

**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, 2019**

**OR**

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

**For the transition period from            to**

**Commission file number: 001-35403**

**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)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	VSTM	The Nasdaq Global Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 October 30, 2019, there were 74,349,659 shares of Common Stock 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, 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 and uncertainties, among other things, regarding: the commercial success of COPIKTRA in the United States; 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; the fact 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; that there is substantial doubt about our ability to continue as a going concern; that third-party payors (including government agencies) may 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, Sanofi, CSPC Pharmaceutical Group, Yakult Honsha Co., Ltd., or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreements; 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 in our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission (SEC) on March 12, 2019, and in any subsequent filing 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, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 103,320	\$ 129,867
Short-term investments	56,908	119,786
Accounts receivable, net	2,203	306
Inventory	478	327
Prepaid expenses and other current assets	4,049	2,973
Total current assets	166,958	253,259
Property and equipment, net	1,041	1,369
Right-of-use asset, net	3,146	—
Intangible assets, net	20,400	21,577
Other assets	1,055	1,031
Total assets	<u>\$ 192,600</u>	<u>\$ 277,236</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 8,842	\$ 10,253
Accrued expenses	21,289	21,108
Lease liability, short-term	379	—
Current portion of long-term debt	—	5,716
Total current liabilities	30,510	37,077
Non-current liabilities:		
Long-term debt	34,882	19,506
Convertible senior notes	101,249	95,231
Lease liability, long-term	3,572	—
Other non-current liabilities	870	1,123
Total liabilities	171,083	152,937
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 shares authorized, no shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.0001 par value; 200,000 shares authorized, 74,314 and 73,806 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	7	7
Additional paid-in capital	507,494	499,741
Accumulated other comprehensive income	27	127
Accumulated deficit	(486,011)	(375,576)
Total stockholders' equity	21,517	124,299
Total liabilities and stockholders' equity	<u>\$ 192,600</u>	<u>\$ 277,236</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>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue:				
Product revenue, net	\$ 4,032	\$ 508	\$ 8,722	\$ 508
License and collaboration revenue	5,000	15,000	5,118	25,000
Total revenue	<u>9,032</u>	<u>15,508</u>	<u>13,840</u>	<u>25,508</u>
Operating expenses:				
Cost of sales - product	371	49	906	49
Cost of sales - intangible amortization	392	31	1,177	31
Research and development	12,219	11,571	33,322	34,886
Selling, general and administrative	22,153	25,426	77,484	51,066
Total operating expenses	<u>35,135</u>	<u>37,077</u>	<u>112,889</u>	<u>86,032</u>
Loss from operations	(26,103)	(21,569)	(99,049)	(60,524)
Interest income	1,005	763	3,770	1,297
Interest expense	(5,041)	(862)	(15,156)	(1,858)
Net loss	<u>\$ (30,139)</u>	<u>\$ (21,668)</u>	<u>\$ (110,435)</u>	<u>\$ (61,085)</u>
Net loss per share—basic and diluted	\$ (0.41)	\$ (0.29)	\$ (1.49)	\$ (0.99)
Weighted average common shares outstanding used in computing net loss per share—basic and diluted	74,228	73,644	73,988	61,995
Net loss	\$ (30,139)	\$ (21,668)	\$ (110,435)	\$ (61,085)
Unrealized (loss) gain on available-for-sale securities	(59)	(2)	(100)	4
Comprehensive loss	<u>\$ (30,198)</u>	<u>\$ (21,670)</u>	<u>\$ (110,535)</u>	<u>\$ (61,081)</u>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(unaudited)**  
**(in thousands, except share data)**

	Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2018</b>	<b>73,806,344</b>	<b>\$ 7</b>	<b>\$ 499,741</b>	<b>\$ 127</b>	<b>\$ (375,576)</b>	<b>\$ 124,299</b>
Net loss	—	—	—	—	(38,102)	(38,102)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(17)	—	(17)
Issuance of common stock resulting from exercise of stock options	46,803	—	75	—	—	75
Issuance of common stock resulting from vesting of restricted stock units and payment of tax withholdings	23,792	—	(43)	—	—	(43)
Stock-based compensation expense	—	—	2,248	—	—	2,248
<b>Balance at March 31, 2019</b>	<b>73,876,939</b>	<b>\$ 7</b>	<b>\$ 502,021</b>	<b>\$ 110</b>	<b>\$ (413,678)</b>	<b>\$ 88,460</b>
Net loss	—	—	—	—	(42,194)	(42,194)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(24)	—	(24)
Stock-based compensation expense	—	—	3,065	—	—	3,065
<b>Balance at June 30, 2019</b>	<b>73,876,939</b>	<b>\$ 7</b>	<b>\$ 505,086</b>	<b>\$ 86</b>	<b>\$ (455,872)</b>	<b>\$ 49,307</b>
Net loss	—	—	—	—	(30,139)	(30,139)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(59)	—	(59)
Issuance of common stock under Employee Stock Purchase Plan	341,701	—	439	—	—	439
Issuance of common stock resulting from vesting of restricted stock units	50,000	—	—	—	—	—
Issuance of common stock resulting from exercise of stock options	45,104	—	54	—	—	54
Stock-based compensation expense	—	—	1,915	—	—	1,915
<b>Balance at September 30, 2019</b>	<b>74,313,744</b>	<b>\$ 7</b>	<b>\$ 507,494</b>	<b>\$ 27</b>	<b>\$ (486,011)</b>	<b>\$ 21,517</b>
<b>Balance at December 31, 2017</b>	<b>50,800,908</b>	<b>\$ 5</b>	<b>\$ 360,823</b>	<b>\$ (2)</b>	<b>\$ (303,142)</b>	<b>\$ 57,684</b>
Net loss	—	—	—	—	(21,050)	(21,050)
Unrealized gain on available-for-sale marketable securities	—	—	—	2	—	2
Issuance of common stock resulting from at-the-market transactions, net of issuance costs of \$0	167,065	—	588	—	—	588
Stock-based compensation expense	—	—	1,328	—	—	1,328
<b>Balance at March 31, 2018</b>	<b>50,967,973</b>	<b>\$ 5</b>	<b>\$ 362,739</b>	<b>\$ —</b>	<b>\$ (324,192)</b>	<b>\$ 38,552</b>
Net loss	—	—	—	—	(18,367)	(18,367)
Unrealized gain on available-for-sale marketable securities	—	—	—	4	—	4
Issuance of common stock resulting from at-the-market transactions, net of issuance costs of \$0	6,314,410	1	23,687	—	—	23,688
Issuance of common stock resulting from follow-on offering, net of issuance costs of \$361	16,111,110	1	81,188	—	—	81,189
Issuance of common stock resulting from exercise of stock options	186,206	—	261	—	—	261
Stock-based compensation expense	—	—	1,540	—	—	1,540
<b>Balance at June 30, 2018</b>	<b>73,579,699</b>	<b>\$ 7</b>	<b>\$ 469,415</b>	<b>\$ 4</b>	<b>\$ (342,559)</b>	<b>\$ 126,867</b>
Net loss	—	—	—	—	(21,668)	(21,668)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(2)	—	(2)
Issuance of common stock resulting from exercise of stock options	123,724	—	376	—	—	376
Stock-based compensation expense	—	—	2,040	—	—	2,040
<b>Balance at September 30, 2018</b>	<b>73,703,423</b>	<b>\$ 7</b>	<b>\$ 471,831</b>	<b>\$ 2</b>	<b>\$ (364,227)</b>	<b>\$ 107,613</b>

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Operating activities</b>		
Net loss	\$ (110,435)	\$ (61,085)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	335	892
Amortization of acquired intangible asset	1,177	31
Amortization of right-of-use asset and lease liability	154	—
Stock-based compensation expense	7,228	4,908
Amortization of deferred financing costs, debt discounts and premiums and discounts on available-for-sale marketable securities	4,426	335
Gain on sale of fixed assets	—	(79)
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,897)	(10,562)
Inventory	(151)	(131)
Prepaid expenses, other current assets and other assets	(1,100)	(1,145)
Accounts payable	(1,411)	2,108
Accrued expenses and other liabilities	7	9,401
Other long-term liabilities	370	—
Net cash used in operating activities	(101,297)	(55,327)
<b>Investing activities</b>		
Purchases of property and equipment	(7)	(1,244)
Sales of property and equipment	—	82
Purchases of investments	(73,186)	(14,912)
Maturities of investments	137,680	4,500
Net cash provided by (used in) investing activities	64,487	(11,574)
<b>Financing activities</b>		
Proceeds from long-term debt, net of issuance costs	9,694	9,900
Proceeds from the exercise of stock options and employee stock purchase program	569	637
Proceeds from the issuance of common stock, net	—	105,156
Net cash provided by financing activities	10,263	115,693
(Decrease) increase in cash, cash equivalents and restricted cash	(26,547)	48,792
Cash, cash equivalents and restricted cash at beginning of period	130,608	82,338
Cash, cash equivalents and restricted cash at end of period	<u>\$ 104,061</u>	<u>\$ 131,130</u>
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Acquired intangible assets included in intangible assets, net and accrued expenses	—	\$ 22,000
Common stock issuance costs included in accounts payable and accrued expenses	<u>15</u>	<u>\$ 15</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 certain hematologic cancers including chronic lymphocytic leukemia/ 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, colorectal cancer, head and neck 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 do not adequately respond to currently available therapies.

The consolidated financial statements include the accounts of Verastem Securities Company and Verastem Europe GmbH, wholly-owned subsidiaries of the Company. All financial information presented has been consolidated and includes the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

As of September 30, 2019, the Company had cash, cash equivalents and short-term investments of \$160.2 million and accumulated deficit of \$486.0 million. The Company is subject to the risks associated with 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 commercial success of COPIKTRA, or any of the Company's investigational product candidates following receipt of regulatory approval, protection of proprietary technology and the continued ability to obtain adequate financing to fund the Company's future operations. 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 as it continues the commercialization of COPIKTRA and the research and development of its product candidates. The Company believes that it may have sufficient funds to meet its obligations within the next twelve months from the date of issuance of these condensed consolidated financial statements. However, COPIKTRA is the Company's only approved product and the Company's business currently depends heavily on its successful commercialization. Successful commercialization of an approved product is an expensive and uncertain process. These uncertainties and risk factors raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that the financial statements are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of Accounting Standards Codification (ASC) 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months from the date of the 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 under the assumption that the Company will continue as a going concern for the next twelve months. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements, or any adjustments that might result from the uncertainty related to the Company's ability to continue as a going concern. 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, 2019 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2019. 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, 2018, as filed with the Securities and Exchange Commission (SEC) on March 12, 2019.

### **Significant Accounting Policies**

The significant accounting policies identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 that require the Company to make estimates and assumptions include accrued research and development expenses, stock-based compensation, revenue recognition, collaborative arrangements, accounts receivable, inventory and intangible assets. During the nine months ended September 30, 2019, there were no material changes to the significant accounting policies, except for the adoption of Accounting Standards Codification (ASC) 842, *Leases*, issued by the Financial Accounting Standards Board (the FASB), which is detailed below.

#### ***Leases***

Effective January 1, 2019, the Company adopted ASC 842. This standard 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.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances within the arrangement. A lease is identified where an arrangement conveys the right to control the use of identified property, plant, and equipment for a period of time in exchange for consideration. Leases which are identified within the scope of ASC 842 and which have a term greater than one year are recognized on the Company's condensed consolidated balance sheets as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize leases with terms of one year or less on its condensed consolidated balance sheets. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates to calculate the present value of lease payments. Incremental borrowing rates are the rates the Company incurs to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with ASC 842, components of a lease are split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the condensed consolidated balance sheets and amortized on a straight-line basis as lease expense.

## **Revenue Recognition**

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services in accordance with ASC 606 *Revenue from Contracts with Customers*. To determine revenue recognition for contracts with its customers, the Company 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. 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, 2019, 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 for the three and nine months ended September 30, 2019.

**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 for the three and nine months ended September 30, 2019.

**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.

Subject to certain limitations, the Company's 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.

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, 2019.

*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 (i) licenses, or options to obtain licenses, to the Company's intellectual property, (ii) research and development activities performed for the collaboration partner, (iii) participation on joint steering committees, and (iv) 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 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.

**Concentrations of credit risk and off-balance sheet risk**

Cash, cash equivalents, short-term investments and trade accounts receivable are financial instruments that potentially subject the Company to concentrations of credit risk. The Company mitigates this risk by maintaining its cash and cash equivalents and investments with high quality, accredited financial institutions. The management of the Company's investments is not discretionary on the part of these financial institutions. As of September 30, 2019, the Company's cash, cash equivalents and short-term investments were deposited at two financial institutions and it has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

As of September 30, 2019, there were two customers that cumulatively made up more than 60% of the Company's trade accounts receivable balance. The Company assesses the creditworthiness of all its customers and sets and reassesses customer credit limits to ensure collectability of any trade accounts receivable balances are assured.

For the three and nine months ended September 30, 2019, there were five customers who each individually accounted for greater than 10% of the Company's total revenues, respectively.

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

In November 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which makes targeted improvements for collaborative arrangements to clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account, adds unit of account guidance in Topic 808 to align with guidance in Topic 606, and clarifies presentation of certain revenues with a collaborative arrangement participant which are not directly related to a third party. ASU 2018-18 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 Financial Accounting Standards Board (FASB) issued Accounting Standard 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 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 will replace the incurred loss impairment methodology under current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The standard will be 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.

### **Recently Adopted Accounting Standards Updates**

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 was 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 adopted this standard prospectively effective January 1, 2019. The adoption of this ASU did not have an effect on the Company's condensed consolidated financial statements or 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 (ASC 842)*. 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 adopted this standard using the optional transition method effective January 1, 2019. Upon adoption of this standard, the Company recognized a lease liability and a corresponding right-of use asset of \$4.0 million and \$3.4 million, respectively, and derecognized a deferred rent liability and a corresponding lease incentive obligation of \$0.4 million and \$0.2 million, respectively. The Company did not record any cumulative effect adjustment to accumulated deficit as a result of adopting this standard. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

### 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, 2019	December 31, 2018
Cash and cash equivalents	\$ 103,320	\$ 129,867
Restricted cash	741	741
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 104,061</b>	<b>\$ 130,608</b>

Amounts included in restricted cash as of September 30, 2019 and December 31, 2018 represent cash received pursuant to a Research Funding Agreement with Leukemia & Lymphoma Society, Inc. (LLS) (the “LLS Research Funding Agreement”), which cash is restricted for future expenditures for specific R&D studies in the amount of approximately \$0.5 million, respectively. Restricted cash also includes cash held to collateralize outstanding letters of credit provided as a security deposit for the Company’s office space located in Needham, Massachusetts, in the amount of approximately \$0.2 million, respectively. Restricted cash related to the LLS Research Funding Agreement is included in prepaid and other current assets, while restricted cash for letters of credit are included in other assets on the consolidated balance sheets.

### 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, 2019			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 102,073	\$ 94,324	\$ 7,749	\$ —
Short-term investments	56,908	—	56,908	—
<b>Total financial assets</b>	<b>\$ 158,981</b>	<b>\$ 94,324</b>	<b>\$ 64,657</b>	<b>\$ —</b>

Description	December 31, 2018			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 127,689	\$ 60,092	\$ 67,597	\$ —
Short-term investments	119,786	—	119,786	—
<b>Total financial assets</b>	<b>\$ 247,475</b>	<b>\$ 60,092</b>	<b>\$ 187,383</b>	<b>\$ —</b>

The Company's cash equivalents and short-term investments consist of U.S. Government money market funds, corporate bonds and commercial paper of publicly traded companies. The 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, 2019 and December 31, 2018.

**Fair Value of Financial Instruments**

The fair value of the Company's long-term debt is determined using a discounted cash flow analysis with 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, 2019 and December 31, 2018 was approximately \$34.9 million and \$25.2 million, respectively. At September 30, 2019, the Company estimates that the fair value of its long-term debt, including the current portion, was approximately \$37.1 million. The fair value of the Company's long-term debt was determined using Level 3 inputs.

The fair value of the Company's 5.00% Convertible Senior Notes due 2048 (the Notes) as of September 30, 2019 was approximately \$64.1 million, which differs from the carrying value of the Notes. The fair value of the Notes was determined using Level 2 inputs.



## 5. Investments

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

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market accounts	\$ 95,571	\$ —	\$ —	\$ 95,571
Corporate bonds and commercial paper (due within 90 days)	7,749	—	—	7,749
<b>Total cash and cash equivalents</b>	<b>\$ 103,320</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 103,320</b>
Investments:				
Corporate bonds and commercial paper (due within 1 year)	\$ 56,881	\$ 27	\$ —	\$ 56,908
<b>Total investments</b>	<b>\$ 56,881</b>	<b>\$ 27</b>	<b>\$ —</b>	<b>\$ 56,908</b>
<b>Total cash, cash equivalents and investments</b>	<b>\$ 160,201</b>	<b>\$ 27</b>	<b>\$ —</b>	<b>\$ 160,228</b>

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash and money market accounts	\$ 62,270	\$ —	\$ —	\$ 62,270
Corporate bonds and commercial paper (due within 90 days)	67,590	\$ 8	\$ (1)	\$ 67,597
<b>Total cash and cash equivalents</b>	<b>\$ 129,860</b>	<b>\$ 8</b>	<b>\$ (1)</b>	<b>\$ 129,867</b>
Investments:				
Corporate bonds and commercial paper (due within 1 year)	\$ 119,666	\$ 132	\$ (12)	\$ 119,786
<b>Total investments</b>	<b>\$ 119,666</b>	<b>\$ 132</b>	<b>\$ (12)</b>	<b>\$ 119,786</b>
<b>Total cash, cash equivalents and investments</b>	<b>\$ 249,526</b>	<b>\$ 140</b>	<b>\$ (13)</b>	<b>\$ 249,653</b>

There were no realized gains or losses on investments for the three and nine months ended September 30, 2019 or 2018, respectively. There were zero and fourteen investments in an unrealized loss position as of September 30, 2019 and December 31, 2018, respectively. None of these investments had been in an unrealized loss position for more than 12 months as of September 30, 2019 and December 31, 2018, respectively. The fair value of these securities as of September 30, 2019 and December 31, 2018 was \$0 and \$46.9 million, respectively, and the aggregate unrealized loss was immaterial. The Company considered the decline in the market value for these securities 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 securities 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, 2019 and December 31, 2018, 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, 2019	December 31, 2018
Raw materials	\$ —	\$ —
Work in process	342	63
Finished goods	136	264
<b>Total inventories</b>	<b>\$ 478</b>	<b>\$ 327</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, 2019	Estimated useful life
Acquired and in-licensed rights	\$ 22,000	14 years
Less: accumulated amortization	(1,600)	
<b>Total intangible assets, net</b>	<b>\$ 20,400</b>	

Acquired and in-licensed rights as of September 30, 2019, 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 the milestone payment of \$22.0 million to Infinity in November 2018.

The Company recorded approximately \$0.4 million and \$1.2 million in amortization expense related to finite-lived intangible assets during the three and nine months ended September 30, 2019 using the straight-line methodology. Estimated future amortization expense for finite-lived intangible assets as of September 30, 2019 is approximately \$0.4 million for the remainder of 2019 and approximately \$1.6 million per year thereafter.

## 8. Accrued expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Compensation and related benefits	5,444	8,749
Contract research organization costs	6,849	6,682
Commercialization costs	2,425	1,979
Interest	3,410	1,786
Consulting fees	1,948	494
Professional fees	624	482
Other	589	936
<b>Total accrued expenses</b>	<b>\$ 21,289</b>	<b>\$ 21,108</b>

## 9. Product revenue reserves and allowances

As of September 30, 2019, 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, 2019 (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, 2018	\$ 29	\$ 88	\$ 157	\$ 2	\$ 276
Provision related to sales in the current year	358	902	364	69	1,693
Adjustments related to prior period sales	—	—	(77)	—	(77)
Credits and payments made	(265)	(709)	(227)	—	(1,201)
<b>Ending balance at September 30, 2019</b>	<b>\$ 122</b>	<b>\$ 281</b>	<b>\$ 217</b>	<b>\$ 71</b>	<b>\$ 691</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.

## 10. Leases

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 \$0.7 million, which increases during the lease term to \$1.1 million for the last twelve-month period.

The Company has accounted for its Needham, Massachusetts office space as an operating lease. The Company's lease contains an option to renew and extend the lease terms and an option to terminate the lease prior to the expiration date. The Company has not included the lease extension or the termination options within the right-of-use asset and lease liability on the condensed consolidated balance sheets as neither option is reasonably certain to be exercised. The Company's lease includes variable non-lease components (e.g., common area maintenance, maintenance, consumables, etc.) that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. The Company does not have any other operating or finance leases.

In calculating the present value of future lease payments, the Company has elected to utilize its incremental borrowing rate based on the remaining lease term at the date of adoption of ASC 842. The Company has elected to account for lease components and associated non-lease components as a single lease component and has allocated all of the contract consideration to the lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied.

As of September 30, 2019, a right-of-use asset of \$3.1 million and lease liability of \$4.0 million are reflected on the condensed consolidated balance sheets. The elements of lease expense were as follows (dollar amounts in thousands):

	Three months ended September 30, 2019	Nine months ended September 30, 2019
<b>Lease Expense</b>		
Operating lease expense	\$ 222	\$ 666
<b>Total Lease Expense</b>	<b>\$ 222</b>	<b>\$ 666</b>
<b>Other Information - Operating Leases</b>		
Operating cash flows paid for amounts included in measurement of lease liabilities	\$ 180	\$ 512
		<b>September 30, 2019</b>
<b>Other Balance Sheet Information - Operating Leases</b>		
Weighted average remaining lease term (in years)		5.7
Weighted average discount rate		14.60%
<b>Maturity Analysis</b>		
Remainder of 2019	\$	204
2020		971
2021		1,020
2022		1,041
2023		1,062
Thereafter		1,538
<b>Total</b>	<b>\$</b>	<b>5,836</b>
Less: Present value discount		(1,885)
<b>Lease Liability</b>	<b>\$</b>	<b>3,951</b>

The Company adopted ASU 2016-02 effective January 1, 2019 using the optional transition method permitted under ASU 2018-11. Accordingly, periods presented prior to January 1, 2019 were not restated to reflect the accounting principles adopted under ASU 2016-02. Prior to adoption, the Company recorded rent expense from its Needham office on a straight-line basis over the term of the lease with the deferred rent obligation included in accrued expenses (current portion) and other liabilities (noncurrent portion) in the condensed consolidated balance sheet as of December 31, 2018. The Company amortized any leasehold improvements over the lesser of the useful life of those improvements or the life of the lease. For the three and nine months ended September 30, 2018, the Company recorded rent expense of \$0.2 and \$0.6 million.

At December 31, 2018, future minimum lease payments under non-cancelable leases under ASC 840 were as follows (in thousands):

2019	\$ 716
2020	971
2021	1,020
2022	1,041
2023	1,062
Thereafter	1,538
<b>Total</b>	<b>\$ 6,348</b>

## 11. Long-term debt

On March 21, 2017, the Company entered into a term loan facility of up to \$25.0 million with Hercules Capital, Inc. (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, March 6, 2018 and October 11, 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 Amended Term Loan), pursuant to certain conditions of funding. On April 23, 2019 (the Amendment Date), the Company entered into the Fourth Amendment (the Amendment) to the Loan and Security Agreement with Hercules. The Amendment amends the Amended Loan Agreement (together with the Amendment, the 2019 Term Loan Agreement).

Per the terms of the Amendment, the Company may borrow up to an aggregate of \$75.0 million, of which \$35.0 million was outstanding immediately as of the Amendment Date (2019 Term A Loan) as a result of the existing outstanding principal of term loans of \$25.0 million under the Amended Loan Agreement being converted into the 2019 Term A Loan, and an additional \$10.0 million being drawn on the Amendment Date. The remaining \$40.0 million of borrowing capacity may be drawn in multiple tranches comprised of (i) a term loan in an amount of up to \$15.0 million upon the Company generating cumulative net product revenues (as defined in the 2019 Term Loan Agreement) of either (a) \$37.5 million on or before April 30, 2020 or (b) \$50.0 million on or before June 30, 2020 (2019 Term B Loan), and (ii) a term loan in an amount of up to \$25.0 million available through December 31, 2021, subject to Hercules' approval and the satisfaction of certain other conditions specified in the 2019 Term Loan Agreement (the 2019 Term C Loan, and together with the 2019 Term A Loan and 2019 Term B Loan, the 2019 Term Loan).

The 2019 Term Loan will mature on December 1, 2022 (2019 Term Loan Maturity Date). Each advance accrues interest at a floating per annum rate equal to the greater of (a) 9.75% or (b) the lesser of (i) 12.00% and (ii) the sum of (x) 9.75% plus (y) (A) the prime rate minus (B) 5.50%. In addition, the Company is required to make a final payment equal to 5.25% of the aggregate original principal balance of all advances upon the earliest to occur (a) 2019 Term Loan Maturity Date, (b) prepayment of the debt or (c) the date the 2019 Term Loan becomes due and payable. The 2019 Term Loan provides for interest-only payments until April 1, 2021, which may be extended to December 1, 2021 pursuant to the Company generating \$40.0 million in net product revenue on a trailing six-month basis on or prior to December 31, 2020 provided that no event of default has occurred. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates). As such, all outstanding balances related to the Amended Term Loan have been classified as long-term debt on the condensed consolidated Balance Sheet as of September 30, 2019.

The 2019 Term Loan is secured by a lien on substantially all of the assets of the Company, other than intellectual property and contains customary covenants and representations, including a liquidity covenant, minimum net revenue covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

On the Amendment Date, the Company was required to pay any outstanding accrued interest as well as the final payment fee equal to 4.5% on the outstanding principal balance of the Amended Term Loan, or \$1.1 million on the existing term loans. No prepayment charges were due as a result of executing the Amendment or conversion of the existing term loans into 2019 Term A Loans.

As of September 30, 2019, the Company has assessed all terms and features of the 2019 Term 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 2019 Term Loan Agreement, including put and call features. The Company determined that all features of the 2019 Term 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, 2019.

The future principal payments under the 2019 Term Loan are as follows as of September 30, 2019 (in thousands):

2021	\$ 14,234
2022	20,766
<b>Total principal payments</b>	<b>\$ 35,000</b>

## 12. Convertible Senior Notes

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). 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, 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. 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 Indenture includes customary covenants and sets forth certain events of default after which the Notes may be declared immediately due and payable and sets 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.

The Company assessed all terms and features of the Notes in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the Notes, including the conversion, put and call features. The conversion feature was initially bifurcated as an embedded derivative but subsequently qualified for a scope exception to derivative accounting upon the Company's stockholders approving an increase in the number of authorized shares of Common Stock. The Company determined that all other features of the Notes were clearly and closely associated with the 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, 2019.

### 13. Stock-based compensation

#### Stock options

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2019 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, 2018	12,522,867	\$ 5.42	7.8	\$ 6,909
Granted	5,804,840	\$ 2.42		
Exercised	(91,907)	\$ 1.41		
Forfeited/cancelled	(1,742,110)	\$ 4.80		
Outstanding at September 30, 2019	16,493,690	\$ 4.46	7.3	\$ 13
Vested at September 30, 2019	7,590,075	\$ 5.52	5.5	\$ 9
Vested and expected to vest at September 30, 2019(1)	15,840,690	\$ 4.49	7.3	\$ 13

(1) This represents the number of vested options as of September 30, 2019, plus the number of unvested options expected to vest as of September 30, 2019.

The fair value of each stock option granted during the nine months ended September 30, 2019 and 2018 was estimated on the grant date using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Nine months ended September 30,	
	2019	2018
Risk-free interest rate	2.10 %	2.63 %
Volatility	86 %	81 %
Dividend yield	—	—
Expected term (years)	5.8	6.0

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 a number of the performance conditions are considered probable of achievement as of September 30, 2018, and as a result recognized approximately \$0.2 million and \$0.7 million of stock-based compensation expense during the three and nine months ended September 30, 2018 related to awards that vest upon the achievement of performance conditions. The Company recognized less than \$0.1 million of stock-based compensation during the three and nine months ended September 30, 2019 related to awards that vest upon the achievement of performance conditions.

At September 30, 2019, there was \$16.8 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 2.93 years.

#### Restricted stock units (RSUs)

The Company awards RSUs to employees under its Amended and Restated 2012 Incentive Plan and its inducement award program. 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, (ii) 100 percent on the first anniversary of the vesting commencement date, or (iii) thirty three and one-third percent (33 1/3%) on the first anniversary of the vesting commencement date and as to an additional eight and two-thirds percent (8.33%) at the end of each successive three-month period thereafter, 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, 2019 is as follows:

	Shares	Weighted- average grant date fair value per share
Outstanding at December 31, 2018	306,750	\$ 5.24
Granted	798,904	\$ 2.57
Vested	(141,439)	\$ 6.93
Forfeited/cancelled	(147,256)	\$ 4.27
Outstanding at September 30, 2019	<u>816,959</u>	<u>\$ 2.54</u>

At September 30, 2019, there was approximately \$1.7 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 2.91 years.

#### **Employee stock purchase plan**

At the Special Meeting of Stockholders, held on December 18, 2018, the stockholders approved the 2018 Employee Stock Purchase Plan (2018 ESPP). On June 21, 2019, the board of directors of the Company amended and restated the 2018 ESPP, to account for certain non-material changes to the plan's administration (the Amended and Restated 2018 ESPP). The Amended and Restated 2018 ESPP provides eligible employees with the opportunity, through regular payroll deductions, to purchase shares of the Company's common stock at 85% of the lesser of the fair market value of the common stock (a) on the date the option is granted, which is the first day of the purchase period, and (b) on the exercise date, which is the last business day of the purchase period. The Amended and Restated 2018 ESPP generally allows for two six-month purchase periods per year beginning in January and July, or such other periods as determined by the compensation committee of our board of directors. The Company has reserved 2,000,000 shares of common stock for the administration of the Amended and Restated 2018 ESPP. The fair value of shares expected to be purchased under the Amended and Restated 2018 ESPP was calculated using the Black-Scholes model with the following assumptions:

	<u>Six Months ended June 30,</u> <u>2019</u>	<u>Three Months ended September 30,</u> <u>2019</u>
Risk-free interest rate	2.46 %	2.10 %
Volatility	79 %	95 %
Dividend yield	—	—
Expected term (years)	0.4	0.5

For the three and nine months ended September 30, 2019, the Company has recognized \$0.1 million and \$0.4 million of stock-based compensation under the Amended and Restated 2018 ESPP. During the three months ended September 30, 2019, the Company issued 341,701 shares of common stock for proceeds of \$0.4 million under the Amended and Restated 2018 ESPP.

#### **14. Net loss per share**

Basic 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. Diluted net loss per common share is calculated by increasing the denominator by the weighted-average number of additional shares that could have been outstanding from securities convertible into common stock, such as stock options and restricted stock units (using the "treasury stock" method), and the Notes (using the "if-converted" method), unless their effect on net loss per share is antidilutive.

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>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Outstanding stock options	16,493,690	12,915,463	16,493,690	12,915,463
Outstanding restricted stock units	816,959	316,875	816,959	316,875
Convertible senior notes	20,936,548	—	20,936,548	—
<b>Total potentially dilutive securities</b>	<b>38,247,197</b>	<b>13,232,338</b>	<b>38,247,197</b>	<b>13,232,338</b>

## 15. License and collaboration agreements

### *Sanofi*

On July 25, 2019, the Company entered into a license and collaboration agreement with Sanofi (the Sanofi Agreement), under which the Company granted exclusive rights to Sanofi to develop and commercialize products containing duvelisib in Russia, the Commonwealth of Independent States (CIS), Turkey, the Middle East and Africa (collectively the “Sanofi Territory”) for the treatment, prevention, palliation or diagnosis of any oncology indication in humans or animals.

Under the terms of the Sanofi Agreement, Sanofi received the exclusive right to develop and commercialize products containing duvelisib in the Sanofi Territory under mutually agreed upon development and commercialization plans at Sanofi’s own cost and expense. In addition, Sanofi received certain limited manufacturing rights in the event the Company is unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to Sanofi during the term of the Sanofi Agreement. The Company retained all rights to duvelisib outside the Sanofi Territory, except for those territories previously and exclusively licensed to other partners.

Sanofi paid the Company an upfront, non-refundable payment of \$5.0 million in August 2019. The Company is also entitled to receive aggregate payments of up to \$42.0 million if certain regulatory and commercial milestones are successfully achieved. Sanofi is obligated to pay the Company double-digit royalties on net sales of products containing duvelisib in the Sanofi Territory, subject to reduction in certain circumstances.

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

The Company first assessed the Sanofi Agreement under ASC 808 to determine whether the Sanofi Agreement (or part of the Sanofi Agreement) represents a collaborative arrangement based on the respective risks, rewards and activities of the parties. 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. The Company concluded that the Sanofi Agreement (or part of the Sanofi Agreement) does not represent a collaborative arrangement under ASC 808. The Company then considered each component in the Sanofi Agreement to determine if ASC 606 should be applied to those components. Generally, the component in the Sanofi Agreement that falls under potential research and development activities is the development of duvelisib specifically in the Sanofi Territory.

For development of duvelisib specifically in the Sanofi Territory, the Company has concluded that Sanofi is a customer with regard to this component in the context of the Sanofi Agreement. As such, the Sanofi Territory component and all related payments are within the scope of ASC 606.

The Company determined that there were two material promises associated with the Sanofi territory-specific activities: (i) an exclusive license to develop and commercialize duvelisib in the Sanofi Territory and (ii) the initial technology transfer. The Company determined that the exclusive license and initial technology transfer were not distinct from one another, as the license has limited value without the initial technology transfer. 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 Sanofi 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 that one performance obligation exists at the outset of the Sanofi Agreement, which is the exclusive license combined with the initial technology transfer.

The Company has determined that the upfront payment of \$5.0 million constituted the transaction price at the outset of the Sanofi 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 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 \$5.0 million as license and collaboration revenue during the quarter ended September 30, 2019.

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

On June 5, 2018, the Company entered into a license and collaboration agreement with Yakult (the Yakult Agreement), 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.

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 on a pro-rata basis. For the three and nine months ended September 30, 2019, there have been no additional milestones achieved under the Yakult Agreement.

Subsequently, on February 28, 2019, the Company entered into a supply agreement with Yakult (the Yakult Supply Agreement), under which the Company agreed to provide Yakult with drug product for clinical and commercial use in accordance with the Yakult Agreement. Under the terms of the Yakult Supply Agreement, the Company also granted to Yakult a limited manufacturing license to fill, finish, package, and label the drug product solely for clinical and commercial purposes in Japan. The Company has recognized \$0.1 million of collaboration revenue under the Yakult Supply Agreement for the nine months ended September 30, 2019.

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

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 (each, a Region and collectively, the CSPC Territory) for the treatment, prevention, palliation or diagnosis of all oncology indications in humans.

As of September 30, 2018, CSPC became obligated to pay the Company an aggregate upfront, non-refundable payment of \$15.0 million. 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 on a pro-rata basis. For the three months ended September 30, 2019, there have been no additional milestones achieved under the CSPC Agreement.

#### **16. 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, 2019 and 2018, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2019 and 2018, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

#### **17. Commitments and contingencies**

The Company has entered into a lease agreement for approximately 27,810 square feet of office space in Needham, Massachusetts. Please refer to Note 10 for further details regarding the minimum aggregate future lease commitments as of September 30, 2019. In conjunction with the execution of the Amended Lease Agreement, the Company has provided a security deposit in the form of a letter of credit in the amount of \$0.2 million as of September 30, 2019 and December 31, 2018. The amount is included in other assets on the condensed consolidated balance sheets as of September 30, 2019.

#### **18. 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:

##### ***Operational Expense Reduction Plan***

On October 28, 2019, the Company committed to an operational plan to reduce overall operating expenses, including the elimination of approximately 40 positions across the Company and other cost-saving measures (the "Restructuring"). The workforce reduction is designed to streamline operations, speed execution, and reflect the focused, account-based approach in the field. The Company expects to complete the workforce reduction by the end of October 2019.

The Company expects the Restructuring to reduce annualized operating expenses by approximately \$25 million beginning in 2020.

The Company has offered one-time termination benefits to the affected employees, including cash severance payments, healthcare benefits, and outplacement assistance.

The Company expects to record a charge of approximately \$1.0 million in the fourth quarter of 2019 as a result of the Restructuring, consisting of one-time termination benefits for employee severance, benefits, and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out over the next three months.

## 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, 2018. 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, 2018.*

### 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 certain 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, mesothelioma, ovarian cancer, colorectal cancer, head and neck cancer, 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 do not adequately respond to 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. 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 was approved by the U.S. Food & Drug Administration (FDA) on September 24, 2018, and is now 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. Continued approval for this FL indication may be contingent upon verification and description of clinical benefits in confirmatory trials.

We are also developing duvelisib for the treatment of multiple types of cancer, the most advanced of which is designed to treat patients with peripheral T-cell lymphoma (PTCL). The development of duvelisib in PTCL has been awarded Fast Track status by the FDA and a registration study is underway. Duvelisib has also received orphan drug designation from the FDA for use in the treatment of certain T-Cell lymphomas, including PTCL. During 2019, we plan to continue to further develop duvelisib through the initiation of a confirmatory study of patients with FL and other sponsored trials. We also plan to report interim data for several ongoing investigator sponsored studies (ISTs).

Our second product candidate, 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 delivered orally and designed to be a potential therapy for patients to take at home under the advice and guidance of their physician. Defactinib is currently being investigated in combination with immunotherapeutic and other agents through ISTs.

Our operations to date have been organizing and staffing our company, business planning, raising capital, identifying and acquiring potential product candidates, undertaking preclinical studies and clinical trials for our product candidates, and initiating U.S. commercial operations following the approval of COPIKTRA. 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 Sanofi, Yakult and CSPC, and the issuance of \$150.0 million aggregate principal amount of Notes in October 2018. With 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, 2019, we had an accumulated deficit of \$486.0 million. Our net loss was \$30.1 million, \$110.4 million, \$21.7 million and \$61.1 million for the three and nine months ended September 30, 2019 and 2018, respectively. We expect to incur significant expenses and increasing operating losses 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.

We believe that we may have sufficient funds to meet our obligations within the next twelve months from the date of issuance of these condensed consolidated financial statements. However, 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. These uncertainties and risk factors raise substantial doubt about our ability to continue as a going concern.

## **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, 2018 related to accrued research and development expenses, stock-based compensation, revenue recognition, collaborative arrangements, accounts receivable, inventory and intangible assets. During the nine months ended September 30, 2019, there were no material changes to the significant accounting policies, except for the adoption of Accounting Standards Codification (ASC) 842, *Leases*, issued by the Financial Accounting Standards Board (the FASB), which is detailed below.

### ***Revenue Recognition***

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 we transfer 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 which goods or services 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. 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, 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, 2019, 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, 2019.

**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 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, 2019.

**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 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.

Subject to certain limitations, our 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.

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, 2019.

*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 (i) licenses, or options to obtain licenses, to our intellectual property, (ii) research and development activities performed for the collaboration partner, (iii) participation on joint steering committees, and (iv) 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 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 as of each reporting period and, if necessary, adjust 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 estimate 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 risks 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, 2019.

### ***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.

## Leases

Effective January 1, 2019, we adopted ASC 842. This standard 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.

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances within the arrangement. A lease is identified where an arrangement conveys the right to control the use of identified property, plant, and equipment for a period of time in exchange for consideration. Leases which are identified within the scope of ASC 842 and which have a term greater than one year are recognized on our condensed consolidated balance sheets as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. We have elected not to recognize leases with terms of one year or less on our condensed consolidated balance sheets. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rates to calculate the present value of lease payments. Incremental borrowing rates are the rates we incur to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with ASC 842, components of a lease are split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. We have elected to account for the lease and non-lease components of each of our operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the condensed consolidated balance sheets and amortized on a straight-line basis as lease expense.

## RESULTS OF OPERATIONS

### Comparison of the three months ended September 30, 2019 and 2018

	Three months ended September 30,			
	2019	2018	Change	% Change
Revenue:				
Product revenue, net	\$ 4,032	\$ 508	\$ 3,524	694%
License and collaboration revenue	5,000	15,000	(10,000)	-67%
Total revenue	9,032	15,508	(6,476)	-42%
Operating expenses:				
Cost of sales - product	371	49	322	657%
Cost of sales - intangible amortization	392	31	361	1165%
Research and development	12,219	11,571	648	6%
Selling, general and administrative	22,153	25,426	(3,273)	-13%
Total operating expenses	35,135	37,077	(1,942)	-5%
Loss from operations	(26,103)	(21,569)	(4,534)	21%
Interest income	1,005	763	242	32%
Interest expense	(5,041)	(862)	(4,179)	485%
Net loss	\$ (30,139)	\$ (21,668)	\$ (8,471)	39%

*Product revenue, net.* Product revenue, net for the three months ended September 30, 2019 (2019 Quarter) was \$4.0 million compared to \$0.5 million for the quarter ended September 30, 2018 (2018 Quarter). Product revenue, net consisted of net product sales of COPIKTRA in the United States. We began commercial sales of COPIKTRA within the United States in September 2018 following receipt of FDA marketing approval. The \$3.5 million increase was driven by an increase in product shipments for COPIKTRA as a result of greater market penetration.

*License and collaboration revenue.* License and collaboration revenue for the 2019 Quarter was \$5.0 million compared to \$15.0 million for the 2018 Quarter. The \$10.0 million decrease was related to a \$15.0 million upfront payment received in connection with our license and collaboration agreement with CSPC in the 2018 Quarter, partially offset by a \$5.0 million upfront payment in connection with our license and collaboration agreement executed with Sanofi in the 2019 Quarter.

*Costs of sales - product.* Costs of sales - product for the 2019 Quarter was \$0.4 million compared to less than \$0.1 million for the 2018 Quarter. The \$0.3 million increase was primarily driven by an increase in the volume of COPIKTRA sold and corresponding increases in royalties, manufacturing and other costs during the 2019 Quarter as compared to the 2018 Quarter. Cost of sales - product 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 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 (NDA) 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 2019 Quarter were expensed prior to the September 2018 FDA marketing approval and, therefore, are not included in cost of sales - product during this period. We expect cost of sales - product to increase in relation to product revenues as we deplete these inventories.

*Research and development expense.* Research and development expense for the 2019 Quarter was \$12.2 million compared to \$11.6 million for the 2018 Quarter. The \$0.6 million increase was primarily related to an increase of \$0.4 million in contract research organization (CRO) costs, and an increase of \$0.3 million related to personnel costs, including non-cash stock-based compensation, partially offset by a decrease of \$0.1 million in consulting costs.

We allocate the expenses related to external research and development services, such as CROs, clinical sites, manufacturing organizations and consultants by project. 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. The following table summarizes our allocation of research and development expenses to our clinical programs, including COPIKTRA and defactinib, for the 2019 Quarter and the 2018 Quarter.

	Three months ended September 30,	
	2019	2018
	(in thousands)	
COPIKTRA	\$ 6,929	\$ 6,703
Defactinib	510	375
Unallocated and other research and development expense	4,337	3,874
Unallocated stock-based compensation expense	443	619
<b>Total research and development expense</b>	<b>\$ 12,219</b>	<b>\$ 11,571</b>

The increase in COPIKTRA related costs of \$0.2 million for the 2019 Quarter as compared to the 2018 Quarter was driven by an increase of \$0.8 million of CRO costs for Confirmatory FL study – entitled DUETTO, \$0.7 million increase in CRO costs related to our Phase 2 Intermittent Dosing study entitled TEMPO, and \$0.3 million increase in CRO costs related to our Phase 2 study for the treatment of PTCL – entitled PRIMO, partially offset by a decrease of \$0.5 million in consulting fees as a result of activities to file an NDA during the 2018 Quarter and a decrease of \$1.0 million of CRO costs as a result of site closures in our Phase 3 DUO and Phase 2 DYNAMO studies throughout 2018 and 2019 as patients continue to complete treatment. Unallocated and other research and development expenses include \$2.8 million and \$2.3 million of personnel costs for the 2019 Quarter and the 2018 Quarter, respectively.

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2019 Quarter was \$22.2 million compared to \$25.4 million for the 2018 Quarter. The decrease of \$3.2 million from the 2018 Quarter to the 2019 Quarter primarily resulted from a decrease of \$2.3 million in consulting and professional fees, primarily related to the support of commercial launch preparation activities in the 2018 Quarter and a decrease of \$0.9 million in personnel related costs, including non-cash stock-based compensation.

*Cost of sales – intangible amortization.* Cost of Sales – intangible amortization for the 2019 Quarter was \$0.4 million compared to less than \$0.1 million for the 2018 Quarter. Cost of sales – intangible amortization was related to the COPIKTRA finite-lived intangible asset which we recognized and began amortizing in September 2018.

*Interest income.* Interest income for the 2019 Quarter was \$1.0 million compared to \$0.8 million for the 2018 Quarter. The increase of \$0.2 million was primarily due to higher investment cost basis and higher interest rates on investments.

*Interest expense.* Interest expense for the 2019 Quarter was \$5.0 million compared to \$0.9 million for the 2018 Quarter. The increase of \$4.1 million was due to the issuance of the Notes in October 2018 and a higher principal balance on our loan and security agreement with Hercules and the acceleration of an end of term fee related to the Hercules loan and security agreement refinancing recorded as interest expense.

### Comparison of the nine months ended September 30, 2019 and 2018

	Nine months ended September 30,			
	2019	2018	Change	% Change
Revenue:				
Product revenue, net	\$ 8,722	\$ 508	\$ 8,214	1617%
License and collaboration revenue	5,118	25,000	(19,882)	-80%
Total revenue	13,840	25,508	(11,668)	-46%
Operating expenses:				
Cost of sales - product	906	49	857	1749%
Cost of sales - intangible amortization	1,177	31	1,146	3697%
Research and development	33,322	34,886	(1,564)	-4%
Selling, general and administrative	77,484	51,066	26,418	52%
Total operating expenses	112,889	86,032	26,857	31%
Loss from operations	(99,049)	(60,524)	(38,525)	64%
Other income				
Interest income	3,770	1,297	2,473	191%
Interest expense	(15,156)	(1,858)	(13,298)	716%
Net loss	<u>\$ (110,435)</u>	<u>\$ (61,085)</u>	<u>\$ (49,350)</u>	<u>81%</u>

*Product revenue, net.* Product revenue, net for the nine months ended September 30, 2019 (2019 Period) was \$8.7 million compared to \$0.5 million for the nine months ended September 30, 2018 (2018 Period). Product revenue, net consisted of net product sales of COPIKTRA in the United States. We began commercial sales of COPIKTRA within the United States in September 2018 following receipt of FDA marketing approval. The \$8.2 million increase was driven by an increase in product shipments for COPIKTRA as a result of greater market penetration.

*License and collaboration revenue.* License and collaboration revenue for the 2019 Period was \$5.1 million compared to \$25.0 million for the 2018 Period. The \$19.9 million decrease was related to a \$10.0 million upfront payment received in connection to our license and collaboration agreement with Yakult and a \$15.0 million upfront payment received in connection to our license and collaboration agreement with CSPC in the 2018 period, partially offset by a \$5.0 million upfront payment received in connection to our collaboration agreement with Sanofi and collaboration revenue of \$0.1 million related to the shipment of clinical supply of COPIKTRA to Yakult and CSPC during the 2019 Period.

*Costs of Sales - Product.* Costs of sales – product for the 2019 Period was \$0.9 million for the 2019 Period compared to less than \$0.1 million for the 2018 period. The \$0.8 million increase was primarily driven by an increase in the volume of COPIKTRA sold and corresponding increases in royalties, manufacturing and other costs during the 2019 Period as compared to the 2018 Period. Cost of sales - product 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 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 (NDA) 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 2019 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 sales - product to increase in relation to product revenues as we deplete these inventories.

*Research and development expense.* Research and development expense for the 2019 Period was \$33.3 million compared to \$34.9 million for the 2018 Period. The \$1.6 million decrease was primarily related to a decrease of \$1.8 million in consulting costs, a decrease of \$0.6 million in CRO costs, and a decrease of \$0.4 million in occupancy costs, partially offset by an increase of \$0.9 million in personnel costs, including non-cash stock-based compensation, and an increase of \$0.3 million in travel and other costs.

We allocate the expenses related to external research and development services, such as CROs, clinical sites, manufacturing organizations and consultants by project. 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. The following table summarizes our allocation of research and development expenses to our clinical programs, including COPIKTRA and defactinib, for the 2019 Period and the 2018 Period.

	<u>Nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>
	(in thousands)	
COPIKTRA	\$ 18,273	\$ 20,187
Defactinib	1,388	1,691
Unallocated and other research and development expense	12,384	11,317
Unallocated stock-based compensation expense	1,277	1,691
<b>Total research and development expense</b>	<b>\$ 33,322</b>	<b>\$ 34,886</b>

The decrease in COPIKTRA related costs of \$1.9 million for the 2019 Period as compared to the 2018 Period was driven by a decrease of \$2.5 million in consulting fees as a result of activities to file an NDA in the 2018 Period and a decrease of \$2.2 million of CRO costs as a result of site closures in our Phase 3 DUO and Phase 2 DYNAMO studies throughout 2018 and 2019 as patients continue to complete treatment, offset in part by an increase of \$1.4 million of costs related to our PRIMO Phase 2 study for the treatment of PTCL and an increase of \$1.4 million related to our Phase

2 Intermittent Dosing study which commenced during the 2019 Period. Unallocated and other research and development expenses include \$8.3 million and \$6.9 million of personnel costs for the 2019 Period and the 2018 Period, respectively.

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2019 Period was \$77.5 million compared to \$51.1 million for the 2018 Period. The increase of \$26.4 million from the 2018 Period to the 2019 Period primarily resulted from increases in personnel related costs, including non-cash stock-based compensation, of \$16.4 million, primarily related to the hiring and staffing of our sales and commercial teams, executive and non-executive separation costs of \$2.3 million, including non-cash stock-based compensation, an increase in consulting and professional fees of \$6.7 million, primarily related to commercial operations following the approval of COPIKTRA in September 2018, and an increase in travel, debt advisory, and other costs of \$3.3 million.

*Cost of Sales – intangible amortization.* Cost of Sales – intangible amortization for the 2019 Period was approximately \$1.2 million compared to less than \$0.1 million for the 2018 Period. Cost of sales – intangible amortization was related to the COPIKTRA finite-lived intangible asset which we recognized and began amortizing in September 2018.

*Interest income.* Interest income for the 2019 Period was \$3.8 million compared to \$1.3 million for the 2018 Period. The increase of \$2.5 million was primarily due to higher investment cost basis and higher interest rates on investments.

*Interest expense.* Interest expense for the 2019 Period was \$15.2 million compared to \$1.9 million for the 2018 Period. The increase of \$13.3 million was due to the issuance of the Notes in October 2018, a higher principal balance and higher interest rates on our loan and security agreement with Hercules and the acceleration of an end of term fee related to the Hercules loan and security agreement refinancing recorded as interest expense.

## **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, CSPC, and Sanofi and the issuance of \$150.0 million aggregate principal amount of Notes in October 2018. With 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. In April 2019, we entered into the 2019 Term Loan Agreement with Hercules in which we received an additional \$10.0 million under the 2019 Term Loan.

As of September 30, 2019, we had \$160.2 million in cash, cash equivalents and short-term investments. We primarily invest our cash, cash equivalents and short-term investments in U.S. Government money market funds and corporate bonds and commercial paper of publicly traded companies. The Company believes that it may have sufficient funds to meet its obligations within the next twelve months from the date of issuance of these condensed consolidated financial statements.

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 our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC on March 12, 2019 and in any subsequent filings with the SEC.

**Cash flows**

The following table sets forth the primary sources and uses of cash for the 2019 Period and the 2018 Period (in thousands):

	Nine months ended September 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (101,297)	\$ (55,327)
Investing activities	64,487	(11,574)
Financing activities	10,263	115,693
<b>Increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>\$ (26,547)</b>	<b>\$ 48,792</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. The \$46.0 million increase in cash used in operating activities for the 2019 Period compared to the 2018 Period was primarily due to an increase in selling, general, and administrative expenses related to the hiring and staffing of our sales and commercial teams related to the post-launch commercial operations supporting COPIKTRA, and due to a \$10.0 million license payment from Yakult and \$5.0 million license payment received from CSPC during the 2018 Period, partially offset by a \$5.0 million license payment received from Sanofi during the 2019 period.

*Investing activities.* The cash provided by investing activities for the 2019 Period relates to the net maturities of investments of \$64.5 million. The cash provided by investing activities for the 2018 Period reflects the net maturities of investments of \$10.4 million, partially offset by net purchases of property, plant, and equipment of \$1.2 million.

*Financing activities.* The cash provided by financing activities for the 2019 Period primarily represents \$9.7 million of net proceeds as a result of the Amendment to the loan and security agreement with Hercules and \$0.6 million of proceeds received related to exercise of stock option and employee stock purchase plan. 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 \$0.6 million related to stock options exercises, offset by the payment of approximately \$0.3 million of issuance costs related to a sale of our common stock during December 2017.

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 and nine months ended September 30, 2019, there were no sales under the ATM. 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, 2019, 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). As of September 30, 2019, we can issue an additional \$26.6 million of gross proceeds under this program.

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 March 21, 2017, we 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, March 6, 2018 and October 11, 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 Amended Term Loan), pursuant to certain conditions of funding.

On April 23, 2019 (the Amendment Date), we entered into the Fourth Amendment (the Amendment) to the Loan and Security Agreement with Hercules. The Amendment amends the Amended Loan Agreement (together with the Amendment, the 2019 Term Loan Agreement).

Per the terms of the Amendment, we may borrow up to an aggregate of \$75.0 million, of which \$35.0 million was outstanding immediately as of the Amendment Date (2019 Term A Loan) as a result of the existing outstanding principal of term loans of \$25.0 million under the Amended Loan Agreement being converted into the 2019 Term A Loan, and an additional \$10.0 million being drawn on the Amendment Date. The remaining \$40.0 million of borrowing capacity may be drawn in multiple tranches comprised of (i) a term loan in an amount of up to \$15.0 million upon us generating cumulative net product revenues (as defined in the 2019 Term Loan Agreement) of either (a) \$37.5 million on or before April 30, 2020 or (b) \$50.0 million on or before June 30, 2020 (2019 Term B Loan), and (ii) a term loan in an amount of up to \$25.0 million available through December 31, 2021, subject to Hercules' approval and certain other conditions specified in the 2019 Term Loan Agreement (the 2019 Term C Loan, and together with the 2019 Term A Loan and 2019 Term B Loan, the 2019 Term Loan). As of September 30, 2019, we have borrowed a total of \$35.0 million in term loans.

The 2019 Term Loan will mature on December 1, 2022 (2019 Term Loan Maturity Date). Each advance accrues interest at a floating per annum rate equal to the greater of (a) 9.75% or (b) the lesser of (i) 12.00% and (ii) the sum of (x) 9.75% plus (y) (A) the prime rate minus (B) 5.50%. The 2019 Term Loan provides for interest-only payments until April 1, 2021, which may be extended to December 1, 2021 pursuant to us generating \$40.0 million in net product revenue on a trailing six-month basis on or prior to December 31, 2020 provided that no event of default has occurred. Thereafter, amortization payments will be payable monthly in equal installments of principal and interest (subject to recalculation upon a change in prime rates).

The 2019 Term Loan is secured by a lien on substantially all of our assets, other than intellectual property and contains customary covenants and representations, including a liquidity covenant, minimum net revenue covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

On the Amendment Date, we were required to pay any outstanding accrued interest as well as the final payment fee equal to 4.5% on the outstanding principal balance of the Amended Term Loan, or \$1.1 million. No prepayment charges were due as a result of executing the Amendment or conversion of the existing term loans into 2019 Term A Loans.

## **License and collaboration agreements**

### **Sanofi**

On July 25, 2019, the Company entered into a license and collaboration agreement with Sanofi (the Sanofi Agreement), under which the Company granted exclusive rights to Sanofi to develop and commercialize products containing duvelisib in Russia, the Commonwealth of Independent States (CIS), Turkey, the Middle East and Africa (collectively the “Sanofi Territory”) for the treatment, prevention, palliation or diagnosis of any oncology indication in humans or animals.

Under the terms of the Sanofi Agreement, Sanofi received the exclusive right to develop and commercialize products containing duvelisib in the Sanofi Territory under mutually agreed upon development and commercialization plans at Sanofi’s own cost and expense. In addition, Sanofi received certain limited manufacturing rights in the event the Company is unable to manufacture or supply sufficient quantities of duvelisib or products containing duvelisib to Sanofi during the term of the Sanofi Agreement. The Company retained all rights to duvelisib outside the Sanofi Territory, except for those territories previously and exclusively licensed to other parties.

Sanofi paid the Company an upfront, non-refundable payment of \$5.0 million in August 2019. The Company is also entitled to receive aggregate payments of up to \$42.0 million if certain regulatory and commercial milestones are successfully achieved. Sanofi is obligated to pay the Company double-digit royalties on net sales of products containing duvelisib in the Sanofi Territory, subject to reduction in certain circumstances.

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

The Company recognized the upfront payment of \$5.0 million as license and collaboration revenue during the quarter ended September 30, 2019.

### **Yakult**

On June 5, 2018, we entered into a license and collaboration agreement with Yakult (the Yakult Agreement), 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.

Subsequently, on February 28, 2019, we entered into a supply agreement with Yakult (the Yakult Supply Agreement), under which we agreed to provide Yakult with drug product for clinical and commercial use in accordance with the Yakult Agreement. Under the terms of the Yakult Supply Agreement, we also granted to Yakult a limited manufacturing license to fill, finish, package, and label the drug product solely for clinical and commercial purposes in Japan.

### **CSPC**

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 (each, a Region and collectively, the CSPC Territory) for the treatment, prevention, palliation or diagnosis of all oncology indications in humans.

### **Funding requirements**

We expect to continue to incur significant expenses and operating losses. We anticipate that our expenses and operating losses will continue 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.

These factors raise substantial doubt about our ability to continue as a going concern. 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, 2018. There have not been any material changes from the contractual obligations and commitments previously disclosed in such report, other than our entering into the Fourth Amendment to the Loan and Security Agreement with Hercules Capital, Inc. This change is more fully described in “Liquidity and Capital Resources” and Note 11, Long-Term Debt 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 short-term investments of \$160.2 million as of September 30, 2019, consisting of cash, U.S. Government money market funds, 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, 2019, an immaterial amount of our total liabilities was denominated in currencies other than the functional currency.

On April 23, 2019, we entered into the 2019 Term Loan Agreement, under which we have borrowed \$35.0 million, inclusive of the original \$25.0 million borrowed under the Amended Term Loan Agreement. The 2019 Term Loan Agreement bears interest per annum equal to the greater of either (a) 9.75% or (b) the lesser of (i) 12.00% and (ii) the sum of (x) 9.75% plus (y) (A) the prime rate minus (B) 5.50%. 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, 2019. As of September 30, 2019, we have borrowed \$35.0 million under the 2019 Term Loan Agreement.

The Notes bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates; however, because these interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if our credit rating improves or other circumstances change.

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

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

Our management, with the participation of our Chief Executive Officer and our Chief Business and Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. 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, 2019, our Chief Executive Officer and our Chief Business and 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**

There have been no changes in our internal control over financial reporting during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## 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, 2018 as filed with the SEC on March 12, 2019, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as filed with the SEC on August 1, 2019. 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, 2018, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, other than as set forth below.

#### ***We may experience difficulties in managing restructurings and restructuring activities may not be as effective as anticipated***

On October 28, 2019, we committed to an operation plan to reduce overall operating expenses, including the elimination of approximately 40 positions. The workforce reduction is designed to streamline operations, speed up execution, and reflect the focused, account-based approach in the field. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. Furthermore, our restructuring plan may be disruptive to our operations. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results, which include net product revenue, and financial condition would be adversely affected. There can be no assurance that we will be successful in implementing our restructuring program. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize COPIKTRA and develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

#### ***We may require additional financing to execute our operating plan and continue to operate as a going concern.***

As required under Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern* (ASC 205-40), we have the responsibility to evaluate whether conditions and/or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. The Company believes that it may have sufficient funds to meet its obligations within the next twelve months from the issuance of these condensed consolidated financial statements. However, this belief relies on the achievement of certain mitigation efforts, to include the successful commercialization of COPIKTRA in the United States, and potentially, the raising of additional capital and reduction of cash expenditures. The analysis under ASC 205-40, initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. Additionally, the Company has historical losses from operations and anticipates that it will continue to incur losses as it continues the commercialization of COPIKTRA and the research and development of its product candidates. COPIKTRA is the Company's only approved product and the Company's business currently depends heavily on its successful commercialization. Successful commercialization of an approved product is an expensive and uncertain process. Accordingly, these uncertainties and risk factors meet the ASC 205-40 standard for raising substantial doubt about our ability to continue as a going concern within one year of the issuance date of our condensed consolidated financial statements. Lack of necessary funds may require us, among other things, to delay, scale back, or eliminate some or all of our planned clinical trials. Because we continue to experience net operating losses, our ability to continue as a going concern is subject to our ability to increase sales of COPIKTRA, obtain necessary capital from outside sources, including obtaining additional capital from the sale of our securities or assets, obtaining loans from financial institutions or entering into additional partnership arrangements. Our continued net operating losses and capital structure increase the difficulty in obtaining such capital, and there can be no assurances that we will be able to obtain such capital on favorable terms or at all. If we are unable to raise capital when needed, we may

be forced to delay, reduce or eliminate our commercial efforts for COPIKTRA or our other research and development activities for our product candidates, or ultimately not be able to continue as a going concern.

**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.**

None.

**Item 6. Exhibits.**

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

**EXHIBIT INDEX**

- 10.1\* †[License and Collaboration Agreement, dated July 25, 2019, between Verastem, Inc. and Sanofi](#)
- 31.1\* [Certification of Principal 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 Principal 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.](#)
- 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.

† Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.



**SIGNATURES**

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

**VERASTEM, INC.**

Date: October 30, 2019

By: \_\_\_\_\_ /s/ BRIAN M. STUGLIK

Brian M. Stuglik  
*Chief Executive Officer*  
*(Principal executive officer)*

Date: October 30, 2019

By: \_\_\_\_\_ /s/ ROBERT GAGNON

Robert Gagnon  
*Chief Business and Financial Officer*  
*(Principal financial and accounting officer)*

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [ \* \* \* ], HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO VERASTEM, INC. IF PUBLICLY DISCLOSED.

**LICENSE AND COLLABORATION AGREEMENT**

**between**

**VERASTEM, INC.**

**and**

**SANOFI**

**DATED**

**July 25, 2019**

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## LICENSE AND COLLABORATION AGREEMENT

This **LICENSE AND COLLABORATION AGREEMENT** (this “*Agreement*”) is made as of July 25, 2019 (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 **SANOFI**, a French corporation, having a place of business at 54, rue la Boétie, 75008 Paris, France (“*Licensee*”). Verastem and Licensee are referred to in this Agreement individually as a “*Party*” and collectively as the “*Parties*.”

### RECITALS

**WHEREAS**, Licensee has experience and expertise in the research, development and commercialization of pharmaceutical products in the Territory (as defined below);

**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 Products 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 a Party, any Entity that controls, is controlled by, or is under common control with such Party. 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 stock 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 any applicable anti-bribery and good business ethics legislation, regulations and/or codes, both national and foreign, including but not limited to, the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act, and

national laws adopted and implemented pursuant to the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

**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 Paris, France, 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 current good manufacturing practice and standards, as provided for (and as amended from time to time) in the “Current Good Manufacturing Practice Regulations” of the U.S. Code of Federal Regulations Title 21 (21 CFR §§ 820), European Regulation 2017/745 concerning medical devices ISO 13485, ISO 14971, any U.S., European, or other Applicable Law, regulations or respective guidance documents now or subsequently established by a Governmental or Regulatory Authority of any country or jurisdiction within the Territory, and any arrangements, additions, or clarifications agreed from time to time between the Parties.

**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** “*Combination Product*” means any pharmaceutical product which contains two or more active pharmaceutical ingredients, at least one of which is the Licensed Compound. For the avoidance of doubt, a Licensed Product containing the Licensed Compound as its sole active pharmaceutical ingredient 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.

**1.15** “*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).

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

**1.17** “*Commercially Reasonable Efforts*” means, with respect to the efforts to be expended by a Party with respect to any Development or Commercialization objective, activity or goal related to a Licensed Product under this Agreement, [\* \* \*].

**1.18** “*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 Existing Confidentiality Agreement, whether made available orally, visually, in writing or in electronic form, and (b) any information that was disclosed by or on behalf of a Party or any of its Affiliates to the other Party or any of its Affiliates prior to the Effective Date pursuant to the confidentiality agreement between Verastem and Licensee, dated January 11, 2018 (the “*Existing Confidentiality Agreement*”). For the avoidance of doubt, the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties.

**1.19** “*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 in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use or (sub)license.



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

1.21 “**Develop**” or “**Development**” or “**Developing**” means all development and regulatory activities for the Licensed Compound or Licensed Products that are directed to obtaining Regulatory Approval(s) of such Licensed Product and to support appropriate usage for such Licensed Product including, but not limited to: 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; activities directed to label expansion (including prescribing information) or obtaining Regulatory Approval for one (1) or more additional Indications following an initial Regulatory Approval for Licensed Products; activities that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining, maintaining or expanding a Regulatory Approval, including but not limited to the conduct of additional Clinical Trials in the Territory; and post-Regulatory Approval product support activities for Licensed Product (including laboratory and clinical efforts directed toward the further understanding of the safety and efficacy of the Licensed Product). For clarity, Development includes phase IV clinical trials and other post-Regulatory Approval clinical trials of Licensed Product.

1.22 “**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 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.

1.23 “**Development Plan**” has the meaning set forth in [Section 4.4](#).

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

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

1.26 “**Early Access Program**” means any program that provides patients with a Licensed Product prior to Regulatory Approval in the Territory and in which the use of such Licensed Product is not primarily intended to obtain information about the safety or effectiveness of a drug. “Early Access Programs” shall include treatment INDs / protocols, Named Patient Supply and compassionate use programs.

1.27 “**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.

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

1.29 “**Existing Confidentiality Agreement**” has the meaning set forth in Section 1.18.

1.30 “**Existing Formulation Product**” has the meaning set forth in Section 6.1(a).

1.31 “**Exploit**”, “**Exploitation**” 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.

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

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

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

1.35 “**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 [\* \* \*] during the immediately preceding Calendar Year.

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

1.37 “**GCP**” means the then-current standards for clinical trials for pharmaceuticals, as set forth in FFDCAs or other Applicable Law, as such standards of good clinical practices are required by the Regulatory Authorities of the European Union and other organizations and Regulatory Authorities in countries for which Licensed Compound is developed, to the extent such standards are not less stringent than United States GCP.

1.38 “**Generic Product**” means, with respect to a Licensed Product and a country in the Territory, a pharmaceutical product that (a) contains the same active pharmaceutical ingredients (and no other active pharmaceutical ingredients) as such Licensed Product or any base form, salt form, pro-drug form, ester, ether, isomer, crystalline polymorph, hydrate or solvate of such active pharmaceutical ingredients, (b) is approved by the applicable Regulatory Authority in such country 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 such Third Party did not purchase such product or its active pharmaceutical ingredients from Licensee or its Affiliates or Sublicensees. With respect to a Licensed Product that is a Combination Product, a Generic Product must, for purposes of this paragraph, contain as active pharmaceutical ingredients the same

combined active pharmaceutical ingredients as such Licensed Product, or any salt, ester, metabolite, or pro-drug thereof, and meet the conditions defined in (b) and (c) above.

**1.39** “*Global Clinical Trial*” means a Clinical Trial conducted by Verastem (or any of its Affiliates, Third Party Licensees or Subcontractors) both inside and outside the Territory under the Global Strategy.

**1.40** “*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.

**1.41** “*GLP*” means the then-current standards for laboratory activities for pharmaceuticals, as set forth in FFDCA or other Applicable Law, as such standards of good laboratory practices as are required by the Regulatory Authorities of the European Union and other organizations and Regulatory Authorities in countries for which Licensed Compound is developed, to the extent such standards are not less stringent than United States GLP.

**1.42** “*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, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

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

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

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

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

**1.47** “*Infinity*” means Infinity Pharmaceuticals, Inc.

**1.48** “*Infinity Agreement*” means that certain Amended and Restated License Agreement, dated November 1, 2016, between Infinity and Verastem.

**1.49** “*Infringed Patent Right*” has the meaning set forth in Section 7.4(c)(i).

**1.50** “*Initial Tech Transfer*” has the meaning set forth in Section 2.6.

**1.51** “*INK*” means Intellikine LLC.

**1.52** “*INK Agreement*” means that certain Amended and Restated Development and License Agreement, dated December 24, 2012, by and between Infinity and INK.

**1.53** “*Invention*” means any Know-How that is first made, discovered, generated, conceived or reduced to practice by or on behalf of a Party (including by its Affiliates, licensees, Sublicensees, Subcontractors or their respective employees, agents) or by or on behalf of both Parties (including by their Affiliates, 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.

**1.54** “*JCC*” has the meaning set forth in Section 3.2(a).

**1.55** “*Know-How*” means all technical information, know-how and data, (in each case, whether or not patentable), including inventions, discoveries, improvements, modifications, trade secrets, specifications, instructions, processes, formulae, materials, design, protocol (including any Clinical Trial protocol), algorithm, forecast, profile, strategy, plan, result, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, nonclinical and clinical data, regulatory data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, manufacture, use, importation, offering for sale or sale of, or which may be useful in studying, testing, developing, producing or formulating, products, or intermediates for the synthesis thereof, 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, the manufacturing data that is necessary to Manufacture the Licensed Compound or Licensed Product (subject to Section 2.2 and Section 6.1) and the Regulatory Documents.

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

**1.57** “*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.

**1.58** “*Licensed Product*” means any pharmaceutical preparation, kit, article of manufacture, composition of matter, material, compound, component or product in final form, in each case, that contains or comprises the Licensed Compound. [\* \* \*]. Each Licensed Product shall be distinguished by dosage form, and for the avoidance of doubt, a Licensed Product containing the Licensed Compound as its sole active pharmaceutical ingredient and each Combination Product shall constitute separate and distinct Licensed Products under this Agreement.

**1.59** “*Licensed Trademarks*” means the trademarks set forth on **Exhibit D** Controlled by Verastem in the Territory.

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

**1.61** “*Licensee IP*” means Licensee Know-How and Licensee Patents. For clarity, Inventions owned by Licensee pursuant to Section 11.1(c) shall be included within the Licensee IP.

**1.62** “*Licensee Know-How*” means all Know-How Controlled by Licensee or its Affiliates that is (a) generated by or on behalf of Licensee or its Affiliates, Sublicensees or Subcontractors on or after the Effective Date in the course of the performance of Licensee’s activities under this Agreement (including any and all data, Clinical Trial data, results, Development Data and Regulatory Documents), (b) relates to the Licensed Compound or Licensed Product, and (c) is necessary or reasonably useful for Exploiting Licensed Products in the Field.

**1.63** “*Licensee Patents*” means all Patent Rights Controlled by Licensee or its Affiliates as of the Effective Date or at any time during the Term that cover (a) the Licensed Compound or Licensed Product (including composition of matter and methods of using, making or detecting the Licensed Compound or Licensed Products) or (b) the Licensee Know-How.

**1.64** “*Major Market Countries*” means [\* \* \*].

**1.65** “*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).

**1.66** “*Named Patient Supply*” means that a Licensed Product is sold for use by an individual patient, based on the decision of a physicians’ commission and imported pursuant to a special import license before any Regulatory Approval is obtained to cover such patient, if allowed under Applicable Laws and the Parties’ policies, procedures and practices.

**1.67** “*Net Sales*” means, (i) with respect to a Licensed Product (subject to clause (ii) below, for a Combination Product) in a particular period, [\* \* \*] 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 unrelated Third Parties during such period, less the following deductions (to the extent included in the [\* \* \*] 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.

**1.68** “*New Formulation Product*” has the meaning set forth in Section 4.4.

**1.69** “**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 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 proceeding relating to issued Patent Right(s).

**1.70** “**Patent Challenge**” means any invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the Patent Rights.

**1.71** “**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.

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

**1.73** “**Pharmacovigilance Agreement**” has the meaning set forth in [Section 5.3](#).

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

**1.75** “**Product Marks**” has the meaning set forth in [Section 11.7\(b\)](#).

**1.76** “**Product Recall**” means any recall or market withdrawal of a Licensed Product in the Territory.

**1.77** “**Public Official**” has the meaning set forth in [Section 9.6\(d\)](#).

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

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

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

**1.81** “**Reference Country**” means a country outside of the Territory that reasonably may be used as country of reference or a price benchmark for the Regulatory Approvals in the countries of the Territory.

**1.82** “**Regulatory Approval**” means, with respect to a Licensed Product in a country, all approvals that are necessary for the Manufacture, Development and Commercialization of such Licensed Product for one or more Indications in such country. For the avoidance of doubt,

Regulatory Approval includes any pricing approvals that may be required by Applicable Law but does not include any reimbursement approvals.

**1.83** “*Regulatory Authority*” means any applicable Governmental Authority involved in granting Regulatory Approval.

**1.84** “*Regulatory Documents*” means any regulatory 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 (including but not limited to, questions and answers between a Regulatory Authority and the sponsor or applicant), 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 Licensed Products.

**1.85** “*Regulatory Exclusivity*” means the ability to exclude Third Parties from Manufacturing or Commercializing a product that could compete with a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country other than through Patent Rights.

**1.86** “*Regulatory Milestone Event*” has the meaning set forth in Section 7.2.

**1.87** “*Regulatory Milestone Payment*” has the meaning set forth in Section 7.2.

**1.88** “*Royalty Term*” means, with respect to a given Licensed Product in a country in the Territory, the period commencing on the First Commercial Sale of such Licensed Product in such country and ending upon 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 any Regulatory Exclusivity with respect to such Licensed Product in such country, or (d) the [\* \* \*] anniversary of the First Commercial Sale of such Licensed Product in such country.

**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** “*Subcontractor*” has the meaning set forth in Section 2.4.

**1.94** “*Sublicensee*” has the meaning set forth in Section 2.3(b).

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

- 1.96 “**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.
- 1.97 “**Term**” has the meaning set forth in Section 12.1.
- 1.98 “**Territory**” means all the countries of Africa, the Middle East-Turkey, and Eurasia, as detailed in **Exhibit C**.
- 1.99 “**Territory Approvals**” has the meaning set forth in Section 5.1(a).
- 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 “**Transition Plan**” has the meaning set forth in Section 2.6.
- 1.103 “**United States**” means the United States of America.
- 1.104 “**Upstream License Agreement**” each of the Infinity Agreement and the INK Agreement.
- 1.105 “**Upstream Licensor**” each of Infinity and INK.
- 1.106 “**Usage Guidelines**” has the meaning set forth in Section 11.7(d)(i).
- 1.107 “**USFDA**” means the United States Food and Drug Administration or any successor Entity thereto.
- 1.108 “**Valid Claim**” means [\* \* \*].
- 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(b) shall be included in the Verastem IP.
- 1.112 “**Verastem Know-How**” means all Know-How Controlled by Verastem 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 the Licensed Compound or 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 Patents”** means all Patent Rights Controlled by Verastem as of the Effective Date or at any time during the Term (subject to the provisions of Section 2.10) that cover the Licensed Compound or Licensed Product in the Territory (including composition of matter, formulations and methods of using, making or detecting the Licensed Compound or 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 Patents existing in the Territory as of the Effective Date are set forth in **Exhibit A**.

**1.114 “Verastem Territory Regulatory Approval Holder”** has the meaning set forth in Section 5.1(a).

## **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 (even as to Verastem and its Affiliates, but subject to Verastem’s retained rights as set forth in Section 2.7), royalty-bearing, non-transferable (except in accordance with Section 14.2) 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) and Commercialize Licensed Products in the Field in the Territory, and (b) obtain, hold and maintain the Regulatory Approvals and any applicable pricing or reimbursement approvals for Licensed Products in the Field in the Territory.

**2.2 Non-Exclusive License Grant to Licensee.** On a Licensed Product-by-Licensed Product basis, Verastem hereby grants to Licensee a non-exclusive, royalty-bearing, non-transferable (except in accordance with Section 14.2) license with the right to grant sublicenses (solely in accordance with Section 2.3), under the Verastem IP to Manufacture such Licensed Product inside and outside of the Territory, solely for purposes of Exploiting such 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 with respect to the limited Manufacturing license granted by Verastem to Licensee to fill, finish, package, and label such Licensed Product, unless and until (i) the occurrence of a Supply Failure by Verastem (as defined in the Supply Agreement) with respect to such Licensed Product or (ii) with respect to a New Formulation Product, Verastem elects not to supply Licensee requirements of such New Formulation Product in accordance with Section 6.1(a).

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

(a) **Sublicense to its Affiliates.** Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant sublicenses of the License to its Affiliates to fulfill any of its obligations under this Agreement, provided that such sublicense shall automatically terminate if such Affiliate ceases to be an Affiliate of Licensee. Licensee shall remain directly responsible for all of its obligations under this Agreement, regardless of whether any such obligation is delegated or sublicensed to an Affiliate, and any breach of the terms or conditions of this Agreement by any of such Affiliate of Licensee shall be deemed a direct breach by Licensee of such terms or conditions of this Agreement.

(b) **Sublicense to Third Parties.**

(i) Licensee shall have the right to grant sublicenses of the License to Third Parties to fulfill any of its obligations under this Agreement (any such Third Party, a “**Sublicensee**”), and Licensee shall notify Verastem in writing of such sublicense (except, for the avoidance of doubt, with respect to Subcontractors). Notwithstanding the foregoing, Licensee shall obtain Verastem’s prior written consent if Licensee wishes to sublicense (i) the Commercialization of one or more Licensed Products in any country in the Territory, or (ii) all or substantially all of Licensee’s rights or obligations to a Third Party under this Agreement.

(ii) Each sublicense granted pursuant to Section 2.3(b)(i) shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement, and Licensee shall ensure that Sublicensees comply with the terms and conditions of this Agreement. Licensee will remain directly responsible for all its obligations under this Agreement, regardless of whether any such obligation is delegated or sublicensed to any of Sublicensees, and any breach of the terms or conditions of this Agreement by such Sublicensees shall be deemed a direct breach by Licensee of such terms or conditions of this Agreement.

(iii) Licensee shall provide Verastem with a copy of any sublicense agreement pursuant to which the applicable Sublicensee is Commercializing Licensed Products (except, for the avoidance of doubt, with respect to Subcontractors), in English, within [\* \* \*] days after the execution of any such sublicense agreement provided that Licensee may redact financial and confidential portions of such sublicense agreement. Further, Licensee will provide Verastem, upon Verastem’s request, with copies of any quality oversight or audit reports from audits that Licensee has conducted on any of its Sublicensees (except with respect to Subcontractors) that Licensee engages to fulfill its obligations under this Agreement to the extent such reports are relevant to such Sublicensees’ conduct of such obligations.

**2.4 Right to Subcontract.**

(a) Licensee shall have the right to engage CROs, contract manufacturing organizations, distributors, wholesalers and other Third Parties to perform its activities under this Agreement (each, a “**Subcontractor**”); provided, that (i) Licensee shall cause its Subcontractors to be bound by written obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, (ii) Licensee shall remain directly responsible for any activities that have been subcontracted to its Subcontractor and shall be responsible for the performance of its Subcontractors, and (iii) any breach by a Subcontractor of the terms and conditions of this Agreement shall be deemed a breach by Licensee of such terms and conditions. Licensee shall Control, or shall cause its Subcontractors to assign to Licensee, all intellectual property rights (x) covering the composition of matter or the method of use of the Licensed Compound or Licensed Product or (y) solely relating to Licensed Compound or Licensed Products (including, for the avoidance of doubt, Development Data solely relating to Licensed Compound or Licensed Product resulting from such subcontracted activities) that are made, discovered, developed or otherwise created by such Subcontractors in the course of performing such subcontracted activities. Further, Licensee shall provide Verastem, upon Verastem’s request, with copies of any quality oversight or audit reports from audits that Licensee has conducted on any of its Subcontractors that Licensee

engages to the extent such reports are relevant to such Subcontractors' conduct of subcontracted activities.

(b) Verastem shall have the right to engage its Subcontractors to perform its activities for which Verastem is assuming obligations under this Agreement; provided that (i) Verastem shall remain directly responsible for any activities that have been subcontracted to its Subcontractor and shall be responsible for the performance of its Subcontractors, and (ii) any breach by a Subcontractor of the terms and conditions of this Agreement shall be deemed a breach by Verastem of such terms and conditions. Verastem shall Control, or shall cause its Subcontractors to assign to Verastem, all intellectual property rights (x) covering the composition of matter or the method of use of the Licensed Compound or Licensed Product or (y) solely relating to the Licensed Compound or Licensed Product (including, for the avoidance of doubt, Development Data solely relating to Licensed Compound or Licensed Product resulting from such subcontracted activities) that are made, discovered, developed or otherwise created by such Subcontractors in the course of performing such subcontracted activities.

## 2.5 Upstream Licenses.

(a) Licensee acknowledges and agrees that:

(i) (A) Verastem obtained the rights to certain Verastem IP from Infinity under the Infinity Agreement; (B) Infinity obtained certain of such rights from INK under the INK Agreement; (C) the License constitutes a sublicense under each applicable Upstream License Agreement; and (D) each such sublicense is subject to the terms and conditions of the applicable Upstream License Agreement;

(ii) it has received redacted copies of the INK Agreement in the form attached hereto as **Exhibit F** and the Infinity Agreement in the form attached hereto as **Exhibit G**;

(iii) Licensee shall, and shall cause its Affiliates and Sublicensees to, comply in all material respects with (A) this Agreement; [\* \* \*] of the INK Agreement in the form attached hereto as **Exhibit F**; and (C) the following provisions of the Infinity Agreement in the form attached hereto as **Exhibit G**: [\* \* \*].

(iv) Licensee shall, and shall cause its Affiliates and Sublicensees to, take any action reasonably requested by Verastem to prevent any potential material breach by Licensee, its Affiliates or Sublicensees of any applicable terms set forth in the INK Agreement in the form attached hereto as **Exhibit F** or the Infinity Agreement in the form attached hereto as **Exhibit G**; and

(v) notwithstanding any provision of this Agreement to the contrary, (A) Verastem may provide a copy of this Agreement, and any amendment to this Agreement, to any Upstream Licensor, and (B) 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; provided that, for each of (A) and (B), such Upstream Licensor is subject to

confidentiality and non-use obligations no less stringent than those set forth in Article 8. Verastem acknowledges and agrees that Licensee may provide to any Affiliate or Sublicensee a copy of the Upstream License Agreement and this Agreement; provided that such Affiliate or Sublicensee is subject to confidentiality and non-use obligations no less stringent than those set forth in Article 8.

(b) [\* \* \*]

(c) [\* \* \*]

**2.6 Disclosure of the Verastem IP.** Verastem shall, in accordance with the transition plan attached hereto as **Exhibit H** (the “**Transition Plan**”), within the timelines indicated in such Transition Plan, furnish to Licensee a then-current data/information package that includes existing Regulatory Documents and existing Development Data that are necessary or reasonably useful for Licensee to Develop and seek Regulatory Approval for Licensed Products in the Territory, including copies of any Regulatory Documents that have been filed with the USFDA or Regulatory Authorities in any country or jurisdiction within the Territory (the “**Initial Tech Transfer**”). The package described in the Transition Plan shall be provided through a secured electronic data room. The costs of such Initial Tech Transfer, and all other activities set forth in the Transition Plan, shall be allocated amongst the Parties in accordance with Section 5.2.

**2.7 Verastem Retained Rights.** Notwithstanding the exclusive nature of the License, Verastem expressly 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).

**2.8 Licenses Grant to Verastem.** Licensee hereby grants to Verastem:

(a) the right 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 the 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.

(b) a non-exclusive, fully-paid, royalty-free, transferable and sublicenseable (through multiple tiers) license under the Licensee IP, to the extent necessary or useful, to Exploit Licensed Products in the Field outside the Territory.

**2.9 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.

**2.10 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 Verastem deems necessary or useful for the Development or Commercialization of Licensed Products in the Field in the Territory, then Verastem shall so notify Licensee in writing of such intellectual property rights, including a

description thereof and 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 terms and conditions of 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).

### **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 JCC meetings (as a non-voting participant). An Alliance Manager may also bring any matter to the attention of the JCC 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 Commercialization Committee.**

(a) **Formation.** No later than [\* \*] days following the Effective Date, the Parties shall establish a joint commercialization committee (the "**JCC**") to formulate the strategy for, 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 JCC will be comprised of an equal number of representatives from each Party and a minimum of two (2) 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 JCC. From time to time, each Party may substitute one or more of its representatives to the JCC upon written notice to the other Party.

(b) **Role and Purpose.** The JCC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement and for sharing the progress, results and other relevant information with respect to Development and Commercialization by the Parties of Licensed Products in the Field; (ii) review, discuss and approve the overall strategy for the Exploitation of Licensed Products in the Field in the Territory; (iii) review, discuss and approve the Commercialization Plan and amendments thereto; and (iv) perform such other functions as expressly set forth in this Agreement or allocated to the JCC by the Parties' written agreement. Each Party shall share information at the JCC in sufficient detail (i) to enable Verastem to assess Licensee's compliance with Licensee's Development and Commercialization obligations hereunder and enable Verastem to comply with Verastem's obligations pursuant to [\* \*] of the Infinity Agreement and (ii) to enable Licensee to comply with its Development and

Commercialization obligations hereunder. For the sake of clarity, Verastem is under no obligation to share the confidential information of Third Party Licensees.

(c) **Limitation of Authority.** The JCC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

(d) **Meetings.** The JCC shall hold meetings [\* \* \*] times per Calendar Year, or with such other frequency as the Parties may agree. The JCC 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 [\* \* \*] each Calendar Year during the period commencing on the Effective Date and ending on the date the JCC is disbanded pursuant to Section 3.2(f), 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 JCC representatives. The Alliance Manager of Verastem shall prepare minutes for each JCC 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 thirty [\* \* \*] thereafter. For the avoidance of doubt, the meetings of the JCC shall be conducted in English, and any materials provided to the JCC in connection with such discussions shall be provided in English.

(e) **Decision-Making.** All decisions of the JCC 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 JCC, the JCC cannot reach a unanimous decision as to such matter within [\* \* \*] days after such matter was brought to the JCC 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 an executive officer of Licensee who has the power and authority to resolve such matter (collectively, the "**Executive Officers**") for resolution. If the Executive Officers cannot resolve such matter within [\* \* \*] days after such matter has been referred to them, then (i) [\* \* \*], provided that Licensee shall not make any decision or take any action that (A) requires Verastem to perform or refrain from performing any activity except as expressly required under this Agreement, or (B) requires Verastem to provide any resources or bear any costs except as expressly required under this Agreement, in each case without first obtaining Verastem's prior written consent.

(f) **Discontinuation of JCC.** The JCC shall continue to exist until the Parties' mutual written agreement to disband the JCC. Once the JCC is disbanded, the JCC 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 JCC 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).

(g) **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 JCC (in a non-voting capacity), in the event that the planned agenda for such 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.** Licensee shall use Commercially Reasonable Efforts to Develop at least one Licensed Product [\* \* \*] in the Field in [\* \* \*].

### **4.2 Clinical Trials.**

(a) In the event that (i) Licensee wishes to conduct a Clinical Trial (including any Phase IV Clinical Trial or investigator-sponsored Clinical Trial) or (ii) a Regulatory Authority in the Territory requires that Licensee conduct a Clinical Trial, then (A) Licensee shall be required to obtain Verastem's prior approval with respect to such Clinical Trial, (B) Licensee shall be responsible for carrying out such Clinical Trials at its sole cost and expense, (C) Verastem shall have the right to review and approve the protocol for such Clinical Trial(s), and (D) if desired by Verastem, the Parties shall enter into a separate agreement to document expectations regarding such Clinical Trial, such as Verastem's audit of any Clinical Trial site engaged by Licensee or its Affiliates or Sublicensees. Licensee will conduct any Clinical Trial 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.

(b) If Verastem plans to conduct a Global Clinical Trial, Verastem shall have the option to contact Licensee to discuss and agree upon whether such Global Clinical Trial should include the Territory [\* \* \*]. With respect to any Global Clinical Trial, Verastem shall [\* \* \*].

**4.3 Development Records.** To the extent applicable, each Party shall maintain complete, current and accurate records of all Development activities conducted by or on behalf of it or its Affiliates, Sublicensees, or Subcontractors, as applicable, 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 the Licensed Product in the Territory and Verastem will obtain Licensee's written consent prior to destroying any records relating to the Development of the Licensed Product that could materially and adversely affect Licensee's Development of the Licensed Product in the Territory. 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. Each Party 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).

**4.4 Development of New Formulation Products.** If Licensee desires to Develop or Commercialize a Combination Product or a Licensed Product in the Field in the Territory in a formulation that Verastem is not currently Commercializing or Developing for Commercialization in the United States (such Combination Product or Licensed Product, a “**New Formulation Product**”), then prior to conducting any Development or Commercialization activities with respect to such New Formulation Product, Licensee will prepare and deliver to Verastem a written development plan describing all Development activities that Licensee proposes to conduct with respect to such New Formulation Product (a “**Development Plan**”) which plan will include, at a minimum: (a) a description of the New Formulation Product and its potential benefits and risks when compared to any Licensed Product then Developed or Commercialized, (b) a list of any Subcontractors that would be involved in such Development, (c) the scope of the Development work, (d) the estimated timeline for such Development, and (e) a proposal for any potential deal terms, such as royalty payments, milestone payments and any other payments to be made by Licensee to Verastem in connection with the proposed Development and Commercialization of such New Formulation Product. Within [\* \* \*] days following Verastem’s receipt of a Development Plan from Licensee, [\* \* \*]. The Parties will determine any royalty payments, milestone payments or other payments to be made by a Party in connection with the Development and Commercialization of such New Formulation Product such Party in accordance with this Section 4.4 and Section 7.8. Except as otherwise set forth in this Section 4.4, Licensee shall not Develop or Commercialize a New Formulation Product at any time during the Term. From time to time following Verastem’s approval of a Development Plan in accordance with this Section 4.4, Licensee shall have the right to propose amendments or modifications to such Development Plan and shall submit such proposed amended or modified Development Plan to Verastem for approval in Verastem’s reasonable discretion. If Verastem approves such proposed amended or modified Development Plan, then such amended or updated Development Plan shall become effective and binding upon the Parties.

## **ARTICLE 5 REGULATORY**

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

(a) Licensee shall use Commercially Reasonable Efforts to seek Regulatory Approval for [\* \* \*], and shall be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the obtaining, holding, maintaining and renewing of Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for all Licensed Products from Regulatory Authorities throughout the Territory. 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. Licensee, its Affiliates, Sublicensees or, if required by Applicable Laws in the Territory, their Subcontractors, shall be the legal and beneficial owner of any Regulatory Approvals granted in the Territory (the “**Territory Approvals**”) and Regulatory Documents relating to the Territory Approvals shall be filed by, and in the name of, Licensee, its Affiliates or Sublicensees or, if required by Applicable Laws in the Territory, their Subcontractors. If Applicable Laws of any country in the Territory require that, in such country, Regulatory Approvals be held by the Regulatory Approval holder of a specific country outside the Territory



(a "**Verastem Territory Regulatory Approval Holder**"), Verastem shall or, if Verastem is not the Verastem Territory Regulatory Approval Holder, shall cause any such Verastem Territory Regulatory Approval Holder to: (i) execute all instruments that are deemed necessary by Regulatory Authorities of such country in the Territory in this respect and/or (ii) execute any agreement with Licensee or its Affiliates for the purpose of transferring to Licensee or its Affiliates certain responsibilities that the Verastem Territory Regulatory Approval Holder may incur by holding the Regulatory Approval in such country of the Territory, all at Licensee's expense.

(b) Licensee shall provide to Verastem for review and comment drafts of any and all Regulatory Documents which Licensee plans to submit to a Regulatory Authority 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. 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 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. 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.

(d) Licensee shall provide to Verastem a list of Reference Countries that may be used as a price benchmark.

## **5.2 Verastem's Responsibilities.**

(a) Following the Initial Tech Transfer, 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, upon Licensee's request, (a) to the extent Controlled by Verastem and not provided under the Initial Tech Transfer, access to Regulatory Approvals, Regulatory Documents and the Development Data (including raw data, records and samples to the extent expressly required by Regulatory Authorities) for Licensed Products inside and outside of the Territory, and (b) reasonable assistance in responding to queries from Regulatory Authorities in the Territory relating to the Licensed Product. [\* \* \*].

(b) Verastem shall provide Licensee with a [\* \* \*] planning of any submissions or approvals of updates or amendments of the approved regulatory dossier in the US and shall use commercially reasonable efforts to provide Licensee with a [\* \* \*] planning of any submissions or approvals or amendments of any approved regulatory dossier in the EU, including those arising from for instance, but not limited to, a change in the Licensed Product specifications, the drug substance synthesis or in the Licensed Product manufacture, change controls, clinical supply issues, out of specifications results, or DMF holder communications. Any exchange of Regulatory

Documents and Development Data under this Agreement shall be done through an effective document repository in such a format that Licensee may perform customization for use in the Territory. Verastem shall provide Licensee with any submission and approval date of updates or amendments within [\* \* \*] Business Days from the date of any such submission and approval.

**5.3 Right of Reference and Use.** Each Party hereby grants to the other Party a right of reference to all Regulatory Documents pertaining to any Licensed Product (including any New Formulation Product) in the Field submitted by or on behalf of such Party or its Affiliates provided that (a) each Party's right of reference to the other Party's Regulatory Documents shall be limited to Regulatory Documents Controlled by such other Party or its Affiliates, (b) Licensee's right of reference to Verastem's Regulatory Documents shall be 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, and (c) Verastem's right of reference to Licensee's Regulatory Documents shall be 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 outside of 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.

#### **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 the Licensed Product, 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 any Clinical Trials conducted by Licensee in the Territory pursuant to Section 4.2, 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 any such Clinical Trials conducted in the Territory, 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 at Verastem's cost and expense.

#### **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 Product, Licensee shall promptly notify Verastem thereof. Verastem shall have the right to request to be present at any such inspection, and Licensee shall consider Verastem's request in good faith. 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 Product, 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 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 Product, 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.** Each Party shall not, and shall use Commercially Reasonable Efforts to cause its Affiliates, Sublicensees (with respect to Licensee), Third Party Licensees (with respect to Verastem) or its Subcontractors not to, take any action with respect to a Licensed Product that could reasonably be expected to have an adverse impact upon the other Party's regulatory status of any Licensed Product. If a Party believes that the other Party is (or any of its Affiliates, Sublicensees (with respect to Licensee), Third Party Licensees (with respect to Verastem) or its Subcontractors are) taking or intends to take any action with respect to a Licensed Product that could have an adverse impact upon other Party's regulatory status of any Licensed Product, then such Party shall have the right to bring the matter to the attention of the JCC and the Parties shall discuss in good faith a resolution of 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 [\* \* \*] hours, 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 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 the 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 Licensed Products and Licensee shall incorporate any reasonable comments received from Verastem. The costs and expenses of any regulatory action 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 Licensed Products in the Territory.

**5.8 Licensed Product Recalls.** In the event that a Regulatory Authority, Verastem or Licensee determines that a Product Recall is required, Licensee and Verastem shall discuss and cooperate in good faith to promptly implement such Product Recall, provided that Licensee shall be responsible for the implementation of such Product Recall in the Territory. The cost of replacement Licensed Product and the Product Recall shall be borne as follows: [\* \* \*]

## ARTICLE 6 SUPPLY AND COMMERCIALIZATION

### 6.1 Supply.

(a) **Supply by Verastem.** Subject to Section 2.2, this 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 Products in bulk capsule form for Development (as applicable) and Commercialization in the Territory during the Term. Such supply of Licensed Product shall be limited solely to the formulation of the Licensed Product 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) (such Licensed Product, an “**Existing Formulation Product**”); provided, however, that in the event Verastem approves a Development Plan for a New Formulation Product in accordance with Section 4.4, Verastem may also elect to supply to Licensee, in its sole discretion, and Licensee hereby agrees to purchase from Verastem, upon Verastem’s election, any and all requirements of such New Formulation Product for Development (as applicable) and Commercialization in the Territory during the Term. Within [\* \* \*] months following the Effective Date, the Parties will execute a separate supply agreement containing supply terms and conditions consistent with the principles set forth on **Exhibit E** hereto (Supply Agreement Key Terms) and typical for such agreements (the “**Supply Agreement**”).

(b) **Quality Agreement.** 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 any Licensed Product in the Territory and containing terms and conditions consistent with the

principles set forth on **Exhibit E** hereto and typical for such agreements (the “**Quality Agreement**”).

(c) **Technology Transfer and Cooperation.** In the event (i) of a Supply Failure (as such term is defined in the Supply Agreement) or (ii) that Verastem elects not to supply Licensee’s requirements of a New Formulation Product in accordance with Section 6.1(a), Verastem shall, and shall cause its Affiliate(s) and Subcontractor(s) to, as applicable, provide Licensee with reasonable support and cooperation, at Verastem’s expense, to complete a technology transfer of the Verastem Know-How related to the Manufacture of the Existing Formulation Product or New Formulation Product (as applicable) to Licensee or its designee in accordance with a technology transfer plan to be agreed upon by the Parties.

**6.2 Commercialization Diligence.** Following receipt of Regulatory Approval for a Licensed Product [\* \* \*] by or on behalf of Licensee, Licensee shall be responsible for, and shall use Commercially Reasonable Efforts to, Commercialize each such Licensed Product in the Field [\* \* \*] in the Territory 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 [\* \* \*] months prior to the anticipated date of the First Commercial Sale of Licensed Product in the Territory. Verastem shall have the right to review and comment on such Commercialization Plan and Licensee shall incorporate any reasonable comments received from Verastem prior to finalizing such Commercialization Plan. Thereafter, from time to time, but at least every [\* \* \*] months, Licensee shall propose updates or amendments to the Commercialization Plan in consultation with Verastem to reflect changes in such plans, including those in response to changes in the marketplace, relative commercial success of such Licensed Product, and other relevant factors that may influence such plan and activities. 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 incorporate 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 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 JCC 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 a 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. Such commercial forecast shall be separate from the supply forecast requirements set forth in Exhibit E and more fully described in the Supply Agreement.

**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.

**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 [\* \* \*] hours, 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.** Within [\* \* \*] Business Days after Effective Date, Verastem shall issue an invoice to Licensee, and Licensee shall pay to Verastem a one-time, non-refundable, non-creditable upfront payment of Five Million Dollars (\$5,000,000) by wire transfer of immediately available funds to account designated in Section 7.4(f).

**7.2 Regulatory Milestone Payments for Existing Formulation Products.** Licensee shall pay to Verastem the non-refundable, non-creditable milestone payments set forth in Table 7.2 below (each, a "Regulatory Milestone Payment") upon the first achievement by Licensee or its Affiliates or Sublicensees of the corresponding regulatory milestone events set forth in Table 7.2 below (each a "Regulatory Milestone Event") for an Existing Formulation Product [\* \* \*]. Licensee shall notify Verastem in writing of the achievement by or on behalf of Licensee, its Affiliates or Sublicensees of any Regulatory Milestone Event promptly following the occurrence thereof, but in no event later than [\* \* \*] Business Days following such occurrence. Verastem shall invoice Licensee accordingly, and Licensee shall pay Verastem each Regulatory Milestone Payment within [\* \* \*] days of the date of invoice; provided, however, that if Licensee achieves a Regulatory Milestone Event [\* \* \*], then Licensee will pay Verastem [\* \* \*]

[* * *]	
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

Each Regulatory Milestone Payment set forth above shall be payable only one-time for the first Existing Formulation Product to achieve the applicable Regulatory Milestone Event.

**7.3 Sales Milestone Payments for Existing Formulation Products.** Licensee shall pay to Verastem the non-refundable, non-creditable milestone payments set forth in Table 7.3 below (each, a "Sales Milestone Payment") [\* \* \*] (each a "Sales Milestone Event"). Within [\* \* \*] Business Days of the achievement of a Sales Milestone Event, Licensee shall notify Verastem of such achievement and Verastem shall issue an invoice accordingly. Licensee shall pay the corresponding Sales Milestone Payment set forth below within [\* \* \*] days of the date of such invoice.

[* * *]	
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

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

**7.4 Royalty Payments to Verastem.**

(a) **Royalty Payments and Rates for Existing Formulation Products.** Licensee shall, on an Existing Formulation Product-by-Existing Formulation Product basis during the applicable Royalty Term, make non-refundable, non-creditable royalty payments to Verastem [\* \* \*]

[* * *]	
[* * *]	[* * *]
[* * *]	[* * *]
[* * *]	[* * *]

(b) **Royalty Termination Date.** Following expiration of the Royalty Term for a given Existing Formulation Product in the Territory (i) no further royalties shall be payable in respect of sales of such Existing Formulation Product in the Territory and (ii) the License granted to Licensee hereunder with respect to such Existing Formulation Product in the Territory shall automatically become fully paid-up, perpetual, irrevocable and royalty-free, in each case only to the extent that (A) the License with respect to such Existing Formulation Product in the Territory has not been terminated prior to expiration of the applicable Royalty Term and (B) Licensee has paid Verastem all royalties payable with respect to such Existing Formulation Product in the Territory throughout the applicable Royalty Term.

(c) **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 Manufacture (to the extent Licensee is permitted to Manufacture pursuant to Section 2.2(i) and is using Verastem IP), or Commercialization in the Territory of an Existing Formulation Product, which intellectual property right (A) is not licensed or sublicensed hereunder, (B) covers the composition of matter of the Licensed Compound or the Existing Formulation Product, Manufacture (to the extent Licensee is permitted to Manufacture pursuant to Section 2.2(i) and is using Verastem IP) or the method of use of such composition of matter in the Field, and (C) is necessary (and not just useful) to Commercialize such Existing Formulation Product (the relevant “*Infringed Patent*”



**Right**”), or (ii) shall be subject to a final court or other binding order or ruling that such Manufacture (to the extent Licensee is permitted to Manufacture pursuant to Section 2.2(i) and is using Verastem IP), or Commercialization of such Existing Formulation 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 such Existing Formulation Product in the Territory, then the amount of Licensee’s royalty payments to Verastem under Section 7.4(a) shall be reduced by [\* \* \*] of the amount paid by Licensee to such Third Party with respect to such Infringed Patent Right in each applicable [\* \* \*] that is reasonably and appropriately allocable to such Existing Formulation Product in the Territory [\* \* \*], subject to Section 7.4(c)(iii). If Licensee licenses any Third Party intellectual property right that, in the absence of such license, would be infringed by the Manufacture (to the extent Licensee is permitted to Manufacture pursuant to Section 2.2 and is using Verastem IP) of an Existing Formulation Product, this Section 7.4(c)(i) only applies if Licensee is Manufacturing in a substantially similar way to how Verastem Manufactured before Licensee began Manufacturing pursuant to Section 2.2 (i.e., Licensee may not license new or cutting edge manufacturing technology that was not being used by Verastem in order to reduce royalties owed hereunder).

(ii) **Generic Entry.** If, on an Existing Formulation Product-by-Existing Formulation Product, [\* \* \*] and country-by-country basis during the Royalty Term for an Existing Formulation Product, there is a (A) sale by a Third Party of one or more Generic Products with respect to an Existing Formulation Product in a country in the Territory and (B) a decrease in Net Sales by Licensee or any of its Affiliates or Sublicensees of an Existing Formulation Product as set forth in **Table 7.4(c)(ii)** below, in each case of (A) and (B), [\* \* \*], then the royalty rates payable by Licensee pursuant to Section 7.4(a) for such Existing Formulation Product in such country shall be reduced by the corresponding Royalty Reduction Percentage set forth in **Table 7.4(c)(ii)** below for the remainder of the Royalty Term for such Existing Formulation Product in such country, subject to Section 7.4(c)(iii).

<b>Table 7.4(c)(ii)</b>	
<b>Decrease in Net Sales by Licensee [* * *]</b>	<b>Royalty Reduction Percentage</b>
[* * *]	[* * *]
[* * *]	[* * *]

(iii) **Cumulative Deductions.** With respect to an Existing Formulation Product in the Territory, in no event shall a deduction or deductions under Section 7.4(c)(i) and Section 7.4(c)(ii) reduce the royalty payment made by Licensee in respect of Net Sales of such Existing Formulation Product in the Territory in any Calendar Quarter to [\* \* \*]. Licensee may carry forward any such reductions permitted under Section 7.4(c)(i) and Section 7.4(c)(ii) that are incurred or accrued in a [\* \* \*] but are not applied against royalty payments due to Verastem in such [\* \* \*] as a result of the foregoing floor and apply such amounts against royalty payments due to Verastem in any subsequent [\* \* \*] until the amount of such reduction has been fully applied against royalty payments due to Verastem.

(d) **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.

(e) **Royalty Reports and Payments.** Within [ \* \* \* ], commencing with [ \* \* \* ], Licensee shall provide Verastem with a report that contains the following information for the applicable [ \* \* \* ], on an Existing Formulation Product-by-Existing Formulation Product and country-by-country basis: [ \* \* \* ]. Each report shall also identify the date of First Commercial Sale of an Existing Formulation Product in each country in the Territory. Concurrent with the delivery of the applicable [ \* \* \* ] report, Verastem shall issue the corresponding invoice and Licensee shall pay in Dollars all royalties due to Verastem with respect to Net Sales by Licensee, its Affiliates and their respective Sublicensees for such [ \* \* \* ].

(f) **Invoices, Payment Method, Currency, and Exchange Rate.** Invoices, indicating the applicable VAT, should be addressed to:

Sanofi  
DAVPA - Licenses & Back Office  
[ \* \* \* ]  
France

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 the following bank account (or such other bank account as Verastem may provide to Licensee in writing):

**Bank Name and Address:** [ \* \* \* ]  
[ \* \* \* ]  
[ \* \* \* ]  
**Account Name:** [ \* \* \* ]  
**ABA Number:** [ \* \* \* ]  
**SWIFT:** [ \* \* \* ]  
**Account Number:** [ \* \* \* ]

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, [ \* \* \* ] 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 or International Financial Reporting Standards, consistently applied. Upon at least [\* \* \*] days’ prior written notice, Licensee will permit an independent certified public accountant of internationally recognized standing selected by Verastem and reasonably acceptable to Licensee, to have access during regular business hours to such records 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 [\* \* \*]. 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 [\* \* \*] percent ([\* \* \*] %) of the amount actually due for the time period being audited, in which case Licensee [\* \* \*]. The right to audit any records underlying any royalty report or supporting any other amount payable under this Agreement shall extend for [\* \* \*] years from the end of the Calendar Year in which a royalty report was delivered or such amount was paid, respectively.

(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.** The Parties hereby acknowledge and agree that (i) under the Applicable Laws as of the Effective Date no withholding or similar Taxes will be imposed or levied on account of any payment made under this Agreement, and (ii) to the extent that there is a change in Applicable Law at any time during the Term such that withholding or other additional potential Taxes may be imposed or levied on account of the payment of any amounts owed under this Agreement, then the Parties shall use Commercially Reasonable Efforts to mitigate the amount of such Taxes that would be required to be withheld or paid, or to mitigate the effect of such change in Applicable Law. Notwithstanding the foregoing, if Licensee is so required by Applicable Law to deduct and withhold Taxes from a payment due and payable to Verastem hereunder, Licensee shall: (a) promptly notify Verastem of such requirement; (b) make such required deduction and withholding from the corresponding payment; (c) pay to the relevant Governmental Authority (*e.g.*, the applicable taxing authority) the full amount required to be so deducted and withheld; and (d) promptly forward to Verastem an official receipt (or certified copy) or other documentation reasonably acceptable to Verastem evidencing such payment to such Governmental Authority(ies). [\* \* \*].

(c) **Cooperation.** The Parties acknowledge and agree that it is the 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.

**7.8 New Formulation Products.** Notwithstanding any provision in this Agreement to the contrary, the Regulatory Milestone Payments owed pursuant to Section 7.2, the Sales Milestone Payments owed pursuant to Section 7.3, and the royalty payments owed pursuant to Section 7.4 shall not apply to any Licensed Product that is a New Formulation Product. Instead, any such payments owed by a Party to the other Party in connection with the Development or Commercialization of any such New Formulation Product shall be determined in accordance with the Development Plan that Verastem accepts with respect to such New Formulation Product pursuant to Section 4.4, and the Parties will in good faith discuss an amendment or side letter to this Agreement and to the Commercialization Plan that reflect the economic proposal set forth in such Development Plan.

## 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 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 provided that in such case on the condition that such Upstream Licensors are bound by written, binding obligations of confidentiality and non-use consistent with this Agreement; 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 (a) such Publication shall not include any Confidential Information of Licensee without Licensee's prior written consent and (b) Verastem shall notify Licensee at least [\* \* \*] days prior to making such Publication and permit Licensee to request a delay in such Publication so that Licensee may file for patent protection as necessary. Licensee shall not have the right to issue any Publication except with the prior written approval of Verastem, such approval not to be unreasonably withheld, conditioned or delayed, 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 JCC) with a copy of such proposed Publication at least [\* \* \*] days prior to the earlier of its presentation or intended submission for publication, or if Licensee has fewer than [\* \* \*] days before submitting such proposed Publication for the reasons of authors, Licensee shall provide Verastem (including the Alliance Manager and all Verastem members of the JCC) with a copy of such proposed Publication as soon as reasonably practicable. 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 (a) the deletion of any Confidential Information of Verastem that Verastem identifies for deletion in Verastem's written comments, and (b) 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 Agreement, which is attached hereto as **Exhibit I**, to be issued by Verastem 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. 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, except as may be required by Applicable Laws. 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. Additionally, 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, except as may be required by Applicable Laws. Verastem shall use Licensee'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 to Sanofi"; provided that Verastem will use Licensee's corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of Licensee shall not be impaired, in a manner consistent with best practices used by Verastem with respect to its other collaborators, and in a manner consistent with Licensee's brand usage policies.

(b) Notwithstanding any provision of this Agreement to the contrary, Verastem 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 Verastem under this Agreement. After a Publication has been made available to the public, each 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 [\* \* \*] 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 I** 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.

## 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;

(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; and

(d) it 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.

**9.2 Representations and Warranties of Verastem.** Verastem represents and warrants to Licensee that as of the Effective Date:

(a) subject to Section 2.5, it Controls the Verastem IP, 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; and

(b) [\* \* \*]

(c) it has not received any written notice from any Third Party asserting or alleging that the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party; and

(d) there is no pending or, to Verastem's knowledge, no threatened (in writing), adverse actions, suits or proceedings against Verastem involving the Verastem IP or the Licensed Compound or Licensed Product; and

(e) it has taken reasonable measures to protect the confidentiality of any Confidential Information in the Verastem Know-How; and

(f) [\* \* \*]

(g) to the actual knowledge of Verastem, there is no use, infringement or misappropriation of the Verastem IP in derogation of the rights granted to Licensee in this Agreement; and

(h) (i) **Exhibit A** attached hereto sets forth a true and correct list of all Verastem Patents existing as of the Effective Date that cover the Licensed Compound or Licensed Product in the Territory; and (ii) such Verastem Patents [\* \* \*] are being diligently prosecuted in the respective patent offices in accordance with Applicable Law [\* \* \*] All renewable and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Verastem Patents have been paid; and

(i) [\* \* \*]

(j) to the actual knowledge of Verastem, the Licensed Trademarks are free of any liens, charges and encumbrances in the Territory; and

(k) to the actual knowledge of Verastem, the research and development of the Licensed Compound and Existing Formulation Product prior to the Effective Date by Verastem, and its Affiliates and service providers, was conducted in compliance, in all material respects, with all Applicable Laws.

### 9.3 [ \* \* \* ].

**9.4 Representations and Warranties of Licensee.** Licensee represents and warrants to Verastem that, as of the Effective Date, 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.

### 9.5 Covenants of Each Party.

Each Party covenants 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; and

(b) In the event that it conducts any Clinical Trial pursuant to Section 4.2, it will only engage Clinical Trial sites that conduct all Clinical Trials in compliance with Applicable Laws in the relevant jurisdiction, including GCP and the ICH Guidelines as applicable; and

(c) [ \* \* \* ]

### 9.6 Compliance with Anti-Corruption Laws.

(a) Notwithstanding anything to the contrary in this Agreement, each Party agrees that:

(i) it shall not, in the performance of this Agreement, perform any actions, or permit its Affiliates, Third Party Licensees (with respect to Verastem), Sublicensees (with respect to Licensee) or Subcontractors to perform any actions, that are prohibited by 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 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;

(b) Each Party represents and warrants that, to its knowledge, neither it 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 it or any of its Affiliates:

(i) has taken any action in violation of any applicable Anti-Corruption Laws; or

(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 9.6(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) Each Party further represents and warrants that, as of the Effective Date, none of the officers, directors or employees of it or of any of its Affiliates or agents acting on behalf of it 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 9.6, “**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.

#### **9.7 Representations regarding Debarment**

(a) Each Party represents and warrants that, as of the Effective Date, and covenants during the Term, that neither it nor its Affiliates nor any of their respective directors, officers, employees, to its knowledge based upon reasonable inquiry:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or under any similar Applicable Laws;

(ii) has been charged with, or convicted of, any felony or misdemeanor under Applicable Laws related to any of the following: (a) the development or approval of any drug product or the regulation of any drug product under the FD&C Act; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, the national laws of individual EU Member States implementing the provisions of these Directives into their national law, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or any similar Applicable Laws; (b) a conspiracy to commit, aid or abet the development or approval of any drug product or regulation of any drug product; (c) health care program-related crimes (involving Medicare, any state health care program, or any healthcare program in any country in the European Union or the Territory) or provision of illegal inducements to physicians or healthcare institutions to recommend, endorse, prescribe, order, supply, purchase, use or administer any drug product; (d) patient abuse, controlled substances, bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records; (e) interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or (f) a conspiracy to commit, aid or abet any of these listed felonies or misdemeanors; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal or state health care programs (including convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any healthcare program in any country in the European Union or in Territory, or excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any United States federal procurement or non-procurement programs or procurement or non-procurement programs in any country in the European Union or in the Territory.

(b) **Notification.** Each Party will notify the other Party promptly, but in no event later than thirty (30) calendar days, after knowledge of any exclusion, debarment, suspension or other ineligibility set forth in Section 9.7(a)(iii) occurring during the Term, or if such Party concludes based on its good faith business judgment that a pending action or investigation is likely to lead to the exclusion, debarment, suspension or other ineligibility of such Party an Affiliate of such Party or any of such Party's or such Party's Affiliates' directors, officers, employees, or consultants.

**9.8 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 LICENSED 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 any Licensed Product by or on behalf of Licensee or any of its Affiliates, Sublicensees or Subcontractors, including product liability claims, (b) the negligence or willful misconduct of Licensee or its Affiliates, Sublicensees or Subcontractors, (c) 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 (d) failure of Licensee or its Affiliates, Sublicensees 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 (i) a claim for which Verastem has an indemnification obligation pursuant to Section 10.2 below, or (ii) 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 negligence or willful misconduct of Verastem or its Affiliates, Third Party Licensees or Subcontractors or (b) 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, in each case of clauses (a) and (b) above, except to the extent such Losses arise out of (i) a claim for which Licensee has an indemnification obligation pursuant to Section 10.1 above, or (ii) 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 [\* \* \*] 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. The Indemnifying Party may not enter into any settlement without the Indemnified Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Indemnifying Party does not assume and conduct the defense of the claim as provided above: (i) the Indemnified Party may assume and conduct the defense of the claim at the Indemnifying Party's expense; (ii) the Indemnified Party may consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), provided that such judgement or settlement shall not include any admission or acknowledgement of liability or fault of the Indemnified Party as a condition of such judgement or settlement; and (iii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party for Losses as provided in this Section 10. 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 [\* \* \*]. Each Party shall provide the other Party with evidence of such insurance upon request. 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) **Inventorship.** For purposes of determining ownership of Inventions pursuant to this Section 11.1, inventorship for patentable Inventions conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with United States patent laws for determining inventorship.

(b) **Verastem.** As between the Parties, Verastem shall retain ownership of the entire right, title and interest in and to (i) all Verastem IP, (ii) all Inventions made solely by employees of Verastem or by other persons acting on Verastem's behalf, and (iii) all Inventions covering the composition of matter or the method of use of Licensed Compound or Licensed Product or solely related to Licensed Compound or Licensed Product, and made jointly by the employees of Verastem or by other persons acting on behalf of both Parties. Further, Verastem shall retain ownership of all Inventions generated in connection with any Global Clinical Trial, except to the extent that such Inventions comprise Licensee IP. 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.

(c) **Licensee.** As between the Parties, Licensee shall retain ownership of (i) all Licensee IP, and (ii) all Inventions [ \* \* \* ] made solely by the employees of Licensee or by other persons acting on Licensee's behalf. For clarity, all Inventions under the foregoing subsection (ii) of this Section 11.1(c) are part of the Licensee IP and licensed to Verastem in the Field outside of the Territory under Section 2.8.

(d) **Assignment.** Each Party would ensure that all employees and other persons acting on its behalf in performing its obligations under this Agreement would be obligated, either pursuant to Applicable Law or pursuant to a binding written agreement, to assign to it, or as it would direct, all Inventions covering the composition of matter or the method of use of Licensed Compound or Licensed Product or solely related to the Licensed Compound or Licensed Products, and made or conceived by such employees or other persons. Licensee shall and hereby does assign to Verastem all right, title and interest in and to any Inventions covering the composition of matter or the method of use of Licensed Compound or Licensed Product or solely related to the Licensed Compound or Licensed Products, and developed jointly by the Parties pursuant to Section 11.1(b)(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(d), 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 no obligation to file Verastem Patents in every single country in the Territory, but will consider in good faith any reasonable proposal of filing by Licensee, [\*\*\*]. Verastem shall have the sole right to control the Patent Prosecution of all of Verastem's patents 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 (A) 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 reasonably in advance of the submission of such proposed filings and correspondence, and Verastem will consider in good faith any reasonable comments so provided by Licensee, [\*\*\*], (B) copies of all material filings and correspondence actually filed with any patent authority in the Territory in connection with the Patent Prosecution of the Verastem Patents, (C) written notice of 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 Verastem Patents in the Territory, and (D) written notice as early as possible prior to abandoning any Verastem Patent in the Territory.

(iii) [\*\*\*]

(iv) Subject to the terms and conditions of the Upstream License Agreements, in the event that Verastem provides Licensee with the written notice described in Section 11.2(a)(ii)(D) above prior to abandoning any Verastem Patent, then Licensee shall have the option, exercisable by delivery of written notice thereof within [\*\*\*] days thereafter, to assume the right (but not the obligation), [\*\*\*] and sole discretion, to control the preparation, filing, prosecution and maintenance of such Verastem Patent [\*\*\*].

(b) **Licensee Patents.** As between the Parties, Licensee shall have the sole right to control the Patent Prosecution of all Licensee Patents [\*\*\*].

(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, or requiring its employees to execute 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 (A) alleged or threatened infringement by a Third Party of (i) any of the Verastem Patents in any country in the Territory or (ii) any of the Licensee Patents in any country in the Territory, which infringement of such Licensee Patents adversely affects or is expected to adversely affect any Licensed Product in such country, 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; or (B) unauthorized use in the Territory by a Third Party of any Know-How within the Verastem IP or Licensee IP (collectively “**Product Infringement**”). For clarity, Product Infringement excludes any Patent Challenge.

(b) **Enforcement Right.**

(i) Verastem shall have the first right, in its sole discretion, to bring and control, including managing and settling, 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. Licensee would, [\* \* \*], have the right, but not the obligation, to participate or be separately represented in such action or proceeding. 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 shall have the right, but not the obligation, subject to any applicable restrictions under the Upstream License Agreements, to take any legal action, [\* \* \*], 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, including managing and settling, 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 (and shall cause its employees to) 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 Defense of Patents Rights

(a) **Notice.** Each Party shall notify the other within [\* \* \*] Business Days of becoming aware of any Patent Challenge brought by a Third Party against (i) any of the Verastem Patents in any country in the Territory or (ii) any of the Licensee Patents in any country in the Territory, which Patent Challenge of such Licensee Patents adversely affects or is expected to adversely affect any Licensed Product in such country, 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.

(b) **Right to defend.**

(i) Verastem shall have the first right, in its sole discretion, to defend and control, including managing and settling, any Patent Challenge relating to the Verastem Patents 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. Licensee would, [\* \* \*], have the right, but not the obligation, to participate or be separately represented in such action or proceeding. In the event Verastem is unable or unwilling to defend or control such Patent Challenge within [\* \* \*] months after the date of notice of such Patent Challenge, Licensee shall have the right, but not the obligation, subject to any applicable restrictions under the Upstream License Agreements, to take any legal action, [\* \* \*], as Licensee deems appropriate to prevent or enjoin such Patent Challenge.

(ii) Licensee shall have the first right to defend and control, including managing and settling, any Patent Challenge relating to the Licensee Patents against any Patent Challenge 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 such Patent Challenge within [\* \* \*] months after the date of notice of such Patent Challenge, 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 Patent Challenge.

(c) **Cooperation.** At the request of the Party defending a Patent Challenge, the other Party shall, and shall cause its employees to, 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 a defense action relating to a claim of Patent Challenge in the Territory shall be first applied against payment of each Party's costs and expenses in connection therewith. [\* \* \*].

## 11.5 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

bona fide claim or assertion of infringement in writing 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, [\* \* \*] and Verastem shall provide reasonable assistance to Licensee at Verastem’s cost and expense; [\* \* \*] Licensee shall keep Verastem informed on the status of such defense action, and Verastem shall, at its own expense, (A) provide reasonable support to Licensee upon Licensee’s reasonable request, and (B) have the right, but not the obligation, to participate or be separately represented in such defense action at its sole option.

(c) Recoveries. [\* \* \*].

**11.6 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 [\* \* \*].

### **11.7 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. Subject to Section 11.7(c), Verastem shall be responsible for the protection and maintenance of the Licensed Trademarks at Verastem’s costs.

(b) **Product Marks.** Subject to Section 11.7(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 provide comments on each proposed Product Mark and use thereof, (ii) give due consideration to Verastem’s comments before selecting any Product Mark or using any Product Mark in commerce, and (iii) not use any trademark Controlled by Verastem or its Affiliates (including Verastem’s corporate name) without Verastem’s prior written consent, such consent not to be unreasonably withheld. Subject to Section 11.7(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) **COPIKTRA.** Verastem acknowledges that Licensee plans to use the Licensed Trademark COPIKTRA in the Territory. Verastem shall use commercially reasonable efforts to carry out all reasonably necessary procedures and perform any reasonable act to apply for, register, renew and ensure the protection of the Licensed Trademark COPIKTRA in the Major Market Countries, [\*\*\*]. In case Licensee wants to use COPIKTRA in another country of the Territory which is not a Major Market Country, Verastem shall, upon Licensee's request, use commercially reasonable efforts to apply for, register, renew and ensure protection of the Licensed Trademark in such country [\*\*\*]. Verastem shall keep Licensee reasonably informed of any trademark prosecution of COPIKTRA in any Major Market Country and other requested countries outside Major Market Countries if applicable. Licensee will notify Verastem in writing in the event that Licensee lost any interest for the Licensed Trademark COPIKTRA in a specific country. Following such notice, [\*\*\*]. Should the Licensed Trademark COPIKTRA be rejected either by a Regulatory Authority or by a Trademark Office, Licensee will use the Licensed Trademark COPIKTIV. If needed, Verastem shall, at Licensee's request apply for, use commercially reasonable efforts to register, renew and ensure protection of the Licensed Trademark COPIKTIV in such country, [\*\*\*].

(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 11.7(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 11.7(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 (A) a material adverse impact on such Licensed Trademarks or the goodwill associated therewith in any country, or (B) a material negative reputational impact on Verastem's or any of its Affiliates' business in any country, or (C) 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 (I) sound trademark usage principles, (II) all Applicable Laws, and (III) 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 11.7, 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.

(iv) Licensee shall not contest, oppose or challenge Upstream Licensors’ ownership of any Licensed Trademark.

(e) **Trademark Infringement by a Third Party**

(i) Licensee hereby agrees to notify Verastem in writing promptly upon learning of any conflicting uses of, or any applications or registrations to use, any mark, name, symbol, device or word that could constitute an act of infringement or of unfair competition (each a Trademark Harm) by a third party in relation to the Licensed Trademarks in the Territory.

(ii) Verastem shall have the first right, in its sole discretion, to bring and control, including managing and settling, any legal action (including administrative oppositions) to defend the Licensed Trademarks, including the trademark COPIKTRA, 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. Licensee would, at its own expense, have the right, but not the obligation, to participate or be separately represented in such action or proceeding. In the event Verastem is unable or unwilling to bring and control legal action to prevent or enjoin such Trademark Harm within [\* \* \*] months after the date of notice of such Trademark Harm, Licensee shall have the right, but not the obligation, subject to any applicable restrictions under the Upstream License Agreements, to take any legal action, at Licensee’s own cost and expense, as Licensee deems appropriate to prevent or enjoin such Trademark Harm.

(iii) At the request of the Party bringing an action related to such Trademark Harm, the other Party shall (and shall cause its employees to) provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating 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.

**11.8 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 country-by-country basis, unless terminated earlier in accordance with this Article 12, until expiration of the last Royalty Term for the last Licensed Product in the Territory (the “**Term**”).

**12.2 Termination**

(a) **Termination by Licensee for Convenience.** At any time, Licensee may terminate this Agreement on a Licensed Product-by-Licensed Product or country-by-country basis by providing written notice of such 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.** 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. For all breaches of this Agreement, the allegedly breaching Party shall have [\* \* \*] days (or, in the case of a payment breach, [\* \* \*] 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 [\* \* \*] (or [\* \* \*]) 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, if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the [\* \* \*] 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.

(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 during the Term [\* \* \*].

(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) **Partial Termination.**

(i) **Major Market Countries.** Verastem shall have the right to terminate all of Licensee's rights under this Agreement with respect to any Licensed Product in a Major Market Country upon delivery of written notice to Licensee in the event of the following:

(1) If Regulatory Approval is required to Commercialize such Licensed Product in such Major Market Country, and (A) Licensee has not submitted an application for Regulatory Approval in such Major Market Country within [\* \* \*] years of the Effective Date, (B) Licensee has not obtained Regulatory Approval in such Major Market Country within [\* \* \*] years of the Effective Date (unless Licensee has submitted an application for such Regulatory Approval and such application remains under review by the applicable Regulatory Authority in such Major Market Country), (C) Licensee has not achieved a First Commercial Sale of such Licensed Product in such Major Market Country before [\* \* \*], or (D) Licensee has obtained Regulatory Approval for such Licensed Product in such Major Market Country and after a First Commercial Sale [\* \* \*]), there have been [\* \* \*] sales of such Licensed Product in such Major Market Country for a period of [\* \* \*] months (or [\* \* \*] months in the case of any country where sales of Licensed Product are made through an annual tender process); and

(2) If Regulatory Approval is not required to Commercialize a Licensed Product in such Major Market Country, and (A) Licensee has not achieved a First Commercial Sale in such Major Market Country by [\* \* \*], or (B) after First Commercial Sale in such Major Market Country, there have been [\* \* \*] sales of such Licensed Product in such Major Market Country for a period of [\* \* \*] months; provided, however, that if Licensee is able to demonstrate, to Verastem's reasonable satisfaction, that Licensee is prevented from achieving the events set forth in the foregoing clauses (1) and (2) due to Development or Commercialization issues that are outside of Licensee's reasonable control, then the Parties will meet and discuss in good faith revising the timeframes set forth in the foregoing clauses (1) and (2) that would otherwise trigger Verastem's right to terminate Licensee's rights under this Agreement with respect to the applicable Major Market Country.

(ii) [\* \* \*]

(f) **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 Effects 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 and the licenses granted by Licensee to Verastem under Section 2.8 of 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.** 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, provided that in cases of termination by Licensee pursuant to Sections 12.2(b) and 12.2(d), as permitted by Applicable Law, such assignment shall be at Verastem's cost and expense. 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), provided that in cases of termination by Licensee pursuant to Sections 12.2(b) and 12.2(d), as permitted by Applicable Law, such transfer and assignment shall be at Verastem's cost and expense. 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.** Provided that Licensee is not in material breach of any obligation under this Agreement at the time of any termination of this Agreement, Licensee shall have the right for [\* \* \*] months thereafter to dispose of all quantities of Licensed Product then in its inventory and to complete Manufacture of and dispose of any work-in-progress then being Manufactured, as though this Agreement had not terminated. Licensee shall pay royalties thereon, in accordance with the provisions of this Agreement, as though this Agreement had not terminated. Notwithstanding the foregoing, at Verastem's election and request, Licensee shall transfer to Verastem or a Third Party designated by Verastem all inventory of Licensed Products [\* \* \*] then in the possession or control of Licensee, its Affiliates or Sublicensees; provided that Verastem shall [\* \* \*].

(e) **Wind Down and Transition.** Licensee shall provide reasonable assistance, at its own cost and expense, for the wind-down or transition, at Verastem's election, of Licensee's, its Affiliates' and its Sublicensees' Development and Commercialization activities for the Licensed Products, provided that in cases of termination by Licensee pursuant to Sections 12.2(b) and 12.2(d), as permitted by Applicable Law, such provision of reasonable assistance shall be at Verastem's cost and expense. Licensee shall, and shall cause its Affiliates and Sublicensees to, reasonably cooperate with Verastem to facilitate orderly transition of the Development and Commercialization of the 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 promote, distribute, sell or otherwise Commercialize the 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 clause (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.

(f) **Ongoing Clinical Trials.** 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 effective as of [\* \* \*] months 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; provided further that in cases of termination by Licensee pursuant to Sections 12.2(b) and 12.2(d), as permitted by Applicable Law, then Verastem 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, provided that in cases of termination by Licensee pursuant to Sections 12.2(b) and 12.2(d), as permitted by Applicable Law, then such orderly wind-down shall be at Verastem's cost and expense.

(g) **Return of Confidential Information.** At the Disclosing Partys election, the Receiving Party shall return (at the Disclosing Party's expense) or destroy all tangible materials comprising, bearing or containing any Confidential Information of the Disclosing Party that are in the Receiving Party's or its Affiliates' or Sublicensees'(with respect to Licensee) or Third Party Sublicensees' (with respect to Verastem) possession or control and provide written certification of such destruction except to the extent that the Receiving Party is required to retain such materials by Applicable Laws; provided that the Receiving Party may retain one (1) copy of such Confidential Information for its legal archives, and provided further, that the Receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information. Any Confidential Information retained by the Receiving Party pursuant to this Section 12.3(g) shall remain subject to the Receiving Party'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 (Definitions), Article 7 (Payments) (except with respect to Section 7.6 (Financial Records and Audits), and solely with respect to any amounts that have accrued prior to the effective date of expiration or termination of this Agreement), Article 8 (Confidentiality; Publication), Article 10 (Indemnification) (solely with respect to indemnifiable events that occur prior to the effective date of expiration or termination of this Agreement), Article 13 (Dispute Resolution) (with respect to any disputes arising during the Term), and Article 14 (Miscellaneous) (as applicable), and Section 2.7 (Verastem Retained Rights), Section 2.9 (No Implied Licenses; Negative Covenant), Section 9.8 (No Other Warranties), Section 11.1 (Ownership), Section 11.2 (Patent Prosecution), Section 11.7(a) (Ownership of the Licensed Trademarks), Section 12.3 (Effects of Termination), Section 12.4 (Bankruptcy Code § 365(n) Election), Section 12.5 (Accrued Rights), Section 12.6 (Survival), and Section 12.7 (Termination Not Sole Remedy), 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 the International Chamber of Commerce (ICC) (or any successor Entity thereto) and in accordance with the Rules of Arbitration of the International Chamber of Commerce 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. The arbitrators' award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(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 by a Party, nor may any right or obligation hereunder be assigned or transferred by a Party (except as expressly permitted under this Agreement), without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may assign this Agreement to a purchaser of all or substantially all of its assets to which this Agreement relates (whether by merger, stock purchase, consolidation, asset purchase, or otherwise) or to any successor Entity resulting from any such merger or consolidation of such Party without the consent of the other Party, provided that (a) such purchaser or successor Entity agrees in writing to be bound by the terms and conditions of this Agreement, and (b) a copy of such writing is provided to the non-assigning Party within [\* \* \*] days of such assignment. Any attempted assignment not in accordance with this Section 14.2 shall be null and void and of no legal effect. Notwithstanding the foregoing, either Party may assign this Agreement and all of its rights and obligations hereunder to an Affiliate without the consent of the other Party, provided that in the case of such assignment, the original Party shall remain jointly and severally liable with such Affiliate. 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 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.  
[\* \* \*]

with a copy to:

Verastem, Inc.  
[\* \* \*]

If to Licensee:

SANOFI  
Global Alliance Management – Strategy & Business Development  
[\* \* \*]

with a copy to:

SANOFI  
Legal Department – Global Functions  
[\* \* \*]

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 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, the Existing Confidentiality Agreement shall be superseded by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Existing 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 Existing 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 or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all 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 pdf copies of counterpart execution pages of this Agreement and such pdf 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.

*{Signature Page Follows}*

**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.**

By: /s/ Dan Paterson

Name: Dan Paterson

Title: President and COO

**SANOFI**

By: /s/ Alban de la Sablière

Alban de la Sablière

Vice-President, Strategy & Business Development

## **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>Territory</b>
<b>Exhibit D:</b>	<b>Licensed Trademarks</b>
<b>Exhibit E:</b>	<b>Supply Agreement Key Terms</b>
<b>Exhibit F:</b>	<b>INK Agreement</b>
<b>Exhibit G:</b>	<b>Infinity Agreement</b>
<b>Exhibit H:</b>	<b>Transition Plan</b>
<b>Exhibit I:</b>	<b>Joint Press Release</b>
<b>Exhibit J:</b>	<b>Letter Agreement</b>

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**Exhibit B**  
**Structure of Licensed Compound**

[\* \* \*]

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**Exhibit C**  
**Territory**

[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]









**Exhibit F**  
**INK Agreement**

[\* \* \*]

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**Exhibit G**  
**Infinity Agreement**

[\* \* \*]

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**Exhibit H**  
**Transition Plan**

[ \* \* \* ]

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**Exhibit I**  
**Press Release**



**Verastem Oncology Signs an Exclusive License Agreement with Sanofi for the Development and Commercialization of COPIKTRA® (duvelisib) in Russia and CIS, Turkey, the Middle East and Africa**

*Verastem Oncology to Receive an Upfront Payment of \$5 Million USD; Then Eligible to Receive Up To \$42 Million USD in Development and Sales Milestones and Double-Digit Percentage Royalties*

*Sanofi Obtains Rights to Develop and Commercialize COPIKTRA in the Licensed Territories*

**BOSTON, MA – July [XX], 2019** – Verastem, Inc. (NASDAQ: VSTM) operating as Verastem Oncology, (or “the Company”), today announced their entry into an exclusive licensing agreement with Sanofi to develop and commercialize Verastem Oncology’s COPIKTRA® (duvelisib), an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, for the treatment of all oncology indications in Russia and CIS, Turkey, the Middle East and Africa.

Under the terms of the agreement, Verastem Oncology shall receive an upfront payment of \$5 million USD. Verastem Oncology is also eligible to receive up to an additional \$42 million USD in development and sales milestone payments, plus double-digit percentage royalties based on future net sales of COPIKTRA in the licensed territories. Sanofi will receive exclusive rights to develop and commercialize COPIKTRA, and hold the marketing authorization and product license for COPIKTRA, in the licensed territories. Sanofi will also have the right to collaborate with Verastem Oncology on certain global development and clinical trial activities.

“Sanofi brings world-class capabilities in developing and commercializing products, making them an ideal partner to bring COPIKTRA to patients in these territories,” said Dan Paterson, President and Chief Operating Officer of Verastem Oncology. “Establishing this third partnership outside the U.S. validates the global potential of COPIKTRA and underscores our commitment to bring COPIKTRA to patients worldwide.”

David Khougazian, Head of Sanofi Genzyme, China & Emerging Markets, commented, “As a specialty care leader, we welcome partnerships that have the potential to bring value for patients and caregivers. This agreement adds to our pipeline an oncology medicine with an innovative mechanism of action and a significant potential of new hope for the patients suffering from those types of blood malignancies with high unmet medical need. Partnering with Verastem Oncology for the development and commercialization of COPIKTRA is consistent with our goals to deliver enhanced patient care and to expand our presence in oncology in Emerging Markets.”

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COPIKTRA was approved in September 2018 by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies. In addition, COPIKTRA has been granted accelerated approval by the FDA for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Accelerated approval in FL was based on overall response rate and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. COPIKTRA includes a Boxed Warning for fatal and serious toxicities including infections, diarrhea or colitis, cutaneous reactions and pneumonitis. See full Prescribing Information for complete Boxed Warning and other important safety information.

### **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).

### **Verastem Oncology Forward Looking Statements**

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 program 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 the risks and uncertainties, among other things, regarding: the commercial success of COPIKTRA in the United States; 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

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of COPIKTRA; the fact 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; that third-party payors (including government agencies) may 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, Sanofi, CSPC Pharmaceutical Group, Yakult Honsha Co., Ltd. or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreements; 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 the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019, as filed with the Securities and Exchange Commission (SEC) on May 9, 2019, its Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC on March 12, 2019 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.

## **Contacts**

### *Investors:*

John Doyle  
Vice President, Investor Relations & Finance  
+1 781-292-4279  
jdoyle@verastem.com

### *Media:*

Lisa Buffington  
Corporate Communications  
+1 781-292-4205  
lbuffington@verastem.com

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**Exhibit J**  
**Letter Agreement**

[\* \* \*]

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## CERTIFICATIONS

I, Brian M. Stuglik, 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/ BRIAN M. STUGLIK

Brian M. Stuglik  
Chief Executive Officer  
(Principal executive officer)

Date: October 30, 2019

## 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 Business and Financial Officer*  
*(Principal financial and accounting officer)*

Date: October 30, 2019

**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, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Brian M. Stuglik, 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/ BRIAN M. STUGLIK

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Brian M. Stuglik  
*Chief Executive Officer*  
*(Principal executive officer)*

Date: October 30, 2019

**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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Gagnon, Chief Business and 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

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Robert Gagnon  
*Chief Business and Financial Officer*  
*(Principal financial and accounting officer)*

Date: October 30, 2019