvelisib) Capsules*

*Exclusive License Agreement Executed with CSPC Pharmaceutical Group Limited for the Development and Commercialization of COPIKTRA in China*

*Company Secures \$150 Million in Gross Proceeds Through an Offering of Convertible Notes*

**BOSTON, MA – November 7, 2018** – Verastem, Inc. (Nasdaq: VSTM) (Verastem Oncology or the Company), focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients, today reported financial results for the third quarter ended September 30, 2018 and provided an overview of certain corporate developments.

“During the third quarter, we achieved a remarkable milestone with our lead product COPIKTRA™ (duvelisib) receiving its first regulatory approval from the U.S. Food and Drug Administration,” said Robert Forrester, President and Chief Executive Officer of Verastem Oncology. “We were also delighted to have signed an exclusive licensing agreement with CSPC Pharmaceutical Group Limited for the development and commercialization of COPIKTRA for all oncology indications in China, further extending the global reach of our product. This is an exciting time at Verastem Oncology, and we believe this is just the beginning for both COPIKTRA and the Company. It is our goal to unlock the potential of PI3K inhibition, initially as a monotherapy, and through novel combinations to potentially expand its use to broader hematologic and solid tumors.”

“The COPIKTRA launch is well underway and proceeding on track,” said Joseph Lobjack, Executive Vice President and Chief Commercial Officer of Verastem Oncology. “We had the necessary staffing in place and were ready to distribute COPIKTRA on the day of approval. Our commercial field force and medical affairs teams are engaging with physicians, and our contracted specialty pharmacy partners are receiving prescriptions. We are thrilled that within six weeks of the approval date, COPIKTRA has been included in the NCCN guidelines and we’ve secured reimbursement coverage, including the top national plans, for 72% of the U.S. Pharmacy lives. This is an exciting time for Verastem Oncology, and I am proud of the team’s diligent efforts and early progress in the launch.”

COPIKTRA (duvelisib)

- **COPIKTRA (duvelisib) Capsules Approved by the FDA** – On September 24, 2018, the U.S. Food and Drug Administration (FDA) approved COPIKTRA, an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma. COPIKTRA was approved for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies. COPIKTRA also received accelerated approval for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The indication in FL is approved under accelerated approval based on overall response rate. Continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory trials. The commercial launch of COPIKTRA is ongoing.
- **COPIKTRA Added to NCCN Guidelines for CLL/SLL and FL** – In early October 2018, following its approval by the FDA, the National Comprehensive Cancer Network® (NCCN) added COPIKTRA to the Clinical Practice Guidelines in Oncology (NCCN Guidelines). Physicians use the NCCN Guidelines as the standard resource for determining the best course of treatment for patients, and the Company believes these updated guidelines will increase awareness for COPIKTRA and help health care providers make informed decisions for patients battling these difficult to treat advanced cancers.
- **Phase 3 DUO Study Results Published in the Journal BLOOD** – In early October 2018, the results of the randomized, multicenter, open-label Phase 3 DUO™ study (NCT02004522), which evaluated COPIKTRA versus ofatumumab in patients with relapsed or refractory CLL/SLL, were published online in the peer-reviewed journal *Blood*. The full manuscript titled “The phase 3 DUO trial: duvelisib versus ofatumumab in relapsed and refractory CLL/SLL,” is available at [www.bloodjournal.org](http://www.bloodjournal.org).
- **Investigator-Sponsored Study Initiated Evaluating COPIKTRA in Combination with Venetoclax** – In early September 2018, the first patient was dosed in a multicenter Phase 1/2 clinical trial investigating COPIKTRA in combination with venetoclax, an oral selective inhibitor of BCL-2, in patients with relapsed or refractory CLL/SLL. Preclinical data support this combination, as COPIKTRA has been shown to upregulate BCL-2 transcript and protein expression levels and potentially enhance the ability of venetoclax to induce apoptosis in ex vivo human CLL cells. The primary objectives of the Phase 1 portion of the trial are to determine the maximum tolerated dose and the recommended Phase 2 dose of venetoclax for this combination regimen. The trial is being led by Matthew Davids, M.D., MMSc, Assistant Professor of Medicine, Harvard Medical School, and Associate Director, Center for Chronic Lymphocytic Leukemia, Dana-Farber Cancer Institute.
- **Eight Abstracts Selected for Presentation at the Upcoming American Society of Hematology 2018 Annual Meeting (ASH 2018)** – In November 2018, the Company announced that eight abstracts were selected for presentation, including one oral presentation, at ASH 2018 which is being held December 1-4, 2018 in San Diego, CA. The oral presentation will highlight data from the Phase 1 study evaluating COPIKTRA in combination with romidepsin in relapsed or refractory peripheral T-cell lymphoma. Additional poster presentations will showcase preclinical and clinical data reinforcing the potential of COPIKTRA.



- **Signed Exclusive License Agreement with CSPC Pharmaceutical Group Limited (CSPC) for the Development and Commercialization of Duvelisib in China** – In September 2018, Verastem Oncology announced its entry into an exclusive license agreement with CSPC to develop and commercialize COPIKTRA in China, Hong Kong, Macau and Taiwan (collectively, the CSPC Territory) for all oncology indications. Under the terms of the agreement, Verastem Oncology is to receive an upfront payment of \$15.0 million and is entitled to receive aggregate payments of up to \$160.0 million if certain development, regulatory and commercial milestones are successfully achieved, plus double-digit royalties on net sales of products containing duvelisib in the CSPC Territory. CSPC will receive exclusive rights to develop and commercialize COPIKTRA and hold the marketing authorization and product license for COPIKTRA in the CSPC Territory. Additionally, CSPC will have the right to collaborate with Verastem Oncology on certain global development and clinical trial activities and will share pro-rata in the cost of studies that they elect to participate in. CSPC is a leading pharmaceutical group in China. CSPC has been listed on the Main Board of the Hong Kong Stock Exchange since 1994 and is currently a constituent stock of the Hang Seng Index. CSPC is a leading developer and manufacturer of innovative and generic drugs in China.
- **Collaboration with The Leukemia & Lymphoma Society for Development of Duvelisib in Peripheral T-Cell Lymphoma** - Verastem Oncology's duvelisib was selected for The Leukemia & Lymphoma Society's (LLS) Therapy Acceleration Program® (TAP) which provides additional resources to support the development of therapies for patients with blood cancers. The Company plans to use the TAP funds to conduct certain translational and clinical activities relating to the development of duvelisib for the treatment of Peripheral T-Cell Lymphoma (PTCL). LLS and Verastem Oncology will share the cost of the PTCL development program, portions of which will be conducted in collaboration with Memorial Sloan Kettering Cancer Center, The Dana-Farber Cancer Institute, The Washington University in St. Louis and Stanford University.
- **Sale of Convertible Senior Notes for Gross Proceeds of \$150 Million** – In October 2018, the Company completed an offering of 5.00% convertible senior notes due 2048 through a registered direct offering. The Company received net proceeds of \$145.1 million, after transaction fees and expenses.
- **Robert E. Gagnon Appointed Chief Financial Officer** – In August 2018, Mr. Gagnon was appointed Chief Financial Officer. He comes to Verastem Oncology from Harvard Bioscience, Inc., where he served as Chief Financial Officer. Prior to Harvard Bioscience, he served as Executive Vice President, Chief Financial Officer and Treasurer at Clean Harbors, Inc., as well as Chief Accounting Officer and Controller at Biogen Idec, Inc. Earlier, he worked in a variety of senior positions at Deloitte & Touche, LLP, and Price Waterhouse Coopers, LLP. Mr. Gagnon holds an M.B.A. from the MIT Sloan School of Management and a Bachelor of Arts degree in accounting from Bentley College. His prior experience heading global finance operations, and his overall business acumen, will be a great asset to the Company as it executes on its growth strategy.
- **Gina Consylman Appointed to Board of Directors** – In October 2018, Ms. Consylman was appointed to the Company's Board of Directors (the Board) and will serve as Chair of the Board's Audit Committee. Ms. Consylman replaces Louise Phanstiel who left the Board to pursue other professional opportunities. Ms. Consylman currently serves as Senior Vice President and Chief Financial Officer of Ironwood Pharmaceuticals, Inc., a commercial biotech company, where she oversees the finance, planning, accounting, tax, treasury and insurance functions. Prior to joining Ironwood, she held various senior level accounting and corporate controller positions at Analogic Corporation, Biogen Inc., and Varian Semiconductor Equipment Associates, Inc. Ms. Consylman holds a Bachelor of Science degree in

accounting from Johnson & Wales University, a Master of Science degree in taxation from Bentley University and is a Certified Public Accountant.

· **Hagop Youssoufian, MSc, M.D., Appointed Head of Medical Strategy** – In October 2018, the Company announced that Dr. Youssoufian would transition to Head of Medical Strategy from his prior role as Head of Hematology and Oncology Development. Dr. Youssoufian will be taking over responsibilities from Diep Le, M.D., Ph.D., who stepped down as Chief Medical Officer.

### **Third Quarter 2018 Financial Results**

License revenue for the three months ended September 30, 2018 (2018 Quarter) was \$15.0 million and was related to an upfront payment pursuant to the license and collaboration agreement executed between Verastem Oncology and CSPC in September 2018. Verastem Oncology had no license revenue during the three months ended September 30, 2017 (2017 Quarter).

Verastem Oncology began commercial sales of COPIKTRA within the United States in September 2018, following receipt of FDA marketing approval on September 24, 2018. For the 2018 Quarter, the Company recorded approximately \$508,000 of net product revenue. Verastem Oncology had no product revenue during the 2017 Quarter.

Costs of revenues, excluding amortization of acquired intangible assets (cost of revenues) of approximately \$49,000 for the 2018 Quarter, consisted of costs associated with the manufacturing of COPIKTRA, royalties owed to Infinity Pharmaceuticals, Inc. (Infinity) on such sales, and certain period costs. Verastem Oncology expensed the manufacturing costs of COPIKTRA as operating expenses in the periods prior to July 1, 2018. Verastem Oncology had no cost of revenues during the 2017 Quarter.

Research and development expense for the 2018 Quarter was \$11.6 million compared to \$17.7 million for the 2017 Quarter. The \$6.1 million decrease from the 2017 Quarter to the 2018 Quarter was primarily related to a decrease of \$6.0 million in license fees related to a one-time milestone payment pursuant to the Infinity license agreement that was recognized in the 2017 Quarter and a decrease of \$1.2 million in consulting fees. These decreases were offset by an increase of \$1.1 million in personnel related costs, including non-cash stock-based compensation.

Selling, general and administrative expense for the 2018 Quarter was \$25.4 million compared to \$5.4 million for the 2017 Quarter. The increase of \$20.0 million from the 2017 Quarter to the 2018 Quarter primarily resulted from an increase in personnel related costs, including non-cash stock-based compensation, of \$9.7 million, primarily related to the hiring and staffing of Verastem Oncology's sales and commercial teams, an increase in consulting and professional fees of \$9.1 million, primarily related to the support of commercial launch preparation activities, and travel and other costs of \$1.2 million.

Amortization of acquired intangible assets for the 2018 Quarter of approximately \$31,000 was related to the COPIKTRA finite-lived intangible asset which Verastem Oncology recognized and began amortizing in September 2018. There was no amortization of acquired intangible assets in the 2017 Quarter.

Net loss for the 2018 Quarter was \$21.7 million, or \$0.29 per share, as compared to a net loss of \$23.1 million, or \$0.61 per share, for 2017 Quarter.

As of September 30, 2018, Verastem Oncology had cash, cash equivalents and investments of \$145.6 million compared to \$86.7 million of cash, cash equivalents and investments as of December 31, 2017. Cash, cash equivalents and investments for the 2018 Quarter does not include the \$145.1 million in net proceeds from the registered direct offering of convertible notes in October 2018.

The number of outstanding common shares as of September 30, 2018 was 73,703,423.

## **Indications and Usage**

### **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory CLL or SLL after at least two prior therapies.

### **Follicular Lymphoma (FL)\***

COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory FL after at least two prior systemic therapies.

*\*This indication is approved under accelerated approval based on overall response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.*

## **COPIKTRA Clinical Trials**

### **Efficacy in Relapsed or Refractory CLL/SLL**

A randomized, multicenter, open-label trial (DUO™; NCT02004522) compared COPIKTRA versus ofatumumab in 319 adult patients with CLL (N = 312) or SLL (N = 7) after at least one prior therapy. The study randomized patients with a 1:1 ratio to receive either COPIKTRA 25mg BID until disease progression or unacceptable toxicity, or ofatumumab for 7 cycles.

The approval of COPIKTRA was based on efficacy and safety analysis of patients with at least 2 prior lines of therapy, where the benefit:risk appeared greater in this more heavily pretreated population compared to the overall trial population.

In this subset (95 randomized to COPIKTRA, 101 to ofatumumab), the median patient age was 69 years (range: 40 to 90 years), 59% were male, and 88% had an ECOG performance status of 0 or 1. Forty-six percent received 2 prior lines of therapy, and 54% received 3 or more prior lines. At baseline, 52% of patients had at least one tumor  $\geq$  5 cm, and 22% of patients had a documented 17p deletion.

During randomized treatment, the median duration of exposure to COPIKTRA was 13 months (range: 0.2 to 37), with 80% of patients receiving at least 6 months and 52% receiving at least 12 months of COPIKTRA. The median duration of exposure to ofatumumab was 5 months (range: < 0.1 to 6).

Efficacy was based on progression-free survival (PFS) as assessed by an Independent Review Committee (IRC). Other efficacy measures included overall response rate (ORR). Efficacy of COPIKTRA compared to ofatumumab specifically in patients treated with at least two prior therapies is below.

Outcome per IRC	COPIKTRA N = 95	Ofatumumab N = 101
<b>PFS</b>		
Number of events, n (%)	55 (58)	70 (69)
Progressive disease	44	62
Death	11	8
Median PFS (SE), months <sup>a</sup>	16.4 (2.1)	9.1 (0.5)
Hazard Ratio (SE), <sup>b</sup> COPIKTRA/ofatumumab	0.40 (0.2)	
<b>Response rate</b>		
ORR, n (%) <sup>c</sup>	74 (78)	39 (39)
CR	0 (0)	0 (0)
PR	74 (78)	39 (39)
Difference in ORR, % (SE)	39 (6.4)	

Abbreviations: CR = complete response; IRC = Independent Review Committee; PFS = progression-free survival; PR = partial response; SE = standard error

<sup>a</sup> Kaplan-Meier estimate

<sup>b</sup> Standard Error of ln(hazard ratio) = 0.2

<sup>c</sup> IWCLL or Revised International Working Group criteria, with modification for treatment-related lymphocytosis

### Efficacy in Relapsed or Refractory FL

Efficacy of COPIKTRA in patients with previously treated FL is based on a single-arm, multicenter trial (DYNAMO™; NCT01882803).

In DYNAMO, COPIKTRA 25 mg BID was administered in patients with FL (N = 83) who were refractory to rituximab and to either chemotherapy or radioimmunotherapy. Refractory disease was defined as less than a partial remission or relapse within 6 months after the last dose. The trial excluded patients with Grade 3b FL, large cell transformation, prior allogeneic transplant, and prior exposure to a PI3K inhibitor or to a Bruton's tyrosine kinase inhibitor.

The median age was 64 years (range: 30 to 82 years), 68% were male, and 37% had bulky disease assessed at baseline (target lesion ≥ 5 cm). Patients had a median of 3 prior lines of therapy (range: 1 to 10), with 94% being refractory to their last therapy and 81% being refractory to 2 or more prior lines of therapy. Most patients (93%) had an ECOG performance status of 0 or 1.

The median duration of exposure to COPIKTRA was 5 months (range: 0.4 to 24), with 41% of patients receiving at least 6 months and 10% receiving at least 12 months of COPIKTRA.

Efficacy was based on overall response rate and duration of response as assessed by an IRC, as shown below.

Endpoint	FL N = 83
ORR, n (%) <sup>a</sup>	35 (42)
95% CI	(31, 54)
CR, n (%)	1 (1)
PR, n (%)	34 (41)
Duration of response	
Range, months	0.0 <sup>+</sup> to 41.9 <sup>+</sup>
Patients maintaining response at 6 months, n/N (%)	15/35 (43)
Patients maintaining response at 12 months, n/N (%)	6/35 (17)

Abbreviations: CI = confidence interval; CR = complete response; IRC = Independent Review Committee; ORR = overall response rate; PR = partial response

<sup>a</sup> Per IRC according to Revised International Working Group criteria

<sup>+</sup> Denotes censored observation

## Important Safety Information

### **WARNING: FATAL AND SERIOUS TOXICITIES: INFECTIONS, DIARRHEA OR COLITIS, CUTANEOUS REACTIONS, and PNEUMONITIS**

See full prescribing information for complete boxed warning

- **Fatal and/or serious infections occurred in 31% of COPIKTRA-treated patients. Monitor for signs and symptoms of infection. Withhold COPIKTRA if infection is suspected.**
- **Fatal and/or serious diarrhea or colitis occurred in 18% of COPIKTRA-treated patients. Monitor for the development of severe diarrhea or colitis. Withhold COPIKTRA.**
- **Fatal and/or serious cutaneous reactions occurred in 5% of COPIKTRA-treated patients. Withhold COPIKTRA.**
- **Fatal and/or serious pneumonitis occurred in 5% of COPIKTRA-treated patients. Monitor for pulmonary symptoms and interstitial infiltrates. Withhold COPIKTRA.**

### **WARNINGS AND PRECAUTIONS**

**Infections:** Serious, including fatal (18/442; 4%), infections occurred in 31% of patients receiving COPIKTRA 25 mg BID (N=442). The most common serious infections were pneumonia, sepsis, and lower respiratory infections. Median time to onset of any grade infection was 3 months (range: 1 day to 32 months), with 75% of cases occurring within 6 months. Treat infections prior to initiation of COPIKTRA. Advise patients to report new or worsening signs and symptoms of infection. For grade 3 or higher infection, withhold COPIKTRA until infection has resolved. Resume COPIKTRA at the same or reduced dose.

Serious, including fatal, *Pneumocystis jirovecii* pneumonia (PJP) occurred in 1% of patients taking COPIKTRA. Provide prophylaxis for PJP during treatment with COPIKTRA and following completion of treatment with COPIKTRA until the absolute CD4<sup>+</sup> T cell count is greater than 200 cells/ $\mu$ L. Withhold COPIKTRA in patients with suspected PJP of any grade, and permanently discontinue if PJP is confirmed.

Cytomegalovirus (CMV) reactivation/infection occurred in 1% of patients taking COPIKTRA. Consider prophylactic antivirals during COPIKTRA treatment to prevent CMV infection including CMV reactivation. For

clinical CMV infection or viremia, withhold COPIKTRA until infection or viremia resolves. If COPIKTRA is resumed, administer the same or reduced dose and monitor patients for CMV reactivation by PCR or antigen test at least monthly.

**Diarrhea or Colitis:** Serious, including fatal (1/442; <1%), diarrhea or colitis occurred in 18% of patients receiving COPIKTRA 25 mg BID (N=442). Median time to onset of any grade diarrhea or colitis was 4 months (range: 1 day to 33 months), with 75% of cases occurring by 8 months. The median event duration was 0.5 months (range: 1 day to 29 months; 75th percentile: 1 month).

Advise patients to report any new or worsening diarrhea. For patients presenting with mild or moderate diarrhea (Grade 1-2) (i.e., up to 6 stools per day over baseline) or asymptomatic (Grade 1) colitis, initiate supportive care with antidiarrheal agents, continue COPIKTRA at the current dose, and monitor the patient at least weekly until the event resolves. If the diarrhea is unresponsive to antidiarrheal therapy, withhold COPIKTRA and initiate supportive therapy with enteric acting steroids (e.g., budesonide). Monitor the patient at least weekly. Upon resolution of the diarrhea, consider restarting COPIKTRA at a reduced dose.

For patients presenting with abdominal pain, stool with mucus or blood, change in bowel habits, peritoneal signs, or with severe diarrhea (Grade 3) (i.e., > 6 stools per day over baseline), withhold COPIKTRA and initiate supportive therapy with enteric acting steroids (e.g., budesonide) or systemic steroids. A diagnostic work-up to determine etiology, including colonoscopy, should be performed. Monitor at least weekly. Upon resolution of the diarrhea or colitis, restart COPIKTRA at a reduced dose. For recurrent Grade 3 diarrhea or recurrent colitis of any grade, discontinue COPIKTRA. Discontinue COPIKTRA for life-threatening diarrhea or colitis.

**Cutaneous Reactions:** Serious, including fatal (2/442; <1%), cutaneous reactions occurred in 5% of patients receiving COPIKTRA 25 mg BID (N=442). Fatal cases included drug reaction with eosinophilia and systemic symptoms (DRESS) and toxic epidermal necrolysis (TEN). Median time to onset of any grade cutaneous reaction was 3 months (range: 1 day to 29 months, 75th percentile: 6 months) with a median event duration of 1 month (range: 1 day to 37 months, 75th percentile: 2 months).

Presenting features for the serious events were primarily described as pruritic, erythematous, or maculo-papular. Less common presenting features include exanthem, desquamation, erythroderma, skin exfoliation, keratinocyte necrosis, and papular rash. Advise patients to report new or worsening cutaneous reactions. Review all concomitant medications and discontinue any medications potentially contributing to the event. For patients presenting with mild or moderate (Grade 1-2) cutaneous reactions, continue COPIKTRA at the current dose, initiate supportive care with emollients, antihistamines (for pruritus), or topical steroids, and monitor the patient closely. Withhold COPIKTRA for severe (Grade 3) cutaneous reaction until resolution. Initiate supportive care with steroids (topical or systemic) or antihistamines (for pruritus). Monitor at least weekly until resolved. Upon resolution of the event, restart COPIKTRA at a reduced dose. Discontinue COPIKTRA if severe cutaneous reaction does not improve, worsens, or recurs. For life-threatening cutaneous reactions, discontinue COPIKTRA. In patients with SJS, TEN, or DRESS of any grade, discontinue COPIKTRA.

**Pneumonitis:** Serious, including fatal (1/442; <1%), pneumonitis without an apparent infectious cause occurred in 5% of patients receiving COPIKTRA 25 mg BID (N=442). Median time to onset of any grade pneumonitis was 4 months (range: 9 days to 27 months), with 75% of cases occurring within 9 months. The median event duration was 1 month, with 75% of cases resolving by 2 months.

Withhold COPIKTRA in patients with new or progressive pulmonary signs and symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on a radiologic exam, or a decline by more than 5% in oxygen saturation, and evaluate for etiology. If the pneumonitis is infectious, patients may be restarted on COPIKTRA at the previous dose once the infection, pulmonary signs and symptoms resolve. For moderate non-infectious pneumonitis (Grade 2), treat with systemic corticosteroids and resume COPIKTRA at a reduced dose upon resolution. If non-infectious pneumonitis recurs or does not respond to steroid therapy, discontinue COPIKTRA. For severe or life-threatening non-infectious pneumonitis, discontinue COPIKTRA and treat with systemic steroids.

**Hepatotoxicity:** Grade 3 and 4 ALT and/or AST elevation developed in 8% and 2%, respectively, of patients receiving COPIKTRA 25 mg BID (N=442). Two percent of patients had both an ALT or AST > 3 X ULN and total bilirubin > 2 X ULN. Median time to onset of any grade transaminase elevation was 2 months (range: 3 days to 26 months), with a median event duration of 1 month (range: 1 day to 16 months).

Monitor hepatic function during treatment with COPIKTRA. For Grade 2 ALT/AST elevation (> 3 to 5 X ULN), maintain COPIKTRA dose and monitor at least weekly until return to < 3 X ULN. For Grade 3 ALT/AST elevation (> 5 to 20 X ULN), withhold COPIKTRA and monitor at least weekly until return to < 3 X ULN. Resume COPIKTRA at the same dose (first occurrence) or at a reduced dose for subsequent occurrences. For grade 4 ALT/AST elevation (> 20 X ULN), discontinue COPIKTRA.

**Neutropenia:** Grade 3 or 4 neutropenia occurred in 42% of patients receiving COPIKTRA 25 mg BID (N=442), with Grade 4 neutropenia occurring in 24% of all patients. Median time to onset of grade  $\geq 3$  neutropenia was 2 months (range: 3 days to 31 months), with 75% of cases occurring within 4 months.

Monitor neutrophil counts at least every 2 weeks for the first 2 months of COPIKTRA therapy, and at least weekly in patients with neutrophil counts < 1.0 Gi/L (Grade 3-4). Withhold COPIKTRA in patients presenting with neutrophil counts < 0.5 Gi/L (Grade 4). Monitor until ANC is > 0.5 Gi/L, then resume COPIKTRA at same dose for the first occurrence or at a reduced dose for subsequent occurrences.

**Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, COPIKTRA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Conduct pregnancy testing before initiating COPIKTRA treatment. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose.

## ADVERSE REACTIONS

### B-cell Malignancies Summary

Fatal adverse reactions within 30 days of the last dose occurred in 8% (36/442) of patients treated with COPIKTRA 25 mg BID. Serious adverse reactions were reported in 289 patients (65%). The most frequent serious adverse reactions that occurred were infection (31%), diarrhea or colitis (18%), pneumonia (17%), rash (5%), and pneumonitis (5%).

Adverse reactions resulted in treatment discontinuation in 156 patients (35%) most often due to diarrhea or colitis, infection, and rash. COPIKTRA was dose reduced in 104 patients (24%) due to adverse reactions, most often due to diarrhea or colitis and transaminase elevation. The most common adverse reactions

(reported in  $\geq 20\%$  of patients) were diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain and anemia.

**CLL/SLL:** Fatal adverse reactions within 30 days of the last dose occurred in 12% (19/158) of patients treated with COPIKTRA and in 4% (7/155) of patients treated with ofatumumab. Serious adverse reactions were reported in 73% (115/158) of patients treated with COPIKTRA and most often involved infection (38%; 60/158) and diarrhea or colitis (23%; 36/158). COPIKTRA was discontinued in 57 patients (36%), most often due to diarrhea or colitis, infection, and rash. COPIKTRA was dose reduced in 46 patients (29%) due to adverse reactions, most often due to diarrhea or colitis and rash. The most common adverse reactions with COPIKTRA (reported in  $\geq 20\%$  of patients) were diarrhea or colitis, neutropenia, pyrexia, upper respiratory tract infection, pneumonia, rash, fatigue, nausea, anemia and cough.

**FL:** Serious adverse reactions were reported in 58% of patients and most often involved diarrhea or colitis, pneumonia, renal insufficiency, rash, and sepsis. The most common adverse reactions ( $\geq 20\%$  of patients) were diarrhea or colitis, nausea, fatigue, musculoskeletal pain, rash, neutropenia, cough, anemia, pyrexia, headache, mucositis, abdominal pain, vomiting, transaminase elevation, and thrombocytopenia. Adverse reactions resulted in COPIKTRA discontinuation in 29% of patients, most often due to diarrhea or colitis and rash. COPIKTRA was dose reduced in 23% due to adverse reactions, most often due to transaminase elevation, diarrhea or colitis, lipase increased and infection.

## **DRUG INTERACTIONS**

- CYP3A Inducers: Coadministration with a strong CYP3A inducer may reduce COPIKTRA efficacy. Avoid coadministration with strong CYP3A4 inducers.
- CYP3A Inhibitors: Coadministration with a strong CYP3A inhibitor may increase the risk of COPIKTRA toxicities. Reduce COPIKTRA dose to 15 mg BID when coadministered with a strong CYP3A4 inhibitor.
- CYP3A Substrates: Coadministration of COPIKTRA with sensitive CYP3A4 substrates may increase the risk of toxicities of these drugs. Consider reducing the dose of the sensitive CYP3A4 substrate and monitor for signs of toxicities of the coadministered sensitive CYP3A substrate.

## **About Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are cancers that affect lymphocytes and are essentially the same disease, with the only difference being the location where the cancer primarily occurs. When most of the cancer cells are located in the bloodstream and the bone marrow, the disease is referred to as CLL, although the lymph nodes and spleen are often involved. When the cancer cells are located mostly in the lymph nodes, the disease is called SLL. The symptoms of CLL/SLL include a tender, swollen abdomen and feeling full even after eating only a small amount. Other symptoms can include fatigue, shortness of breath, anemia, bruising easily, night sweats, weight loss, and frequent infections. However, many patients with CLL/SLL will live for years without symptoms. There are approximately 200,000 patients in the US affected by CLL/SLL with nearly 20,000 new diagnoses this year alone. While there are therapies currently available, real-world data reveals that a significant number of patients either relapse following treatment, become refractory to current agents, or are unable to tolerate treatment, representing a significant medical need. The potential of additional oral agents, particularly as a monotherapy that can be used in the general community physician's armamentarium, may hold significant value in the treatment of patients with CLL/SLL.



## **About Follicular Lymphoma**

Follicular lymphoma (FL) is typically a slow-growing or indolent form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes, making it a B-cell lymphoma. This lymphoma subtype accounts for 20 to 30 percent of all NHL cases, with more than 140,000 people in the US with FL and more than 13,000 newly diagnosed patients this year. Common symptoms of FL include enlargement of the lymph nodes in the neck, underarms, abdomen, or groin, as well as fatigue, shortness of breath, night sweats, and weight loss. Often, patients with FL have no obvious symptoms of the disease at diagnosis. Follicular lymphoma is usually not considered to be curable, but more of a chronic disease, with patients living for many years with this form of lymphoma. The potential of additional oral agents, particularly as a monotherapy that can be used in the general community physician's armamentarium, may hold significant value in the treatment of patients with FL.

## **About COPIKTRA™ (duvelisib)**

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant B-cells. PI3K signaling may lead to the proliferation of malignant B-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment.<sup>2,3,4</sup> COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. COPIKTRA is also being developed by Verastem Oncology for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status, and is being investigated in combination with other agents through investigator-sponsored studies.<sup>5</sup> For more information on COPIKTRA, please visit [www.COPIKTRA.com](http://www.COPIKTRA.com). Information about duvelisib clinical trials can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **About Verastem Oncology**

Verastem Oncology (Nasdaq: VSTM) is a commercial biopharmaceutical company committed to the development and commercialization of medicines to improve the lives of patients diagnosed with cancer. We are driven by the strength, tenacity and courage of those battling cancer – single-minded in our resolve to deliver new therapies that not only keep cancer at bay, but improve the lives of patients diagnosed with cancer. Because for us, it's personal.

Our first FDA approved product is now available for the treatment of patients with certain types of indolent non-Hodgkin's lymphoma (iNHL). Our pipeline comprises product candidates that seek to treat cancer by modulating the local tumor microenvironment. For more information, please visit [www.verastem.com](http://www.verastem.com).

## **Forward looking statements notice**

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements regarding the development and activity of Verastem Oncology's lead product COPIKTRA, and Verastem Oncology's PI3K and FAK programs generally, its commercialization of COPIKTRA, the potential commercial success of COPIKTRA, the anticipated adoption of COPIKTRA by patients and physicians, the structure of its planned and pending clinical trials and the timeline and indications for clinical development, regulatory submissions and commercialization activities. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target,"

"potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include, among other things, uncertainties regarding the launch timeline and commercial success of COPIKTRA in the United States; uncertainties regarding physician and patient adoption of COPIKTRA, including those related to the safety and efficacy of COPIKTRA; the uncertainties inherent in research and development of COPIKTRA, such as negative or unexpected results of clinical trials; whether and when any applications for COPIKTRA may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities in any other jurisdictions may approve any such other applications that may be filed for COPIKTRA, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether COPIKTRA will be commercially successful in such jurisdictions; Verastem Oncology's ability to obtain, maintain and enforce patent and other intellectual property protection for COPIKTRA and its other product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of COPIKTRA; that regulatory authorities in the U.S. or other jurisdictions, if approved, could withdraw approval; whether preclinical testing of Verastem Oncology's product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for Verastem Oncology's product candidates is uncertain; the risk that third party payors (including government agencies) will not reimburse for COPIKTRA; that there may be competitive developments affecting Verastem Oncology's product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that COPIKTRA or Verastem Oncology's other product candidates will cause unexpected safety events, experience manufacturing or supply interruptions or failures, or result in unmanageable safety profiles as compared to their levels of efficacy; that COPIKTRA will be ineffective at treating patients with lymphoid malignancies; that Verastem Oncology will be unable to successfully initiate or complete the clinical development and eventual commercialization of its product candidates; that the development and commercialization of Verastem Oncology's product candidates will take longer or cost more than planned; that Verastem Oncology may not have sufficient cash to fund its contemplated operations; that Verastem Oncology or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreement; that Verastem Oncology may be unable to make additional draws under its debt facility or obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that Verastem Oncology will not pursue or submit regulatory filings for its product candidates, including for duvelisib in patients with CLL/SLL or FL in other jurisdictions; and that Verastem Oncology's product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients.

Other risks and uncertainties include those identified under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission (SEC) on November 7, 2018, its Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the SEC on March 13, 2018 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology's views as of the date hereof, and the Company does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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<sup>1</sup> Decision Resources Group 2018 Estimates.<sup>2</sup> Winkler D.G., Faia K.L., DiNitto J.P. et al. PI3K-delta and PI3K-gamma inhibition by IPI-145 abrogates immune responses and suppresses activity in autoimmune and inflammatory disease models. *Chem Biol* 2013; 20:1-11.<sup>3</sup> Reif K et al. Cutting Edge: Differential Roles for Phosphoinositide 3 kinases, p110-gamma and p110-delta, in lymphocyte chemotaxis and homing. *J Immunol* 2004;173:2236-2240.<sup>4</sup> Schmid M et al. Receptor Tyrosine Kinases and TLR/IL1Rs Unexpectedly activate myeloid cell PI3K, a single convergent point promoting tumor inflammation and progression. *Cancer Cell* 2011;19:715-727.<sup>5</sup> www.clinicaltrials.gov, NCT03372057.

**Verastem, Inc.**  
**Condensed Consolidated Balance Sheets**  
(in thousands)

	<u>September 30,</u> <u>2018</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2017</u>
Cash, cash equivalents and investments	\$ 145,639	\$ 86,672
Accounts receivable, net	10,562	—
Inventory	131	—
Prepaid expenses and other current assets	2,397	1,115
Property and equipment, net	1,210	861
Intangible assets, net	21,969	—
Other assets	1,247	1,143
<b>Total assets</b>	<b><u>\$ 183,155</u></b>	<b><u>\$ 89,791</u></b>
Accounts payable, accrued expenses and other current liabilities	\$ 53,441	\$ 17,128
Long-term debt	21,535	14,828
Other liabilities	566	151
Stockholders' equity	107,613	57,684
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 183,155</u></b>	<b><u>\$ 89,791</u></b>

**Verastem, Inc.**  
**Unaudited Condensed Consolidated Statements of Operations**  
(in thousands, except per share amounts)

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>Revenue:</b>				
License revenue	\$ 15,000	\$ —	\$ 25,000	\$ —
Product revenue, net	508	—	508	—
<b>Total revenue</b>	<b>15,508</b>	<b>—</b>	<b>25,508</b>	<b>—</b>
<b>Operating expenses:</b>				
Costs of revenues, excluding amortization of acquired intangible assets	49	—	49	—
Research and development	11,571	17,743	34,886	35,170
Selling, general and administrative	25,426	5,394	51,066	14,582
Amortization of acquired intangible assets	31	—	31	—
<b>Total operating expenses</b>	<b>37,077</b>	<b>23,137</b>	<b>86,032</b>	<b>49,752</b>
<b>Loss from operations</b>	<b>(21,569)</b>	<b>(23,137)</b>	<b>(60,524)</b>	<b>(49,752)</b>
Interest income	763	121	1,297	416
Interest expense	(862)	(110)	(1,858)	(231)
<b>Net loss</b>	<b>\$ (21,668)</b>	<b>\$ (23,126)</b>	<b>\$ (61,085)</b>	<b>\$ (49,567)</b>
<b>Net loss per share—basic and diluted</b>	<b>\$ (0.29)</b>	<b>\$ (0.61)</b>	<b>\$ (0.99)</b>	<b>\$ (1.33)</b>
<b>Weighted-average number of common shares used in net loss per share-basic and diluted</b>	<b>73,644</b>	<b>37,630</b>	<b>61,995</b>	<b>37,207</b>