UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

X	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 193	34
	FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017	

or

0 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 000-19319

Vertex Pharmaceuticals Incorporated

(Exact name of registrant as specified in its charter)

Massachusetts

(State or other jurisdiction of

incorporation or organization)

50 Northern Avenue, Boston, Massachusetts
(Address of principal executive offices)

04-3039129

(I.R.S. Employer Identification No.)

02210

(Zip Code)

Registrant's telephone number, including area code (617) 341-6100

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 x No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No o

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

Large accelerated filer x

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

Emerging growth company o

(Do not check if a smaller reporting 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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common Stock, par value \$0.01 per share

249,068,782

Class

Outstanding at April 21, 2017

VERTEX PHARMACEUTICALS INCORPORATED FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2017

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"We," "us," "Vertex" and the "Company" as used in this Quarterly Report on Form 10-Q refer to Vertex Pharmaceuticals Incorporated, a Massachusetts corporation, and its subsidiaries.

"Vertex," "KALYDECO®" and "ORKAMBI®" are registered trademarks of Vertex. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

Part I. Financial Information

Item 1. Financial Statements

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Statements of Operations (unaudited) (in thousands, except per share amounts)

Three Months Ended March 31, 2017 2016 Revenues: Product revenues, net \$ 480,622 \$ 394,410 Royalty revenues 1,551 3,596 Collaborative revenues 232,545 74 Total revenues 714,718 398,080 Costs and expenses: Cost of product revenues 46,242 49,789 Royalty expenses 746 860 Research and development expenses 273,563 255,860 Sales, general and administrative expenses 113,326 105,214 Restructuring expenses, net 9,999 687 Total costs and expenses 443,876 412,410 Income (loss) from operations 270,842 (14,330)Interest expense, net (16,765)(20,698)Other (expenses) income, net (544)4,411 Income (loss) before provision for income taxes 253,533 (30,617)Provision for income taxes 3,985 5,485 249,548 (36,102)Net income (loss) Income attributable to noncontrolling interest (1,792)(5,529)Net income (loss) attributable to Vertex \$ 247,756 (41,631)Amounts per share attributable to Vertex common shareholders: Net income (loss): Basic \$ 1.01 \$ (0.17)Diluted \$ 0.99 \$ (0.17)Shares used in per share calculations: Basic 246,024 243,831 Diluted 248,700 243,831

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Statements of Comprehensive Income (Loss) (unaudited)

(in thousands)

	7	Three Months Ended March 31,				
		2017	2016			
Net income (loss)	\$	249,548	\$	(36,102)		
Changes in other comprehensive income (loss):						
Unrealized holding gains on marketable securities, net of tax		3,534		229		
Unrealized losses on foreign currency forward contracts, net of tax		(6,681)		(5,212)		
Foreign currency translation adjustment		(2,001)		(1,740)		
Total changes in other comprehensive income (loss)		(5,148)		(6,723)		
Comprehensive income (loss)		244,400		(42,825)		
Comprehensive income attributable to noncontrolling interest		(1,792)		(5,529)		
Comprehensive income (loss) attributable to Vertex	\$	242,608	\$	(48,354)		

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Balance Sheets

(unaudited) (in thousands, except share and per share amounts)

		March 31,		December 31,
		2017		2016
Assets				
Current assets:				
Cash and cash equivalents	\$	1,003,679	\$	1,183,945
Marketable securities, available for sale	•	405,103		250,612
Restricted cash and cash equivalents (VIE)		44,564		47,762
Accounts receivable, net		207,955		201,083
Inventories		82,020		77,604
Prepaid expenses and other current assets		128,493		70,534
Total current assets		1,871,814		1,831,540
Property and equipment, net		708,395		698,362
Intangible assets		284,340		284,340
Goodwill		50,384		50,384
Cost method investments		20,276		20,276
Other assets		11,494		11,885
Total assets	\$	2,946,703	\$	2,896,787
Liabilities and Shareholders' Equity				
Current liabilities:				
Accounts payable	\$	63,145	\$	61,451
Accrued expenses		277,962		315,249
Deferred revenues, current portion		6,057		6,005
Accrued restructuring expenses, current portion		7,634		6,047
Capital lease obligations, current portion		19,270		19,426
Customer deposits		104,774		73,416
Credit facility		_		300,000
Other liabilities, current portion		10,954		10,943
Total current liabilities		489,796		792,537
Deferred revenues, excluding current portion		5,742		6,632
Accrued restructuring expenses, excluding current portion		613		1,907
Capital lease obligations, excluding current portion		30,355		34,976
Deferred tax liability		135,402		134,063
Construction financing lease obligation, excluding current portion		498,775		486,359
Advance from collaborator		74,760		73,423
Other liabilities, excluding current portion		28,467		28,699
Total liabilities		1,263,910		1,558,596
Commitments and contingencies				
Shareholders' equity:				
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding Common stock, \$0.01 par value; 500,000,000 shares authorized; 248,890,834 and 248,300,517 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively		2,459		2,450
Additional paid-in capital		6,616,975		6,506,795
Accumulated other comprehensive income		16,025		21,173
Accumulated deficit		(5,135,451)		(5,373,836)
Total Vertex shareholders' equity		1,500,008		1,156,582
Noncontrolling interest		182,785		181,609
Total shareholders' equity		1,682,793		1,338,191
Total liabilities and shareholders' equity	\$	2,946,703	\$	2,896,787

VERTEX PHARMACEUTICALS INCORPORATED

Condensed Consolidated Statements of Shareholders' Equity and Noncontrolling Interest (unaudited) (in thousands)

_	Common Stock					Accumulated Other										
	Shares		Amount]	Additional Paid-in Capital				Accumulated Deficit		Total Vertex Shareholders' Equity		Noncontrolling Interest		Total Shareholders' Equity	
Balance at December 31, 2015	246,307	\$	2,427	\$	6,197,500	\$	1,824	\$	(5,261,784)	\$	939,967	\$	153,661	\$	1,093,628	
Other comprehensive loss, net of tax	_		_		_		(6,723)		_		(6,723)		_		(6,723)	
Net loss	_		_		_		_		(41,631)		(41,631)		5,529		(36,102)	
Issuance of common stock under benefit plans	980		2		9,147		_		_		9,149		_		9,149	
Stock-based compensation expense					56,317						56,317		(71)		56,246	
Balance at March 31, 2016	247,287	\$	2,429	\$	6,262,964	\$	(4,899)	\$	(5,303,415)	\$	957,079	\$	159,119	\$	1,116,198	
-																
Balance at December 31, 2016	248,301	\$	2,450	\$	6,506,795	\$	21,173	\$	(5,373,836)	\$	1,156,582	\$	181,609	\$	1,338,191	
Cumulative effect adjustment for adoption of new accounting guidance	_		_		9,371				(9,371)		_		_		_	
Other comprehensive loss, net of tax	_		_		_		(5,148)		_		(5,148)		_		(5,148)	
Net income	_		_		_		_		247,756		247,756		1,792		249,548	
Issuance of common stock under benefit plans	590		9		31,019		_		_		31,028		_		31,028	
Stock-based compensation expense	_		_		69,790		_		_		69,790		_		69,790	
Other	_				_		_		_		_		(616)		(616)	
Balance at March 31, 2017	248,891	\$	2,459	\$	6,616,975	\$	16,025	\$	(5,135,451)	\$	1,500,008	\$	182,785	\$	1,682,793	

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Statements of Cash Flows (unaudited) (in thousands)

	Three	Three Months End		
	2017		2016	
Cash flows from operating activities:				
Net income (loss)	\$	249,548 \$	(36,102)	
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Stock-based compensation expense		68,982	55,472	
Depreciation and amortization expense		14,850	16,415	
Deferred income taxes		1,212	2,060	
Impairment of property and equipment		1,946	_	
Other non-cash items, net		(5,152)	(3,835)	
Changes in operating assets and liabilities:				
Accounts receivable, net		(5,118)	(2,512)	
Inventories		(3,650)	(4,771)	
Prepaid expenses and other assets		(47,178)	(7,325)	
Accounts payable		717	(343)	
Accrued expenses and other liabilities		(9,931)	(29,922)	
Accrued restructuring expense		305	(1,459)	
Deferred revenues		(839)	(2,815)	
Net cash provided by (used in) operating activities		265,692	(15,137)	
Cash flows from investing activities:				
Purchases of marketable securities	(:	248,273)	(224,624)	
Maturities of marketable securities		98,393	131,173	
Expenditures for property and equipment		(11,159)	(11,974)	
Decrease in restricted cash and cash equivalents (VIE)		3,198	2,637	
Decrease in other assets		60	80	
Net cash used in investing activities	(:	157,781)	(102,708)	
Cash flows from financing activities:				
Issuances of common stock under benefit plans		11,249	8,846	
Payments on revolving credit facility	(;	300,000)	_	
Advance from collaborator		5,000	_	
Payments on capital lease obligations		(4,703)	(4,041)	
Payments on construction financing lease obligation		(117)	(103)	
Repayments of advanced funding		(994)	_	
Net cash (used in) provided by financing activities	(:	289,565)	4,702	
Effect of changes in exchange rates on cash		1,388	2,620	
Net decrease in cash and cash equivalents	(1	180,266)	(110,523)	
Cash and cash equivalents—beginning of period	1,	183,945	714,768	
Cash and cash equivalents—end of period	\$ 1,	003,679 \$	604,245	
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$	17,527 \$	20,603	
Cash paid for income taxes	\$	1,164 \$	581	
Capitalization of costs related to construction financing lease obligation	\$	12,549 \$	_	
Issuances of common stock from employee benefit plans receivable	\$	19,847 \$	593	

A. Basis of Presentation and Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by Vertex Pharmaceuticals Incorporated ("Vertex" or the "Company") in accordance with accounting principles generally accepted in the United States of America ("GAAP").

The condensed consolidated financial statements reflect the operations of (i) the Company, (ii) its wholly-owned subsidiaries and (iii) consolidated variable interest entities (VIEs). All material intercompany balances and transactions have been eliminated. The Company operates in one segment, pharmaceuticals.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the financial position and results of operations for the interim periods ended March 31, 2017 and 2016.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2016, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 that was filed with the Securities and Exchange Commission (the "SEC") on February 23, 2017 (the "2016 Annual Report on Form 10-K").

Use of Estimates and Summary of Significant Accounting Policies

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the amounts of revenues and expenses during the reported periods. Significant estimates in these condensed consolidated financial statements have been made in connection with the calculation of revenues, inventories, research and development expenses, stock-based compensation expense, restructuring expense, the fair value of intangible assets, goodwill, contingent consideration, noncontrolling interest, the consolidation of VIEs, leases, the fair value of cash flow hedges and the provision for or benefit from income taxes. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections that management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

The Company's significant accounting policies are described in Note A, "Nature of Business and Accounting Policies," in the 2016 Annual Report on Form 10-K.

Recent Accounting Pronouncements

In 2014, the Financial Accounting Standards Board ("FASB") issued new guidance applicable to revenue recognition that will be effective January 1, 2018. Early adoption was permitted for the year-ending December 31, 2017. The new guidance applies a more principles based approach to recognizing revenue. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration that an entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new guidance must be adopted using either a modified retrospective approach or a full retrospective approach for all periods presented. Under the modified retrospective method, the cumulative effect of applying the standard would be recognized at the date of initial application within retained earnings. Under the full retrospective approach, the standard would be applied to each prior reporting period presented. Upon adoption, the Company will use the modified retrospective method. The Company is in the process of evaluating the new guidance and determining whether the expected effect is material to its condensed consolidated financial statements. The Company has formed a project team to review its portfolio of existing customer contracts and current accounting policies to identify and assess the potential differences that would result from applying the requirements of the new standard. The Company is also in the process of implementing appropriate changes to its controls to

support revenue recognition and disclosure under the new standard. The new guidance could impact the Company's accounting for product shipments to certain countries through early access programs, including the French early access programs, whereby the associated product has received regulatory approval but the reimbursement rate has not been finalized.

In 2015, the FASB issued amended guidance applicable to inventory. The amended guidance simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. The amended guidance became effective for the Company during the first quarter of 2017. Adoption of the amended guidance did not have a significant effect on its condensed consolidated financial statements.

In 2016, the FASB issued amended guidance applicable to share-based compensation to employees that simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The amended guidance became effective for the Company during the first quarter of 2017. The amended guidance eliminates the requirement that excess tax benefits be realized as a reduction in current taxes payable before the associated tax benefit can be recognized as an increase in additional paid-in capital. This created approximately \$410.8 million of deferred tax asset ("DTA") relating to federal and state net operating losses ("NOLs") that are fully reserved by an equal increase in valuation allowance. The Company recorded DTAs of approximately \$404.7 million relating to Federal NOLs and approximately \$6.1 million relating to State NOLs, both of which are offset by a full valuation allowance. Upon adoption, the Company also elected to change its accounting policy to account for forfeitures as they occur. The change was applied on a modified retrospective basis with a cumulative effect adjustment to accumulated deficit of \$9.4 million, which increased the accumulated deficit as of January 1, 2017. This change also resulted in an increase to DTA by \$3.4 million, which is offset by a full valuation allowance. As a result, there was no cumulative-effect adjustment to accumulated deficit. The provisions related to the recognition of excess tax benefits in the income statement and classification in the statement of cash flows were adopted prospectively, and as such, the prior periods were not retrospectively adjusted.

In January 2016, the FASB issued amended guidance related to the recording of financial assets and financial liabilities. Under the amended guidance, equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) are to be measured at fair value with changes in fair value recognized in net income. However, an entity has the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. Changes in measurement under either alternative will be recognized in net income. The amended guidance is effective for the year-ending December 31, 2018. Early adoption is permitted. The Company expects the implementation of this standard to have an impact on its consolidated financial statements and related disclosures, as the Company held publicly traded equity investments at March 31, 2017 as well as equity investments accounted for under the cost method. A cumulative-effect adjustment to the balance sheet will be recorded as of the beginning of the fiscal year of adoption. The implementation of this amended guidance is expected to increase volatility in net income as the volatility currently recorded in other comprehensive income related to changes in the fair market value of available-for-sale equity investments will be reflected in net income after adoption.

In January 2017, the FASB issued amended guidance related to business combinations. The amended guidance clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new accounting guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company early adopted this new guidance as of January 1, 2017 and will apply this new guidance to future acquisitions.

In January 2017, the FASB issued amended guidance related the subsequent measurement of goodwill. The amended guidance eliminates a step from the goodwill impairment test. Under the amended guidance, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The amended guidance is effective for the year-ending December 31, 2020. Early adoption is permitted. The Company does not expect a significant effect on its condensed consolidated financial statements upon adoption of this new guidance.

For a discussion of other recent accounting pronouncements please refer to Note A, "Nature of Business and Accounting Policies—Recent Accounting Pronouncements," in the 2016 Annual Report on Form 10-K.

B. Product Revenues, Net

The Company sells its products principally to a limited number of specialty pharmacy providers and selected regional wholesalers in North America as well as government-owned and supported customers in international markets (collectively, its "Customers"). The Company's Customers in North America subsequently resell the products to patients and health care providers. The Company recognizes net revenues from product sales upon delivery to the Customer as long as (i) there is persuasive evidence that an arrangement exists between the Company and the Customer, (ii) collectibility is reasonably assured and (iii) the price is fixed or determinable.

In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from sales to Customers and (ii) reasonably estimate its net product revenues upon delivery to its Customers' locations. The Company calculates gross product revenues based on the price that the Company charges its Customers. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and Customer fees, (b) estimated government and private payor rebates, chargebacks and discounts, (c) estimated reserves for expected product returns and (d) estimated costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers.

The Company makes significant estimates and judgments that materially affect the Company's recognition of net product revenues. In certain instances, the Company may be unable to reasonably conclude that the price is fixed or determinable at the time of delivery, in which case it defers the recognition of revenues. Once the Company is able to determine that the price is fixed or determinable, it recognizes the revenues associated with the units in which revenue recognition was deferred. ORKAMBI net product revenues do not include any revenues from product sales in France. The Company began distributing ORKAMBI through early access programs in the fourth quarter of 2015. The Company's condensed consolidated balance sheet includes \$104.8 million collected as of March 31, 2017 in France related to ORKAMBI that is classified as customer deposits. The Company expects that revenues from these early access programs will be recognized in the period that a formal reimbursement agreement in France is reached based on the terms of such agreement.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2017:

			Rebates,				
	T	rade	Chargebacks		Product	Other	
	Allo	wances	and Discounts		Returns	Incentives	Total
				(in t	housands)		
Balance at December 31, 2016	\$	2,568	\$ 81,927	\$	3,492	\$ 1,214	\$ 89,201
Provision related to current period sales		5,638	28,567		370	6,093	40,668
Adjustments related to prior period sales		(169)	(2,344)		(48)	(56)	(2,617)
Credits/payments made		(5,654)	(27,916)		(170)	(4,428)	(38,168)
Balance at March 31, 2017	\$	2,383	\$ 80,234	\$	3,644	\$ 2,823	\$ 89,084

C. Collaborative Arrangements and Pending Acquisition

Cystic Fibrosis Foundation Therapeutics Incorporated

The Company has a research, development and commercialization agreement with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") that was originally entered into in May 2004, and was most recently amended on October 13, 2016 (the "2016 Amendment"). Pursuant to the agreement, as amended, the Company has agreed to pay royalties ranging from low single digits to mid-single digits on potential sales of certain compounds first synthesized and/or tested between March 1, 2014 and August 31, 2016 and tiered royalties ranging from single digits to sub-teens on any approved drugs first synthesized and/or tested during a research term on or before February 28, 2014, including KALYDECO (ivacaftor), ORKAMBI (lumacaftor in combination with ivacaftor), lumacaftor and tezacaftor. For combination products,

such as ORKAMBI, sales will be allocated equally to each of the active pharmaceutical ingredients in the combination product.

In the first quarter of 2016, CFFT earned a commercial milestone payment of \$13.9 million from the Company upon achievement of certain sales levels of lumacaftor. There are no additional commercial milestone payments payable by the Company to CFFT pursuant to the agreement. Pursuant to the 2016 Amendment, the CFFT provided the Company an upfront program award of \$75.0 million and agreed to provide development funding to the Company of up to \$6.0 million annually. The program award plus any future development funding represent a form of financing pursuant to Accounting Standards Codification (ASC) 730, *Research and Development*, and thus the amounts are recorded as a liability on the condensed consolidated balance sheet, primarily reflected in Advance from collaborator. The liability is reduced over the estimated royalty term of the agreement. Reductions in the liability are reflected as an offset to cost of product revenues and as interest expense.

The Company began marketing KALYDECO in the United States and certain countries in the European Union in 2012 and began marketing ORKAMBI in the United States in 2015. The Company received approval for ORKAMBI In the European Union in 2015 and in Canada and Australia in 2016. The Company has royalty obligations to CFFT for ivacaftor, lumacaftor and tezacaftor until the expiration of patents covering those compounds. The Company has patents in the United States and European Union covering the composition-of-matter of ivacaftor that expire in 2027 and 2025, respectively, subject to potential patent extensions. The Company has patents in the United States and European Union covering the composition-of-matter of lumacaftor that expire in 2030 and 2026, respectively, subject to potential extension. The Company has patents in the United States and European Union covering the composition-of-matter of tezacaftor that expire in 2027 and 2028, respectively, subject to potential extension.

CRISPR Therapeutics AG

In October 2015, the Company entered into a strategic collaboration, option and license agreement (the "CRISPR Agreement") with CRISPR Therapeutics AG and its affiliates ("CRISPR") to collaborate on the discovery and development of potential new treatments aimed at the underlying genetic causes of human diseases using CRISPR-Cas9 gene editing technology. The Company has the exclusive right to license up to six CRISPR-Cas9-based targets. In connection with the CRISPR Agreement, the Company made an upfront payment to CRISPR of \$75.0 million and a \$30.0 million investment in CRISPR pursuant to a convertible loan agreement that converted into preferred stock in January 2016. The Company expensed \$75.0 million to research and development, and the \$30.0 million investment was recorded at cost and is classified as a long-term asset on the Company's condensed consolidated balance sheets. In the second quarter of 2016, the Company made an additional preferred stock investment in CRISPR of approximately \$3.1 million. In connection with CRISPR's initial public offering in October 2016, the Company purchased \$10 million of common shares at public offering price and the Company's preferred stock investments in CRISPR converted into common shares. As of March 31, 2017, the Company recorded the CRISPR common shares it holds at fair value and included the fair value of the common shares in its marketable securities and the unrecognized gain related to these common shares in accumulated other comprehensive income (loss) on the condensed consolidated balance sheet.

The Company will fund all of the discovery activities conducted pursuant to the CRISPR Agreement. For potential hemoglobinapathy treatments, including treatments for sickle cell disease, the Company and CRISPR will share equally all research and development costs and worldwide revenues. For other targets that the Company elects to license, the Company would lead all development and global commercialization activities. For each of up to six targets that the Company elects to license, other than hemoglobinapathy targets, CRISPR has the potential to receive up to \$420.0 million in development, regulatory and commercial milestones and royalties on net product sales.

The Company may terminate the CRISPR Agreement upon 90 days' notice to CRISPR prior to any product receiving marketing approval or upon 270 days' notice after a product has received marketing approval. The CRISPR Agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the CRISPR Agreement will continue in effect until the expiration of the Company's payment obligations under the CRISPR Agreement.

Merck KGaA

On January 10, 2017, the Company entered into a strategic collaboration and license agreement (the "Merck KGaA Agreement") with Merck KGaA, Darmstadt, Germany ("Merck KGaA"). Pursuant to the Merck KGaA Agreement, the Company granted Merck KGaA an exclusive worldwide license to research, develop and commercialize four oncology research and development programs. Under the Merck KGaA Agreement, the Company granted Merck KGaA exclusive, worldwide rights to two clinical-stage programs targeting DNA damage repair: its ataxia telangiectasia and Rad3-related protein inhibitor program, including VX-970 and VX-803, and its DNA-dependent protein kinase inhibitor program, including VX-984. In addition, the Company granted Merck KGaA exclusive, worldwide rights to two pre-clinical programs.

The Merck KGaA Agreement provided for an up-front payment from Merck KGaA to the Company of \$230.0 million. During the first quarter of 2017, the Company received \$193.6 million of the up-front payment and the remaining \$36.4 million was remitted to the German tax authorities. Pursuant to a tax treaty between the United States and Germany, the Company filed a refund application for the tax withholding and expects to receive the refund in approximately six months. The income tax receivable is included in Prepaid expenses and other current assets at March 31, 2017. In addition to the up-front payment, the Company will receive tiered royalties on potential sales of licensed products, calculated as a percentage of net sales, that range from (i) mid-single digits to mid-twenties for clinical-stage programs and (ii) mid-single digits to high single digits for the pre-clinical research programs. Merck KGaA has assumed full responsibility for development and commercialization costs for all programs.

The Company evaluated the deliverables, primarily consisting of a license to the four programs and the obligation to complete certain fully-reimbursable research and development and transition activities as directed by Merck KGaA, pursuant to the Merck KGaA Agreement, under the multiple element arrangement accounting guidance. The Company concluded that the license has stand-alone value from the research and development and transition activities based on the resources and know-how possessed by Merck KGaA, and thus concluded that there are two units of accounting in the arrangement. The Company determined the relative selling price of the units of accounting based on the Company's best estimate of selling price. The Company utilized key assumptions to determine the best estimate of selling price for the license, which included future potential net sales of licensed products, development timelines, reimbursement rates for personnel costs, discount rates, and estimated third-party development costs. The Company utilized a discounted cash flow model to determine its best estimate of selling price for the license and determined the best estimate of selling price for the research and development and transition activities based on what it would sell the services for separately. Based on this analysis, the Company recognized approximately \$231.7 million in collaborative revenues related to the up-front payment upon delivery of the license and to the research and development and transition activities provided during the quarter. The Company recorded the reimbursement for the research and development and transition activities as revenue in the Company's consolidated statements of operations primarily due to the fact that the Company is the primary obligor in the arrangement. The Company expects to provide research and development and transition activities through the end of the fiscal year and will recognize the revenues and associated expenses as the services are provided.

Merck KGaA may terminate the Merck KGaA Agreement or any individual program by providing 90 days' notice, or, in the case of termination of a program with a product that has received marketing approval, 180 days' notice. The Merck KGaA Agreement also may be terminated by either party for a material breach by the other party, subject to notice and cure provisions. Unless earlier terminated, the Merck KGaA Agreement will continue in effect until the date on which the royalty term and all payment obligations with respect to all products in all countries have expired.

Variable Interest Entities

The Company has entered into several agreements pursuant to which it has licensed rights to certain drug candidates from third-party collaborators, which has resulted in the consolidation of the third parties' financial statements into the Company's condensed consolidated financial statements as VIEs. In order to account for the fair value of the contingent payments, which consist of milestone, royalty and option payments, related to these collaborations under GAAP, the Company uses present-value models based on assumptions regarding the probability of achieving the relevant milestones, estimates of future product sales and the appropriate discount rates. The Company bases its estimate of the probability of achieving the relevant milestones on industry data for similar

assets and its own experience. The discount rates used in the valuation model represent a measure of credit risk and market risk associated with settling the liabilities. Significant judgment is used in determining the appropriateness of these assumptions at each reporting period. Changes in these assumptions could have a material effect on the fair value of the contingent payments. The following collaborations are reflected in the Company's financial statements as consolidated VIEs:

Parion Sciences, Inc.

In June 2015, the Company entered into a strategic collaboration and license agreement (the "Parion Agreement") with Parion Sciences, Inc. ("Parion"). Pursuant to the agreement, the Company is collaborating with Parion to develop investigational epithelial sodium channel ("ENaC") inhibitors, including VX-371 (formerly P-1037) and VX-551 (formerly P-1055), for the potential treatment of CF, and all other pulmonary diseases. The Company is leading development activities for VX-371 and VX-551 and is responsible for all costs, subject to certain exceptions, related to development and commercialization of the compounds.

Pursuant to the Parion Agreement, the Company has worldwide development and commercial rights to Parion's lead investigational ENaC inhibitors, VX-371 and VX-551, for the potential treatment of CF and all other pulmonary diseases and has the option to select additional compounds discovered in Parion's research program. Parion received an \$80.0 million up-front payment and has the potential to receive up to an additional (i) \$490.0 million in development and regulatory milestone payments for development of ENaC inhibitors in CF, including \$360.0 million related to global filing and approval milestones, (ii) \$370.0 million in development and regulatory milestones for VX-371 and VX-551 in non-CF pulmonary indications and (iii) \$230.0 million in development and regulatory milestones should the Company elect to develop an additional ENaC inhibitor from Parion's research program. The Company has agreed to pay Parion tiered royalties that range from the low double digits to mid-teens as a percentage of potential sales of licensed products.

The Company may terminate the Parion Agreement upon 90 days' notice to Parion prior to any licensed product receiving marketing approval or upon 180 days' notice after a licensed product has received marketing approval. If the Company experiences a change of control prior to the initiation of the first Phase 3 clinical trial for a licensed product, Parion may terminate the Parion Agreement upon 30 days' notice, subject to the Company's right to receive specified royalties on any subsequent commercialization of licensed products. The Parion Agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the Parion Agreement will continue in effect until the expiration of the Company's royalty obligations, which expire on a country-by-country basis on the later of (i) the date the last-to-expire patent covering a licensed product expires or (ii) ten years after the first commercial sale in the country.

The Company determined that it has a variable interest in Parion via the Parion Agreement, and that the variable interest represents a variable interest in Parion as a whole since the fair value of the ENaC inhibitors represents more than half of the total fair value of Parion's assets. The Company also concluded that it is the primary beneficiary as it has the power to direct the activities that most significantly affect the economic performance of Parion and it has the obligation to absorb losses and right to receive benefits that potentially could be significant to Parion. Accordingly, the Company consolidated Parion's financial statements beginning on June 4, 2015. However, the Company's interests in Parion are limited to those accorded to the Company in the Parion Agreement.

While there was a transfer of \$80.0 million to Parion, the cash remained within the Company's condensed consolidated financial statements since Parion is part of the consolidated entity. The cash received, net of any cash spend by Parion, is classified as restricted cash and cash equivalents (VIE) within the condensed consolidated balance sheet as it is attributed to the noncontrolling interest holders of Parion. When determining the valuation of goodwill, the fair value of consideration for the license is zero since there was no consideration transferred outside the condensed consolidated financial statements. The Company recorded \$255.3 million of intangible assets on the Company's condensed consolidated balance sheet for Parion's in-process research and development assets. These in-process research and development assets relate to Parion's pulmonary ENaC platform, including the intellectual property related to VX-371 and VX-551, that are licensed by Parion to the Company. The Company also recorded the fair value of the net assets attributable to noncontrolling interest of \$164.3 million, deferred tax liability of \$91.0 million resulting from a basis difference in the intangible assets and certain other net

liabilities held by Parion of \$10.5 million. The difference between the fair values of the consideration and noncontrolling interest and the fair value of Parion's net assets was recorded as goodwill.

BioAxone Biosciences, Inc.

In October 2014, the Company entered into a license and collaboration agreement (the "BioAxone Agreement") with BioAxone Biosciences, Inc. ("BioAxone"), which resulted in the consolidation of BioAxone as a VIE beginning on October 1, 2014. The Company paid BioAxone initial payments of \$10.0 million in the fourth quarter of 2014.

BioAxone has the potential to receive up to \$90.0 million in milestones and fees, including development, regulatory and milestone payments and a license continuation fee. In addition, BioAxone would receive royalties and commercial milestones on future net product sales of VX-210, if any. The Company recorded an in-process research and development intangible asset of \$29.0 million for VX-210 and a corresponding deferred tax liability of \$11.3 million attributable to BioAxone. The Company holds an option to purchase BioAxone at a predetermined price. The option expires on the earliest of (a) the day the FDA accepts the Biologics License Application submission for VX-210, (b) the day the Company elects to continue the license instead of exercising the option to purchase BioAxone and (c) March 15, 2018, subject to the Company's option to extend this date by one year.

Aggregate VIE Financial Information

An aggregate summary of net income attributable to noncontrolling interest related to the Company's VIEs for the three months ended March 31, 2017 and 2016 is as follows:

	Three Months Ended March 31,					
		2017	2	016		
		(in thousands)				
Loss attributable to noncontrolling interest before provision for income taxes	\$	1,547	\$	839		
Provision for income taxes		391		3,062		
Increase in fair value of contingent payments		(3,730)		(9,430)		
Net income attributable to noncontrolling interest	\$	(1,792)	\$	(5,529)		

The increase in the noncontrolling interest holders' claim to net assets with respect to the fair value of the contingent payments in the three months ended March 31, 2017 was primarily due to changes in market interest rates and the time value of money. During the three months ended March 31, 2017 and 2016, the increase in the fair value of the contingent payments related to the Company's VIEs was as follows:

•	Three Months Ended March 31,						
	2017		2016				
	(in tho	usands)	1				
\$	2,830	\$	9,000				
	900		430				

As of March 31, 2017, the fair value of the contingent payments related to the Parion Agreement and the BioAxone Agreement was \$241.6 million and \$18.9 million, respectively. As of December 31, 2016, the fair value of the contingent milestone and royalty payments related to the Parion collaboration and the BioAxone collaboration was \$238.8 million and \$18.0 million, respectively.

The following table summarizes items related to the Company's VIEs included in the Company's condensed consolidated balance sheets as of the dates set forth in the table:

	March 31, 2017		Γ	December 31, 2016	
	(in thousands)				
Restricted cash and cash equivalents (VIE)	\$	44,564	\$	47,762	
Prepaid expenses and other current assets		5,957		6,812	
Intangible assets		284,340		284,340	
Goodwill		19,391		19,391	
Other assets		687		399	
Accounts payable		1,080		415	
Taxes payable		1,159		1,330	
Other current liabilities		1,998		2,137	
Deferred tax liability, net		133,058		131,446	
Other liabilities		300		300	
Noncontrolling interest		182,785		181,609	

The Company has recorded the VIEs' cash and cash equivalents as restricted cash and cash equivalents (VIE) because (i) the Company does not have any interest in or control over the VIEs' cash and cash equivalents and (ii) the Company's agreements with each VIE do not provide for the VIEs' cash and cash equivalents to be used for the development of the assets that the Company licensed from the applicable VIE. Assets recorded as a result of consolidating the Company's VIEs' financial condition into the Company's balance sheet do not represent additional assets that could be used to satisfy claims against the Company's general assets.

Other Collaborations

The Company has entered into various agreements pursuant to which it collaborates with third parties, including inlicensing and outlicensing arrangements. Although the Company does not consider any of these arrangements to be material, the most notable of these arrangements are described below.

Moderna Therapeutics, Inc.

In July 2016, the Company entered into a strategic collaboration and licensing agreement (the "Moderna Agreement") with Moderna Therapeutics, Inc. ("Moderna") pursuant to which the parties are seeking to identify and develop messenger Ribonucleic Acid ("mRNA") Therapeutics for the treatment of CF. In connection with the Moderna Agreement in the third quarter of 2016, the Company made an upfront payment to Moderna of \$20.0 million and a \$20.0 million cost-method investment in Moderna pursuant to a convertible promissory note that converted into preferred stock in August 2016. Moderna has the potential to receive future development and regulatory milestones of up to \$275.0 million, including \$220.0 million in approval and reimbursement milestones, as well as tiered royalty payments on future sales.

Under the terms of the Moderna Agreement, Moderna will lead discovery efforts and the Company will lead all preclinical, development and commercialization activities associated with the advancement of mRNA Therapeutics that result from this collaboration and will fund all expenses related to the collaboration.

The Company may terminate the Moderna Agreement by providing advanced notice to Moderna, with the required length of notice dependent on whether any product developed under the Moderna Agreement has received marketing approval. The Moderna Agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the Moderna Agreement will continue in effect until the expiration of the Company's payment obligations under the Moderna Agreement.

Janssen Pharmaceuticals, Inc.

In June 2014, the Company entered into an agreement (the "Janssen Influenza Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen Inc."), which was amended in October 2014 to clarify certain roles and responsibilities of the parties.

Pursuant to the Janssen Influenza Agreement, Janssen Inc. has an exclusive worldwide license to develop and commercialize certain drug candidates for the treatment of influenza, including VX-787. The Company received non-refundable payments of \$35.0 million from Janssen Inc. in 2014, which were recorded as collaborative revenue. The Company has the potential to receive development, regulatory and commercial milestone payments as well as royalties on future product sales, if any, Janssen Inc. may terminate the Janssen Influenza Agreement, subject to certain exceptions, upon six months' notice.

Janssen Inc. is responsible for costs related to the development and commercialization of the compounds. During the three months ended March 31, 2017 and 2016, the Company recorded reimbursement for these development activities of \$0.9 million and \$3.5 million, respectively. The reimbursements are recorded as a reduction to development expense in the Company's condensed consolidated statements of operations primarily due to the fact that Janssen Inc. directs the activities and selects the suppliers associated with these activities.

Pending Acquisition

Concert Pharmaceuticals

On March 6, 2017, the Company entered into an asset purchase agreement (the "Concert Agreement") with Concert Pharmaceuticals ("Concert"). Pursuant to the Concert Agreement, the Company will acquire certain assets including CTP-656 from Concert. CTP-656 is an investigational CFTR potentiator that has the potential to be used as part of future once-daily combination regimens of CFTR modulators that treat the underlying cause of CF. As part of the Concert Agreement, Vertex will pay Concert \$160 million in cash for all worldwide development and commercialization rights to CTP-656. If CTP-656 is approved as part of a combination regimen to treat CF, Concert could receive up to an additional \$90 million in milestones based on regulatory approval in the U.S. and reimbursement in the UK, Germany or France. The Concert Agreement is subject to approval by Concert's shareholders and clearance under the Hart-Scott-Rodino Antitrust Improvements Act. The waiting period had not expired as of March 31, 2017; therefore, there was no accounting impact relating to this agreement during the three months ended March 31, 2017. The Company is in the process of evaluating the expected accounting effect of the pending transaction on its consolidated financial statements.

D. Earnings Per Share

Basic net loss per share attributable to Vertex common shareholders is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock and restricted stock units that have been issued but are not yet vested. Diluted net loss per share attributable to Vertex common shareholders is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive.

The following table sets forth the computation of basic and diluted net income (loss) per share for the periods ended:

	Three Months Ended Marc			March 31,
	2017			2016
	(in t	housands, excep	t per s	share amounts)
Basic net income (loss) attributable to Vertex per common share calculation:				
Net income (loss) attributable to Vertex common shareholders	\$	247,756	\$	(41,631)
Less: Undistributed earnings allocated to participating securities		(406)		_
Net income (loss) attributable to Vertex common shareholders—basic	\$	247,350	\$	(41,631)
Basic weighted-average common shares outstanding		246,024		243,831
Basic net income (loss) attributable to Vertex per common share	\$	1.01	\$	(0.17)
Diluted net income (loss) attributable to Vertex per common share calculation:				
Net income (loss) attributable to Vertex common shareholders	\$	247,756	\$	(41,631)
Less: Undistributed earnings allocated to participating securities		(401)		_
Net income (loss) attributable to Vertex common shareholders—diluted	\$	247,355	\$	(41,631)
Weighted-average shares used to compute basic net income (loss) per common share		246,024		243,831
Effect of potentially dilutive securities:				
Stock options		2,037		_
Restricted stock and restricted stock units		627		_
Other		12		_
Weighted-average shares used to compute diluted net income (loss) per common share		248,700		243,831
Diluted net income (loss) attributable to Vertex per common share	\$	0.99	\$	(0.17)

The Company did not include the securities in the following table in the computation of the net income (loss) per share attributable to Vertex common shareholders calculations because the effect would have been anti-dilutive during each period:

	Three Months E	nded March 31,
	2017	2016
	(in thou	sands)
Stock options	8,303	12,619
Unvested restricted stock and restricted stock units	807	3,565

E. Fair Value Measurements

The fair value of the Company's financial assets and liabilities reflects the Company's estimate of amounts that it would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in

which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on

an ongoing basis.

Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for

similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing

the asset or liability.

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument. As of March 31, 2017, the Company's investments were primarily in money market funds, corporate equity securities, corporate debt securities and commercial paper.

As of March 31, 2017, all of the Company's financial assets that were subject to fair value measurements were valued using observable inputs. The Company's financial assets valued based on Level 1 inputs consisted of money market funds, corporate debt securities, commercial paper and corporate equity securities. The Company's financial assets valued based on Level 2 inputs consisted of corporate debt securities and commercial paper, which consisted of investments in highly-rated investment-grade corporations.

The following table sets forth the Company's financial assets (excluding VIE cash and cash equivalents) and liabilities subject to fair value measurements:

Fair	Value Measurements	as
	of March 31 2017	

		of March 31, 2017							
		Fair Value Hierarchy							
		Total		Level 1		Level 2		Level 3	
				(in tho	usands	s)			
Financial instruments carried at fair value (asset position):									
Cash equivalents:									
Money market funds	\$	313,629	\$	313,629	\$	_	\$	_	
Corporate debt securities		11,027		11,027		_		_	
Commercial paper		6,834		6,834		_		_	
Marketable securities:									
Corporate equity securities		69,372		69,372		_		_	
Corporate debt securities		203,181		_		203,181		_	
Commercial paper		132,550		_		132,550		_	
Prepaid and other current assets:									
Foreign currency forward contracts		8,318		_		8,318		_	
Other assets:									
Foreign currency forward contracts		249		_		249		_	
Total financial assets	\$	745,160	\$	400,862	\$	344,298	\$	_	
Financial instruments carried at fair value (liability position):			-		-				
Other liabilities, current portion:									
Foreign currency forward contracts	\$	(613)	\$	_	\$	(613)	\$	_	
Other liabilities, excluding current portion:	-	(0-0)	•		-	(323)	•		
Foreign currency forward contracts		(86)		_		(86)		_	
Total financial liabilities	\$	(699)	\$		\$		\$	_	
	Fair Value Measurements as of December 31, 2016								
					Fair V	alue Hierarchy	7		
		Total		Level 1		Level 2		Level 3	
			(in thousands)						
Financial instruments carried at fair value (asset position):									
Cash equivalents:									
Money market funds	\$	280,560	\$	280,560	\$	_	\$	_	
Marketable securities:									
Government-sponsored enterprise securities		15,508		15,508		_		_	
Corporate equity securities		64,560		64,560		_		_	
Commercial paper		59,404		_		59,404		_	
Corporate debt securities		111,140		_		111,140		_	
Prepaid and other current assets:									
Foreign currency forward contracts		14,407		_		14,407		_	
Other assets:									
Foreign currency forward contracts		1,186	\$	_		1,186	\$	_	
Total financial assets	\$	546,765	\$	360,628	\$	186,137	\$	_	
Financial instruments carried at fair value (liability position):					_		_		
Other liabilities, current portion:									
Other liabilities, current portion: Foreign currency forward contracts	\$	(144)	\$	_	\$	(144)	\$	_	

The Company's VIEs invested in cash equivalents consisting of money market funds of \$44.1 million as of March 31, 2017, which are valued based on Level 1 inputs. These cash equivalents are not included in the table above. The Company's noncontrolling interest related to VIEs includes the fair value of the contingent payments, which consist of milestone, royalty and option payments, which are valued based on Level 3 inputs. Please refer to Note C, "Collaborative Arrangements," for further information.

F. Marketable Securities

A summary of the Company's cash, cash equivalents and marketable securities is shown below:

	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Fair Value
				(in tho	housands)		
As of March 31, 2017							
Cash and cash equivalents:							
Cash and money market funds	\$	985,818	\$	_	\$	_	\$ 985,818
Commercial paper		6,834		_		_	6,834
Corporate debt securities		11,027		_		_	11,027
Total cash and cash equivalents	\$	1,003,679	\$	_	\$	_	\$ 1,003,679
Marketable securities:							
Corporate equity securities		43,213		26,159		_	69,372
Commercial paper (matures within 1 year)		132,640		1		(91)	132,550
Corporate debt securities (matures within 1 year)		180,465		3		(143)	180,325
Corporate debt securities (matures after 1 year)	\$	22,882	\$	_	\$	(26)	\$ 22,856
Total marketable securities	\$	379,200	\$	26,163	\$	(260)	\$ 405,103
Total cash, cash equivalents and marketable securities	\$	1,382,879	\$	26,163	\$	(260)	\$ 1,408,782
As of December 31, 2016							
Cash and cash equivalents:							
Cash and money market funds	\$	1,183,945	\$	_	\$	_	\$ 1,183,945
Total cash and cash equivalents	\$	1,183,945	\$	_	\$	_	\$ 1,183,945
Marketable securities:							
Government-sponsored enterprise securities (matures within 1 year)	\$	15,506	\$	2	\$	_	\$ 15,508
Corporate equity securities		43,213		21,347		_	64,560
Commercial paper (matures within 1 year)		59,331		73		_	59,404
Corporate debt securities (matures within 1 year)		111,225		_		(85)	111,140
Total marketable securities	\$	229,275	\$	21,422	\$	(85)	\$ 250,612
Total cash, cash equivalents and marketable securities	\$	1,413,220	\$	21,422	\$	(85)	\$ 1,434,557

The Company has a limited number of marketable securities in insignificant loss positions as of March 31, 2017, which the Company does not intend to sell and has concluded it will not be required to sell before recovery of the amortized costs for the investment at maturity. There were no charges recorded for other-than-temporary declines in fair value of marketable securities nor gross realized gains or losses recognized in the three months ended March 31, 2017 and 2016.

G. Accumulated Other Comprehensive Income (loss)

A summary of the Company's changes in accumulated other comprehensive income (loss) by component is shown below:

	Foreign Currency Translation Adjustment				ealized Gains (Losses) n Foreign Currency ward Contracts, net of tax	Total
			(in tho	usands)		
Balance at December 31, 2016	\$	(7,862)	\$ 17,522	\$	11,514	\$ 21,173
Other comprehensive (loss) income before reclassifications		(2,001)	3,534	1	(2,802)	(1,269)
Amounts reclassified from accumulated other comprehensive loss		_	_	-	(3,879)	(3,879)
Net current period other comprehensive (loss) income	\$	(2,001)	\$ 3,534	\$	(6,681)	\$ (5,148)
Balance at March 31, 2017	\$	(9,863)	\$ 21,055	\$	4,833	\$ 16,025

Tì				Unrealized Gains (Losses) on Foreign Currency Forward Contracts, net of tax			Total
			(in thousa	nds)			
\$	(2,080)	\$	126	\$	3,778	\$	1,824
	(1,740)		229		(3,827)		(5,338)
s					(1,385)		(1,385)
\$	(1,740)	\$	229	\$	(5,212)	\$	(6,723)
\$	(3,820)	\$	355	\$	(1,434)	\$	(4,899)
•	\$ \$ \$ \$ \$ \$	\$ (2,080) (1,740) ss \$ (1,740)	\$ (2,080) \$ (1,740) \$ \$ (1,740) \$	Translation Adjustment on Marketable Securities \$ (2,080) \$ 126 (1,740) 229 35 — — \$ (1,740) \$ 229	Foreign Currency Unrealized Holding Gains on Marketable Securities Forward	Foreign Currency Translation Adjustment Unrealized Holding Gains on Foreign Currency Forward Contracts, net of tax	Foreign Currency Translation Adjustment Unrealized Holding Gains on Marketable Securities Forward Contracts, net of tax

H. Hedging

The Company maintains a hedging program intended to mitigate the effect of changes in foreign exchange rates for a portion of the Company's forecasted product revenues denominated in certain foreign currencies. The program includes foreign currency forward contracts that are designated as cash flow hedges under GAAP having contractual durations from one to eighteen months.

The Company formally documents the relationship between foreign currency forward contracts (hedging instruments) and forecasted product revenues (hedged items), as well as the Company's risk management objective and strategy for undertaking various hedging activities, which includes matching all foreign currency forward contracts that are designated as cash flow hedges to forecasted transactions. The Company also formally assesses, both at the hedge's inception and on an ongoing basis, whether the foreign currency forward contracts are highly effective in offsetting changes in cash flows of hedged items on a prospective and retrospective basis. If the Company determines that a (i) foreign currency forward contract is not highly effective as a cash flow hedge, (ii) foreign currency forward contract has ceased to be a highly effective hedge or (iii) forecasted transaction is no longer probable of occurring, the Company would discontinue hedge accounting treatment prospectively. The Company measures effectiveness based on the change in fair value of the forward contracts and the fair value of the hypothetical foreign currency forward contracts with terms that match the critical terms of the risk being hedged. As of March 31, 2017, all hedges were determined to be highly effective and the Company had not recorded any ineffectiveness related to the hedging program.

The following table summarizes the notional amount of the Company's outstanding foreign currency forward contracts designated as cash flow hedges:

	As of March 31, 2017	As of De	cember 31, 2016
Foreign Currency	(in tho	usands)	_
Euro	\$ 187,375	\$	164,368
British pound sterling	66,133		65,237
Australian dollar	28,645		23,776
Total foreign currency forward contracts	\$ 282,153	\$	253,381

The following table summarizes the fair value of the Company's outstanding foreign currency forward contracts designated as cash flow hedges under GAAP included on the Company's condensed consolidated balance sheets:

As of March 31, 2017

Assets			Liabilities							
Classification	I	Fair Value	Classification		Fair Value					
(in thousands)										
Prepaid and other current assets	\$ 8,318		Other liabilities, current portion	\$	(613)					
Other assets 249		Other liabilities, excluding current portion		(86)						
Total assets	\$ 8,567		Total liabilities	\$	(699)					

As of December 31, 2016

Assets		Liabilities	
Classification	Fair Value	Classification	Fair Value

(in thousands)

Prepaid and other current assets	\$ 14,407	Other liabilities, current portion	\$ (144)
Other assets	1,186	Other liabilities, excluding current portion	_
Total assets	\$ 15,593	Total liabilities	\$ (144)

The following table summarizes the potential effect of offsetting derivatives by type of financial instrument on the Company's condensed consolidated balance sheets:

	As of March 31, 2017							
	 ss Amounts ecognized	Gross Amoun Offset	ts G	Presented		oss Amounts Not Offset	L	egal Offset
Foreign currency forward contracts			(in thousands)				
Total assets	\$ 8,567	\$ -	- \$	8,567	\$	(699)	\$	7,868
Total liabilities	\$ (699)	\$ -	- \$	(699)	\$	699	\$	_

		As of December 31, 2016								
	_	Pross Amounts Recognized	Gross Am Offse			oss Amounts Presented		ross Amounts Not Offset	I	egal Offset
Foreign currency forward contracts					(in	thousands)				
Total assets	\$	15,593	\$	_	\$	15,593	\$	(144)	\$	15,449
Total liabilities	\$	(144)	\$	_	\$	(144)	\$	144	\$	_

I. Inventories

Inventories consisted of the following:

	As of March 31, 2017	As of December 31, 2016
	(in	thousands)
Raw materials	\$ 9,17	2 \$ 6,348
Work-in-process	60,92	1 56,672
Finished goods	11,92	7 14,584
Total	\$ 82,02	0 \$ 77,604

Based on its evaluation of, among other factors, information regarding tezacaftor's safety and efficacy, the Company has begun capitalizing insignificant inventory costs for tezacaftor manufactured in preparation for its potential product launch. In periods prior, the Company expensed costs associated with tezacaftor's raw materials and work-in-process as a development expense. The Company is planning to submit a New Drug Application to the United States Food and Drug Administration and a Marketing Authorization Application to the European Medicines Agency for tezacaftor in combination with ivacaftor during the third quarter of 2017. The Company plans to continue to monitor the status of the tezacaftor regulatory process and the other factors used to determine whether or not to capitalize the tezacaftor inventory and, if there are significant negative developments regarding tezacaftor, the Company could be required to impair previously capitalized costs.

J. Intangible Assets and Goodwill

Intangible Assets

As of March 31, 2017 and December 31, 2016, in-process research and development intangible assets of \$284.3 million were recorded on the Company's condensed consolidated balance sheet. In 2015, the Company recorded an in-process research development intangible asset of \$255.3 million related to Parion's pulmonary ENaC platform, including the intellectual property related to VX-371 and VX-551, that are licensed by Parion to the Company. In 2014, the Company recorded an in-process research development intangible asset of \$29.0 million related to VX-210 that is licensed by BioAxone to the Company.

Goodwill

As of March 31, 2017 and December 31, 2016, goodwill of \$50.4 million was recorded on the Company's condensed consolidated balance sheet.

K. Long-term Obligations

Fan Pier Leases

In 2011, the Company entered into two lease agreements, pursuant to which the Company leases approximately 1.1 million square feet of office and laboratory space in two buildings (the "Buildings") at Fan Pier in Boston, Massachusetts (the "Fan Pier Leases"). The Company commenced lease payments in December 2013, and will make lease payments pursuant to the Fan Pier Leases through December 2028. The Company has an option to extend the term of the Fan Pier Leases for an additional ten years.

Because the Company was involved in the construction project, the Company was deemed for accounting purposes to be the owner of the Buildings during the construction period and recorded project construction costs incurred by the landlord. Upon completion of the Buildings, the Company evaluated the Fan Pier Leases and determined that the Fan Pier Leases did not meet the criteria for "sale-leaseback" treatment. Accordingly, the Company began depreciating the asset and incurring interest expense related to the financing obligation in 2013. The Company bifurcates its lease payments pursuant to the Fan Pier Leases into (i) a portion that is allocated to the Buildings and (ii) a portion that is allocated to the land on which the Buildings were constructed. The portion of the lease obligations allocated to the land is treated as an operating lease that commenced in 2011.

Property and equipment, net, included \$485.7 million and \$489.0 million as of March 31, 2017 and December 31, 2016, respectively, related to construction costs for the Buildings. The carrying value of the Company's lease agreement liability for the Buildings was \$472.5 million and \$472.6 million as of March 31, 2017 and December 31, 2016, respectively.

San Diego Lease

On December 2, 2015, the Company entered into a lease agreement for 3215 Merryfield Row, San Diego, California with ARE-SD Region No. 23, LLC. Pursuant to this agreement, the Company agreed to lease approximately 170,000 square feet of office and laboratory space in a building to be built in San Diego, California. The lease will commence upon completion of the building, scheduled for the first half of 2018, and will extend for 16 years from the commencement date. Pursuant to the lease agreement, during the initial 16-year term, the Company will pay an average of approximately \$10.2 million per year in aggregate rent, exclusive of operating expenses. The Company has the option to extend the lease term for up to two additional five-year terms.

Because the Company is involved in the construction project, the Company is deemed for accounting purposes to be the owner of the San Diego building during the construction period and recorded project construction costs incurred by the landlord. The Company bifurcates its lease payments pursuant to the San Diego Lease into (i) a portion that is allocated to the San Diego building and (ii) a portion that is allocated to the land on which the San Diego building was constructed. Although the Company will not begin making lease payments pursuant to the San Diego Lease until the commencement date, the portion of the lease obligation allocated to the land is treated for accounting purposes as an operating lease that commenced in the fourth quarter of 2016. Upon completion of the San Diego building, the Company will evaluate the San Diego Lease and determine if the San Diego Lease meets the criteria for "sale-leaseback" treatment. If the San Diego Lease meets the "sale-leaseback" criteria, the Company will remove the asset and the related liability from its consolidated balance sheet and treat the San Diego Lease as either an operating or a capital lease based on the Company's assessment of the accounting guidance. The Company expects that upon completion of construction of the San Diego building the San Diego Lease will not meet the "sale-leaseback" criteria. If the San Diego Lease does not meet "sale-leaseback" criteria, the Company will treat the San Diego Lease as a financing obligation and will depreciate the asset over its estimated useful life. The Company has capitalized \$28.9 million and \$15.0 million as of March 31, 2017 and December 31, 2016, respectively.

Revolving Credit Facility

In October 2016, the Company entered into a Credit Agreement (the "Credit Agreement") with Bank of America, N.A., as administrative agent and the lenders referred to therein. The Credit Agreement provides for a \$500.0 million revolving facility, \$300.0 million of which was drawn at closing (the "Loans"). The Credit Agreement also provides that, subject to satisfaction of certain conditions, the Company may request that the borrowing capacity under the Credit Agreement be increased by an additional \$300.0 million. The Credit Agreement matures on October 13, 2021.

The proceeds of the borrowing under the Credit Agreement were used primarily to repay the Company's then outstanding indebtedness under the Macquarie Loan. The Loans will bear interest, at the Company's option, at either a base rate or a Eurodollar rate, in each case plus an applicable margin. Under the Credit Agreement, the applicable margins on base rate loans range from 0.75% to 1.50% and the applicable margins on Eurodollar loans range from 1.75% to 2.50%, in each case based on the Company's consolidated leverage ratio (the ratio of the Company's total consolidated debt to the Company's trailing twelve-month EBITDA).

The Loans are guaranteed by certain of the Company's domestic subsidiaries and secured by substantially all of the Company's assets and the assets of the Company's domestic subsidiaries (excluding intellectual property, owned and leased real property and certain other excluded property) and by the equity interests of the Company's subsidiaries, subject to certain exceptions. Under the terms of the Credit Agreement, the Company must maintain, subject to certain limited exceptions, a consolidated leverage ratio of 3.00 to 1.00 and consolidated EBITDA of at least \$200.0 million, in each case to be measured on a quarterly basis.

The Credit Agreement contains customary representations and warranties and usual and customary affirmative and negative covenants. The Credit Agreement also contains customary events of default. In the case of a continuing event of

default, the administrative agent would be entitled to exercise various remedies, including the acceleration of amounts due under outstanding loans. In February 2017, the Company repaid all \$300.0 million outstanding under the Credit Agreement.

Term Loan

In July 2014, the Company entered into a credit agreement with the lenders party thereto, and Macquarie US Trading LLC ("Macquarie"), as administrative agent. The credit agreement provided for a \$300.0 million senior secured term loan ("Macquarie Loan"). On October 13, 2016, the Company terminated and repaid all outstanding obligations under the Macquarie Loan.

The Macquarie Loan initially bore interest at a rate of 7.2% per annum, which was reduced to 6.2% per annum based on the FDA's approval of ORKAMBI. The Term Loan bore interest at a rate of LIBOR plus 5.0% per annum during the third year of the term.

The Company incurred \$5.3 million in fees paid to Macquarie that were recorded as a discount on the Macquarie Loan and were recorded as interest expense using the effective interest method over the term of the loan in the Company's condensed consolidated statements of operations.

L. Stock-based Compensation Expense

During the three months ended March 31, 2017 and 2016, the Company recognized the following stock-based compensation expense:

Three Months Ended March 31,				
	2017		2016	
	(in tho	usands)		
\$	26,981	\$	26,260	
	40,745		27,533	
	2,064		2,524	
	(808)		(845)	
\$	68,982	\$	55,472	
				
\$	44,837	\$	34,448	
	24,145		21,024	
\$	68,982	\$	55,472	
	\$	\$ 26,981 40,745 2,064 (808) \$ 68,982 \$ 44,837 24,145	\$ 26,981 \$ 40,745 \$ 2,064 \$ 8 68,982 \$ \$ \$ \$ 44,837 \$ 24,145	

The following table sets forth the Company's unrecognized stock-based compensation expense by type of award and the weighted-average period over which that expense is expected to be recognized:

1 10	01 1/141	CII 51, -	-017
			Weighted-av

As of March 31, 2017

	Uı	nrecognized Expense (in thousands)	Weighted-average Recognition Period (in years)	
Type of award:				
Stock options	\$	200,906		2.65
Restricted stock and restricted stock units	\$	291,088		2.57
ESPP share issuances	\$	2,016		0.43

The following table summarizes information about stock options outstanding and exercisable at March 31, 2017:

		Options Outstanding			Options I	Exer	xercisable			
Range of Exercise Prices	Number Outstanding	Weighted-average Remaining Contractual Life	,	Weighted-average Exercise Price	Number Exercisable	,	Weighted-average Exercise Price			
	(in thousands)	(in years)		(per share)	(in thousands)		(per share)			
\$18.93-\$20.00	134	0.85	\$	18.93	134	\$	18.93			
\$20.01-\$40.00	1,576	2.95	\$	33.77	1,576	\$	33.77			
\$40.01-\$60.00	1,678	5.34	\$	48.36	1,678	\$	48.36			
\$60.01-\$80.00	1,279	6.88	\$	75.86	924	\$	75.61			
\$80.01-\$100.00	5,932	8.65	\$	89.51	1,757	\$	89.81			
\$100.01-\$120.00	1,572	7.79	\$	109.33	799	\$	109.30			
\$120.01-\$134.69	1,427	8.22	\$	130.53	668	\$	130.27			
Total	13,598	7.19	\$	82.60	7,536	\$	71.52			

M. Other Arrangements

Sale of HIV Protease Inhibitor Royalty Stream

In 2008, the Company sold to a third party its rights to receive royalty payments from GlaxoSmithKline plc, net of royalty amounts to be earned by and due to a third party, for a one-time cash payment of \$160.0 million. These royalty payments relate to net sales of HIV protease inhibitors, which had been developed pursuant to a collaboration agreement between the Company and GlaxoSmithKline plc. As of March 31, 2017, the Company had \$11.8 million in deferred revenues related to the one-time cash payment, which it is recognizing over the life of the collaboration agreement with GlaxoSmithKline plc based on the units-of-revenue method. In addition, the Company continues to recognize royalty revenues equal to the amount of the third-party subroyalty and an offsetting royalty expense for the third-party subroyalty payment.

N. Income Taxes

The Company is subject to United States federal, state, and foreign income taxes. For the three months ended March 31, 2017, the Company recorded a provision for income taxes of \$4.0 million. The provision for income taxes recorded in the three months ended March 31, 2017 included a provision of \$0.4 million related to the Company's VIEs' income tax provision. The Company has no liability for taxes payable by the Company's VIEs and the income tax provision and related liability have been allocated to noncontrolling interest (VIE). For the three months ended March 31, 2016, the Company recorded a provision for income taxes of \$5.5 million. The provision for income taxes recorded in the three months ended March 31, 2016 included a benefit of \$3.1 million related to the Company's VIEs' income tax provision.

As of March 31, 2017 and December 31, 2016, the Company did not have unrecognized tax benefits. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of March 31, 2017, no interest and penalties have been accrued. The Company does not expect that its unrecognized tax benefits will materially increase within the next twelve months. The Company did not recognize any material interest or penalties related to uncertain tax positions as of March 31, 2017 and December 31, 2016.

The Company continues to maintain a valuation allowance against certain deferred tax assets where it is more likely than not that the deferred tax asset will not be realized because of its extended history of annual losses.

As described in Footnote A, the Company adopted Accounting Standards Update (ASU) 2016-09, during the three month period ended March 31, 2017. The ASU eliminates additional paid in capital ("APIC") pools and requires excess tax benefits and tax deficiencies to be recorded in the consolidated statement of operations when the awards vest or are settled. Amendments related to accounting for excess tax benefits have been adopted prospectively resulting in a tax benefit of \$0.4 million for the three months ended March 31, 2017. In connection with the adoption of this new standard, the Company recorded a cumulative-effect adjustment of \$410.8 million as of January 1, 2017 to accumulated deficit and deferred tax assets, with an equal offsetting adjustment to the valuation allowance. In addition, the Company has recorded \$9.4 million related to the impact from adoption of the provisions related to forfeiture rates to accumulated deficit. This change also increased the deferred tax assets by \$3.4 million that is offset by an increase to the valuation allowance in the same amount.

The Company files United States federal income tax returns and income tax returns in various state, local and foreign jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination in the United States or any other major taxing jurisdiction for years before 2011, except where the Company has net operating losses or tax credit carryforwards that originate before 2011. The Company currently is under examination by Canada Revenue Agency for the years ending December 31, 2011 through December 31, 2013. No adjustments have been reported.

At March 31, 2017, foreign earnings, which were not significant, have been retained indefinitely by foreign subsidiary companies for reinvestment; therefore, no provision has been made for income taxes that would be payable upon the distribution of such earnings, and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability. Upon repatriation of those earnings, in the form of dividends or otherwise, the Company would be subject to United States federal income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries.

O. Restructuring Liabilities

Research and Development Restructuring

In February 2017, the Company decided to consolidate its research activities into its Boston, Milton Park and San Diego locations and to close the research site in Canada. As a result, the Company is in the process of closing one of its research sites. In connection with this decision, approximately 70 positions were affected. The Company estimates that it will incur aggregate restructuring charges of approximately \$11.3 million to \$13.0 million, including \$6.8 million for employee salary, severance and benefit costs, \$2.0 million in assets associated with the restructuring that have become impaired and \$2.5 million to \$4.2 million for other costs primarily related to the Company's exit from the facility.

The restructuring charge and other activities recorded during the three months ended March 31, 2017 and the related liability balance as of March 31, 2017 were as follows:

		Months Ended March 31,
		2017
	(in	thousands)
Liability, beginning of the period	\$	_
Restructuring expense		9,218
Cash payments		(3,258)
Asset impairments and other non-cash expense		(2,233)
Liability, end of the period	\$	3,727

2003 Kendall Restructuring

In 2003, the Company adopted a plan to restructure its operations to coincide with its increasing internal emphasis on advancing drug candidates through clinical development to commercialization. The restructuring liability relates to specialized laboratory and office space that is leased to the Company pursuant to a 15-year lease that terminates in 2018. The Company has not used more than 50% of this space since it adopted the plan to restructure its operations in 2003. This unused laboratory and office space currently is subleased to third parties.

The activities related to the restructuring liability for the three months ended March 31, 2017 and 2016 were as follows:

	T	Three Months Ended March 31,					
		2017		2016			
		usands)					
Liability, beginning of the period	\$	4,328	\$	7,944			
Restructuring expense		485		203			
Cash payments		(5,264)		(3,931)			
Cash received from subleases		2,976		3,008			
Liability, end of the period	\$	2,525	\$	7,224			

Fan Pier Move Restructuring

In connection with the relocation of its Massachusetts operations to Fan Pier in Boston, Massachusetts, which commenced in 2013, the Company is incurring restructuring charges related to its remaining lease obligations at its facilities in Cambridge, Massachusetts. The majority of these restructuring charges were recorded in the third quarter of 2014 upon decommissioning three facilities in Cambridge. During the first quarter of 2015, the Company terminated two of these lease agreements resulting in a credit to restructuring expense equal to the difference between the Company's estimated future cash flows related to its lease obligations for these facilities and the termination payment paid to the Company's landlord on the effective date of the termination. The third major facility included in this restructuring activity is 120,000 square feet of the Kendall Square Facility that the Company continued to use for its operations following its 2003 Kendall Restructuring. The rentable square footage in this portion of the Kendall Square Facility was subleased to a third party in February 2015. The Company will continue to incur charges through April 2018 related to the difference between the Company's estimated future cash flows related to this portion of the Kendall Square Facility, which include an estimate for sublease income to be received from the Company's sublessee and its actual cash flows. The Company discounted the estimated cash flows related to this restructuring activity at a discount rate of 9%.

The activities related to the restructuring liability for the three months ended March 31, 2017 and 2016 were as follows:

	Three Months Ended March 31,					
	2017	7		2016		
Liability, beginning of the period	\$	3,626	\$	5,964		
Restructuring expense		296		233		
Cash payments		(4,405)		(3,156)		
Cash received from subleases		2,478		2,408		
Liability, end of the period	\$	1,995	\$	5,449		

Other Restructuring Activities

The Company has engaged in several other restructuring activities that are unrelated to its 2003 Kendall Restructuring and Fan Pier Move Restructuring. The most significant activity commenced in October 2013 when the Company adopted a restructuring plan that included (i) a workforce reduction primarily related to the commercial support of INCIVEK following the continued and rapid decline in the number of patients being treated with INCIVEK as new medicines for the treatment of HCV infection neared approval and (ii) the write-off of certain assets. This action resulted from the Company's decision to focus its investment on future opportunities in CF and other research and development programs.

The remaining restructuring activities were completed in 2016. As such, there was no outstanding liability as of March 31, 2017. The activities related to the Company's other restructuring liabilities for the three months ended March 31, 2016 were as follows:

	1	Three Months Ended March 31,
		2016
		(in thousands)
Liability, beginning of the period	\$	1,450
Restructuring expense		251
Cash payments		(439)
Liability, end of the period	\$	1,262

P. Commitments and Contingencies

Guaranties and Indemnifications

As permitted under Massachusetts law, the Company's Articles of Organization and By-laws provide that the Company will indemnify certain of its officers and directors for certain claims asserted against them in connection with their service as an officer or director. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is unlimited. However, the Company has purchased directors' and officers' liability insurance policies that could reduce its monetary exposure and enable it to recover a portion of any future amounts paid. No indemnification claims currently are outstanding, and the Company believes the estimated fair value of these indemnification arrangements is minimal.

The Company customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trial investigators and sites in its drug development programs, sponsored research agreements with academic and not-for-profit institutions, various comparable agreements involving parties performing services for the Company and its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery, development and commercialization collaboration agreements. With respect to the Company's clinical trials and sponsored research agreements, these indemnification provisions typically apply to any claim asserted against the investigator or the investigator's institution relating to personal injury or property damage, violations of law or certain breaches of the Company's contractual obligations arising out of the research or clinical testing of the Company's compounds or drug candidates. With respect to lease agreements, the indemnification provisions typically apply to claims asserted against the landlord relating to personal injury or property damage caused by the Company, to violations of law by the Company or to

certain breaches of the Company's contractual obligations. The indemnification provisions appearing in the Company's collaboration agreements are similar to those for the other agreements discussed above, but in addition provide some limited indemnification for its collaborator in the event of third-party claims alleging infringement of intellectual property rights. In each of the cases above, the indemnification obligation generally survives the termination of the agreement for some extended period, although the Company believes the obligation typically has the most relevance during the contract term and for a short period of time thereafter. The maximum potential amount of future payments that the Company could be required to make under these provisions is generally unlimited. The Company has purchased insurance policies covering personal injury, property damage and general liability that reduce its exposure for indemnification and would enable it in many cases to recover all or a portion of any future amounts paid. The Company has never paid any material amounts to defend lawsuits or settle claims related to these indemnification provisions. Accordingly, the Company believes the estimated fair value of these indemnification arrangements is minimal.

Other Contingencies

The Company has certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a reserve for contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no material contingent liabilities accrued as of March 31, 2017 or December 31, 2016.

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

OVERVIEW

We are in the business of discovering, developing, manufacturing and commercializing medicines for serious diseases. We use precision medicine approaches with the goal of creating transformative medicines for patients in specialty markets. Our business is focused on developing and commercializing therapies for the treatment of cystic fibrosis, or CF, and advancing our research and development programs in other indications, while maintaining our financial strength. Our two marketed products are ORKAMBI (lumacaftor in combination with ivacaftor) and KALYDECO (ivacaftor).

Cystic Fibrosis

ORKAMBI and KALYDECO are approved to treat approximately 40% of the 75,000 CF patients in North America, Europe and Australia. ORKAMBI (lumacaftor in combination with ivacaftor) is approved as a treatment for approximately 25,000 patients who have two copies (homozygous) of the F508del mutation in their cystic fibrosis transmembrane conductance regulator, or *CFTR*, gene. KALYDECO (ivacaftor) is approved for the treatment of approximately 4,000 CF patients who have the G551D mutation or other specified mutations in their *CFTR* gene. Our goal is to develop treatment regimens that will provide benefits to as many patients with CF as possible and will enhance the benefits that currently are being provided to patients taking our medicines.

CF Development Programs

We have multiple development programs in the field of CF, including:

- Tezacaftor is a corrector compound that we are evaluating in a Phase 3 development program in combination with ivacaftor in multiple CF patient populations who have at least one copy of the F508del mutation in their *CFTR* gene.
 - In the first quarter of 2017, we obtained positive results from two Phase 3 clinical trials that showed statistically significant improvements in lung function (percent predicted forced expiratory volume in one second, or ppFEV1) in patients with CF 12 years of age and older who have certain mutations in their CFTR gene. The 24-week EVOLVE clinical trial evaluated tezacaftor in combination with ivacaftor in patients with CF who are homozygous for the F508del mutation in their CFTR gene. This clinical trial met its primary endpoint with a mean absolute improvement in ppFEV1 through 24 weeks of 4.0 percentage points from baseline compared to placebo (p < 0.0001). The second clinical trial, EXPAND, was an 8-week crossover clinical trial that evaluated the combination treatment in patients with CF who have one mutation that results in residual CFTR function and one F508del mutation. This clinical trial met the primary endpoints of absolute change in ppFEV1 from baseline to the average of the Week 4 and Week 8 measurements, with the tezacaftor/ivacaftor combination treatment demonstrating a mean absolute improvement of 6.8 percentage points compared to placebo (p < 0.0001) and the ivacaftor monotherapy group demonstrating a mean absolute improvement of 4.7 percentage points compared to placebo (p < 0.0001). Across both clinical trials, the tezacaftor/ivacaftor combination treatment was generally well tolerated. Based on these results, we plan to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, in the third quarter of 2017.</p>
 - We expect to complete enrollment in a third Phase 3 clinical trial in the first half of 2017 evaluating tezacaftor in combination with ivacaftor
 in patients 12 years of age or older who have one copy of the F508del mutation and a second mutation that results in a gating
 mutation in the CFTR gene that has been shown to be responsive to ivacaftor alone.
 - We are conducting a Phase 3 clinical trial of the tezacaftor/ivacaftor combination in patients with CF six to eleven years of age in the U.S.
 The clinical trial is evaluating the safety and tolerability of the tezacaftor/ivacaftor combination in children who are homozygous for the F508del mutation and in children who have one copy of the F508del mutation and a gating or residual function mutation.
- VX-152, VX-440, VX-659 and VX-445 are next-generation CFTR corrector compounds that we are evaluating as part of triple combination treatment regimens. We are conducting Phase 2 clinical trials of VX-152 and VX-440 in patients with CF and Phase 1 clinical trials of VX-659 and VX-445 in healthy volunteers and patients with CF. We expect data for three of these triple combinations in patients with CF in the second half of 2017 and for the fourth triple combination that includes VX-445 in patients with CF in early 2018. We recently amended the Phase 2 clinical

trial evaluating VX-152, which was originally designed to evaluate two weeks of triple combination dosing, to add the evaluation of four weeks of triple combination dosing.

• VX-371, an investigational epithelial sodium channel, or ENaC, inhibitor, is being evaluated in a Phase 2 development program and which we exclusively licensed from Parion Sciences, Inc., or Parion, in 2015.

Research and Development

We are engaged in a number of other research and mid- and early-stage development programs, including in the areas of pain and neurology. We have also entered into third-party collaborations pursuant to which we are engaged in the discovery and development of nucleic acid-based therapies for a variety of diseases, including CF. We plan to continue investing in our research programs and fostering scientific innovation in order to identify and develop transformative medicines. Our current research programs include programs targeting cystic fibrosis, adrenoleukodystrophy, alpha-1 antritrypsin deficiency, sickle cell disease and polycystic kidney disease. We believe that pursuing research in diverse areas allows us to balance the risks inherent in drug development and may provide drug candidates that will form our pipeline in future years.

Discovery and development of a new pharmaceutical product is a difficult and lengthy process that requires significant financial resources along with extensive technical and regulatory expertise and can take 10 to 15 years or more. Potential drug candidates are subjected to rigorous evaluations, driven in part by stringent regulatory considerations, designed to generate information concerning efficacy, side-effects, proper dosage levels and a variety of other physical and chemical characteristics that are important in determining whether a drug candidate should be approved for marketing as a pharmaceutical product. Most chemical compounds that are investigated as potential drug candidates never progress into development, and most drug candidates that do advance into development never receive marketing approval. Because our investments in drug candidates are subject to considerable risks, we closely monitor the results of our discovery, research, clinical trials and nonclinical studies and frequently evaluate our drug development programs in light of new data and scientific, business and commercial insights, with the objective of balancing risk and potential. This process can result in abrupt changes in focus and priorities as new information becomes available and as we gain additional understanding of our ongoing programs and potential new programs, as well as those of our competitors.

If we believe that data from a completed registration program support approval of a drug candidate, we submit an NDA to the FDA requesting approval to market the drug candidate in the United States and seek analogous approvals from comparable regulatory authorities in foreign jurisdictions. To obtain approval, we must, among other things, demonstrate with evidence gathered in nonclinical studies and well-controlled clinical trials that the drug candidate is safe and effective for the disease it is intended to treat and that the manufacturing facilities, processes and controls for the manufacture of the drug candidate are adequate. The FDA and foreign regulatory authorities have substantial discretion in deciding whether or not a drug candidate should be granted approval based on the benefits and risks of the drug candidate in the treatment of a particular disease, and could delay, limit or deny regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for the drug candidate involved will be harmed.

Collaboration Arrangements

We have entered into collaborations with biotechnology and pharmaceutical companies in order to acquire rights or to license drug candidates or technologies that enhance our pipeline and/or our research capabilities. Over the last several years, we entered into collaboration agreements with:

- CRISPR Therapeutics AG, or CRISPR, pursuant to which we are collaborating on the discovery and development of potential new
 treatments aimed at the underlying genetic causes of human diseases using CRISPR-Cas9 gene editing technology;
- · Parion, pursuant to which we are developing epithelial sodium channel, or ENaC, inhibitors for the treatment of pulmonary diseases;
- Moderna Therapeutics, Inc., or Moderna, pursuant to which we are seeking to identify and develop mRNA therapeutics for the treatment of CF; and
- BioAxone Biosciences, Inc., or BioAxone, pursuant to which we are evaluating VX-210 as a potential treatment for patients who have spinal cord injuries.

Generally, when we in-license a technology or drug candidate, we make upfront payments to the collaborator, assume the costs of the program and agree to make contingent payments, which could consist of milestone, royalty and option payments. Depending on many factors, including the structure of the collaboration, the significance of the drug candidate that we license to the collaborator's operations and the other activities in which our collaborators are engaged, the accounting for these transactions can vary significantly. For example, the upfront payments and expenses incurred in connection with our CRISPR

and Moderna collaborations are being expensed as research expenses because the collaboration represents a small portion of these collaborators overall business. CRISPR's and Moderna's activities unrelated to our collaborations have no effect on our consolidated financial statements. Parion and BioAxone are being accounted for as variable interest entities, or VIEs, and are included in our consolidated financial statements due to (i) the significance of the respective licensed programs to Parion and BioAxone as a whole, (ii) our power to control the significant activities under each collaboration and (iii) our obligation to absorb losses and right to receive benefits that potentially could be significant. Each of our consolidated VIEs are engaging in activities unrelated to our collaboration, including in the case of Parion, seeking to develop novel treatments for pulmonary and ocular diseases. The revenues and expenses unrelated to the programs we in-license from our VIEs are immaterial to our consolidated financial statements. In each case, the activities unrelated to our collaboration represent less than 1% of our total revenues and total expenses. Because we consolidate our VIEs, we evaluate the fair value of the contingent payments payable by us on a quarterly basis. Changes in the fair value of these contingent future payments affect net income attributable to Vertex on a dollar-for-dollar basis, with increases in the fair value of contingent payments payable by us to a VIE resulting in an increase in net income attributable to Vertex (or an increase in net loss attributable to Vertex) and decreases in the fair value of contingent payments payable by us to a VIE resulting in an increase in net income attributable to Vertex).

We have also out-licensed internally developed programs to collaborators who are leading the development of these programs. These outlicense arrangements include our collaboration agreements with:

- · Merck KGaA, which is advancing four oncology research and development programs; and
- Janssen Pharmaceuticals, Inc. which is developing JNJ-3872 (formerly VX-787) for the treatment of influenza.

Pursuant to these outlicensing arrangements, our collaborators are responsible for the research, development and commercialization costs associated with these programs and we are entitled to receive contingent milestone and/or royalty payments. As a result, we do not expect to incur significant expenses in connection with these programs and have the potential for future collaborative and/or royalty revenues resulting from these programs.

Regulatory Compliance

Our marketing of pharmaceutical products is subject to extensive and complex laws and regulations. We have a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems, and through the promotion of a culture of compliance. Among other laws, regulations and standards, we are subject to various U.S. federal and state laws, and comparable foreign laws pertaining to health care fraud and abuse, including anti-kickback and false claims statutes, and laws prohibiting the promotion of drugs for unapproved or off-label uses. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration to induce the referral of business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from presenting for payment to third-party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. We expect to continue to devote substantial resources to maintain, administer and expand these compliance programs globally.

Reimbursement

Sales of our products depend, to a large degree, on the extent to which our products are covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. We dedicate substantial management and other resources in order to obtain and maintain appropriate levels of reimbursement for our products from third-party payors, including governmental organizations in the United States and ex-U.S. markets. In the United States, we continue to engage in discussions with numerous commercial insurers and managed health care organizations, along with government health programs that are typically managed by authorities in the individual states. In Europe and other ex-U.S. markets, we are working to obtain government reimbursement for ORKAMBI on a country-by-country basis, because in many foreign countries patients are unable to access prescription pharmaceutical products that are not reimbursed by their governments. In the fourth quarter of 2016, we reached a pricing and reimbursement agreement for ORKAMBI with the German Federal Association of the Statutory Health Insurances. Consistent with our experience with KALYDECO when it was first approved, we expect reimbursement discussions in ex-U.S. markets may take a significant period of time.

Recent Pending Transaction

Concert Pharmaceuticals

In March 2017, we entered into an asset purchase agreement with Concert Pharmaceuticals, Inc. Pursuant to the agreement, we expect to acquire certain assets including CTP-656 from Concert. CTP-656 is an investigational CFTR potentiator that has the potential to be used as part of future once-daily combination regimens of CFTR modulators that treat the underlying cause of CF. As part of the agreement, we will pay Concert \$160 million in cash for all worldwide development and commercialization rights to CTP-656. If CTP-656 is approved as part of a combination regimen to treat CF, Concert could receive up to an additional \$90 million in milestones based on regulatory approval in the U.S. and reimbursement in the UK, Germany or France. The agreement remains subject to approval by Concert's shareholders and clearance under the Hart-Scott-Rodino Antitrust Improvements Act. Therefore, there was no accounting impact relating to this agreement during the three months ended March 31, 2017. We are in the process of evaluating the expected accounting effect of the pending transaction on our consolidated financial statements.

RESULTS OF OPERATIONS

	Three Months Ended March 31,			Increase/(l	Decrease)			
	2017		2016		2017 2016		\$	%
	(in thousands)							
Revenues	\$	714,718	\$	398,080	\$ 316,638	80%		
Operating costs and expenses		443,876		412,410	31,466	8%		
Other items, net		(23,086)		(27,301)	4,215	15%		
Net income (loss) attributable to Vertex	\$	247,756	\$	(41,631)	\$ 289,387	n/a		

Net Income (Loss) Attributable to Vertex

Net income attributable to Vertex was \$247.8 million in the first quarter of 2017 as compared to a net loss attributable to Vertex of \$(41.6) million in the first quarter of 2016. Our revenues increased significantly in the first quarter of 2017 as compared to the first quarter of 2016 due to \$230.0 million in one-time collaborative revenues related to the strategic collaboration and license agreement we established with Merck KGaA in the first quarter of 2017 and increased ORKAMBI and KALYDECO net product revenues. Our operating costs and expenses increased in the first quarter of 2017 as compared to the first quarter of 2016 primarily due to increases in research and development expenses, sales, general and administrative expenses and restructuring expenses, partially offset by a \$13.9 million commercial milestone made in the first quarter of 2016. In the near term, we expect net income (loss) attributable to Vertex will be dependent on expected increases in ORKAMBI net product revenues.

Diluted Net Income (Loss) Per Share Attributable to Vertex Common Shareholders

Diluted net income per share attributable to Vertex common shareholders was \$0.99 in the first quarter of 2017 as compared to a diluted net loss per share attributable to Vertex common shareholders of \$(0.17) in the first quarter of 2016.

Revenues

	Three Months Ended March 31,			Increase/(Decrease)						
	 2017		2016		2016		2017 2016		\$	%
	 (in thousands)									
Product revenues, net	\$ 480,622	\$	394,410	\$	86,212	22 %				
Royalty revenues	1,551		3,596		(2,045)	(57)%				
Collaborative revenues	232,545		74		232,471	n/a				
Total revenues	\$ 714,718	\$	398,080	\$	316,638	80 %				

Product Revenues, Net

	Three Months Ended March 31,					Increase/(I)ecrease)		
		2017		2016		2016		\$	%
	(in thousands)								
ORKAMBI	\$	294,861	\$	223,128	\$	71,733	32 %		
KALYDECO		185,715		170,509		15,206	9 %		
INCIVEK		46		773		(727)	(94)%		
Total product revenues, net	\$	480,622	\$	394,410	\$	86,212	22 %		

Our total net product revenues increased in the first quarter of 2017 as compared to the first quarter of 2016 due to increased net product revenues from ORKAMBI and KALYDECO. In the first quarter of 2017 and 2016, we recognized approximately \$31.4 million and \$8.8 million, respectively, in ex-U.S. ORKAMBI net product revenues. Our condensed consolidated balance sheets include \$104.8 million collected as of March 31, 2017, in France related to ORKAMBI, which has not resulted in any revenues. We believe that the level of our ORKAMBI revenues during 2017 will be dependent upon whether, when and on what terms we are able to obtain reimbursement in additional ex-U.S. markets, the number and rate at which additional patients begin treatment with ORKAMBI, the proportion of initiated patients who remain on treatment and the compliance rates for patients who remain on treatment.

The increase in KALYDECO net product revenues in the first quarter of 2017 as compared to the first quarter of 2016 included approximately \$9 million in one-time revenue credits in the first quarter of 2017 primarily related to the finalization

of reimbursement agreements in certain European countries. In the first quarter of 2017 and 2016, we recognized approximately \$84.2 million and \$75.6 million, respectively, in ex-U.S. KALYDECO net product revenues.

We have withdrawn INCIVEK, which we previously marketed as a treatment for hepatitis C virus infection, from the market in the United States. We may continue to have small adjustments to INCIVEK revenues over the next several quarters as we adjust our INCIVEK reserves for rebates, chargebacks and discounts.

Royalty Revenues

Our royalty revenues were \$1.6 million in the first quarter of 2017 as compared to \$3.6 million in the first quarter of 2016. Our royalty revenues consist of (i) revenues related to a cash payment we received in 2008 when we sold our rights to certain HIV royalties and (ii) revenues related to certain third-party royalties payable by our collaborators on sales of HIV and HCV drugs that also result in corresponding royalty expenses.

Collaborative Revenues

Our collaborative revenues were \$232.5 million in the first quarter of 2017 as compared to \$0.1 million in the first quarter of 2016. The increase was due to revenue recognized related to the one-time upfront payment we received from Merck KGaA in the first quarter of 2017. Our collaborative revenues have historically fluctuated significantly from one period to another and may continue to fluctuate in the future.

Operating Costs and Expenses

	Three Months Ended March 31,			Increase/(Decrease)			
	 2017	2016		- \$		%	
	 (in thousands)						
Cost of product revenues	\$ 46,242	\$	49,789	\$	(3,547)	(7)%	
Royalty expenses	746		860		(114)	(13)%	
Research and development expenses	273,563		255,860		17,703	7 %	
Sales, general and administrative expenses	113,326		105,214		8,112	8 %	
Restructuring expenses, net	9,999		687		9,312	1,355 %	
Total costs and expenses	\$ 443,876	\$	412,410	\$	31,466	8 %	

Cost of Product Revenues

Our cost of product revenues includes the cost of producing inventories that corresponded to product revenues for the reporting period, plus the third-party royalties payable on our net sales of our products. Pursuant to our agreement with Cystic Fibrosis Foundation Therapeutics Incorporated, or CFFT, our tiered third-party royalties on sales of KALYDECO and ORKAMBI, calculated as a percentage of net sales, range from the single digits to the sub-teens.

In the first quarter of 2016, our cost of product revenues included a \$13.9 million commercial milestone that was earned by CFFT related to sales of ORKAMBI. There are no further commercial milestones payable to CFFT. In future periods, we expect our cost of product revenues to be dependent on our net product revenues with a lower royalty rate at the beginning of each year due to the tiered royalty structure.

Royalty Expenses

Royalty expenses include expenses related to a subroyalty payable to a third party on net sales of an HIV protease inhibitor sold by GlaxoSmithKline and third-party royalties payable upon net sales of telaprevir by our collaborators in their territories. Royalty expenses do not include royalties we pay to CFFT on sales of KALYDECO and ORKAMBI, which instead are included in cost of product revenues.

Research and Development Expenses

	Three Months Ended March 31,				Increase/(Decrease)		
	-	2017		2016		\$	%
	(in thousands)						
Research expenses	\$	73,056	\$	63,010	\$	10,046	16%
Development expenses		200,507		192,850		7,657	4%
Total research and development expenses	\$	273,563	\$	255,860	\$	17,703	7%

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Our research and development expenses include internal and external costs incurred for research and development of our drugs and drug candidates. We do not assign our internal costs, such as salary and benefits, stock-based compensation expense, laboratory supplies and other direct expenses and infrastructure costs, to individual drugs or drug candidates, because the employees within our research and development groups typically are deployed across multiple research and development programs. These internal costs are significantly greater than our external costs, such as the costs of services provided to us by clinical research organizations and other outsourced research, which we allocate by individual program. All research and development costs for our drugs and drug candidates are expensed as incurred.

Since January 1, 2014, we have incurred \$3.2 billion in research and development expenses associated with drug discovery and development. The successful development of our drug candidates is highly uncertain and subject to a number of risks. In addition, the duration of clinical trials may vary substantially according to the type, complexity and novelty of the drug candidate and the disease indication being targeted. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from nonclinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activities. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a project and are difficult to predict. Therefore, accurate and meaningful estimates of the ultimate costs to bring our drug candidates to market are not available.

In 2016 and the three months ended March 31, 2017, costs related to our CF programs represented the largest portion of our development costs. Any estimates regarding development and regulatory timelines for our drug candidates are highly subjective and subject to change. We are planning to submit an NDA and an MAA for tezacaftor in combination with ivacaftor in the third quarter of 2017. We cannot make a meaningful estimate when, if ever, our other clinical development programs will generate revenues and cash flows.

Research Expenses

	Three Months Ended March 31,		Increase/(Decreas		
	2017		2016	 \$	%
		(in th	ousands)		
Research Expenses:					
Salary and benefits	\$ 21,533	\$	20,710	\$ 823	4%
Stock-based compensation expense	13,691		10,656	3,035	28%
Laboratory supplies and other direct expenses	11,365		9,874	1,491	15%
Outsourced services	7,337		4,161	3,176	76%
Infrastructure costs	19,130		17,609	1,521	9%
Total research expenses	\$ 73,056	\$	63,010	\$ 10,046	16%

We maintain a substantial investment in research activities. Our research expenses increased by 16% in the first quarter of 2017 as compared to the first quarter of 2016. We expect to continue to invest in our research programs with a focus on identifying drug candidates with the goal of creating transformative medicines.

Development Expenses

	Three Months Ended March 31,				Increase/(Decrease)		
	 2017		2016		\$		
	 (in thousands)						
Development Expenses:							
Salary and benefits	\$ 51,954	\$	44,351	\$	7,603	17 %	
Stock-based compensation expense	31,146		23,792		7,354	31 %	
Laboratory supplies and other direct expenses	11,030		8,250		2,780	34 %	
Outsourced services	73,435		84,488		(11,053)	(13)%	
Drug supply costs	1,949		2,653		(704)	(27)%	
Infrastructure costs	30,993		29,316		1,677	6 %	
Total development expenses	\$ 200,507	\$	192,850	\$	7,657	4 %	

Our development expenses increased by 4% in the first quarter of 2017 as compared to the first quarter of 2016 due to increases in expenses related to our employees partially offset by decreases in our outsourced services expenses.

Sales, General and Administrative Expenses

		Three Months	Ended March 31	,	Increase/(Decrease)
	_	2017	2016		\$	%
	_		(in thousands)			
inistrative expenses	\$	113,326	\$ 105	214	\$ 8,112	8%

Sales, general and administrative expenses increased by 8% in the first quarter of 2017 as compared to the first quarter of 2016, primarily due to increased investment in commercial support for ORKAMBI in ex-U.S. markets.

Restructuring Expense, Net

We recorded restructuring expenses of \$10.0 million in the first quarter of 2017 as compared to restructuring expenses of \$0.7 million in the first quarter of 2016. The increase in our restructuring expenses in the first quarter of 2017 primarily relate to our decision to consolidate our research activities into our Boston, Milton Park and San Diego locations and to close our research site in Canada.

Other Items

Interest Expense, Net

Interest expense, net was \$16.8 million in the first quarter of 2017 as compared to \$20.7 million in the first quarter of 2016. The decrease in interest expense, net in the first quarter of 2017 as compared to the first quarter of 2016 was primarily due to the repayment of the \$300.0 million of the revolving credit facility in February 2017. During the remainder of 2017, we expect to incur approximately \$45 million of interest expense associated with the leases for our corporate headquarters and our interest expense related to our revolving credit facility will be dependent on whether, and to what extent, we reborrow amounts under the existing facility.

Other (Expense) Income, Net

Other (expense) income, net was an expense of \$0.5 million in the first quarter of 2017 as compared to income of \$4.4 million in the first quarter of 2016. Other (expense) income, net in each of the first quarter of 2017 and the first quarter of 2016 was primarily due to foreign exchange gains and losses.

Income Taxes

We recorded a provision for income taxes of \$4.0 million in the first quarter of 2017 as compared to \$5.5 million in the first quarter of 2016. The provision for income taxes in the first quarter of 2017 was primarily related to state income tax expense in jurisdictions where there are no net operating losses as well as several foreign jurisdictions. The provision for income taxes in the first quarter of 2016 was due to income tax on our VIEs.

Noncontrolling Interest (VIEs)

The net (income) loss attributable to noncontrolling interest (VIEs) recorded on our condensed consolidated statements of operations reflects Parion and BioAxone's net loss (income) for the reporting period, adjusted for any changes in the noncontrolling interest holders' claim to net assets, including contingent milestone, royalty and option payments. A summary of net income attributable to noncontrolling interest related to our VIEs for the three months ended March 31, 2017 and 2016 is as follows:

	T	Three Months Ended March 31,			
		2017		2016	
	(in thousands)				
Loss attributable to noncontrolling interest before provision for income taxes	\$	1,547	\$	839	
Provision for income taxes		391		3,062	
Increase in fair value of contingent payments		(3,730)		(9,430)	
Net income attributable to noncontrolling interest	\$	(1,792)	\$	(5,529)	

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2017, we had cash, cash equivalents and marketable securities of \$1.41 billion, which represented a decrease of \$26 million from \$1.43 billion as of December 31, 2016. In the first quarter of 2017, our cash, cash equivalents

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and marketable securities balance decreased due to the \$300.0 million repayment of our revolving credit facility, partially offset by cash received from our collaboration with Merck KGaA in the first quarter of 2017 and cash receipts from product sales. We expect that our future cash flows will be substantially dependent on CF product sales.

Sources of Liquidity

We intend to rely on our existing cash, cash equivalents and marketable securities together with cash flows from product sales as our primary source of liquidity. We are receiving cash flows from sales of ORKAMBI and KALYDECO from the United States and ex-U.S. markets. Future net product revenues for ORKAMBI from ex-U.S. markets will be dependent on, among other things, the timing of and ability to complete reimbursement discussions in European countries.

In February 2017, we repaid the \$300.0 million we had borrowed under our \$500.0 million revolving credit facility. We may repay and reborrow amounts under the revolving credit agreement without penalty. Subject to certain conditions, we may request that the borrowing capacity under this credit agreement be increased by an additional \$300.0 million.

In 2015, we also received significant proceeds from the issuance of common stock under our employee benefit plans, but we received limited proceeds from employee benefit plans in 2016 and the amount and timing of future proceeds from employee benefits plans is uncertain. Other possible sources of liquidity include strategic collaborative agreements that include research and/or development funding, commercial debt, public and private offerings of our equity and debt securities, development milestones and royalties on sales of products, software and equipment leases, strategic sales of assets or businesses and financial transactions. Negative covenants in our credit agreement may prohibit or limit our ability to access these sources of liquidity.

Future Capital Requirements

We incur substantial operating expenses to conduct research and development activities and to operate our organization. Under the terms of our credit agreement entered into in October 2016, we are required to repay all outstanding principal amounts in 2021. We also have substantial facility and capital lease obligations, including leases for two buildings in Boston, Massachusetts that continue through 2028 and capital expenditures for our building under construction in San Diego, California. In addition, we have entered into certain collaboration agreements with third parties that include the funding of certain research, development and commercialization efforts with the potential for future milestone and royalty payments by us upon the achievement of preestablished developmental and regulatory targets. In the first quarter of 2017, we entered into an asset purchase agreement with Concert pursuant to which we expect to make a \$160.0 million payment contingent upon approval by Concert's shareholders and clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

We expect that cash flows from ORKAMBI and KALYDECO, together with our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the amounts of future revenues generated by ORKAMBI and KALYDECO and the potential introduction of one or more of our other drug candidates to the market, the level of our business development activities and the number, breadth, cost and prospects of our research and development programs.

Financing Strategy

We have a \$500.0 million revolving credit facility that we entered into in October 2016. We may repay and reborrow amounts under the revolving credit agreement without penalty. In addition, subject to certain conditions, we may request that the borrowing capacity under this credit agreement be increased by an additional \$300.0 million. We may raise additional capital through public offerings or private placements of our securities or securing new collaborative agreements or other methods of financing. We will continue to manage our capital structure and will consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

Our commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the Securities and Exchange Commission, or SEC, on February 23, 2017. There have been no material changes from the contractual commitments and obligations previously disclosed in that Annual Report on Form 10-K, except that:

• In February 2017, we repaid the outstanding \$300 million balance of our revolving credit facility.

• In March 2017, we entered into an asset purchase agreement with Concert to acquire certain assets including CTP-656 from Concert. Upon closing, we will be required to pay Concert \$160 million in cash for all worldwide development and commercialization rights to CTP-656.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reported periods. These items are monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are reflected in reported results for the period in which the change occurs. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate. During the three months ended March 31, 2017, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on February 23, 2017.

RECENT ACCOUNTING PRONOUNCEMENTS

For a discussion of recent accounting pronouncements please refer to Note A, "Basis of Presentation and Accounting Policies—Recent Accounting Pronouncements."

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market risk-sensitive instruments are held for trading purposes.

Interest Rate Risk

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment-grade corporate bonds and commercial paper, and money market funds. These investments are denominated in U.S. dollars. All of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term-to-maturity of our investment instruments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase or decrease by an immaterial amount.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro, Swiss Franc, British Pound, Australian Dollar and Canadian Dollar against the U.S. dollar. The current exposures arise primarily from cash, accounts receivable, intercompany receivables, payables and inventories. Both positive and negative affects to our net revenues from international product sales from movements in foreign currency exchange rates are partially mitigated by the natural, opposite affect that foreign currency exchange rates have on our international operating costs and expenses.

We have a foreign currency management program with the objective of reducing the effect of exchange rate fluctuations on our operating results and forecasted revenues and expenses denominated in foreign currencies. We currently have hedges for Euro, British Pound and Australian Dollar. These cash flow hedges qualify for hedge accounting. As of March 31, 2017, we held foreign exchange forward contracts with notional amounts totaling \$282.2 million. As of March 31, 2017, our outstanding foreign exchange forward contracts had a net fair value of \$7.9 million.

Based on our foreign currency exchange rate exposures at March 31, 2017, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts that are designated as cash flow hedges by approximately \$28.2 million at March 31, 2017. The resulting loss on these forward contracts would be offset by the gain on the underlying transactions and therefore would have minimal impact on future anticipated earnings and cash flows. Similarly, adverse fluctuations in exchange rates that would decrease the fair value of our foreign exchange forward contracts that are not designated as hedge instruments would be offset by a positive impact of the underlying monetary assets and liabilities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, as of March 31, 2017 our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Controls Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) occurred during the three months ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

There have been no material changes from the legal proceedings previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the Securities and Exchange Commission, or SEC, on February 23, 2017.

Item 1A. Risk Factors

Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on February 23, 2017. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K, except that:

Our business depends on the success of tezacaftor in combination with ivacaftor, which has not been approved by the FDA or the European Commission. If we are unable to obtain marketing approval or experience material delays in obtaining marketing approval for lumacaftor in combination with ivacaftor, our business will be materially harmed.

In the first quarter of 2017, we obtained positive results from two Phase 3 clinical trials of tezacaftor in combination with ivacaftor that showed statistically significant improvements in lung function in patients with CF 12 years of age and older who have certain mutations in their *CFTR* gene. Based on these results, we plan to submit an NDA in the United States and an MAA in Europe for this potential combination regimen in the third quarter of 2017. Obtaining approval of an NDA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful. Obtaining marketing approval for the combination of tezacaftor and ivacaftor in one country or region does not ensure that we will be able to obtain marketing approval in any other country or region. Obtaining approval to market the combination of tezacaftor and ivacaftor will depend on many factors, including:

• whether or not the FDA and European regulatory authorities determine that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies demonstrates that tezacaftor in combination with ivacaftor is safe and effective as a treatment for patients for whom marketing approval is sought;

- whether or not the FDA and European regulatory authorities are satisfied that the manufacturing facilities, processes and controls for the combination of tezacaftor and ivacaftor are adequate, that the labeling is satisfactory and that plans for post-marketing studies, safety monitoring and risk evaluation and mitigation are sufficient; and
- the timing and nature of the FDA and European Medicines Agency, or EMA's, comments and questions regarding the NDA and MAA for the combination of lumacaftor and ivacaftor, the scheduling and recommendations of any advisory committee meeting to consider the combination of tezacaftor and ivacaftor, the time required to respond to the FDA or EMA's comments and questions and to obtain the final labeling for the combination of tezacaftor and ivacaftor and any other delays that may be associated with the NDA and MAA review process.

Even if a product is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. If we experience material delays in obtaining marketing approval for the combination of tezacaftor and ivacaftor in either the United States or Europe, our future net product revenues and cash flows will be adversely effected. If we do not obtain approval to market the combination of tezacaftor and ivacaftor in the United States or Europe, our business will be materially harmed. Additionally, even if the combination of tezacaftor and ivacaftor receives marketing approval, coverage and reimbursement may not be available and, even if it is available, the level of reimbursement may not be satisfactory. The regulations that govern pricing, coverage and reimbursement for drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. Adverse pricing limitations or a delay in obtaining coverage and reimbursement will hinder our future net product revenues and may harm our business.

We may not realize the anticipated benefits of our pending acquisition of CTP-656 from Concert Pharmaceuticals, Inc.

In March 2017, we entered into an asset purchase agreement with Concert Pharmaceuticals, Inc., or Concert, pursuant to which we expect to acquire certain assets including CTP-656, an investigational CFTR potentiator that has the potential to be used as part of future once-daily combination regimens of CFTR modulators that treat the underlying cause of CF. Acquisitions are inherently risky and we may not realize the anticipated benefits of such transaction, which involves numerous risks including:

- that we fail to successfully develop and/or integrate CTP-656 into our pipeline in order to achieve our strategic objectives;
- that we receive inadequate or unfavorable data from clinical trials evaluating the CTP-656 in combination with other CFTR modulators; and
- the potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges of CTP-656 or any
 of the other assets acquired from Concert, including but not limited to, problems, liabilities or other shortcomings or challenges with respect to
 intellectual property, product quality, safety, and other known and unknown liabilities.

In addition, the acquisition remains subject to approval by Concert's shareholders and clearance under the Hart-Scott-Rodino Antitrust Improvements Act. If we do not complete the acquisition successfully and in a timely manner, we may not realize the benefits of the acquisition or license to the extent anticipated.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and, in particular, our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Part I-Item 2, contain or incorporate a number of forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding:

- our expectations regarding the amount of, timing of and trends with respect to our revenues, costs and expenses and other gains and losses, including those related to net product revenues from KALYDECO and ORKAMBI;
- our expectations regarding clinical trials, development timelines, timing of our receipt of data from our ongoing and planned clinical trials and regulatory authority filings and submissions for our products and drug candidates, including the planned NDA and MAA submissions for tezacaftor in combination with ivacaftor and the ongoing and planned clinical trials to evaluate our next-generation correctors;

- our ability to successfully market KALYDECO and ORKAMBI or any of our other drug candidates for which we obtain regulatory approval;
- the data that will be generated by ongoing and planned clinical trials and the ability to use that data to advance compounds, continue development or support regulatory filings;
- our beliefs regarding the support provided by clinical trials and preclinical and nonclinical studies of our drug candidates for further investigation, clinical trials or potential use as a treatment;
- our plan to continue investing in our research and development programs and our strategy to develop our drug candidates, alone or with third partycollaborators;
- the establishment, development and maintenance of collaborative relationships;
- potential business development activities;
- the potential closing of the Concert transaction;
- potential fluctuations in foreign currency exchange rates;
- our ability to use our research programs to identify and develop new drug candidates to address serious diseases and significant unmet medical needs; and
- our liquidity and our expectations regarding the possibility of raising additional capital.

Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties. Many factors mentioned in this Quarterly Report on Form 10-Q will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially from expected results. We also provide a cautionary discussion of risks and uncertainties under "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on February 23, 2017. These are factors and uncertainties that we think could cause our actual results to differ materially from expected results. Other factors and uncertainties besides those listed there could also adversely affect us.

Without limiting the foregoing, the words "believes," "anticipates," "plans," "intends," "expects" and similar expressions are intended to identify forward-looking statements. There are a number of factors and uncertainties that could cause actual events or results to differ materially from those indicated by such forward-looking statements, many of which are beyond our control. In addition, the forward-looking statements contained herein represent our estimate only as of the date of this filing and should not be relied upon as representing our estimate as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

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

Issuer Repurchases of Equity Securities

The table set forth below shows all repurchases of securities by us during the three months ended March 31, 2017:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Purchased Under the Plans or Programs
January 1, 2017 to January 31, 2017	26,293	\$0.01	_	_
February 1, 2017 to February 28, 2017	11,980	\$0.01	_	_
March 1, 2017 to March 31, 2017	44,802	\$0.01	_	_

The repurchases were made under the terms of our Amended and Restated 2006 Stock and Option Plan and our Amended and Restated 2013 Stock and Option Plan. Under these plans, we award shares of restricted stock to our employees that typically are subject to a lapsing right of repurchase by us. We may exercise this right of repurchase if a restricted stock

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recipient's service to us is terminated. If we exercise this right, we are required to repay the purchase price paid by or on behalf of the recipient for the repurchased restricted shares, which typically is the par value per share of \$0.01. Repurchased shares are returned and are available for future awards under the terms of our Amended and Restated 2013 Stock and Option Plan.

Item 6. Exhibits

Exhibit	
Number	Exhibit Description
10.1	Strategic Collaboration and License Agreement, between Vertex Pharmaceuticals Incorporated and Merck KGaA, Darmstadt, Germany, dated January 10, 2017 †
10.2	Asset Purchase Agreement, dated March 3, 2017, by and among Vertex Pharmaceuticals (Europe) Ltd., as Buyer, Vertex Pharmaceuticals Inc., as Guarantor, and Concert Pharmaceuticals, Inc.
10.3	First Amendment to Lease, effective March 1, 2017, between ARE-SD Region No. 23, LLC and Vertex Pharmaceuticals Incorporated.
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation
101.LAB	XBRL Taxonomy Extension Labels
101.PRE	XBRL Taxonomy Extension Presentation
101.DEF	XBRL Taxonomy Extension Definition

[†] Confidential portions of this document have been filed separately with the Securities and Exchange Commission pursuant to a request for confinential treatment.

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.

Vertex Pharmaceuticals Incorporated

April 28, 2017	By:	/s/ Ian F. Smith
	_	Ian F. Smith

Executive Vice President, Chief Operating Officer and Chief Financial Officer (principal financial officer and duly authorized officer)

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Triple asterisks denote omissions.

STRATEGIC COLLABORATION AND LICENSE AGREEMENT

BETWEEN

VERTEX PHARMACEUTICALS INCORPORATED

AND

MERCK KGAA

STRATEGIC COLLABORATION AND LICENSE AGREEMENT

This Strategic Collaboration and License Agreement (this "**Agreement**") is entered into as of January 10, 2017 (the "**Execution Date**") by and between Vertex Pharmaceuticals Incorporated, a corporation organized under the laws of The Commonwealth of Massachusetts ("**Vertex**"), and Merck KGaA, a corporation with general partners under the laws of the Federal Republic of Germany, located at Frankfurter Strasse 250, 64293 Darmstadt Germany ("**Merck**"). Vertex and Merck each may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

RECITALS

WHEREAS, Vertex owns or controls certain Patents and Know-How relating to ATR Compounds, DNA-PK Compounds, [***] Compounds and [***] Compounds;

WHEREAS, Merck is a pharmaceutical company that has extensive experience and expertise in the development and commercialization of pharmaceutical products for the treatment of serious diseases;

WHEREAS, Vertex and Merck desire to enter into this Agreement, pursuant to which Vertex will grant a license to Merck to Vertex's above-mentioned Patents and Know-How in order for Merck to Research, Develop, Manufacture, have Manufactured, Commercialize, use, import, export and keep the ATR Compounds, the DNA-PK Compounds, the [***] Compounds and the [***] Compounds; and

WHEREAS, Vertex and Merck will include the [***], if any, into the collaboration.

NOW, THEREFORE, in consideration of the respective covenants, representations, warranties and agreements set forth herein, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the following capitalized terms will have the following meanings:

- 1.1. "Accounting Standards" means (a) with respect to Merck, IFRS or (b) with respect to Vertex, GAAP.
- 1.2. "Adverse Event" has the meaning set forth in the Applicable Law for such term (or comparable term), and will generally mean any untoward medical occurrence in a subject in any Clinical Trial who has received a Licensed Compound, Product, medical device or placebo, and which does not necessarily have a causal relationship with such Licensed Compound, Product, medical device or placebo, including any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the applicable Licensed Compound, Product, medical device or placebo whether or not related to such Licensed Compound, Product, medical device or placebo.

- 1.3. "Affected Calendar Quarter" has the meaning set forth in Section 5.2.3.
- 1.4. "Affiliate" means, as of any point in time and for so long as such relationship continues to exist with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another Person if it (a) owns or controls, directly or indirectly, more than 50% of the equity securities of the subject Person entitled to vote in the election of directors (or, in the case of a Person that is not a corporation, for the election of the corresponding managing authority), or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).
 - 1.5. "Agreement" has the meaning set forth in the Preamble.
 - 1.6. "Alliance Manager" has the meaning set forth in Section 3.3.1.
- 1.7. "**Applicable Law**" means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.
- 1.8. "**Approval Application**" means an NDA or similar application or submission for a Product filed with a Regulatory Authority in a country or group of countries to obtain marketing approval for a biological or pharmaceutical product in that country or group of countries.
 - 1.9. "ATR" means the ataxia telangiectasia and Rad3-related kinase.
- 1.10. "ATR Compound" means any of (a)(i) the compound known as VX-970 with the chemical formula set forth on Schedule 1.10, (ii) the compound known as VX-803 with the chemical formula set forth on Schedule 1.10 or (iii) the compound known as [***] with the chemical formula set forth on Schedule 1.10, (b) any compound that inhibits ATR and that is originally claimed or Covered by any claim contained in the Licensed Patent [***] as filed on [***] or (c) [***] of any of the foregoing.
 - 1.11. "ATR Product" means any Product containing an [***] or a [***].
 - 1.12. [***] means, with respect to a Licensed Compound or Product in any country [***].
- 1.13. [***] arising out of the Research, Development, Manufacturing or Commercialization of a Licensed Compound or Product and [***].
 - 1.14. "Breaching Party" means the Party that the other Party believes is in material breach of this Agreement.
- 1.15. "**Business Day**" means a Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in Boston, Massachusetts are authorized or obligated to close.

- 1.16. "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.
- 1.17. "Calendar Year" means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.
- 1.18. "cGMP" means current good manufacturing practices and standards as provided for (and as amended from time to time) in European Community Directive 91/356/EEC (principles and guidelines of good manufacturing practice for medicinal products) and the current Good Manufacturing Practice Regulations to the US Code of Federal Regulations Title 21 (21 CFR 210 and 21 CFR 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7A or equivalent laws, rules, or regulations of an applicable Regulatory Authority at the time of Manufacture.
- 1.19. "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates.
- 1.20. "Clinical Trial" means a study in humans that is required to be or is otherwise conducted in accordance with GCP and is designed to generate data in support of an Approval Application.
 - 1.21. "Clinical Trials Transfer Plan" has the meaning set forth in Section 2.1.4(a).
- 1.22. "**Combination Product**" means a Product containing [***] together with one or more other active ingredients, or with one or more products, devices or components.
 - 1.23. "Commercialization Plan" has the meaning set forth in Section 2.4.3.
- 1.24. "Commercialize" or "Commercializing" means to (a) market, promote, distribute, offer for sale, sell, have sold, import, export or otherwise commercialize a Product, (b) conduct activities, other than Research, Development and Manufacturing, in preparation for the foregoing activities, including obtaining Price Approval or (c) conduct post-Marketing Approval studies (including Clinical Trials). When used as a noun, "Commercialization" means any activities involved in Commercializing.
- 1.25. **"Commercially Reasonable Efforts"** means with respect to the efforts to be expended by a Party, with respect to any [***] to accomplish such objective. With respect to any

objective relating to the Research, Development, Manufacture or Commercialization of a Licensed Compound or Product by a Party, "Commercially Reasonable Efforts" means that [***], taking into account, without limitation, with respect to each Licensed Compound or Product, (a) [***], (b) [***], (c) [***] involved, (d) [***], (e) [***] in the marketplace, (f) [***], such as [***] of the Licensed Compounds or Product, and (g) other relevant [***]. "Commercially Reasonable Efforts" will be determined on a [***] and activities that are conducted [***] will be considered in determining whether Commercially Reasonable Efforts have been applied in such other countries. For clarity, Commercially Reasonable Efforts will not mean that a Party guarantees that it will actually accomplish the applicable task or objective.

- 1.26. **"Competitive Infringement"** has the meaning set forth in Section 6.4.2.
- 1.27. "Competitive Product" means, with respect to a particular Product in a particular country, a product on the market in such country commercialized by any Third Party that is not a Sublicensee and that did not purchase such product in a chain of distribution that included any of Merck or its Affiliates or Sublicensees, that (a) is approved by the applicable Regulatory Authority, under any then-existing laws and regulations in the applicable country pertaining to approval of generic products, as a "generic" version of such Product, which approval uses such Product as a reference product and relies on or references information in the Approval Application for such Product, or (b) is otherwise recognized by the applicable Regulatory Authority as an interchangeable product to such Product.
- 1.28. "Compulsory License" means a compulsory license under Vertex's Licensed Technology obtained by a Third Party through the order, decree, or grant of a competent governmental body or court, authorizing such Third Party to research, develop, make, have made, use, sell, offer to sell, keep, import or export a Competitive Product or Product in the Field in any country in the Territory.
- 1.29. "**Conduct**" means, with respect to any Clinical Trial, to (a) sponsor, support or perform, directly or indirectly through a Third Party, such Clinical Trial, (b) provide to a Third Party funding for, or clinical supplies (including placebos) for use in, such Clinical Trial or (c) conduct wind down activities with respect to such Clinical Trial.
- 1.30. "Confidential Information" means, with respect to each Party, all Know-How or other information, including proprietary information (whether or not patentable) regarding or embodying such Party's technology, products, business information or objectives, that is communicated in any way or form by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, pursuant to this Agreement or that certain confidentiality agreement between Vertex and Merck dated [***], whether or not such Know-How or other information is identified as confidential at the time of disclosure. The terms of this Agreement will be considered Confidential Information of both Parties, with both Parties deemed to be the Receiving Party of such Confidential Information. Notwithstanding any provision of this Section 1.30 to the contrary, Confidential Information does not include any Know-How or information that: (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving

- Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement; (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. Confidential Information disclosed to the Receiving Party hereunder will not be deemed to fall within the foregoing exceptions merely because broader or related information falls within such exceptions, nor will combinations of elements or principles be considered to fall within the foregoing exceptions merely because individual elements of such combinations fall within such exceptions.
- 1.31. "Control" or "Controlled" means with respect to any Know-How or Patent or other data, information or Materials, possession of the ability (whether by sole or joint ownership, license or otherwise), other than pursuant to this Agreement, by a Party or its Affiliate(s) to grant, without violating the terms of any agreement with a Third Party, a license, access or other right in, to or under such Know-How or Patent or other data, information or Materials. Notwithstanding anything in this Agreement to the contrary, following a Change of Control of a Party, such Party and its Affiliates will be deemed to not Control any Patents or Know-How that are owned or controlled by the Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (other than any Affiliate of such Party prior to the Change of Control) (a) prior to the closing of such Change of Control, except to the extent that any such Patents or Know-How were developed by such Third Party or its Affiliates prior to such Change of Control using or incorporating such Party's or its pre-existing Affiliates's Know-How or Patents, or (b) after such Change of Control to the extent that such Patents or Know-How are developed or conceived by such Third Party or its Affiliates (other than such Party or its pre-existing Affiliates) after such Change of Control without using or incorporating such Party's or its pre-existing Affiliates's Know-How or Patents.
- 1.32. "Cover," "Covering" or "Covers" means, as to a compound or product, or the method of manufacture of, method of treatment using, or any other use of such compound or product (including identifying patient groups for treatment with such compound or product), and a Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, keeping, selling, offering for sale or importation of such compound or product would infringe such Patent or, as to a pending claim included in such Patent, the making, using, keeping, selling, offering for sale or importation of such compound or product, or the method of manufacture of, the method of treatment using, or any other use of such compound or product (including identifying patient groups for treatment with such compound or product), would infringe such Patent if such pending claim were to issue in an issued patent.
- 1.33. "CREATE Act" means the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c) (2)-(c)(3).
- 1.34. "**Development**" means, with respect to a Licensed Compound or Product, all clinical and non-clinical research and development activities conducted after filing of an IND for

such Licensed Compound or Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Trials (other than post-Marketing Approval Clinical Trials), regulatory affairs, pharmacovigilance, Clinical Trial regulatory activities and obtaining and maintaining Marketing Approval. When used as a verb, "Develop" or "Developing" means to engage in Development.

- 1.35. "**Development Plan**" has the meaning set forth in Section 2.1.2.
- 1.36. "**Development Report**" has the meaning set forth in Section 2.1.5.
- 1.37. "**Diligence Milestone**" has the meaning set forth in Section 2.5.4.
- 1.38. "Disclosing Party" has the meaning set forth in Section 10.1.
- 1.39. "**Dispute**" has the meaning set forth in Section 11.13.
- 1.40. "**Distributor**" means a Third Party to whom Merck or its Affiliates or Sublicensees grant a right to sell or distribute a Product, that purchases its requirements for such Product from Merck or its Affiliates or Sublicensees, has no significant responsibility for marketing and promotion of the Product, and does not otherwise make any royalty or other payments to Merck or its Affiliates or Sublicensees with respect to its intellectual property rights or Products, including any payments that are calculated on the basis of a percentage of, or profit share on, such Third Party's sale of Products.
 - 1.41. "DNA-PK" means the DNA-dependent protein kinase.
- 1.42. "**DNA-PK Compound**" means any of (a)(i) the compound known as VX-984 with the chemical formula set forth on Schedule 1.42 or (ii) any other compound with a chemical formula set forth on Schedule 1.42, (b) any compound that inhibits DNA-PK that is originally claimed or Covered by any claim contained in the Licensed Patent [***] as filed on [***], in the Licensed Patent [***] as filed on [***] or in the Licensed Patent [***] as filed on [***] or (c) [***] of any of the foregoing.
 - 1.43. "**DNA-PK Product**" means any Product containing a [***] or a [***].
 - 1.44. "**DOJ**" has the meaning set forth in Section 1.78.
 - 1.45. "Editing" has the meaning set forth in Section 1.62.
- 1.46. "**Effective Date**" means the Business Day following the date on which HSR Clearance has occurred with respect to the HSR Filing(s).
 - 1.47. "EMA" means the European Medicines Agency and any successor entity thereto.
 - 1.48. [***] means any of (a) any [***] or (b) any [***] any of the foregoing.

- 1.49. [***] means any Product containing [***] or a [***].
- 1.50. "**European Commission**" means the European Commission or any successor entity that is responsible for granting marketing approvals authorizing the sale of pharmaceuticals in the European Union.
- 1.51. "European Union" or "EU" means (a) the economic, scientific and political organization of member states as it may be constituted from time to time, which as of the Execution Date consists of Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland and that certain portion of Cyprus included in such organization, (b) any member country of the European Economic Area that is not otherwise a member of the European Union, and (c) any country not otherwise included in clauses (a) or (b) that participates in the unified filing system under the auspices of the EMA. For clarity, European Union will at all times be deemed to include each of Italy, Germany, France, the United Kingdom and Spain.
 - 1.52. **"Execution Date"** has the meaning set forth in the Preamble.
- 1.53. "**Executive Officers**" means the Chief Scientific Officer of Merck, initially Luciano Rossetti di Valdalbero, and the Chief Scientific Officer of Vertex, initially David Altshuler, or their respective designees.
 - 1.54. "Existing Clinical Trials" means those Clinical Trials set forth on Schedule 1.54.
 - 1.55. "Existing Clinical Trials Transfer Outline" has the meaning set forth in Section 2.1.4(a).
 - 1.56. "FDA" means the United States Food and Drug Administration and any successor entity thereto.
- 1.57. "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.
 - 1.58. "Field" means all human and non-human diagnostic, prophylactic and therapeutic uses.
- 1.59. "**First Commercial Sale**" means with respect to a Product, the first sale of such Product by Merck, its Affiliate or its Sublicensee to a Third Party resulting in Net Sales in a particular country after any required Marketing Approval for the Product has been obtained in such country; *provided* that the following will not constitute a First Commercial Sale: (a) any sale of a Product to an Affiliate or Sublicensee; (b) any sale of a Product for use in Clinical Trials, pre-clinical studies or other Research or Development activities; (c) the disposal or transfer of a Product for a bona fide charitable purpose; or (d) compassionate use and "named patient sales"; *provided*, *however*, any

first sale of a Product in France resulting in Net Sales under the French ATU program will constitute a "First Commercial Sale" of such Product in France.

- 1.60. **"Force Majeure"** means a condition, the occurrence and continuation of which is beyond the reasonable control of a Party, including an act of God, governmental acts or restrictions, war, civil commotion, labor strike or lock-out, epidemic, flood, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.
 - 1.61. "FTC" has the meaning set forth in Section 1.78.
- 1.62. "FTE" means [***] hours of work per [***] devoted to activities under this Agreement, including providing cooperation, assistance or support to Merck under this Agreement, that is carried out by [***] qualified employees (excluding Third Party contractors) of Vertex or its Affiliates.
- 1.63. "FTE Costs" means, for any period, the FTE Rate multiplied by the number of FTEs of Vertex or its Affiliates who perform a specified activity under this Agreement.
- 1.64. "FTE Rate" means \$[***], the fully-loaded cost (including all consumables, etc.) for the work of [***] FTE; provided that such rate will [***] or [***] on [***] of each Calendar Year (starting with [***]) in accordance with the percentage year-over-year increase or decrease in the [***]. The FTE Rate includes (a) all [***] and (b) [***].
 - 1.65. "GAAP" means United States generally accepted accounting principles, consistently applied.
 - 1.66. [***] means the [***].
- 1.67. [***] means any of (a) any [***] that is described by the chemical formulae set forth on Schedule 1.67 or (b) [***] of any of the foregoing.
 - 1.68. [***] means any small molecule compound that [***].
 - 1.69. [***] means any Product containing a [***] or a [***].
- 1.70. "GCP" means good clinical practices, which are the then-current standards for Clinical Trials for pharmaceuticals, as set forth in the FD&C Act or other Applicable Law, and such standards of good clinical practice as are required by the Regulatory Authorities of the European Union and other organizations and Governmental Authorities in countries for which the applicable Licensed Compound or Product is intended to be Developed, to the extent such standards are not less stringent than United States standards.
 - 1.71. [***].
 - 1.72. [***].

- 1.73. "Global Safety Database" or "GSD" means the safety database system used to capture, process, and report ICSRs. For purposes of this Agreement, the GSD is the database containing safety information for ATR Compounds and DNA-PK Compounds and is the authoritative data source for Individual Case Safety Report (ICSR) reporting and analysis.
- 1.74. "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards in jurisdictions outside of the United States, to the extent such standards are not less stringent than United States standards.
- 1.75. "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.
- 1.76. "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder, or foreign equivalent thereof under Applicable Law.
- 1.77. "**HSR Clearance**" means, with respect to the applicable agreement or transaction, the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.
- 1.78. "HSR Filing" means (a) a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) filing by Vertex and Merck with the United States Federal Trade Commission (the "FTC") and the Antitrust Division of the United States Department of Justice (the "DOJ") with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto, or (b) equivalent filings, if any, with applicable Governmental Authorities where such filings are required.
- 1.79. "**IFRS**" means the International Financial Reporting Standards, the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.
- 1.80. "**IND**" means any Investigational New Drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations or a similar application or submission for a Product filed with a Regulatory Authority in a country or group of countries.
- 1.81. "**Individual Case Safety Report**" or "**ICSR**" means a report providing the most complete information related to an individual adverse event case at a certain point of time.
 - 1.82. "**Infringement**" has the meaning set forth in Section 6.4.1
 - 1.83. "**Inventory**" has the meaning set forth in Section 4.2.3.
 - 1.84. "**Joint Agreement Know-How**" has the meaning set forth in Section 6.1.2.

- 1.85. "Joint Agreement Patents" has the meaning set forth in Section 6.1.2.
- 1.86. "Joint Agreement Technology" has the meaning set forth in Section 6.1.2.
- 1.87. **"Know-How"** means any scientific or technical information, data and results, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including pre-clinical and clinical protocols and data from studies and Clinical Trials, chemical structures, chemical sequences, information, discoveries, inventions, know-how, formulas, trade secrets, devices, practices, protocols, regulatory filings, techniques, methods, processes, concepts, ideas, specifications, formulations, formulae, data, case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing, summaries and information contained in submissions to and information from Regulatory Authorities, procedures and developments, whether or not patentable; *provided* that Know-How does not include Patents but includes the disclosure of any patent application that has remained unpublished due to abandonment or lapse of the patent application.
 - 1.88. "Knowledge" means the actual knowledge of the following Vertex executives, [***].
 - 1.89. "Liability" has the meaning set forth in Section 8.1.1.
 - 1.90. "Licensed Compound" means any ATR Compound, DNA-PK Compound, [***] Compound or [***] Compound.
- 1.91. "Licensed Know-How" means (a) any Know-How (i) Controlled by Vertex or its Affiliates on the Effective Date and (ii) actually used by Vertex or its Affiliates in the Research, Development or Manufacture of any Licensed Compound in the Field on or prior to the Effective Date, (b) any Vertex Agreement Know-How or Joint Agreement Know-How and (c) any Know-How Controlled by Vertex or its Affiliates under the Proposed ICR License Agreement, if such agreement is entered by Vertex or any of its Affiliates, in the case of each clause (a), (b) and (c), that is [***] to Research, Develop, Manufacture or Commercialize any Licensed Compound or Product in the Field.
- 1.92. "Licensed Patents" means (a) any Patents Controlled by Vertex or its Affiliates on the Effective Date that Cover any Licensed Compound, (b) any Patents filed after the Effective Date and Controlled by Vertex or its Affiliates that claim or cover any Licensed Know-How described in clause (a) of Section 1.91, including any patent filed after the Effective Date that claims or covers any [***] Compound or any [***] Compound, (c) any Vertex Agreement Patents or Joint Agreement Patents that Cover any Licensed Compound or Product, (d) any Patents anywhere in the Territory that claim priority from the same or are otherwise derived therefrom, such as by way of continuation, continuation-in-part, division, forming the basis of a supplementary protection certificates or patent term extensions and (e) any Patents Controlled by Vertex or its Affiliates under [***], that Cover any Licensed Compound. A list of Licensed Patents as of the Effective Date is set forth on Schedule 1.92. From time to time during the Term, the Parties will update Schedule 1.92 upon mutual agreement to list all Licensed Patents as of such time.

- 1.93. "Licensed Technology" means the Licensed Patents and Licensed Know-How.
- 1.94. "Manufacture" or "Manufactured" or "Manufacturing" means activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a Licensed Compound or Product.
- 1.95. "Marketing Approval" means, with respect to a Product in a particular jurisdiction, all approvals, licenses, registrations or authorizations necessary for the Commercialization of such Product in such jurisdiction, including, with respect to the United States, approval of an Approval Application for such Product by the FDA and with respect to the European Union, approval of an Approval Application for such Product by the European Commission or the applicable Regulatory Authority in any particular country in the EU. For clarity, Marketing Approval does not include Price Approval.
- 1.96. "Materials" means all biological materials or chemical compounds arising out of a Party's activities under this Agreement and provided by such Party to the other Party for use by the other Party or otherwise provided by a Party for use by the other Party, in each case, to conduct activities pursuant to this Agreement, including Licensed Compounds, Clinical Trial samples, cell lines, compounds, lipids, assays, viruses and vectors.
 - 1.97. "Merck" has the meaning set forth in the Preamble.
 - 1.98. "Merck Agreement Know-How" has the meaning set forth in Section 6.1.3.
 - 1.99. "Merck Agreement Patents" has the meaning set forth in Section 6.1.3.
 - 1.100. "Merck Agreement Technology" has the meaning set forth in Section 6.1.3.
- 1.101. "[***]" means any compound that (a) [***] with respect to which Merck or any of its Affiliates or sublicensees [***] and (b) was [***] Merck or any of its Affiliates or sublicensees or a Third Party acting on Merck's or any of its Affiliate's or sublicensee's behalf.
- 1.102. [***] means (a) any compound that (i) [***] with respect to which Merck or any of its Affiliates or sublicensees has filed an IND prior to the Effective Date or [***] and (ii) was [***] Merck or any of its Affiliates or sublicensees or a Third Party acting on Merck's or any of its Affiliate's or sublicensee's behalf or (b) any of (x) [***] with the chemical formula set forth on Schedule 1.102, (y) any compound that [***] as listed in Schedule 1.102 or (z) any [***] of any of the foregoing.
- 1.103. [***] means any [***] (a) with respect to which Merck or any of its Affiliates or sublicensees [***], (b) that is [***] Merck or any of its Affiliates or sublicensees or a Third Party acting on Merck's or any of its Affiliate's or sublicensee's [***].
 - 1.104. "Merck Indemnified Party" has the meaning set forth in Section 8.1.2.

- 1.105. [***] means any [***] (a) with respect to [***], (b) that is [***]Merck or any of its Affiliates or sublicensee [***] or (c) that is [***] by Merck or any of its Affiliates or sublicensees or a Third Party acting on Merck's or any of its Affiliate's or sublicensee's behalf [***].
- 1.106. "NDA" means a new drug application that is submitted to the FDA for Marketing Approval for a Product, pursuant to 21 C.F.R. § 314.3.
- 1.107. "Net Sales" means the gross invoiced price for Products sold by Merck, its Affiliates or Sublicensees (the "Selling Party") to independent or unaffiliated Third Party purchasers, less the following deductions with respect to such sales that are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented as a deduction in accordance with applicable Accounting Standards to be specifically attributable to actual sales of such Products:
- (a) credits or allowances on account of price adjustments, recalls, claims, damaged goods, rejections or returns of items previously sold (including Product returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt, including provisions for bad debts;
- (b) insurance, customs charges, freight, shipping and other transportation costs incurred in shipping Products to such non-related parties, to the extent incurred by a Selling Party and not reimbursed by a non-related party;
- (c) sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the distribution, use or sale of such Product;
- (d) discounts (including trade, quantity, cash discounts and fees for services), cash and non-cash coupons, copayment support programs, retroactive price reductions, and charge back payments and rebates granted to any non-related party (including to governmental entities or agencies, purchasers, reimbursers, customers, Distributors, wholesalers, and group purchasing organizations and managed care organizations (and other similar entities and institutions)); and
- (e) rebates (or their equivalent), administrative fees (e.g., Federal Supply Schedule-Industrial Funding Fee, administration rebates for all chargeback units sold to Big 4/OGA contracted entities, etc.), chargebacks and retroactive price adjustments and any other similar allowances granted to non-related parties (including to Governmental Authorities, purchasers, reimbursers, customers, Distributors, wholesalers, and managed care organizations (and other similar entities and institutions)) that effectively reduce the selling price or gross sales of the Product.

Only items that are deducted from the Selling Party's gross sales of Product(s), as included in the Selling Party's published financial statements and that are in accordance with applicable Accounting Standards, will be deducted from such gross sales for purposes of the calculation of Net Sales.

A qualifying amount may be deducted only once regardless of the number of the preceding categories that describe such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with the next quarterly report. Sales between or among Merck,

its Affiliates and Sublicensees will be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by Merck or any such Affiliates or Sublicensees. [***]. Further, transfers or dispositions of the Products at a price [***] the Supply Costs thereof:

- (i) [***].
- (ii) [***], or
- (iii) [***],

shall not, in each case, be deemed sales of such Products for purposes of this definition of "Net Sales." For clarity, [***].

If a sale, transfer or other disposition with respect to a Product in a country in the Territory involves consideration other than cash or is not at arm's length, the Net Sales from such sale, transfer or other disposition will be calculated on the average Net Sales price of the Product in arm's length sales for cash in the relevant country during the same Calendar Quarter as such sale, transfer or other disposition or in the absence of such sales, the fair market value of the Product as mutually determined by the Parties.

In the event that a Product under this Agreement is sold in form of a Combination Product, then Net Sales for such Combination Product shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the perceived relative value contributions of the Product and the other ingredient or component in the Combination Product, as reflected in their respective market prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, the International Chamber of Commerce shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

In the event a Product is "bundled" for sale together with one or more other products in a country (a "**Product Bundle**"), then Net Sales for such Product shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the relative value contributions of the Product and the other products in the Product Bundle, as reflected in their individual sales prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, the International Chamber of Commerce shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

- 1.108. "Non-Breaching Party" means the Party that believes the other Party is in material breach of this Agreement.
- 1.109. "Out-of-Pocket Costs" means, with respect to a Party, costs and expenses paid by such Party to Third Parties (or payable to Third Parties and accrued in accordance with applicable Accounting Standards), other than employees of such Party or its Affiliates. For clarity, all fees due by Vertex to any contract-research organization in connection with Existing Clinical Trials shall be understood as Out-of-Pocket Costs.

- 1.110. "Party" or "Parties" has the meaning set forth in the Preamble.
- 1.111. "Patents" means the rights and interests in and to issued patents and pending patent applications in any country, jurisdiction or region (including inventor's certificates and utility models), including all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and all patents granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing.
- 1.112. "**Person**" means an individual, sole proprietorship, 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, including a government or political subdivision or department or agency of a government.
- 1.113. **"Phase 1 Clinical Trial**" means any Clinical Trial as described in 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial.
- 1.114. "**Phase 3 Clinical Trial**" means any Clinical Trial as described in 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial.
 - 1.115. "Pre-Clinical Projects Transfer Plan" has the meaning set forth in Section 2.1.6.
- 1.116. "**Price Approval**" means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination.
- 1.117. "**Proceeding**" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation that is, has been or may in the future be commenced, brought, conducted or heard at law or in equity or before any Governmental Authority.
- 1.118. **"Product"** means any pharmaceutical product, medical therapy, preparation, substance, or formulation comprising or employing a Licensed Compound, [***].
 - 1.119. **"Product Bundle"** has the meaning set forth in Section 1.107.
- 1.120. "**Program**" means, as applicable, (a) Merck's Research, Development, Manufacture and Commercialization of ATR Compounds and ATR Products, (b) Merck's Research, Development, Manufacture and Commercialization of DNA-PK Compounds and DNA-PK Products, (c) Merck's Research, Development, Manufacture or Commercialization of [***] Compounds and [***] Products or (d) Merck's Research, Development, Manufacture and Commercialization of [***] Compounds and [***] Products.

- 1.121. "**Program Abandonment**" means, with respect to a single Program, prior to the First Commercial Sale of a Product in such Program, the failure of Merck or any of its Affiliates or Sublicensees to initiate or conduct any material Research or Development activities (including, for the avoidance of doubt, activities directed to resolving any clinical hold) with respect to any Licensed Compound or Product in such Program during any [***] period; *provided* that such [***] period will automatically be tolled so long as and to the extent that failure to initiate or conduct any material Research or Development is a result of a Force Majeure, Third Party supply failure or safety issue and Merck is using Commercially Reasonable Efforts to resolve such Force Majeure, Third Party supply failure or safety issue.
 - 1.122. [***].
- 1.123. "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, as well as handling re-examinations and reissues with respect to such Patent, together with the conduct of interferences, derivation proceedings, the defense of oppositions, post-grant patent proceedings (such as Inter Partes Review and Post Grant Review) and other similar proceedings (such as interferences, oppositions, re-examinations, reissues, revocation or nullification proceedings) with respect to the particular Patent. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" will not include any other enforcement actions taken with respect to a Patent.
 - 1.124. [***] means the protein known as [***] identifiable by its [***] and [***] and encoded by the gene [***],[***].
 - 1.125. [***] means any small molecule compound that at therapeutically active levels [***] or [***] (a) [***] or (b) [***].
 - 1.126. "**Receiving Party**" has the meaning set forth in Section 10.1.
 - 1.127. "**Recipient**" has the meaning set forth in Section 10.6.
- 1.128. "**Regulatory Approval**" means the technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of Approval Applications, supplements and amendments, pre- and post- approvals, and labeling approvals) of any Regulatory Authority, necessary for the research, development, clinical testing, commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of a pharmaceutical product in a regulatory jurisdiction, including Marketing Approval but excluding Price Approval.
- 1.129. "**Regulatory Authority**" means, with respect to a country in the Territory, any national (*e.g.*, the FDA), supranational (*e.g.*, the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of Regulatory Approvals or Price Approvals for pharmaceutical products in such country or countries.
- 1.130. "**Regulatory Filings**" means, collectively: (a) all INDs, Approval Applications, establishment license applications, Drug Master Files, applications for designation as an "Orphan

Product(s)" under the Orphan Drug Act, for "Fast Track" status under Section 506 of the FD&C Act (21 U.S.C. § 356) or for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FD&C Act (21 U.S.C. § 355(b)(4)(B)) and all other similar filings (including counterparts of any of the foregoing in any country or region in the Territory); (b) any applications for Regulatory Approval or Price Approval and other applications, filings, dossiers or similar documents submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval or Price Approval from that Regulatory Authority; (c) any Patent-related filings with any Regulatory Authority; (d) all supplements and amendments to any of the foregoing; and (e) all data and other information contained in, and correspondence with any Regulatory Authority relating to, any of the foregoing.

- 1.131. "**Representatives**" has the meaning set forth in Section 10.6.
- 1.132. "**Research**" means conducting research activities to discover, design, optimize, deliver and advance Licensed Compounds and Products, including pre-clinical studies and optimization, but specifically excluding Development, Manufacture and Commercialization. When used as a verb, "Researching" means to engage in Research.
 - 1.133. "Research Report" has the meaning set forth in Section 2.1.8.
 - 1.134. "Rights" has the meaning set forth in Section 11.2.
 - 1.135. "**Royalty Information**" has the meaning set forth in Section 10.6.
- 1.136. "Royalty Term" means, (a) with respect to a Product containing a Licensed Compound in a country, the period commencing on the first sale of such Product giving rise to Net Sales in such country and ending upon the latest of: (i) the expiration of the last Valid Claim of any Licensed Patent or any Patent Controlled by Merck or any of its Affiliates or Sublicensees that Covers such Product or the Licensed Compound in such Product in such country or (ii) [***] after the First Commercial Sale of such Product in such country and (b) with respect to a Product that does not contain a Licensed Compound in a country, the period commencing on the first sale of such Product giving rise to Net Sales in such country and ending [***] after the First Commercial Sale of such Product in such country.
 - 1.137. "**Selling Party**" has the meaning set forth in Section 1.107.
 - 1.138. "Storage Facility" has the meaning set forth in Section 4.2.3.
- 1.139. "**Sublicense**" means, directly or indirectly, to sublicense, grant any other right with respect to, or agree not to assert, the rights granted to Merck hereunder. When used as a noun, "Sublicense" means any agreement to Sublicense.
- 1.140. "**Sublicensee**" means an Affiliate or Third Party, other than a Distributor, to whom Merck (or a Sublicensee or Affiliate) sublicenses any of the rights granted to Merck hereunder during the Term.

- 1.141. "Supply Cost" means the actual fully-burdened cost to, and Out-of-Pocket Costs incurred by, either Party or its Affiliates or Sublicensees for the Manufacture of a Licensed Compound or Product containing a Licensed Compound, calculated using a methodology consistent with applicable Accounting Standards; *provided* that under no circumstances will (a) Supply Costs incurred by either Party's Affiliate or Sublicensee be double counted or (b) any mark-up among either Party and its applicable Affiliates or Sublicensees be included as a Supply Cost. For a Licensed Compound or Product containing a Licensed Compound that either Party, its Affiliate or Sublicensee purchases from a Third Party, Supply Cost will be equal to the fully-loaded price paid to such Third Party to purchase such Licensed Compound or Product.
 - 1.142. "TC" has the meaning set forth in Section 3.1.1.
 - 1.143. "**Term**" has the meaning set forth in Section 9.1.
- 1.144. "**Terminated Products**" means, with respect to a termination of this Agreement, (a) in the case of a termination of this Agreement in its entirety, all Licensed Compounds and Products containing a Licensed Compound and (b) in the case of a termination of this Agreement in part with respect to a Program, all Licensed Compounds and Products containing a Licensed Compound in such Program.
 - 1.145. "**Territory**" means all countries of the world.
 - 1.146. "Third Party" means any Person other than Vertex, Merck or their respective Affiliates.
 - 1.147. "Third-Party Infringement Claim" has the meaning set forth in Section 6.3.
 - 1.148. "United States" or "U.S." means the United States of America and all of its districts, territories and possessions.
- 1.149. "Valid Claim" means a claim (a) of any issued, unexpired United States or foreign Patent, which has not, in the country of issuance, lapsed, or been donated to the public, been revoked, abandoned, withdrawn, disclaimed, denied, held invalid or unenforceable by a court of competent jurisdiction or governmental or supra-governmental agency of competent jurisdiction, in an unappealed or unappealable decision or admitted to be invalid or unenforceable, or (b) of any United States or foreign patent application, which has not, in the country in question, been cancelled, withdrawn, abandoned, held invalid by a court of competent jurisdiction or governmental or supra-governmental agency of competent jurisdiction, in an unappealed or unappealable decision or admitted to be invalid or unenforceable. Notwithstanding the foregoing, on a country-by-country basis, a patent application pending for more than [***] years will not be considered to have any Valid Claim for purposes of this Agreement unless and until a patent that meets the criteria set forth in clause (a) above with respect to such application issues.
 - 1.150. "Vertex" has the meaning set forth in the Preamble.
 - 1.151. "Vertex Agreement Know-How" has the meaning set forth in Section 6.1.1.

- 1.152. "Vertex Agreement Patents" has the meaning set forth in Section 6.1.1.
- 1.153. "Vertex Background Patents" means (a) (i) those Vertex Agreement Patents included in the Licensed Patents and (ii) those Patents filed after the Effective Date and Controlled by Vertex or its Affiliates that claim or cover any Licensed Know-How described in clause (a) of Section 1.91, in each case ((i) and (ii)), that are not primarily related to the Research, Development, Manufacture or Commercialization of Licensed Compounds or Products, (b) those Patents set forth on Schedule 1.153 and (c) all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and all patents granted on the Patents referenced in clause (a) and (b), and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing. All Vertex Background Patents as of the Effective Date are listed on Schedule 1.153. For the avoidance of doubt, Vertex Background Patents are a sub-group of Licensed Patents that are subject to the special provisions in accordance with ARTICLE 6.
 - 1.154. "Vertex Indemnified Party" has the meaning set forth in Section 8.1.1.

ARTICLE 2.

RESEARCH, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

2.1. Research & Development.

- 2.1.1. <u>Generally.</u> Merck will have sole and exclusive control over all matters relating to the Research and Development of Licensed Compounds and Products in the Field in the Territory. Subject to Section 2.1.9, Merck shall be solely responsible for all of the costs and expenses of all Research and Development activities performed by Vertex or its Affiliates or Third Parties after the Effective Date related to Licensed Compounds and Products containing Licensed Compounds.
- 2.1.2. **Development Plan**. Merck will conduct Research and Development activities with respect to Licensed Compounds and Products for each Program in accordance with a reasonably detailed Development plan outlining anticipated activities in connection with the Research and Development of Licensed Compounds and Products for such Program (each, a "**Development Plan**"). The initial Development Plans for the ATR Compounds and ATR Products and for the DNA-PK Compounds and DNA-PK Products are attached hereto as Schedule 2.1.2. Promptly following [***] for an [***] Product or [***] Product, Merck will provide the TC with a Development Plan for the [***] Compounds and [***] Products or for the [***] Compounds and [***] Products, as applicable, and the TC will review and comment on such Development Plan. Merck [***] from Vertex's representatives on the TC on each such Development Plan. Merck will prepare updates to each Development Plan no less than [***] for so long as activities are taking place under such Development Plan and provide such updates to the TC for its review and comment. Merck [***] from Vertex's representatives on the TC on such updates. All Development Plans and all updates to Development Plans proposed by Merck pursuant to this Section 2.1.2 will contain proposed activities consistent with Merck's obligations under Sections 2.5.1, 2.5.2 and 2.5.4;

provided that, for the avoidance of doubt, neither the fact that Merck has provided the TC with proposed Development Plans nor the incorporation by Merck of comments from the Vertex representatives on the TC pursuant to this Section 2.1.2 nor the performance by Merck of the activities contained in any such Development Plan will preclude any claim by Vertex or a finding that Merck is not in compliance with Sections 2.5.1, 2.5.2 or 2.5.4. Merck will conduct Research and Development activities with respect to the applicable Licensed Compounds and Products in accordance with each Development Plan. Following the disbandment of the TC in accordance with Section 3.1.5, Merck will provide such Development Plans and the updates thereto directly to Vertex and [***] from Vertex on such Development Plans and updates thereto.

2.1.3. **Reporting**. For so long as Merck is conducting activities under a Development Plan, no later than [***], Merck will provide Vertex with a reasonably detailed report regarding the status of Merck's Research and Development under such Development Plan. Such reports may inter alia be provided to Vertex in conjunction with meetings and other communications between the representatives of Vertex and Merck on the TC for so long as the TC exists. No more than [***] and upon Vertex's request, appropriate employees of Merck engaged in activities under the Development Plan will meet with employees designated by Vertex to discuss the Research and Development of Licensed Compounds and Products. Following the first Clinical Trial that establishes proof-of-concept for a Product, the Parties will discuss the results of such Clinical Trial and Merck's plans regarding the disclosure of such results.

2.1.4. Existing Clinical Trials.

- (a) The Parties will coordinate the efficient transfer of the Conduct of each Existing Clinical Trial from Vertex to Merck. To enable such transfer, Vertex will use Commercially Reasonable Efforts to continue to Conduct each Existing Clinical Trial, at Merck's cost (to the extent set forth in this Section 2.1.4) and direction, consistent with the protocol of such Existing Clinical Trial as it exists on the Execution Date, until the earlier of (i) the completion of such Existing Clinical Trial, (ii) the transfer of such Existing Clinical Trial to Merck, or (iii) the receipt of Merck's written request to terminate such Existing Clinical Trial. Schedule 1.54 contains an overview of the Existing Clinical Trials, including their current protocols, as well as a preliminary outline of a transfer plan (the "Existing Clinical Trials Transfer Outline"). The Parties agree that the transfer dates set forth on Schedule 1.54 for each such Existing Clinical Trial describes their current understanding of transfer timelines, assuming, among other things, Merck's qualification of respective manufacturing sites. In case Merck's qualification of the contract manufacturing organizations being used by Vertex to Manufacture Clinical Trial supply of Licensed Compounds and Products as of the Execution Date fails, the Parties will cooperate to resolve any such failure prior to the transfer of the Existing Clinical Trials to Merck; provided that in no event will Vertex be obligated to provide support in resolving such failures after the date that is [***] from the Effective Date unless the Parties agree otherwise. The costs of such assistance will be paid by Merck in accordance with Section 2.1.9.
- (b) The TC shall, within [***] of the Effective Date, expand the Existing Clinical Trials Transfer Outline into a more detailed transfer plan, including a

timeline as well as a cost estimate, which detailed transfer plan shall be consistent with the protocols of the Existing Clinical Trials as they exist on the Execution Date (the "Clinical Trials Transfer Plan") and have oversight and monitor the transfer activities contemplated hereunder. Vertex will not be obligated to take any action in connection with its Conduct of Existing Clinical Trials that violates Applicable Law or is unethical, and, notwithstanding anything in this Agreement to the contrary, if any Existing Clinical Trial is being Conducted by a Third Party on the Effective Date pursuant to an agreement with Vertex or any of its Affiliates, such Existing Clinical Trial will be conducted in accordance with such agreement, and if such Third Party terminates any such agreement in accordance with the terms of such agreement, Vertex will be under no obligation to continue such Existing Clinical Trial.

- (c) Promptly following the Effective Date, Vertex will provide Merck with a reasonably detailed, good faith estimate of the Out-of-Pocket Costs, FTE Costs and Supply Cost (if any) expected to be incurred by Vertex or its Affiliates in Conducting the Existing Clinical Trials in accordance with the Clinical Trials Transfer Plan, and Vertex will periodically, but no less frequently than [***] during which the Parties are conducting activities under the Clinical Trials Transfer Plan, provide Merck with updates to such estimate. In addition, if Vertex anticipates that the costs to be incurred by Vertex to Conduct the Existing Clinical Trials in accordance with the Clinical Trials Transfer Plan during any Calendar Quarter will exceed the aggregate estimated cost of such activities in such good faith estimate by more than [***] of the relevant aggregate quarterly cost estimate, Vertex will promptly notify Merck, provide an updated estimate and make appropriate personnel available to discuss the relevant factors leading to such anticipated excess costs. The Parties will then decide on whether certain activities under the Clinical Trials Transfer Plan shall be conducted despite such anticipated excess costs. In case no agreement can be reached between the Parties with this regard, Merck may [***]; provided that (i) [***] any such activity would violate Applicable Law or the terms of any agreement to which Vertex is subject or be unethical [***] and (ii) [***] with respect to such activity.
- 2.1.5. <u>Development Reports</u>. For each Calendar Quarter in which Vertex is Conducting any Existing Clinical Trial, Vertex will provide Merck with a reasonably detailed report regarding the status and results of any such Existing Clinical Trial (a "**Development Report**").
- 2.1.6. <u>Transfer of Pre-Clinical Projects</u>. With respect to the Research of [***] Compound and the [***] Compound, the Parties agree that the TC shall develop, within [***] of the Effective Date, a detailed plan pursuant to which such Research projects will be transferred to Merck (the "Pre-Clinical Projects Transfer Plan"). Such plan shall describe in reasonable detail the tasks necessary to transfer such projects and the Research activities to be performed by Vertex after the Effective Date prior to such transfer, including a timeline as well as a cost estimate therefor. No later than [***] during which the Parties are conducting activities under the Pre-Clinical Projects Transfer Plan, Vertex will provide Merck with an update to the cost estimate for the Pre-Clinical Projects Transfer Plan. Prior to the adoption of the Pre-Clinical Projects Transfer Plan, Vertex will conduct Research activities with respect to the [***] Compound and the [***] Compound solely at Merck's direction and at Merck's cost. If Vertex anticipates that the aggregate costs of activities performed under the Pre-Clinical Projects Transfer Plan during any Calendar Quarter will exceed

the aggregate estimated cost of such activities in the Pre-Clinical Projects Transfer Plan by more than [***] of the relevant aggregate quarterly cost estimate, Vertex will promptly notify Merck and make appropriate personnel available to discuss the relevant factors leading to such anticipated excess costs. The Parties will then decide on whether certain activities under the Pre-Clinical Projects Transfer Plan shall be conducted or not despite such anticipated excess costs. In case no agreement can be reached between the Parties with this regard, Merck may [***]; provided that (a) [***] any such activity would violate Applicable Law or the terms of any Agreement to which Vertex is subject or be unethical, [***] and (b) [***] incurred with respect to such activity.

- 2.1.7. **Review of On-Going Research and Development Activities**. Promptly following the Effective Date, the TC will review all Research and Development activities being performed by Vertex or its Affiliates or by Third Parties as of the Effective Date related to the Licensed Compounds and Products containing Licensed Compounds and determine whether such activities should be continued or terminated and wound down (in the case of activities being performed by Third Parties, if such termination is permitted by the agreement with such Third Party); *provided* that, other than as set forth in Section 2.1.4 with respect to the Existing Clinical Trials or Section 2.1.6 with respect to the transfer of the Research projects, Vertex will be under no obligation to perform any new Research and Development activities beyond those that are ongoing as of the Execution Date, but Vertex may, in its sole discretion, perform new Research and Development activities if requested by Merck and at Merck's direction and expense (subject to Section 2.1.9).
- 2.1.8. **Pre-Clinical Research Reports**. For each Calendar Quarter in which Vertex is continuing to perform Research in accordance with the Pre-Clinical Projects Transfer Plan or pursuant to Section 2.1.7, if any, Vertex will provide Merck with a reasonably detailed report regarding the status and results of any such activity (a "**Research Report**").
- 2.1.9. **Cost Reimbursement**. Vertex will invoice Merck within [***] after the end of each Calendar Quarter for all FTE Costs (subject to this Section 2.1.9), Out-of-Pocket Costs and Supply Costs incurred by Vertex or its Affiliates in such Calendar Quarter for (a) conducting or winding down any Research or Development activities related to the Licensed Compounds or Products after the Effective Date, including Conducting any Existing Clinical Trial pursuant to Section 2.1.4 and conducting Research or Development activities pursuant to Sections 2.1.6 and 2.1.7, (b) transferring any Research projects pursuant to Section 2.1.6, (c) providing support pursuant to Section 2.2.3(a), (d) transferring Licensed Know-How pursuant to Section 4.2.1 and providing support therefor under Section 4.2.4 and (e) transferring or storing Inventory pursuant to Section 4.2.3; *provided* that Merck will have no obligation to reimburse Vertex for any such costs in excess of any applicable cost estimate to the extent that such excess costs (i) are a result of Vertex's [***] or (ii) were incurred for an activity that [***] such activity would violate Applicable Law or the terms of any agreement to which Vertex is subject or be unethical, and Vertex [***] or (B) that were incurred for an activity that [***] such activity would violate Applicable Law or the terms of any agreement to which Vertex is subject or be unethical. Merck will pay such invoices within [***] after receipt thereof. Notwithstanding anything to the contrary in this Agreement, Vertex will provide Merck with up to [***] of FTE support under Sections 2.1.4, 2.1.6, 2.1.7, 2.2.3(a) and 4.2 at no cost and will not include any FTE Costs in an invoice under this Section 2.1.9 for such support until

such time as Vertex has provided such [***] of FTE support. If Merck requests support beyond such [***] of FTE support or Vertex is otherwise obligated to provide FTE support beyond [***] pursuant to Sections 2.1.4, 2.1.6, 2.1.7, 2.2.3(a) and 4.2, Vertex will provide such support at Merck's cost, and such FTE Costs will be included in the applicable invoice.

2.2. Regulatory Matters.

- 2.2.1. **Responsibilities**. Subject to Section 2.2.3, Merck or its designated Affiliates and Sublicensees will have the sole authority to (a) prepare and file Regulatory Filings, each in its own name, and applications for Regulatory Approval and Price Approval for all Licensed Compounds and Products in the Field in the Territory, and (b) communicate with Regulatory Authorities with respect to the Licensed Compounds and Products in the Field in the Territory, both prior to and following Regulatory Approval and Price Approval.
- 2.2.2. **Ownership**. Ownership of all rights in and to all Regulatory Filings, Regulatory Approvals and Price Approvals directed to any Licensed Compound or Product in the Field in each country of the Territory will be held in the name of Merck, its Affiliate, designee or Sublicensee.

2.2.3. **Participation by Vertex**.

- (a) Merck will provide Vertex with copies of all material correspondence related to a Licensed Compound or Product between Merck and a Regulatory Authority. Upon Merck's reasonable request and at Merck's expense (subject to Section 2.1.9), Vertex will support the Development of Licensed Compounds and Products by (i) providing Regulatory Authorities with access to, and the right to audit, any data or other Licensed Know-How and associated documents that are in Vertex's Control and are relied on by Merck in its Regulatory Filings for Licensed Compounds and Products and (ii) having one or more representatives of Vertex attend material meetings and teleconferences with Regulatory Authorities regarding the Development of Licensed Compounds and Products if requested by Merck. Notwithstanding anything to the contrary contained herein, for so long as Vertex is Conducting any Existing Clinical Trial, Merck will not respond to any material correspondence related to any such Existing Clinical Trial with any Regulatory Authority or make any filing or submission to any Regulatory Authority related to any such Existing Clinical Trial without first obtaining Vertex's prior written consent [***] if any statement or action proposed in such response, filing or submission would violate Applicable Law or is unethical.
- (b) For so long as Vertex is Conducting any Existing Clinical Trial, Vertex will provide Merck with copies of all material correspondence related to any such Existing Clinical Trial between Vertex and a Regulatory Authority. Vertex will allow Merck a reasonable opportunity to review and comment on Vertex's proposed response to any material correspondence related to any such Existing Clinical Trial with any Regulatory Authority in advance of the transmission of such response, and Vertex will [***] by Merck in connection therewith. Unless required by Applicable Law (as determined in good faith by [***]), Vertex will not make any filing or submission to any Regulatory Authority related

to any Existing Clinical Trial or any Licensed Compound or Product without first obtaining Merck's prior written consent.

- 2.2.4. <u>Assignment of Existing Regulatory Filings</u>. The Parties will coordinate the efficient transfer to Merck of the Regulatory Filings set forth on Schedule 2.2.4; *provided* that, in any event, upon Merck's reasonable request, Vertex will assign such Regulatory Filings to Merck and will take all steps necessary to effect such transfer as promptly as practicable after such request.
- 2.2.5. <u>Global Safety Database</u>. Within [***] of the Effective Date, Vertex will draft and submit to Merck for review a Pharmacovigilance Agreement (PVA) which will provide for the transfer of the GSD from Vertex to Merck as promptly as practicable, as well as the transfer of subsequently-generated safety data appropriate for the GSD from Vertex to Merck for as long as Vertex is Conducting any Existing Clinical Trial.
- 2.3. **Manufacturing**. Merck will have the exclusive right to Manufacture and supply Licensed Compounds and Products itself or through one or more of its Affiliates or through Third Parties selected by Merck in its sole discretion for Research, Development and Commercialization in the Field in the Territory.

2.4. **Commercialization**.

- 2.4.1. **General**. Merck will have sole and exclusive control over all matters relating to the Commercialization of Products in the Field in the Territory.
- 2.4.2. **Branding**. Merck or its designated Affiliates or Sublicensees will select and own all trademarks used in connection with the Commercialization of any Product in the Field in the Territory. Vertex will not use nor seek to register, anywhere in the Territory, any trademark that is confusingly similar to any trademark used by or on behalf of Merck, its Affiliates or Sublicensees in connection with any Product.
- 2.4.3. **Commercialization Plan**. Starting [***] prior to the date on which Merck reasonably anticipates that the First Commercial Sale of a Product will occur, Merck will provide Vertex with a high-level Commercialization plan for such Product for each country in which Merck will sell such Product (each, a "**Commercialization Plan**"). If Merck is Commercializing more than one Product in a country, the Commercialization Plan for such country will include the foregoing information for each such Product. After an initial Commercialization Plan has been provided to Vertex, Merck will update such Commercialization Plan [***] for so long as activities are taking place under such Commercialization Plan and provide such updates to Vertex for its review.
- 2.4.4. **Reporting**. For so long as Merck is conducting activities under a Commercialization Plan, but no later than [***], Merck will provide Vertex with a high-level report regarding the status of Merck's Manufacturing and Commercialization activities under such plan. Such reports may be provided to Vertex in conjunction with meetings and other communications between the representatives of Vertex and Merck on the TC for so long as the TC exists.

2.5. Merck Diligence.

- 2.5.1. <u>Development Diligence as to Clinical Projects</u>. Merck (acting directly or through one or more Affiliates or Sublicensees) will use Commercially Reasonable Efforts to Research, Develop and obtain Marketing Approval for [***] in the [***].
- 2.5.2. **Development Diligence as to Pre-Clinical Projects**. Merck (acting directly or through one or more of its Affiliates or Sublicensees) will use Commercially Reasonable Efforts to Research, Develop and obtain Marketing Approval for [***] in the [***].
- 2.5.3. <u>Commercial Diligence</u>. Merck (acting directly or through one or more of its Affiliates or Sublicensees) will use Commercially Reasonable Efforts to Commercialize, including seeking Price Approval, [***] in [***] where Merck or its designated Affiliates or Sublicensees receive Marketing Approval for such Product.
- 2.5.4. <u>Diligence Milestones</u>. Without limiting Merck's obligation under Sections 2.5.1, 2.5.2 or 2.5.3, Merck shall use Commercially Reasonable Efforts to achieve the following milestones for each Program identified below (each, a "**Diligence Milestone**") by the date set forth below opposite each such Program; *provided* that the period to achieve such milestone will [***] and to the extent that [***].

Program	Diligence Milestone	Achievement Date
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

2.6. <u>Applicable Laws</u>. Merck will, and will require its Affiliates, Sublicensees and subcontractors to, comply with all Applicable Law in its and their Research, Development, Manufacture and Commercialization of Licensed Compounds and Products, including where appropriate cGMP, GCP and GLP (or similar standards). Without limiting the foregoing, Merck will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction.

ARTICLE 3. GOVERNANCE

3.1. Transition Committee.

3.1.1. **Formation**. Within [***] after the Effective Date, the Parties will establish a transition committee (the "**TC**") to oversee and coordinate activities related to the

technology transfer set forth in Section 4.2 and the Conduct of the Existing Clinical Trials. The TC will be comprised of [***] representatives from each Party. In addition, each Party may invite [***] of additional representatives to participate in discussions and meetings of the TC. Each Party's representatives on the TC and all other individuals participating in discussions and meetings of the TC on behalf of a Party will be subject to confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provision of ARTICLE 10. [***] will designate the chairperson of the TC. The chairperson of the TC will be responsible for setting the agenda for meetings of the TC with input from the other members, and for conducting the meetings of the TC. The TC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence.

3.1.2. **Responsibilities**. The TC will:

- (a) establish, based on the Existing Clinical Trials Transfer Outline, a detailed Clinical Trials Transfer Plan which describes in detail the steps to be taken to transfer to Merck, or one of Merck's Affiliates, the ongoing Existing Clinical Trials in an efficient manner without compromising the same which plan shall include timelines for the transfer activities and a cost estimate which cost estimate the Parties shall agree upon in good faith;
- (b) oversee and monitor the Conduct of the Existing Clinical Trials and the transfer of the Existing Clinical Trials to Merck in accordance with the Clinical Trials Transfer Plan;
- (c) oversee the technology transfer from Vertex to Merck with respect to the Licensed Know-How in accordance with Section 4.2;
- (d) establish, oversee and monitor the Pre-Clinical Projects Transfer Plan and prepare a cost estimate for such activities;
- (e) review on-going Research and Development activities related to the Licensed Compounds and determine whether such activities should be completed or terminated in accordance with Section 2.1.7; and
 - (f) perform such other duties as are specifically assigned to the TC under this Agreement.

3.1.3. Meetings; Minutes.

- (a) The TC will meet in person [***] on such dates and at such times and places as agreed to by the members of the TC. Each Party will be responsible for its own expenses relating to attendance at, or participation in, TC meetings.
- (b) The Alliance Managers will provide the members of the TC with draft written minutes for approval from each meeting within [***] after each such meeting. The responsibility for preparing the minutes will alternate between the Alliance Managers

on a meeting-by-meeting basis. If the minutes of any meeting of the TC are not approved by the TC (with each Party's representatives on the TC collectively having one vote) within [***] after the meeting, the objecting Party will append a notice of objection with the specific details of the objection to the proposed minutes.

- 3.1.4. **Decision-Making**. The TC will provide a forum for the Parties to plan, oversee and monitor the Parties' activities under this Agreement, including the activities under the Clinical Trials Transfer Plan and the Pre-Clinical Projects Transfer Plan. If the TC is unable to reach consensus with respect to a particular matter within the scope of its planning, oversight and monitoring function for more than [***], the matter will be referred to the Executive Officers, who will use reasonable efforts to reach agreement on such matters. If such Executive Officers are unable to reach consensus with respect to a particular matter within [***] after the matter is first referred to such Executive Officers, [***] will have the right to make the final decision with respect to such matter; *provided* that [***] (a) will take into reasonable consideration the recommendations and concerns raised by [***], (b) will make such decisions in good faith using reasonable business judgment, which will not be unreasonably delayed and (c) will not have the right to: (i) amend, modify or waive compliance with any term or condition of this Agreement; (ii) make any decision that is expressly stated to require the mutual agreement of the Parties; (iii) resolve any claim or dispute regarding whether or in what amount a payment is owed under this Agreement; (iv) exercise its final decision-making authority in a manner that would require [***] to perform any act that would violate Applicable Law or the terms of any agreement relating to the Research or Development of Licensed Compounds or Products to which [***] is subject; or (v) make a determination that a Party is in material breach of any obligation under this Agreement.
- 3.1.5. **Discontinuation of the TC**. The TC will continue to exist until the later to occur of (a) completion of the technology transfer set forth in Section 4.2 or (b) completion of the last Existing Clinical Trial Conducted by Vertex.
- 3.2. **Other Committees**. The Parties may, by mutual agreement, form such other committees or working groups as may be necessary or desirable to facilitate activities under this Agreement. Each such committee or working group will have no decision making authority under this Agreement.

3.3. Alliance Managers.

3.3.1. <u>Appointment</u>. Each Party will appoint a representative of such Party to act as its alliance manager under this Agreement (each, an "Alliance Manager"). Each Party may replace its Alliance Manager at any time upon notice to the other Party. The initial Alliance Managers will be:

For Vertex: Petra Sansom

For Merck: David Christopher Godfrey

3.3.2. **Specific Responsibilities**. The Alliance Managers may attend meetings of the TC but may not be members of the TC. The Alliance Managers will serve as the

primary contact point between the Parties for the purpose of providing each Party with information regarding the other Parties' activities pursuant to this Agreement and will have the following responsibilities:

- (a) schedule meetings of the TC and circulate draft written minutes as provided in Section 3.1.3(b);
- (b) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;
- (c) provide a single point of communication for seeking consensus both internally within the respective Party's organization and between the Parties regarding key strategy and planning issues; and
 - (d) perform such other functions as requested by the TC.

ARTICLE 4. LICENSE GRANTS; TECHNOLOGY AND MATERIALS TRANSFER

4.1. License Grant to Merck.

4.1.1. <u>License</u>. Subject to the terms of this Agreement, Vertex hereby grants to Merck and its Affiliates an exclusive (even as to Vertex subject to Section 4.1.4), royalty-bearing, right and license under Vertex's and its Affiliates' interest in the Licensed Technology to Research, Develop, Manufacture, have Manufactured, use, keep, sell, offer for sale, import, export and Commercialize any Licensed Compound or Product in the Field in the Territory.

4.1.2. <u>Covenant Not to Sue</u>.

- (a) Subject to the terms of this Agreement, Vertex shall not, and shall cause its Affiliates not to, sue or commence any claim, cause of action, lawsuit or litigation against Merck or its Affiliates or Sublicensees for misappropriation of any Know-How (other than Licensed Know-How) Controlled by Vertex on the Effective Date that is necessary or useful to Research, Develop, Manufacture or Commercialize any Licensed Compound or Product in the Field in connection with Merck's or any of its Affiliates' or Sublicensees' Researching, Developing, Manufacturing, having Manufactured, using, keeping, selling, offering for sale, importing, exporting or Commercializing any Licensed Compound or Product in the Field in the Territory.
- (b) Subject to the terms of this Agreement, on a Product-by-Product basis, Vertex shall not, and shall cause its Affiliates not to, sue or commence any claim, cause of action, lawsuit or litigation against Merck or its Affiliates or Sublicensees for infringement of any Patents (other than Licensed Patents) Controlled by Vertex after the Effective Date and prior to the expiration of the Royalty Term for such Product to the extent necessary to Research, Develop, Manufacture or Commercialize such Product or the Licensed Compounds contained in such Product in the Field in connection with Merck's or any of its

Affiliates' or Sublicensees' Researching, Developing, Manufacturing, having Manufactured, using, keeping, selling, offering for sale, importing, exporting or Commercializing such Product or the Licensed Compounds contained in such Product in the Field in the Territory.

4.1.3. <u>Sublicensing</u>. Merck and its Affiliates may grant Sublicenses, in whole or in part, of any rights granted to Merck by Vertex under this Agreement through multiple tiers of Sublicenses to one or more Sublicensees. Each such Sublicense will be consistent with the terms of this Agreement and will require such Sublicensee to comply with all applicable terms of this Agreement. Merck will remain responsible for each Sublicensee's compliance with the applicable terms of this Agreement. Within [***] after the grant of a Sublicense, Merck will provide a true copy of such Sublicense to Vertex; *provided* that such copy may be redacted except as necessary for Vertex to ensure such Sublicense complies with the terms hereof.

4.1.4. Retained Rights; Gene Integration.

- (a) Notwithstanding the license granted to Merck pursuant to Section 4.1.1, subject to the terms of this Agreement, (i) Vertex will retain rights under the Licensed Technology for the purpose of performing its obligations under this Agreement, including Sections 2.1.4, 2.1.6 and 2.1.7, and (ii) Vertex may retain the Licensed Compounds, Products containing Licensed Compounds and any associated data in its and its Affiliates internal compound screening libraries, toxicology databases, drug metabolism and pharmacokinetics (DMPK) databases and other internal libraries and databases, and Vertex and its Affiliates may use, make and have made such Licensed Compounds, Products and associated data for Research purposes (excluding any *in vivo* study); *provided*, *however*, that, except as set forth in Sections 4.1.4(b) and 4.1.4(c), neither Vertex nor any of its Affiliates will Develop or Commercialize any Licensed Compound or Product in the Field in the Territory.
- (b) Notwithstanding the license granted to Merck pursuant to Section 4.1.1, Vertex and its Affiliates retain, and may license to Third Parties, the non-exclusive right under the Licensed Technology to Research and Develop, and Manufacture for Research and Development, [***] and Products containing [***], but excluding the [***], in the Territory, solely in the field of [***], excluding the treatment, prevention or diagnosis of any cancer, and solely in combination with one or more pharmaceutical products, medical therapies, preparations, substances, or formulations for which either (A) such product, therapy, preparation, substance or formulation was researched or developed, in whole or in part, by or on behalf of Vertex or its Affiliates or (B) the research, development, manufacture, commercialization or other exploitation of such product, therapy, preparation, substance or formulation is Covered by any claim contained in any Patent owned by or licensed to Vertex or its Affiliates that is not a Licensed Patent and Licensed Know-How.
- (c) Upon Vertex's request, the Parties shall [***] a license agreement under which Merck would grant Vertex and its Affiliates an exclusive license, but not exclusive as to Merck, under Merck's interest in the Licensed Technology and Merck

Agreement Technology to Manufacture and Commercialize Products containing [***], in the field of [***] in one or more countries in the Territory.

4.2. <u>Technology Transfer</u>.

- 4.2.1. <u>Initial Transfer</u>. To the extent not previously provided, Vertex will transfer to Merck a copy of all Licensed Know-How in its possession or Control as of the Effective Date, including any documentation (whether held in paper or electronic format) or similar removable media. Vertex will transfer such Licensed Know-How to Merck within [***] following the Effective Date at Merck's cost and expense subject to Section 2.1.9. Vertex will continue to provide Merck with access to the "Vertex" electronic document data room already provided to Merck in connection with this Agreement for an additional [***] after the Effective Date.
- 4.2.2. <u>Updates</u>. Following the initial transfer described in Section 4.2.1, for so long as Vertex is Conducting any Existing Clinical Trial, Vertex will provide [***] updates to Merck regarding any newly generated Licensed Know-How in each Development Report. Such Development Reports shall be delivered [***] by Vertex to Merck. For so long as Vertex is Conducting any Existing Clinical Trial, Vertex will share with Merck all relevant data associated with each such Existing Clinical Trial utilizing an electronic data room. Vertex will set-up such electronic data room within [***] following the Effective Date. Merck shall bear the cost for such electronic data room. Such data which belongs in the GSD may be shared utilizing other means and such means will be documented in the Pharmacovigilance Agreement referred to in Section 2.2.5.
- 4.2.3. <u>Inventory</u>. At any time after the Effective Date, upon Merck's request and subject to Vertex's right to retain Licensed Compounds and Products in sufficient quantities for Vertex to Conduct the Existing Clinical Trials to the extent required hereunder, Vertex shall transfer the Materials set forth on Schedule 4.2.3 (the "Inventory") to Merck in compliance with the following process: Within [***] from the date of receipt of Merck's written request, for any Inventory not necessary to be retained by Vertex in order to Conduct the Existing Clinical Trials and that is identified as held by Vertex or any of its Affiliates on Schedule 4.2.3, Vertex will, at Merck's expense, ship such Inventory to an address provided by Merck, delivered [***]; provided that if Merck does not notify Vertex of an address for such shipment within [***] from the Effective Date, Vertex may destroy such Inventory. Within [***] from the Effective Date, for any Inventory identified as held by a Third Party on Schedule 4.2.3, Merck will either (a) make arrangements with the Third Party storing such Inventory (the "Storage Facility") to ship such Inventory to Merck or (b) enter into an agreement directly with the Storage Facility to continue storing such Inventory at Merck's expense. Vertex will notify the Storage Facility of the transfer of such Inventory to Merck as needed to facilitate the shipment of such Inventory to Merck or the continued storage of such Inventory by the Storage Facility at Merck's expense and will execute all transfer letters or other documentation necessary in connection therewith. Notwithstanding anything contained herein, if Merck does not notify Vertex of its election to either ship or continue storing such Inventory with the Storage Facility within [***] from the Effective Date pursuant to this Section 4.2.3, Vertex may destroy such Inventory. With respect to any Inventory stored by a Storage Facility in any country or jurisdiction outside of the United States, Merck will be responsible for obtaining, completing and presenting to the applicable government authority all export documentation, fees and licenses required to ship

such Inventory. In case Inventory is not sufficient to complete the Existing Clinical Trials, or to secure supply of Licensed Compounds during the hand-over period of Third Party vendor contracts as defined in Section 4.2.5, the TC shall agree on the strategy according to which Vertex shall use Commercially Reasonable Efforts to supply Licensed Compound in addition to Inventory for use in the Existing Clinical Trials in accordance with the Clinical Trials Transfer Plan. The costs of such supply of Licensed Compound shall be reimbursed by Merck in accordance with Section 2.1.4.

- 4.2.4. **Personnel**. To assist with the transfer of Licensed Know-How under this Section 4.2, Vertex will make its personnel reasonably available to Merck during normal business hours to transfer such Licensed Know-How at Merck's expense (subject to Section 2.1.9). Notwithstanding anything in this Agreement to the contrary, Vertex will only be obligated to provide support under this Section 4.2 for [***] from the Effective Date; *provided* that if the transfer of Licensed Know-How to Merck is not complete at such time, [***].
- 4.2.5. Third Party Vendors or Contractors; Assigned Contracts. Schedule 4.2.5(a) identifies the material Third Party vendors and contractors that Vertex currently engages in the Development or Manufacture for clinical use of the Licensed Compounds and Products. Vertex and Merck will use Commercially Reasonable Efforts to transfer such relationships to Merck by assigning any relevant agreements with such vendor or contractor to Merck or its designated Affiliate in whole if such agreement relates solely to the Development or Manufacture for clinical use of Licensed Compounds and Products in the Field in the Territory or in part with respect to the Licensed Compounds and Products or any ongoing activities with respect thereto if such agreement does not relate solely to the Development or Manufacture for clinical use of Licensed Compounds and Products in the Field in the Territory; provided that if any such assignment is not permitted by such agreement, Vertex and Merck will use Commercially Reasonable Efforts to obtain consent to such assignment. Promptly following the Effective Date, the TC will review the Agreements set forth on Schedule 4.2.5(a) and determine whether there are any pending option periods or other time-limited obligations with respect to which Merck may want to take action. Vertex hereby assigns all of its right, title and interest in each agreement with a Third Party for the Research of Licensed Compounds or Products set forth on Schedule 4.2.5(b), and Merck hereby assumes all liabilities and obligations of Vertex or its Affiliates arising on or after the Effective Date under each such agreement; provided that if the assignment of any such agreement requires consent of the Third Party counterparty, such assignment will be effective upon receipt of such consent.
- 4.3. **No Implied Licenses**. Except as expressly provided in this Agreement, no Party will be deemed by estoppel or implication to have granted to the other Party any licenses or other right with respect to any intellectual property.

ARTICLE 5. FINANCIAL PROVISIONS

5.1. <u>Up-Front Fee</u>. In partial consideration of Vertex's grant of the rights and licenses to Merck, within [***] from the Effective Date, Merck will pay Vertex a one-time, non-refundable, non-creditable, up-front fee of two-hundred and thirty million USD (\$230,000,000) payable by wire transfer of immediately available funds.

5.2. Royalties.

5.2.1. Royalty Rates.

(a) As further consideration for Vertex's grant of the rights and licenses to Merck, subject to Sections 5.2.2–5.2.6, on a Product-by-Product and country-by-country basis and during the Royalty Term for such Product in such country, Merck will pay Vertex tiered royalties based on [***], in each case ((i) and (ii)), sold by Merck, its Affiliates or Sublicensees in the Field in the Territory during a Calendar Year at the rates set forth in the applicable table below. The obligation to pay royalties will be imposed only once with respect to the same unit of a Product.

[***] containing an [***]	
Calendar Year Net Sales (in U.S. Dollars) of all [***] in the Territory	Royalty Rates as a Percentage (%) of Net Sales of [***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]	
Calendar Year Net Sales (in U.S. Dollars) of all [***] in the Territory	Royalty Rates as a Percentage (%) of Net Sales of [***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) As further consideration for Vertex's grant of the rights and licenses to Merck, subject to Sections 5.2.2–5.2.6, on a Product-by-Product and country-by-country basis and during the Royalty Term for such Product in such country, Merck will pay Vertex tiered royalties based on [***], in each case ((i) - (iii)), sold by Merck, Merck's Affiliates or Merck's Sublicensees in the Field in the Territory during a Calendar Year at the rates set forth in the table below. The obligation to pay royalties will be imposed only once with respect to the same unit of a Product.

[***]		
Calendar Year Net Sales (in U.S. Dollars) of all [***], as applicable, in the Territory	Royalty Rates as a Percentage (%) of Net Sales of [***], as applicable	
[***]		
[***]	[***]	
[***]		
[***]		
[***]	[***]	
[***]		
[***]		
[***]	[***]	
[***]		
[***]		
[***]	[***]	
[***]		
[***]		
[***]	[***]	
[***]		
[***]		
[***]	[***]	
[***]		

By way of illustration, assume in a Calendar Year that (i) aggregate worldwide annual Net Sales of all [***]in USD totals \$[***]and (ii) no adjustments or deductions to payments under this Section 5.2 apply. The total royalties due and payable by Merck to Vertex for such Net Sales would be [***]USD (\$[***]), calculated as follows:

[***] x [***]% = [***]

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[***] x [***] % = [***]
Total Royalty = [***]
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For purposes of determining whether a royalty threshold has been attained, only Net Sales that are subject to a royalty payment shall be included in the total amount of Net Sales. In addition, in no event shall the manufacture of a Product give rise to a royalty obligation. For clarity, Merck's obligation to pay royalties to Vertex under this Section 5.2 is imposed only once with respect to the same unit of Product, regardless of the number of Licensed Patents pertaining thereto.

- 5.2.2. **Compulsory License**. In the event that Vertex or Merck receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country, then Vertex or Merck (whoever has first notice) shall promptly notify the other Party. For the avoidance of doubt, for purposes of calculating the royalties due to Vertex under Section 5.2.1 with respect to sales of the Product by any compulsory licensee, Merck's Net Sales from such sales shall be calculated based solely on the actual royalty payments, if any, paid by the compulsory licensee to Merck under the Compulsory License. In addition, should Merck grant a Sublicense to a Third Party in any country to avoid the imposition of such a Compulsory License, the royalty rate payable under Section 5.2.1 to Vertex shall also be adjusted to match any lower royalty rate payable by such Sublicensee for such country under such Sublicense; *provided* that Merck will not enter into any such Sublicense with royalty rates lower than those otherwise payable under Section 5.2.1 without Vertex's consent, which shall not be unreasonably be withheld, and all Net Sales from such Sublicensee will be allocated to the lowest royalty tier(s) under Section 5.2.1 for the applicable Product.
- 5.2.3. **Reduction for Competition.** If one or more Competitive Products with respect to a Product is marketed and sold in a given country by one or more Third Parties during any Calendar Quarter during the Royalty Term (the "**Affected Calendar Quarter**"), Net Sales of such Product in such country, for purposes of calculating the royalty owed under Section 5.2.1 for the Affected Calendar Quarter, will be [***] of such Product during such Affected Calendar Quarter has [***]to the [***]of such Product in such country during the [***] Calendar Quarters [***]to the Calendar Quarter during which such Competitive Product(s) was first marketed and sold in such country. For the avoidance of doubt, in the case that Net Sales in an Affected Calendar Quarter were [***]but in subsequent Calendar Quarters [***]again to the level of the average of the [***]Calendar Quarters immediately prior to the Calendar Quarter during which such Competitive Product(s) was first marketed and sold in such country, [***] to the Net Sales shall apply anymore.
- 5.2.4. **Third Party Licenses**. Merck may [***] from the royalties payable to Vertex under this Section 5.2 with respect to Net Sales of a Product in a country [***] with respect to such [***]; *provided* that Merck may [***] with respect to such Product in such country to the extent resulting from [***].
- 5.2.5. [***], and in the event that Vertex [***] and in such event, Vertex shall [***]. For the avoidance of doubt, if Vertex or any of its Affiliates [***] and if Vertex or any

of its Affiliates does [***] Merck or any of its Affiliates [***] of this Section 5.2.5 and to Section 5.2.4.

If Vertex does not [***] and Merck or any of its Affiliates [***] Merck or any of its Affiliates is [***] in accordance with Section 5.2.4. [***].

- 5.2.6. **Royalty Deductions**. Notwithstanding anything to the contrary herein, in no event will the combined effect of all reductions to Net Sales or the royalties payable to Vertex under Sections 5.2.2 and 5.2.4 reduce the royalty payable by Merck to Vertex under this Section 5.2 for any Product in any country during a Calendar Quarter to less than [***] of the amount that would otherwise be due under Section 5.2.1. Merck will be entitled to carry forward to subsequent Calendar Quarters any amounts with respect to which Merck would have been entitled to make a deduction pursuant to Sections 5.2.2 and 5.2.4 but is unable to take such deduction pursuant to the first provision in this Section 5.2.6. For the avoidance of doubt, no royalty floor shall apply to any reduction set forth under Section 5.2.3.
- 5.2.7. Royalty Reports and Timing of Payment. Following the first sale of a Product giving rise to Net Sales and continuing for the remainder of the Term, within [***] after the end of each Calendar Quarter, Merck will deliver a report to Vertex specifying on a Product-by-Product and country-by-country basis: (a) Net Sales accrued in the relevant Calendar Quarter; (b) to the extent such Net Sales include sales not denoted in U.S. Dollars, a summary of the conversion of such amounts to U.S. Dollars in accordance with Section 5.3.2, (c) royalties payable on such Net Sales and (d) any deductions applied by Merck in accordance with Sections 5.2.2, 5.2.3 or 5.2.4. All royalty payments due under this Section 5.2 for each Calendar Quarter will be due and payable within [***] after the end of each Calendar Quarter during which the royalty obligation accrued.
- 5.2.8. **Flash Reports**. As soon as practicable, but in no event later than [***] from the last day of each Calendar Quarter, Merck will provide Vertex with a flash report providing a good faith estimate of Net Sales accrued in the preceding Calendar Quarter and the royalties payable to Vertex on such Net Sales on a Product-by-Product and country-by-country basis. The flash report may be based on forecasted numbers and it is understood that final reported Net Sales for purposes of calculating the royalty owed under Section 5.2.1 may vary.
- 5.2.9. [***]. Merck acknowledges that (a) the Licensed Know-How and the Know-How contained in the [***] and that without such Know-How [***] (b) access to the Licensed Know-How and the rights with respect to the [***] and (c) the royalties set forth in Section 5.2.1 are, [***] The Parties agree that [***].
- 5.2.10. Non-binding Forecast Report. As soon as practicable, but in no event later than [***] before the start of a new Calendar Year during the Royalty Term of any Product, Merck will provide Vertex with an annual forecast report providing a good faith estimate of Net Sales which will accrue in the next Calendar Year on a quarterly basis and the royalties payable to Vertex on such Net Sales on a Product-by-Product and country-by-country basis. The non-binding forecast report is based on forecasted numbers and it is understood that final reported Net Sales for purposes of calculating the royalty owed under Section 5.2.1 may vary.

5.3. **Payment Terms**.

5.3.1. <u>Currency; Payment Method</u>. All payments under this Agreement will be paid in U.S. Dollars, by wire transfer to an account designated by Vertex (which account Vertex may update from time to time in writing). Upon written notice from Vertex (or any direct or indirect permitted assignee, transferee or pledgee of the Rights), Merck will deliver any future payments contemplated by this Agreement, together with the royalty reports required under Section 5.2.7, in accordance with the directions in such written notice. Invoices from Vertex shall be addressed to:

Merck KGaA Accounts Payables Frankfurter Strasse 250 64293 Darmstadt Germany de.invoices@merckgroup.com

With a copy to: Merck KGaA Alliance Management Healthcare Frankfurter Strasse 250 64293 Darmstadt Germany

Attn.: David Christopher Godfrey, Director

- 5.3.2. Exchange. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. Dollars, such amounts will be converted to their U.S. Dollar equivalent using Merck's then-current standard procedures and methodology consistent with IFRS, including Merck's then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. Dollars or, in the case of Merck's Sublicensees, such similar methodology, consistently applied. Merck's current standard procedures and methodology for converting amounts into their U.S. Dollar equivalent is attached as Schedule 5.3.2. If Merck changes its standard procedures and methodology for converting amounts into their U.S. Dollar equivalents, Merck will provide adequate information and documentation to Vertex to allow Vertex to recognize royalty revenue under this Agreement in accordance with GAAP. Calculation of Net Sales will exclude hedging and foreign exchange gain or loss realized through a hedging program.
- 5.4. Withholding Tax. Where any sum due to be paid to Vertex hereunder is subject to any withholding or similar tax, Merck will pay such withholding or similar tax to the appropriate Government Authority and deduct the amount paid from the amount then due to Vertex and within [***] transmit to Vertex an official tax certificate or other evidence of such withholding sufficient to enable Vertex to claim such payment of taxes. The Parties will cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties and other payments made by Merck to Vertex under this Agreement. Vertex will provide

Merck any tax forms that may be reasonably necessary in order for Merck not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax.

5.5. Value Added Tax.

- 5.5.1. For VAT purposes invoiced amounts are net amounts. In case payments under this Agreement are subject to VAT in the U.S., VAT shall be added to the net amounts and be paid by Merck to Vertex. Vertex shall remit such VAT to the proper tax authorities and shall cooperate with Merck in any way reasonably requested by Merck, to obtain available reductions, credits or refunds of any VAT amount attributable to services contemplated in this Agreement unless otherwise stated by local law. Merck is entitled to receive a proper invoice where any value added tax amount is shown separately, if applicable.
- 5.5.2. If payments under this Agreement are subject to the reverse-charge-mechanism under the German VAT code, VAT is owed by Merck. Merck will pay this VAT for Vertex according to the German tax laws (reverse-charge-mechanism). In this case, Vertex ensures to refer to the reverse-charge-mechanism on its invoice. Vertex shall comply with any additional reasonable requests of Merck in relation to such invoices.

5.6. **Records**; Audits.

- 5.6.1. Merck will at all times keep and maintain accurate and complete records regarding Net Sales during the [***] Calendar Years. Vertex will at all times maintain accurate and complete records regarding FTE Costs, Supply Costs and Out-of-Pocket Costs incurred in connection with the Conduct of the Existing Clinical Trials for as long as required by Applicable Law, but in no case [***] following the period during which such costs were incurred.
- 5.6.2. Upon [***] prior written notice from a Party, the other Party will permit an independent certified public accounting firm of internationally recognized standing, selected by the notifying Party and reasonably acceptable to the other Party, to examine the relevant books and records of the other Party and its Affiliates and Sublicensees, as may be reasonably necessary to verify (a) the royalty reports submitted by Merck in accordance with Section 5.2.7 or (b) the FTE Costs, Out-of-Pocket Costs and Supply Costs invoiced in accordance with this Agreement.
- 5.6.3. An examination by any particular Party under this Section 5.6 will occur [***] in any Calendar Year and will be limited to the pertinent books and records for any Calendar Year ending not more than [***] before the date of the request. The accounting firm will be provided access to such books and records at the examined Party's or its Affiliates' or Sublicensees' facilities or facilities where such books and records are normally kept and such examination will be conducted during the examined Party's or its Affiliate's or Sublicensee's, as applicable, normal business hours. The examined Party may require the accounting firm to sign a customary non-disclosure agreement before providing the accounting firm access to its facilities or

records. Upon completion of the audit, the accounting firm will provide both Merck and Vertex a written report disclosing whether the reports or invoices submitted by the examined Party are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to the Parties. If the report or invoice submitted by a Party results in an underpayment or overpayment, the Party owing the underpaid or overpaid amount will promptly pay such amount to the other Party.

- 5.6.4. The costs and fees of any audit conducted by Vertex under this Section 5.6 will be borne by Vertex, unless such audit reveals an underpayment of amounts owed to Vertex of more than [***] percent of the amount that was owed by Merck with respect to the relevant period, in which case, Merck will reimburse Vertex for the reasonable expense incurred by Vertex in connection with the audit. The costs and fees of any audit conducted by Merck under this Section 5.6 will be borne by Merck, unless such audit reveals an overpayment of amounts owed to Vertex of more than [***] percent of the amount that was owed by Merck with respect to the relevant period, in which case, Vertex will reimburse Merck for the reasonable expense incurred by Merck in connection with the audit.
- 5.7. **Late Payment**. Any payments or portions thereof due hereunder that are not paid when due will accrue interest from the date due until paid at an annual rate (but with interest accruing on a daily basis) equal to the one-month London Interbank Offered Rate (LIBOR) for U.S. Dollars as reported in the Wall Street Journal on the first day after the date on which the applicable payment was due (or the maximum allowed by Applicable Law, if less).

ARTICLE 6. INTELLECTUAL PROPERTY

- 6.1. <u>Ownership of Agreement Technology</u>. For purposes of determining ownership under this Section 6.1, inventorship will be determined in accordance with United States patent laws (regardless of where the applicable activities occurred).
- 6.1.1. **Vertex Agreement Technology**. As between the Parties, Vertex will be the sole owner of any Know-How discovered, developed, invented or created solely by Vertex or its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance of activities under this Agreement ("**Vertex Agreement Know-How**") and any Patents that claim or cover such Know-How ("**Vertex Agreement Patents**"), and will retain all of its rights thereto, subject to any assignment, rights or licenses expressly granted by Vertex to Merck under this Agreement.
- 6.1.2. <u>Joint Agreement Technology</u>. Any Know-How discovered, developed, invented or created jointly by (a) Vertex, its Affiliates or Third Parties acting on its or their behalf and (b) Merck, its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance activities under this Agreement (including in any meeting of the TC) ("Joint Agreement Know-How"), and any Patents that claim or cover such Know-How ("Joint Agreement Patents," and together with the Joint Agreement Know-How, the "Joint Agreement Technology"), will be owned jointly by Vertex and Merck [***], including all rights thereto, subject to any rights or licenses expressly granted by one Party to the other Party under this Agreement. Except as

expressly provided in this Agreement, neither Party will have any obligation [***] with respect to, or to [***], Joint Agreement Technology by reason of joint ownership thereof, and each Party [***]laws of any jurisdiction to [***].

- 6.1.3. Merck Agreement Technology. As between the Parties, Merck will be the sole owner of any Know-How discovered, developed, invented or created solely by Merck or its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance of activities under this Agreement ("Merck Agreement Know-How") and any Patents that claim or cover such Know-How ("Merck Agreement Patents" and together with the Merck Agreement Know-How, the "Merck Agreement Technology"), and will retain all of its rights thereto, subject to any rights or licenses expressly granted by Merck to Vertex under this Agreement.
- 6.1.4. **Patents Claiming Licensed Know-How**. As between the Parties, Vertex will be the sole owner of any Patents that claim or cover any Licensed Know-How described in clause (a) of Section 1.91 and will retain all of Vertex's rights thereto, subject to any assignment, rights or licenses expressly granted by Vertex to Merck under this Agreement.

6.2. Prosecution and Maintenance of Patents.

6.2.1. Filing Strategy as to Certain Patents. With respect to any of the Vertex Agreement Patents or any of those Patents to be filed after the Effective Date and Controlled by Vertex or its Affiliates that claim or cover any Licensed Know-How described in clause (a) of Section 1.91, to be filed and prosecuted under this Agreement, the Parties will discuss in good faith and before any patent filing a reasonable filing strategy in order to determine whether any of the patent applications to be filed will be primarily related to the Research, Development, Manufacture or Commercialization of Licensed Compounds or Products or not. The Parties will aim to agree on a filing strategy which allows for separate patent applications on subject matter primarily related to the Research, Development, Manufacture or Commercialization of Licensed Compounds or Products.

6.2.2. <u>Licensed Patents</u>.

- (a) As between the Parties, Merck will have the first right, at Merck's expense, to control the Prosecution and Maintenance of the Licensed Patents (excluding the Vertex Background Patents) using counsel reasonably acceptable to Vertex. Merck will keep Vertex reasonably informed with respect to such Prosecution and Maintenance and consult in good faith with Vertex regarding such matters. If Merck decides to abandon any such Patent, Merck will provide Vertex with notice at least [***] prior to the date such abandonment would become effective. Following such notice, Vertex may elect, upon written notice to Merck, to control the Prosecution and Maintenance of such Patent at its own expense, and Merck will cooperate with Vertex to enable Vertex to assume such control.
- (b) Unless otherwise agreed by the Parties and as between the Parties, filing, Prosecution and Maintenance of Patents that claim or cover any Licensed Know-How described in clause (a) of Section 1.91 will be handled as follows:

- (i) Merck will have the sole right to file Patents that claim or cover any Licensed Know-How described in clause (a) of Section 1.91 to the extent it primarily relates to a [***] Compound or an [***] Compound. Merck may, however, request that Vertex prepare and file in consultation with Merck, at Merck's sole cost and expense, such patent application, and Merck will reimburse Vertex based on a mutually agreed good-faith cost-estimate for all reasonable FTE Costs and Out-of-Pocket Costs incurred by Vertex in the preparation and filing of such patent application within [***] after receipt of an invoice from Vertex. Further Prosecution and Maintenance of such patent application and any patent applications claiming priority from such patent application under the [***] shall be in accordance with Section 6.2.2(a);
- (ii) Vertex will have the sole right to file Patents that claim or cover any Licensed Know-How described in clause (a) of Section 1.91 other than that referred to in Section 6.2.2(b)(i). Merck may request that Vertex prepares and files a patent application claiming any such Know-How. Vertex shall reasonably consider such request and determine whether to prepare and file such a patent application; *provided* that Vertex may only elect not to file such patent application if Vertex has a bona fide strategic reason not to file such patent application. If Vertex elects to prepare and file such patent application, Vertex will draft such patent application and [***]. If not already determined prior to the filing in accordance with Section 6.2.1, the Parties will discuss after such application is filed in good faith whether such patent application is a Vertex Background Patent. If such patent application is not a Vertex Background Patent, (A) Merck will reimburse Vertex based on a mutually agreed good-faith cost estimate for all reasonable FTE Costs and Out-of-Pocket Costs incurred by Vertex in the preparation and filing of such patent application within [***] after receipt of an invoice from Vertex therefor and (B) further Prosecution and Maintenance of such patent application and any patent applications claiming priority from such patent application under the [***] shall be in accordance with Section 6.2.2(a), and if such patent application is a Vertex Background Patent, the preparation and filing of such patent application by Vertex will be at Vertex's expense and further Prosecution and Maintenance of such patent application and any patent applications claiming priority from such patent application under the [***] shall be in accordance with Section 6.2.3.
- 6.2.3. <u>Vertex Background Patents</u>. As between the Parties, Vertex will have the sole right, at Vertex's expense, to control the Prosecution and Maintenance of the Vertex Background Patents. Vertex will keep Merck reasonably informed with respect to such Prosecution and Maintenance and consult in good faith with Merck regarding such matters, including by providing Merck with a copy of material communications to and from any patent authority regarding such Vertex Background Patents, and by providing Merck drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Merck to review and comment thereon. Vertex will [***] comments received from Merck with respect to such Vertex drafts.

- 6.2.4. Other Agreement Patents. Merck will have the sole right, at Merck's expense, to control the Prosecution and Maintenance of the Merck Agreement Patents. Vertex will have the sole right, at Vertex's expense, to control the Prosecution and Maintenance of the Vertex Agreement Patents that are not included in the Licensed Patents. Upon identification of any Joint Agreement Patent that is not a Licensed Patent, the Parties will discuss in good faith and determine which Party will be primarily responsible for the Prosecution and Maintenance of such Joint Agreement Patent in consultation with the other Party, and the Parties will share equally the costs of Prosecution and Maintenance of such Joint Agreement Patent.
- 6.2.5. <u>Cooperation</u>. Vertex and Merck will obtain the cooperation of their respective employees or obligated Third Parties that are inventors in the preparation, filing, and prosecution of Vertex Agreement Patents, Merck Agreement Patents or Joint Agreement Patents, as applicable. Any cooperation or assistance provided by Vertex to Merck, at the request of Merck, in the Prosecution and Maintenance of any Merck Agreement Patent under this Agreement will be at Merck's expense. In each case, the Parties will agree on a good-faith cost estimate for such cooperation or assistance beforehand. Vertex will invoice Merck within [***] after the end of each Calendar Quarter for all FTE Costs and Out-of-Pocket Costs incurred by Vertex in connection with any such cooperation or assistance, and Merck will reimburse Vertex for all Out-of-Pocket Costs incurred by Vertex in connection with any cooperation or assistance provided by Vertex to Merck, at the request of Merck, in the Prosecution and Maintenance of any other Patent under this Agreement. In each case, the Parties will agree on a good-faith cost estimate for such cooperation or assistance beforehand. Vertex will invoice Merck within [***] after the end of each Calendar Quarter for all Out-of-Pocket Costs incurred by Vertex in connection with any such cooperation or assistance, and Merck will pay such invoices within [***] after receipt thereof.
- 6.3. **Defense of Claims Brought by Third Parties**. If any Third Party brings a claim or otherwise asserts that a Product or Licensed Compound manufactured, used or sold by Merck, its Affiliates or Sublicensees infringes such Third Party's Patent or misappropriates such Third Party's Know-How (each, a "Third-Party Infringement Claim"), the Party first having notice of the claim or assertion will promptly notify the other Party. Merck will have the sole right to undertake and control the defense or settlement of any Third-Party Infringement Claim using counsel of its choice, at its cost and expense. If Vertex is named as a defendant in such suit, Vertex will have the right to participate in such defense and settlement with its own counsel, at its cost. Merck will not enter into any settlement of any Third-Party Infringement Claim that is instituted or threatened to be instituted against Vertex without Vertex's prior written consent; *except that*, such consent will not be required if such settlement includes a release of all liability in favor of Vertex or an assumption of any unreleased liability by Merck. As requested by Merck, Vertex will provide reasonable cooperation and assistance to Merck in connection with Merck's control of the defense or settlement of a Third-Party Infringement Claim. Such cooperation and assistance will include executing all necessary and proper documents and taking such actions as will be appropriate to allow Merck to control the defense and settlement of such Third-Party Infringement Claim. Merck will reimburse Vertex for the reasonable Out-of-Pocket Costs incurred by Vertex in providing such assistance and cooperation; *except that* Merck will have no obligation to reimburse Vertex for any costs or expenses

incurred if Vertex exercises its right to participate in the defense and settlement of a Third-Party Infringement Claim with its own counsel. Merck will keep Vertex reasonably informed of the progress of any Third-Party Infringement Claim. To the extent reasonable, both Parties will cooperate in good faith to (a) ensure that Merck has the ability to continue to Commercialize Products and (b) avoid or minimize any additional royalties on Products.

6.4. Enforcement of Licensed Technology.

- 6.4.1. <u>Duty to Notify of Infringement</u>. If either Party learns of an infringement, unauthorized use, misappropriation or threatened infringement by a Third Party with respect to any Licensed Technology (an "Infringement"), such Party will promptly notify the other Party in writing and will provide such other Party with available information regarding such Infringement.
- 6.4.2. **Enforcement**. Merck will have the first right, but not the obligation, to institute, prosecute, and control a Proceeding with respect to any Infringement with respect to Licensed Technology other than any Vertex Background Patent by counsel of its own choice, at its own expense. This right shall include the right of promptly taking over any proceedings regarding the declaration of non-infringement that may be instituted against Vertex as the proprietor of the Licensed Patents (excluding the Vertex Background Patents). If Merck fails to initiate a Proceeding within [***] after written notice of such Infringement is first provided by a Party under Section 6.4.1, Vertex will have the right to initiate and control a Proceeding with respect to such Infringement by counsel of its own choice, at its own expense and Merck will have the right, at its own expense, to be represented in any such action by counsel of its own choice. Following prior good faith consultation with and approval by Merck (which approval may only be withheld by Merck for a bona fide strategic reason), Vertex will have the sole right, but not the obligation, to institute, prosecute, and control a Proceeding with respect to any Infringement by reason of the making, using, offering to sell, selling or importing of a compound or product that would be competitive with a Licensed Compound or Product in the Field in the Territory (a "Competitive Infringement") with respect to any Vertex Background Patent by counsel of its own choice, at its own expense. For the avoidance of doubt, this Section 6.4.2 shall apply to any counter-claims of the Third Party including any invalidation or revocation action or claim as well as to any isolated invalidation, nullity or revocation action brought by any Third Party before a court of competent jurisdiction.

6.4.3. **Joinder**.

- (a) If a Party initiates a Proceeding in accordance with this Section 6.4, the other Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the Proceeding. Subject to Section 6.4.4, the costs and expenses of each Party incurred pursuant to this Section 6.4.3(a) will be borne by the Party initiating such Proceeding.
- (b) If one Party initiates a Proceeding in accordance with this Section 6.4, the other Party may join such Proceeding as a party plaintiff where necessary for such other Party to seek lost profits with respect to such infringement.

- 6.4.4. **Share of Recoveries**. Any damages or other monetary awards recovered with respect to a Proceeding brought pursuant to this Section 6.4 will be shared as follows:
 - (a) the amount of such recovery will first [***]; then
 - (b) any remaining proceeds constituting direct or actual damages for acts of infringement [***]; and
 - (c) any remaining proceeds constituting punitive or treble damages will be allocated between the Parties as follows: [***].
- 6.4.5. <u>Settlement</u>. Notwithstanding anything to the contrary under this ARTICLE 6, neither Party may enter a settlement, consent judgment or other voluntary final disposition of a suit under this ARTICLE 6 that disclaims, limits the scope of, admits the invalidity or unenforceability of, or grants a license, covenant not to sue or similar immunity under a Patent Controlled by the other Party or its Affiliates without first obtaining the written consent of the Party that Controls the relevant Patent.

6.5. Other Infringement.

- 6.5.1. **Joint Agreement Patents Excluding Licensed Patents**. With respect to the infringement of a Joint Agreement Patent that is not a Licensed Patent, the Parties will cooperate in good faith to bring suit together against such infringing party or the Parties may decide to permit one Party to solely bring suit. Any damages or other monetary awards recovered with respect to a Proceeding brought pursuant to this Section 6.5.1 will be shared as follows: (a) [***]; then (b) any remaining proceeds will be allocated as follows: (i) [***]; and (ii) [***].
- 6.5.2. <u>Merck Agreement Patents</u>. Merck will retain all rights to pursue an infringement of any Merck Agreement Patents, and Merck will retain all recoveries with respect thereto.
- 6.5.3. <u>Non-Competitive Infringement of Vertex Background Patents</u>. Except as set forth in Section 6.4 with respect to Competitive Infringement, Vertex will retain all rights to pursue an infringement of any Vertex Background Patent, and Vertex will retain all recoveries with respect thereto.
- 6.5.4. <u>Vertex Agreement Patents Excluding Licensed Patents</u>. Vertex will retain all rights to pursue an infringement of any Vertex Agreement Patent that is not a Licensed Patent, and Vertex will retain all recoveries with respect thereto.
- 6.6. **Patent Listing**. Merck will have the sole right, but not the obligation, to submit to all applicable Regulatory Authorities patent information pertaining to each applicable Product pursuant to 21 U.S.C. § 355(b)(1)(G) or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction.
- 6.7. **CREATE Act**. Notwithstanding anything to the contrary in this ARTICLE 6, neither Party will have the right to make an election under the CREATE Act when exercising its

rights under this ARTICLE 6 without the prior written consent of the other Party, which will not be unreasonably withheld, conditioned or delayed. With respect to any such permitted election, the Parties will use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act. Notwithstanding the foregoing, the other Party's consent under this Section 6.7 will not be required in connection with an obviousness-type double patenting rejection in any patent application claiming a Licensed Compound, Product, or uses thereof.

- 6.8. **Patent Term Extension**. Merck will be solely responsible for obtaining patent term restoration in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to a Product. Merck will determine which relevant patents will be extended (including by filing supplementary protection certificates and any other extensions that are now or in the future become available). Vertex will abide by Merck's determination and cooperate, as reasonably requested by Merck, in connection with the foregoing (including by providing appropriate information and executing appropriate documents).
- 6.9. **Recording**. If Merck deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority in one or more jurisdictions in the Territory, Vertex will reasonably cooperate to execute and deliver to Merck any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Merck's reasonable judgment, to complete such registration or recordation. Merck will reimburse Vertex for all reasonable Out-of-Pocket Costs, including attorneys' fees, incurred by Vertex in complying with the provisions of this Section 6.9.
- 6.10. **Unitary Patent System**. With regard to each Licensed Patent (excluding any Vertex Background Patents) and each Joint Agreement Patent (including, unless the Parties otherwise agree, each Joint Agreement Patent that is not a Licensed Patent), Merck will have the exclusive right to decide whether to opt-in or opt-out of the EU Unitary Patent System, and Vertex will make any required statements and filings accordingly. With regard to each Merck Agreement Patent, Merck will have the exclusive right to opt-in or opt-out of the EU Unitary Patent System. Vertex will have the exclusive right to opt-in or opt-out of the EU Unitary Patent System for all Vertex Background Patents and all Vertex Agreement Patents that are not Licensed Patents. For clarity, "to opt-in or opt-out" refers to both the right to have or have not a European patent application or an issued European patent registered to have unitary effect within the meaning of Regulation (EU) No 1257/2012 of December 17, 2012 as well as the Agreement on a Unified Patent Court as of February 19, 2013; and to the right to opt-in or opt-out from the exclusive competence of the Unified Patent Court in accordance with Article 83 (3) of that Agreement on a Unified Patent Court. Without limiting the generality of the foregoing, unless a Party or its Affiliate has expressly opted in to the EU Unitary Patent System with respect to a given Patent, the other Party will not initiate any action under the EU Unitary Patent System without such Party's prior written approval, such approval to be granted or withheld in such Party's sole discretion.

6.11. **Trademarks**. As between the Parties, all trademarks and trade dress rights used in connection with Commercialization of the Products in the Field in the Territory will be owned exclusively by Merck.

ARTICLE 7. REPRESENTATIONS AND WARRANTIES

- 7.1. **Representations and Warranties of Merck**. Merck hereby represents and warrants to Vertex, as of the Execution Date and Effective Date, that:
 - (a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;
 - (b) it (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
 - (c) this Agreement has been duly executed and delivered on behalf of Merck, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof;
 - (d) the execution, delivery and performance of this Agreement by Merck will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;
 - (e) it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement; and
 - (f) no IND has been filed by Merck or any of its Affiliates with respect to any compound that [***].
- 7.2. **Representations and Warranties of Vertex**. Except as disclosed in any supplement or amendment provided to Merck pursuant to Section 7.3, Vertex hereby represents and warrants to Merck, as of the Execution Date and Effective Date, that:
 - (a) Vertex is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;
 - (b) Vertex (i) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

- (c) this Agreement has been duly executed and delivered on behalf of Vertex, and constitutes a legal, valid and binding obligation, enforceable against Vertex in accordance with the terms hereof;
- (d) the execution, delivery and performance of this Agreement by Vertex will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which Vertex is a party or by which Vertex is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over Vertex;
- (e) Vertex has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement;
- (f) the Licensed Technology constitutes all Patents and Know-How owned by or licensed to Vertex or its Affiliates that (i) in the case of Know-How, was actually used by Vertex or its Affiliates in the Research, Development or Manufacture of any Licensed Compound in the Field on or prior to the Effective Date and will be necessary or useful to Research, Develop, Manufacture or Commercialize any Licensed Compound in the Field and (ii) in the case of Patents, Cover the Research, Development, Manufacture or Commercialization of any Licensed Compound existing on the Effective Date in the Field;
- (g) Vertex and its Affiliates are the sole (except as set forth on Schedule 7.2(g)) and exclusive owner or exclusive ([***]) licensee of the Licensed Patents, all of which are free and clear of any liens, charges and encumbrances, and neither any license granted by Vertex or its Affiliates to any Third Party, nor any license granted by any Third Party to Vertex or its Affiliates conflicts with the license grants to Merck hereunder and Vertex is entitled to grant all rights and licenses (or sublicenses, as the case may be) under the Licensed Patents it purports to grant to Merck under this Agreement;
- (h) Schedules 1.92 and 1.153, respectively, set forth a true, correct and complete list of all Licensed Patents and Vertex Background Patents as of the Effective Date;
- (i) [***], the issued Licensed Patents are valid and enforceable patents and no Third Party (i) is infringing any Licensed Patents or (ii) has challenged the extent, validity or enforceability of any Licensed Patents (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);
- (j) [***] and except as disclosed to Merck orally prior to the Execution Date, it has complied with all Applicable Laws, including any disclosure requirements of the United States Patent and Trademark Office or any analogous foreign Governmental Authority, in connection with the Prosecution and Maintenance of the

Licensed Patents and has timely paid all filing and renewal fees payable with respect to any such Patents for which it controls Prosecution and Maintenance;

- (k) Vertex has obtained assignments from the inventors of all inventorship rights relating to the Licensed Patents;
- (l) Vertex and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Licensed Know-How that constitutes trade secrets under the Uniform Trade Secrets Act;
- (m) except as set forth on Schedule 7.2(m), no Licensed Patents are subject to any funding agreement with any government or governmental agency;
- (n) there are no judgments or settlements against or owed by Vertex or its Affiliates [***], pending or threatened (in writing) claims or litigation, in either case relating to the Licensed Technology;
- (o) there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending [***], threatened against Vertex, any of its Affiliates or any Third Party, in each case in connection with the Licensed Technology or relating to the transactions contemplated by this Agreement;
- (p) [***], the Research, Development or Manufacture of the Vertex compounds identified as VX-970, VX-803, [***]VX-984 has not infringed any valid and enforceable issued Patents owned or Controlled by a Third Party in the Territory as of the Execution Date;
- (q) [***] and except as set forth on Schedule 7.2(q), the Commercialization of the Vertex compounds identified as VX-970, VX-803 and VX-984 for the uses and indications commensurate with Clinical Trials (i) that are open for recruitment, (ii) are actively recruiting patients, (iii) have completed recruitment of patients but have not yet reached their endpoint(s) or (iv) for which a final Clinical Trial report has been issued for each such compound and the Vertex compound identified as [***], in each case, will not infringe any valid and enforceable issued Patents owned or Controlled by a Third Party in the Territory as of the Execution Date;
- (r) Vertex has not employed ([***], has not used a contractor or consultant that has employed) any Person debarred by the FDA (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in any capacity in connection with this Agreement;
- (s) [***] and except as set forth on Schedule 7.2(s), the Inventory (i) is free of material defects (including defects in packaging, labeling and storage) and (ii) has

been Manufactured in material compliance with all applicable specifications and all Applicable Laws;

- (t) Vertex and its Affiliates have good and valid title to, or the right to transfer (or cause to be transferred), the Inventory, free and clear of any liens and encumbrances;
- (u) Schedule 2.2.4 sets forth all Regulatory Filings filed by Vertex with any Regulatory Authority that relate to a Licensed Compound or Product in the Field;
- (v) as of the Execution Date, Vertex is [***] and has provided Merck with a copy of the [***]as of the Execution Date;
- (w) [***], the Know-How and Patent(s) [***] Vertex or its Affiliates [***] existing as of the Execution Date include all Know-How and Patents [***];
- (x) if Vertex or any of its Affiliates enters the [***] prior to the Effective Date, Vertex has the right, power and authority to grant to Merck the rights granted to Merck hereunder with respect to the [***], the grant of a sublicense under the [***] rights and obligations of Merck set forth in this Agreement do not contravene nor are they inconsistent with or in conflict with [***];
 - (y) [***]if entered by Vertex or any of its Affiliates prior to the Effective Date, constitutes [***];
- (z) all tangible information and data provided by or on behalf of Vertex to Merck on or before the Effective Date in contemplation of this Agreement was and is true, accurate and complete in all material respects; and
- (aa) (i) the chemical formulae set forth in Schedule 1.48 comprises all small molecule compounds synthesized and screened by Vertex or its Affiliates before the Execution Date that were identified to [***] (as reasonably determined by Vertex) (A) [***] or (B) [***] and (ii) the chemical formulae set forth in Schedule 1.68 comprises all small molecule compounds synthesized and screened by Vertex or its Affiliates before the Execution Date that were [***].
- 7.3. **Updates to Representations and Warranties**. On or prior to the date that is [***] following HSR Clearance with respect to this Agreement, Vertex will deliver to Merck a certificate executed by a duly authorized officer of Vertex containing representations and warranties as of the Effective Date that are either (a) identical to the representations and warranties set forth in Section 7.2 or (b) identical to the representations and warranties set forth in Section 7.2, except for any supplement or amendment to such representations and warranties with respect to any event, condition, fact or circumstance occurring after the Execution Date that, if existing or occurring on or prior to the Execution Date, would have been required to be set forth or described in such representations and warranties as of the Execution Date, or that is necessary to correct or modify any information in such representations and warranties that has been rendered inaccurate by an

event, condition, fact or circumstance occurring after the Execution Date. If Vertex does not deliver the representations and warranties under the foregoing clause (a) or (b), Vertex will be deemed to have delivered to Merck on the date that is [***] following HSR Clearance with respect to this Agreement representations and warranties that are identical to such representations and warranties set forth in Section 7.2. The representations and warranties will be deemed supplemented and amended as provided in this Section 7.3 for all purposes hereunder, including for purposes of indemnification set forth in Section 8.1.2.

- 7.4. Merck Covenants. Merck hereby covenants to Vertex that Merck and its Affiliates and Sublicensees will not use the Licensed Technology to Research, Develop, Manufacture, have Manufactured, Commercialize, use, import, export or keep the Licensed Compounds or Products in the field of cystic fibrosis during the Term, unless the Parties mutually agree otherwise in advance and in writing. The Parties acknowledge and agree that any breach of this Section 7.4 shall (a) entitle Vertex to specific performance without the need to show irreparable harm or the inadequacy of money damages and without the requirement of having to post bond or other security, as well as any further relief that may be granted by a court of competent jurisdiction and (b) shall be deemed a material breach of this Agreement for purposes of Section 9.2.2(b).
 - 7.5. **Vertex Covenants**. Vertex hereby covenants to Merck that, except as expressly permitted under this Agreement:
 - (a) Vertex will, and will require its Affiliates and will use Commercially Reasonable Efforts to require its subcontractors to, comply with all Applicable Law in its and their Research and Development of Licensed Compounds and Products;
 - (b) Vertex will not, and will cause its Affiliates not to (i) license, sell, assign or otherwise transfer to any Person any Licensed Technology (or agree to do any of the foregoing) other than in connection with a Change of Control, in a manner that conflicts with the rights granted to Merck hereunder or (ii) incur or permit to exist, with respect to any Licensed Technology, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness) which conflicts with the rights granted to Merck hereunder;
 - (c) Vertex will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction;
 - (d) Vertex will inform Merck in writing promptly if it or any Person engaged by Vertex or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Vertex's Knowledge, is threatened, relating to the debarment or conviction of Vertex, any of its Affiliates or any such Person performing services hereunder or thereunder;

- (e) if Vertex has not entered the [***] prior to the Effective Date, Vertex will use Commercially Reasonable Efforts to negotiate and execute the [***] will result in any [***] thereunder or, if such agreement is subsequently assigned to Merck, as a party thereto); and
- (f) except as permitted under Section 4.1.4, Vertex will not use the Licensed Technology to Research, Develop, Manufacture, have Manufactured, Commercialize, use, import, export or keep the Licensed Compounds or Products in the Field during the Term, unless the Parties mutually agree otherwise in advance and in writing. The Parties acknowledge and agree that any breach of this Section 7.5(f) shall (a) entitle Merck to specific performance without the need to show irreparable harm or the inadequacy of money damages and without the requirement of having to post bond or other security, as well as any further relief that may be granted by a court of competent jurisdiction and (b) shall be deemed a material breach of this Agreement for purposes of Section 9.2.2(a).
- 7.6. **Disclaimer**. Except as otherwise expressly set forth in this Agreement, neither Party nor its Affiliates makes any representation or extends any warranty of any kind, either express or implied, including any warranty of merchantability or fitness for a particular purpose. Vertex and Merck understand that each Product is the subject of ongoing Research and Development and that neither Party can assure the safety, usefulness or commercial or technical viability of any Product.
- 7.7. Execution Date Covenants of Vertex. During the period between the Execution Date and the Effective Date Vertex will not, and will cause its Affiliates not to: (a) assign, transfer, license, convey or otherwise encumber its right, title or interest in or to any Patent or Know-How (including by granting any option or covenant not to sue with respect thereto) that would be a Licensed Patent or constitute Licensed Know-How but for such assignment, transfer, license, conveyance or encumbrance, other than any such assignment, transfer, license, conveyance or other encumbrance that would not conflict with the rights granted to Merck hereunder, (b) enter into an agreement, written or oral, with a Third Party granting such Third Party any rights to Research, Develop, Manufacture or Commercialize the Licensed Compounds or Products for any indication in any country or jurisdiction in the Territory or (c) execute [***] if such execution will result in any financial obligations to Merck (other than any liabilities that may arise out of any non-performance under [***] by Merck as a sublicensee thereunder or, if such agreement is subsequently assigned to Merck, as a party thereto), except in the case of each of clauses (a), (b) and (c) without Merck's prior written consent, such consent not to be unreasonably conditioned, withheld or delayed.

During the period between the Execution Date and the Effective Date, Vertex will maintain (i) the Existing Clinical Trials and the Inventory (except to the extent used in the Conduct of the Existing Clinical Trials after the Execution Date), (ii) any agreement with any Third Party vendor or contractor related to the Research, Development or Manufacture of the Licensed Compounds or Products unless such agreement is terminated by a Third Party for reasons other than breach by Vertex, (iii) the Licensed Patents (except to the extent such patents are designated as Patents "Under Abandonment" in Schedule 1.88) and (iv) all Regulatory Filings set forth on Schedule 2.2.4. As far as legally permissible, the Parties will reasonably cooperate to resolve any issues resulting out of

any obligation mentioned in this Section 7.7. If such cooperation is not legally permissible, Vertex will resolve any such issue in accordance with this Agreement independently from Merck.

ARTICLE 8. INDEMNIFICATION; INSURANCE

8.1. **Indemnification**.

- 8.1.1. <u>Indemnification by Merck</u>. Merck will indemnify Vertex, its Affiliates, and its and its Affiliates' employees, officers and directors (each, a "Vertex Indemnified Party") from and against any and all loss, damage, injury, settlement, judgment, award, fine, penalty, tax, fee, cost or expense (including reasonable attorneys' fees and expenses) (collectively, "Liability") that the Vertex Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party suit, investigation, claim or demand resulting from or arising out of:
 - (a) any claims arising out of the Research, Development, Manufacture, Commercialization, import, export, storage or use of any Licensed Compound or Product by, on behalf of, or under the authority of Merck, including any Existing Clinical Trial Conducted by Vertex or any of its Affiliates or any Research activities conducted by Vertex or any of its Affiliates under Sections 2.1.6 or 2.1.7;
 - (b) the breach by Merck of any of its representations, warranties or covenants set forth in this Agreement; or
 - (c) the negligence or willful misconduct of Merck or any Merck Indemnified Party;

and except, in each above-mentioned case, to the extent such claims fall within the scope of Vertex's indemnification obligations under Section 8.1.2.

- 8.1.2. <u>Indemnification by Vertex</u>. Vertex will indemnify Merck, its Affiliates and its Affiliates' employees, officers and directors, Sublicensees and Distributors (each, a "Merck Indemnified Party") from and against any and all Liability that the Merck Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party suit, investigation, claim or demand resulting from or arising out of:
 - (a) any claims of any nature arising out of Vertex's or its Affiliate's Research, Development, Manufacture, Commercialization, import, export, storage or use of any Licensed Compound or Product prior to the Effective Date or after termination of this Agreement;
 - (b) the breach by Vertex of any of its representations, warranties or covenants set forth in this Agreement; or

(c) the negligence or willful misconduct of Vertex or any Vertex Indemnified Party;

and except, in each above-mentioned case, to the extent such claims fall within the scope of Merck's indemnification obligations under Section 8.1.1.

8.1.3. **Procedure**. As a condition to a Party's right to receive indemnification under this ARTICLE 8, it shall (a) promptly notify the other Party in writing as soon as it becomes aware of a claim or suit for which such Party may seek indemnification hereunder; provided that such Party's failure to deliver such written notice will relieve the indemnifying Party of liability to such Party under Sections 8.1.1 or 8.1.2, as applicable, only to the extent such delay is prejudicial to the indemnifying Party's ability to defend such claim; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel; provided, however, that the indemnifying Party will not have the right to control the defense, settlement or compromise of such claim if (i) the indemnified Party will have one or more legal or equitable defenses available to it which are different from or in addition to those available to the indemnifying Party, and, in the reasonable opinion of the indemnified Party, counsel for the indemnifying Party could not adequately represent the interests of the indemnified Party because such interests could be in conflict with those of the indemnifying Party or (ii) the indemnifying Party will not have assumed the defense, settlement or compromise of such claim in a timely fashion (but in any event within 30 days of notice of such claim). In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee or involves anything other than the payment of monetary awards for which the indemnifying Party will be fullyresponsible without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this ARTICLE 8 with respect to claims or suits settled or compromised without its prior written consent. If the indemnifying Party assumes the defense of any claim or suit, the indemnified Party will be entitled to participate in such claim or suit at its expense. The assumption of the defense by the indemnifying Party will not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the indemnified Party with respect to such claim or suit, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the indemnified Party's claim for indemnification. If it is ultimately determined that the indemnifying Party is not obligated to indemnify the indemnified Party from and against such claim, the indemnified Party will reimburse the indemnifying Party for any Liability incurred by the indemnifying Party in its defense of such claim.

8.2. **Insurance**.

8.2.1. <u>Coverage</u>. During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts,

that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self-insured, provide to the other Party upon request, a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 8.2.

- 8.2.2. <u>Post-Termination Obligations</u>. Merck will maintain the insurance required under Section 8.2.1 beyond the expiration or termination of this Agreement for a reasonable period after the period during which Merck or its Affiliates or Sublicensees were Developing or Commercializing any Licensed Compound or Product, which in no event will be less than [***].
- 8.2.3. **Affiliates, Sublicensees and Distributors**. Merck will require all of its Affiliates, Sublicensees and Distributors to comply with the provisions and obligations under this Section 8.2 as if such entity were Merck.
- 8.3. Limitation of Consequential Damages; Limitation of Liability. EXCEPT FOR (A) CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 8, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER LAW FOR ANY BREACH OF BY THE OTHER PARTY OF ITS CONFIDENTIALITY AND NON-USE OBLIGATIONS UNDER ARTICLE 10. IN NO EVENT SHALL ANY EMPLOYEE OF VERTEX IDENTIFIED IN SECTION 1.88 HAVE ANY PERSONAL LIABILITY FOR ANY BREACH BY VERTEX OF ANY REPRESENTATION OR WARRANTY MADE IN THIS AGREEMENT.

ARTICLE 9. TERM; TERMINATION

- 9.1. **Term; Expiration**. This Agreement is effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this ARTICLE 9, will expire as follows (such period, the "**Term**"); *provided*, *however*, that Sections 7.1, 7.2, 7.7, 9.1, 9.2.2, 10.1, 10.2, 10.4 and 11.1 will become binding and effective as of the Execution Date:
 - (a) on a country-by-country and Product-by-Product basis, on the date on which the Royalty Term with respect to such Product in such country expires; and

(b) in its entirety upon the expiration of all payment obligations under this Agreement with respect to all Products in all countries.

9.2. Termination of the Agreement.

9.2.1. <u>Merck's Termination for Convenience</u>. Merck may terminate this Agreement in its entirety or in part with respect to a Program for convenience by providing written notice of its intent to terminate to Vertex, in which case, such termination will be effective (a) 90 days after Vertex's receipt of such notice if no Product in any Program subject to such termination has received Marketing Approval or (b) 180 days after Vertex's receipt of such written notice if any Product in any Program subject to such termination has received Marketing Approval.

9.2.2. Termination for Material Breach.

- (a) Merck's Right to Terminate. If Merck believes that Vertex is in material breach of this Agreement, Merck may deliver written notice of such material breach to Vertex. If the breach is curable, Vertex will have [***] following its receipt of such written notice to cure such breach. If Vertex fails to cure such breach within such [***] period or the breach is not subject to cure, Merck may terminate this Agreement (i) if such breach relates solely to a particular Program, with respect to the Program affected by such breach, or (ii) if such breach relates to all Programs or this Agreement as a whole, with respect to all Programs, by providing written notice to Vertex, in which case, this Agreement will terminate on the date on which Vertex receives such written notice.
- (b) <u>Vertex's Right to Terminate</u>. If Vertex believes that Merck is in material breach of this Agreement, Vertex may deliver written notice of such material breach to Merck. If the breach is curable, Merck will have [***] following its receipt of such written notice to cure such breach (except to the extent such breach involves the failure to make a payment when due, which breach must be cured within [***] following its receipt of such written notice). If Merck fails to cure such breach within the [***] or [***] period, as applicable, or the breach is not subject to cure, Vertex may terminate this Agreement (i) if such breach relates solely to a particular Program, with respect to the Program affected by such breach, or (ii) if such breach relates to all Programs or this Agreement as a whole, with respect to all Programs, by providing written notice to Merck, in which case, this Agreement will terminate, in whole or in part, as applicable, on the date on which Merck receives such written notice.
- (c) <u>Merck's and Vertex's Right to Terminate</u>. If the Effective Date has not occurred within [***] after the date on which any HSR Filing is made, either Party may terminate this Agreement upon written notice to the other Party, in which case, this Agreement will terminate on the date on which the other Party receives such written notice.
- 9.2.3. <u>Disputes Regarding Material Breach</u>. Notwithstanding the foregoing, if the Breaching Party in Section 9.2.2 disputes in good faith the existence, materiality, or failure to cure of any breach, and provides written notice to the Non-Breaching Party of such dispute within the relevant cure period, the Non-Breaching Party will not have the right to terminate

this Agreement in accordance with Section 9.2.2, unless and until the relevant dispute has been resolved in accordance with Section 11.13. During the pendency of such dispute, all the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

- 9.2.4. <u>Termination for Insolvency</u>. If either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [***] after the filing thereof, the other Party may terminate this Agreement in its entirety by providing written notice of its intent to terminate this Agreement to the insolvent Party, in which case, this Agreement will terminate on the date on which the insolvent Party receives such written notice.
- 9.2.5. **Termination for Program Abandonment**. If Program Abandonment occurs with respect to a Program, Vertex may terminate the Agreement with respect to such Program at any time by providing prior written notice to Merck, in which case, this Agreement will terminate on the date on which Merck receives such written notice.

9.3. Consequences of Expiration or Termination of the Agreement.

- 9.3.1. **In General**. If this Agreement expires or is terminated by a Party pursuant to this ARTICLE 9, the following terms will apply to any Product in any country that is the subject of such expiration or termination:
 - (a) each Party will take all action required under Section 10.3;
 - (b) termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such expiration or termination. Such expiration or termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement;
 - (c) the following provisions of this Agreement will survive the expiration or termination of this Agreement: ARTICLE 1, Section 4.3, Section 5.3, Section 5.4, Section 5.5, Section 5.6, Section 5.7, Section 6.1, Section 6.2.4, Section 7.6, ARTICLE 8, ARTICLE 9, ARTICLE 10 and ARTICLE 11. In addition, Section 4.1, Section 7.4 and Section 6.5.1 will survive the expiration but not termination of this Agreement; and
 - (d) solely if this Agreement expires pursuant to Section 9.1, as of the effective date of the expiration of the Royalty Term with respect to a given Product and country, the license from Vertex to Merck under Section 4.1.1 shall convert to a fully paid, royalty free, irrevocable, perpetual, exclusive, and sublicensable license under the Licensed Technology to Research, Develop, Manufacture, have Manufactured, use, import, export, keep and Commercialize such Product in the Field in such country.

- 9.3.2. **Early Termination**. If this Agreement is terminated in its entirety by a Party pursuant to Sections 9.2.1, 9.2.2(a), 9.2.2(b) or 9.2.4 or in part with respect to a Program by a Party pursuant to Sections 9.2.1, 9.2.2(a), 9.2.2(b) or 9.2.5, the following terms will apply:
 - (a) the licenses and covenants not to sue granted by Vertex to Merck under this Agreement will terminate in their entirety or with respect to the Terminated Products, as applicable, except with respect to any Product sold by Merck in accordance with Section 9.3.2(k);
 - (b) except as set forth in this Section 9.3, Merck will have no further rights and Vertex will have no further obligations with respect to the Terminated Products in the Territory;
 - (c) any Sublicense of Merck will, at the Sublicensee's option, survive such termination on the condition that the relevant Sublicensee is not in material breach of any of its obligations under such Sublicensee. In order to effect this provision, at the request of the Sublicensee, Vertex will enter into a direct license with the Sublicensee on substantially the same terms as the Sublicense; *provided* that Vertex will not be required to undertake obligations in addition to those required by this Agreement, and Vertex's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license;
 - (d) Merck will, as promptly as practicable and to the extent permitted by Applicable Law, transfer to Vertex, at Merck's cost if such termination is by Merck pursuant to Section 9.2.1 or by Vertex pursuant to Sections 9.2.2(b), 9.2.4 or 9.2.5 or at Vertex's cost if such termination is by Merck pursuant to Sections 9.2.2(a) or 9.2.4, (i) possession and ownership of all Regulatory Approvals, Regulatory Filings, Price Approvals, regulatory correspondence and conversation logs relating to the Research, Development, Manufacture or Commercialization of any Terminated Product in the Territory, and (ii) copies of all data (including Adverse Event data, clinical data and pre-clinical data), reports, records, materials and sales and marketing related information in Merck's or its Affiliates' Control to the extent that such data, reports, records, materials or information relate to the Research, Development, Manufacture or Commercialization of any Terminated Product in the Territory; and following the effective date of termination, Merck will execute all documents and take all such further actions as may be reasonably requested by Vertex in order to give effect to the foregoing transfer. Merck will appoint Vertex as Merck's and its Affiliates' agent solely to the extent necessary to effectuate the transfer of Regulatory Approvals, Regulatory Filings and Price Approvals related to any Terminated Product in the Territory from Merck or its Affiliates to Vertex;
 - (e) effective upon such termination, Merck hereby grants to Vertex an exclusive, royalty-bearing (except as set forth in Section 9.3.2(f)), irrevocable, perpetual license, which Vertex may sublicense through multiple tiers, under all (i) Merck Agreement Technology and (ii) any other Patents and Know-How used by or on behalf of Merck or any of its Affiliates or Sublicensees in the Research, Development, Commercialization or Manufacture of any Terminated Product prior to the effective date of termination, in each

case ((i) and (ii)), to the extent Controlled by Merck or its Affiliates to research, develop, manufacture, have manufactured, use, keep, sell, offer for sale, import, export and commercialize such Terminated Products in the Field in the Territory; provided that if the grant of such license to Vertex with respect to any Know-How or Patent or Vertex's exercise of such license would trigger a royalty or other payment to a Third Party or would require compliance with any provision of any license between Merck and a Third Party, Merck will so notify Vertex in writing and such Know-How or Patent will only be included in the foregoing license if, following receipt of such notice, Vertex agrees in writing to reimburse Merck for all such payments to such Third Party and comply with any such provision;

- (f) unless this Agreement is terminated by Vertex pursuant to Section 9.2.2(b), Vertex will pay Merck or its designated Affiliate the following royalties on worldwide Net Sales of each Terminated Product (including Net Sales by Vertex's Affiliates and licensees): (i) if the effective date of termination occurs on or before the [***] of the Effective Date, a royalty of [***] of each Terminated Product, (ii) if the effective date of termination occurs after the [***] of the Effective Date, a royalty of [***] of each Terminated Product, and (iii) if the effective date of termination occurs after the [***] of the Effective Date, a royalty of [***] of each Terminated Product. The terms of Sections 1.107, 1.136, 5.3, 5.4, 5.5, 5.6 and 5.7 will apply with respect to Vertex's payment of such royalty, *mutatis mutandis*. If this Agreement is terminated by Vertex pursuant to Section 9.2.2(b), the license granted to Vertex in Section 9.3.2(e) will be royalty-free;
- (g) Merck will promptly transfer and assign to Vertex all of Merck's Affiliates' rights, title and interests in and to any trademarks and trade dress rights owned by Merck or its Affiliates and used solely and exclusively in the Commercialization of any Terminated Product;
- (h) if Vertex so requests, and to the extent permitted under Merck's obligations to Third Parties on the effective date of termination, Merck will transfer to Vertex any Third Party agreements relating solely and exclusively to the Research, Development, Manufacture or Commercialization of any Terminated Product to which Merck or any of its Affiliates is a party, subject to any required consents of such Third Party, which Merck will use Commercially Reasonable Efforts to obtain promptly, and, with respect to Third Party agreements to which Merck or any of its Affiliates is a party that relate to the Research, Development, Manufacture or Commercialization of Terminated Products but not solely and exclusively thereto or to the extent any such consent, as applicable, has not or cannot be obtained with respect to such agreement that does relate exclusively to Terminated Products, then, as requested by Vertex, Merck will, and will cause its Affiliates to, to the extent permitted by the terms of such agreement, cooperate with Vertex in a mutually agreeable arrangement under which Vertex will obtain substantially all of the practical benefit and burden under such agreement to the extent applicable to such Terminated Products, including by entering into appropriate and reasonable alternative arrangements on mutually agreeable terms and enforcing, at Vertex's cost and expense and for the account of Merck, any and all rights of

Merck, or such Affiliate, as applicable, against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise;

- (i) unless expressly prohibited by any Regulatory Authority, at the request of Vertex, Merck will transfer control to Vertex of all Clinical Trials of any Terminated Product being Conducted by Merck or any of its Affiliates or Sublicensees as of the effective date of termination and Merck will continue to Conduct such Clinical Trials, at Vertex's costs, for up to four months to enable such transfer to be completed without interruption of any such Clinical Trial; *provided* that (i) Vertex will not have any obligation to continue any Clinical Trial unless required by Applicable Law, and (ii) with respect to each Clinical Trial for which such transfer is requested by Vertex but is expressly prohibited by the applicable Regulatory Authority, if any, Merck will continue to Conduct such Clinical Trial to completion, at Vertex's cost. The Conduct of any Clinical Trials by Merck in accordance with this Section 9.3.2(i) will be at Vertex's direction; *provided* that Merck will not be obligated to take any action in connection with such Conduct that it believes violates Applicable Law or is unethical;
- (j) Merck will, and will cause its Affiliates and Sublicensees to, provide Vertex written notice of the quantity of Terminated Products that Merck, its Affiliates and Sublicensees have in inventory for use or sale in the Territory, and (except to the extent any such Sublicensee retains rights to such inventory pursuant to Section 9.3.2(c)) Vertex will have the option, exercisable within [***] following the effective date of termination, to purchase any inventory of Terminated Products at the Supply Cost [***]. If Vertex exercises such right to purchase such inventory, Merck will grant, and hereby does grant, and will cause its Affiliates and Sublicensees to grant, a royalty-free right and license to any house marks, trademarks, names and logos of Merck or its Affiliates or Sublicensees contained therein for a period of [***] in order to sell such inventory. Upon such exercise, the Parties will establish mutually agreeable payment and delivery terms for the sale of such inventory at the price described above;
- (k) in case Vertex does not exercise the right to purchase any such inventory pursuant to 9.3.2(j), Merck and its Affiliates and Sublicensees shall be entitled, during the [***] period following such termination, to sell any commercial inventory of Terminated Product(s) which remains on hand as of the date of the termination, so long as Merck pays to Vertex the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement;
- (l) to the extent Merck or any of its Affiliates or Sublicensees Manufactured (itself or through a Third Party) any Terminated Products for all or any portion of the Territory on the date of notice of termination, Merck will supply Vertex with any such Terminated Products that had been Manufactured as of such date on commercially reasonably and customary terms and at the Supply Cost thereof plus a [***] for Research, Development and Commercialization in the Territory until the earlier of (i) [***] after the effective date of termination or (ii) if Merck or its Affiliates or Sublicensees use one or more Third Parties

to Manufacture such Terminated Products, such time as all agreements with all such Third Parties for the Manufacture of any such Terminated Products are transferred to Vertex;

- (m) Merck will provide any other assistance reasonably requested by Vertex for the purpose of allowing Vertex or its designee to proceed expeditiously with the Research, Development, Manufacture and Commercialization of any Terminated Products during the [***] period starting on the effective date of termination;
- (n) Merck will continue to pay royalties on Net Sales of any Product that contains a [***] pursuant to Section 5.2 until the expiration of the Royalty Term for such Product; and
- (o) if such termination is pursuant to Sections 9.2.1 or 9.2.2(a), immediately following Merck's notification of termination to Vertex pursuant to Sections 9.2.1 or 9.2.2(a), the diligence obligations in Sections 2.5.1-2.5.3 shall no longer apply and Merck shall have the right to wind-down all then on-going Development, Manufacturing or Commercialization activities with respect to the Terminated Products.

9.3.3. <u>Termination on Bankruptcy or Insolvency.</u>

- (a) <u>Bankruptcy Code</u>. All rights and licenses granted under or pursuant to this Agreement by Vertex are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, if applicable, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code.
- (b) <u>Continuing Rights</u>. The Parties agree that Merck, as licensor of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of bankruptcy proceeding by or against Vertex, Merck shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Merck's possession, shall be promptly delivered to it (i) following any such commencement of a bankruptcy proceeding upon Merck's written request therefor, unless Vertex elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (a), following the rejection of this Agreement by Vertex upon written request therefor by Merck.
- 9.3.4. <u>Other Remedies</u>. Termination of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such termination. Termination of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect or limit, any rights or remedies that otherwise may be available at law or in equity.

ARTICLE 10. CONFIDENTIALITY

- Confidentiality. During the Term and for [***] thereafter, each Party (the "Receiving Party") receiving any Confidential Information of the other Party (the "Disclosing Party") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not publish, or allow to be published, and will not otherwise disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose, except, in each case, to the extent expressly permitted under this Agreement or otherwise agreed in writing. Without limiting the generality of the foregoing, to the extent that either Party provides the other Party any Confidential Information owned by any Third Party, the Receiving Party will handle such Confidential Information in accordance with the terms of this ARTICLE 10.
- 10.2. **Authorized Disclosure**. Notwithstanding Section 10.1, each Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary to:
 - (a) file or prosecute patent applications as contemplated by this Agreement;
 - (b) prosecute or defend litigation;
 - (c) exercise its rights and perform its obligations hereunder;
 - (d) subject to the remainder of this Section 10.2, its advisors (including attorneys and accountants), actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein (which may include professional ethical obligations); or
 - (e) comply with Applicable Law.

In addition to the foregoing, Merck may disclose Vertex's Confidential Information to Third Parties in connection with the actual or potential Research, Development, Manufacture or Commercialization of Licensed Compounds or Products; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein; and *provided*, *further*, that if such Third Party is a competitor of Vertex, Merck will not make such disclosure without Vertex's prior written consent.

- If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to Sections 10.2(b) or 10.2(e), the Disclosing Party will, to the extent possible, give reasonable advance written notice of such disclosure to the other Party and take reasonable measures to ensure confidential treatment of such information.
- 10.3. <u>Termination of this Agreement</u>. Following the termination of this Agreement, if requested by the Disclosing Party, at the Receiving Party's election, the Receiving Party will return or destroy, all data, files, records and other materials containing or comprising the Disclosing Party's Confidential Information, except to the extent such Confidential Information is necessary to conduct surviving obligations or exercise surviving rights. Notwithstanding the foregoing, (a) the Receiving Party will be permitted to retain one copy of such data, files, records, and other materials for archival

and legal compliance purposes and (b) the Receiving Party will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by the Receiving Party's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its standard archiving and back-up procedures

10.4. <u>SEC Filings and Other Disclosures</u>. Either Party may disclose the terms of this Agreement to the extent required to comply with Applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory; *provided* that such Party will provide the other Party a reasonable opportunity to review such planned disclosure and reasonably consider the other Party's comments regarding confidential treatment sought for such disclosure.

10.5. Public Announcements; Publications.

- 10.5.1. Announcements. Within [***] after the Execution Date, the Parties will issue press releases regarding the signing of this Agreement in a mutually agreed form. Except (a) as set forth in the preceding sentence and (b) as required to comply with Applicable Law (including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory), neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. Notwithstanding the foregoing, subject to Sections 10.1, 10.2 and 10.5.2, Merck may make [***] concerning its Research, Development, Manufacture or Commercialization activities with respect to any Licensed Compound or Product under this Agreement [***]; provided, however, that where reasonably possible, Merck will provide Vertex with written notice of such [***] at least [***] in advance, provide Vertex with an opportunity to review such [***] and [***] provided by Vertex with respect thereto.
- 10.5.2. Publications. During the Term, Vertex will submit to Merck for review and approval any proposed [***] related to any Licensed Compound or Product or any activities conducted pursuant to this Agreement relating to [***]. Vertex will submit written copies of such proposed publication or presentation to Merck no later than [***] before submission for publication or presentation (or [***] in advance in the case of an abstract). Merck will provide its comments with respect to such publications and presentations within [***] after its receipt of such written copy (or [***] in the case of an abstract). During the Term, Vertex will not submit any such [***] for publication without the prior approval of Merck, not to be unreasonably withheld, conditioned or delayed. If Merck approves of the submission of any publication, presentation or abstract, then, if requested by Merck, Vertex will redact Merck's Confidential Information from any such proposed publication or presentation. Vertex will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication.
- 10.6. <u>Transfer or Sale of Royalty Rights</u>. In connection with the sale, assignment, transfer or pledge as a security of all or any part of the Rights, Vertex may disclose on an ongoing basis to any Third Party that has (or proposes to have) an interest (whether direct or indirect) in the Rights (each, a "**Recipient**"), and to such Recipient's affiliates, auditors, bankers, co-investors, employees, insurance providers, investors, lenders, sublicensees or trustees (collectively,

"Representatives"), (a) a Merck-approved (such approval not be unreasonably withheld, conditioned or delayed) redacted copy of this Agreement, including a redacted version of any amendments supplements and other modifications hereto, and a Merck-approved (such approval not be unreasonably withheld, conditioned or delayed) redacted copy of any other agreement between Vertex and Merck relating to the Rights and (b) (i) royalty reports provided by Merck under Section 5.2.7 and (ii) notices, reports and correspondence provided under ARTICLE 6 hereof and other notices, reports and correspondence relating to or involving this Agreement that could reasonably be expected to affect the Rights, in each case ((i) and (ii)), following Merck's prior approval on a case-by-case basis, which approval will not be unreasonably withheld, conditioned or delayed (collectively, the "Royalty Information"); provided, however, that each such Recipient will agree, on behalf of itself and its Representatives, to keep such Royalty Information confidential on terms no less restrictive than those set forth in this Agreement pursuant to a non-disclosure agreement between Vertex (or an Affiliate of Vertex) and such Recipient.

ARTICLE 11. MISCELLANEOUS

11.1. HSR Act Compliance.

- 11.1.1. HSR Filing. Each of Vertex and Merck will make all HSR Filings as soon as reasonably practicable and advisable after the Execution Date (but in no event later than [***] after the Execution Date, unless Vertex consents to an extension upon Merck's reasonable request), unless the Parties together determine that no HSR Filings are required for the activities and licenses contemplated under this Agreement. The Parties will cooperate with one another to the extent necessary in the preparation of any such filings. Merck will be responsible for any filing fee in connection with the HSR Filings, and each Party will be responsible for its own costs and expenses associated with the preparation and management of its filings.
- 11.1.2. HSR Clearance. In connection with obtaining HSR Clearance with respect to the HSR Filings, Vertex and Merck will use their respective Commercially Reasonable Efforts to resolve as promptly as practicable any objections that may be asserted by the FTC or the Antitrust Division of the DOJ with respect to the transactions notified in the applicable HSR Filing(s). The term "Commercially Reasonable Efforts" as used in this Section 11.1 will not require Vertex or Merck to (a) sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer, or dispose of any portion of the assets, operations, rights, product lines, or businesses, or interests therein, of itself or any of its Affiliates (or consent to any of the foregoing actions), (b) restrain, restrict, prohibit, or limit the ability of Vertex or Merck to conduct its business or own its assets (or consent to any of the foregoing actions) or (c) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to challenge this Agreement or impose any of the restrictions referenced in clause (a) or (b) above.
- 11.1.3. <u>Cooperation</u>. In connection with obtaining HSR Clearance with respect to the HSR Filings, each of Vertex and Merck will (a) cooperate with each other in connection with any investigation or other inquiry relating to an HSR Filing and the transactions contemplated by this Agreement; (b) keep the other Party or its counsel informed of any communication received

from or given to the FTC or DOJ relating to an HSR Filing and the transactions contemplated by this Agreement (and provide a copy to the other Party if such communication is in writing); (c) reasonably consult with each other in advance of any meeting or conference with the FTC or DOJ relating to an HSR Filing and the transactions contemplated hereby, and, to the extent permitted by the FTC or DOJ, give the other Party or its counsel the opportunity to attend and participate in such meetings and conferences; and (d) permit the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel concerning, any submission, filing or written communication (and documents submitted therewith) intended to be given to the FTC or DOJ relating to an HSR Filing and transactions contemplated hereby.

- 11.2. Assignment. This Agreement will not be assignable by any Party to any Third Party without the prior written consent of the non-assigning Party. Notwithstanding the foregoing, either Party may assign this Agreement or its rights and obligations under this Agreement, without the written consent of the other Party, to an Affiliate or to a Third Party that acquires all or substantially all of the business or assets of such Party to which this Agreement relates (whether by merger, reorganization, acquisition, sale or otherwise), and agrees in writing to be bound by the terms of this Agreement. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.2 will be void. Notwithstanding anything to the contrary and subject to prior written notice to Merck, Vertex may sell, assign or otherwise transfer or pledge as a security all or any part of its rights to receive royalties and other related payments under this Agreement (collectively, "Rights") without the prior consent of Merck, and any permitted assignee, pledgee or other transferee of such Rights may likewise sell, assign or otherwise transfer or pledge as a security all or any part of such assignee, pledgee or other transferee Rights without the prior written consent of Merck, and Vertex or such assignee, pledgee or other transferee may disclose Royalty Information in accordance with Section 10.6 as if such permitted assignee, pledgee or other transferee were Vertex.
- 11.3. **Performance and Exercise by Affiliates**. Each Party shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates or subcontractors and the performance of such obligations by any such Affiliate or subcontractor shall be deemed to be performance by such Party; *provided*, *however*, that such Party shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate or subcontractor performing obligations of such Party hereunder shall be deemed to be a failure by such Party to perform such obligations. For clarity, the foregoing means that each Party may designate an Affiliate or subcontractor to perform its obligations hereunder or to be the recipient of the other Party's performance obligations hereunder.
- 11.4. **Force Majeure**. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides written notice of the Force Majeure to the other Party. Such excuse will continue for so long as the condition constituting a Force Majeure continues, on the condition that the nonperforming Party continues to use Commercially Reasonable Efforts to remove or mitigate the Force Majeure.

- 11.5. **Representation by Legal Counsel**. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, no presumption will exist or be implied against the Party that drafted such terms and provisions.
- 11.6. **Notices**. All written notices which are required or permitted hereunder will be in writing and sufficient if delivered personally or sent by nationally-recognized overnight courier, addressed as follows:

If to Vertex:

Vertex Pharmaceuticals Incorporated Attn: Business Development 50 Northern Avenue Boston, Massachusetts 02110

with a copy to:

Vertex Pharmaceuticals Incorporated Attn: Corporate Legal 50 Northern Avenue Boston, Massachusetts 02110

and:

Ropes & Gray LLP Attn: Marc Rubenstein 800 Boylston Street Boston, Massachusetts 02199

If to Merck:

Merck KGaA Alliance Management Healthcare Frankfurter Strasse 250 64293 Darmstadt Germany

Attn: David Christopher Godfrey, Director

with a copy to:

Merck KGaA Head of Legal Healthcare Frankfurter Strasse 250 64293 Darmstadt Germany

or to such other address as the Party to whom written notice is to be given may have furnished to the other Party in writing in accordance herewith. In addition, each Party will deliver a

courtesy copy to the other Party's Alliance Manager concurrently with such notice. Any such written notice will be deemed to have been given and received by the other Party: (a) when delivered if personally delivered; or (b) on receipt if sent by overnight courier.

- 11.7. **Amendment**. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each of Vertex and Merck.
- 11.8. <u>Waiver</u>. No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either Party of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.
- 11.9. <u>Severability</u>. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause of portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.
- 11.10. **Descriptive Headings**. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 11.11. **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries that may be imposed upon or related to Merck or Vertex from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.
- 11.12. **Governing Law**. This Agreement, and all claims arising under or in connection therewith, will be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof. All disputes arising out of or in connection with this Agreement shall only be brought in and subject to the competent courts in New York, New York and any appellate court having jurisdiction over appeals from such courts.
- 11.13. <u>Dispute Resolution</u>. If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), it will be resolved pursuant to this Section 11.13.

- 11.13.1. <u>Escalation</u>. Either Party may refer any Dispute to the Executive Officers of the Parties, who will confer in good faith on the resolution of the issue, by delivering written notice to the other Party. If the Executive Officers are not able to agree on the resolution of any such issue within 30 days (or such other period of time as mutually agreed by the Executive Officers) after such issue was first referred to them, then proceedings may be brought by either Party in any court of competent jurisdiction in New York, New York.
- 11.13.2. **Equitable Relief**. Notwithstanding the foregoing in this Section 11.13, nothing contained in this Agreement will in any way limit or preclude a Party from, at any time, seeking or obtaining equitable relief hereunder, whether preliminary or permanent, including a temporary or permanent restraining order, preliminary or permanent injunction, specific performance or any other form of equitable relief, from any court of competent jurisdiction in New York, New York if necessary to protect the interests of such Party.
- 11.14. **Entire Agreement**. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including that certain confidentiality agreement between Vertex and Merck dated [***], which is hereby superseded and replaced in its entirety as of the Effective Date.
- 11.15. <u>Independent Contractors</u>. Both Parties are independent contractors under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.
- 11.16. Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will 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 will 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 will be construed to include the Person's successors and assigns, (f) the words "herein," "hereof" and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules or Exhibits will be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will 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), (i) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (j) any action or occurrence deemed to be effective as of a particular date will be deemed to be effective as of 11:59 PM ET on such date and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

- 11.17. **No Third Party Rights or Obligations**. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligations in any Person not a Party to this Agreement.
- 11.18. **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 11.19. **Counterparts**. This Agreement may be executed in two counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by digital transmission (*e.g.*, .pdf), each of which will be binding when received by the applicable Party.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Execution Date.

VERTEX PHARMACEUTICALS INCORPORATED

MERCK KGAA

By:	By:
Name: Jeff Leiden	Name:
Title: President, CEO and Chairman	Title:
	By:
	Name:
	Title:

[Signature Page to Strategic Collaboration and License Agreement]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 202 pages were omitted. [***]

Existing Clinical Trials

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [***]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 183 pages were omitted. [***]

Licensed Patents

(Please see also Schedule 1.153 for Vertex Background Patents which are incorporated herein by reference)

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 8 pages were omitted. [***]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [***]

Schedule 1.153 Vertex Background Patents

ATR Program

[***]

DNA-PK Program

Initial Development Plans

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 15 pages were omitted. [***]

Schedule 2.2.4

Assigned Regulatory Filings

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Schedule 4.2.3

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Schedule 4.2.5(a)

Third Party Vendors or Contractors

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 2 pages were omitted. [***]

Schedule 4.2.5(b)

Assigned Contracts

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Schedule 5.3.2

Merck's Standard Procedures and Methodology for Currency Conversion

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 1 page was omitted. [***]

Schedule 7.2(g) Jointly-Owned Licensed Patents

Schedule 7.2(m) Government Funded Patents

Schedule 7.2(q) Non-Infringement

Schedule 7.2(s)
Inventory

Asset Purchase Agreement

Dated as of March 3, 2017

between

Concert Pharmaceuticals, Inc., as Seller

and

Vertex Pharmaceuticals (Europe) Limited, as Buyer

and, solely for purposes of Section 10.14 herein,

Vertex Pharmaceuticals Incorporated, as Guarantor

Americas 92425100

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Exhibit F-1 -- Form of Buyer FDA Letter

Form of Buyer Orphan Designation LetterForm of Escrow Agreement Exhibit F-2

Exhibit G

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "**Agreement**") is entered into as of March 3, 2017 between Concert Pharmaceuticals, Inc., a Delaware corporation ("**Seller**"), Vertex Pharmaceuticals (Europe) Limited, a U.K. limited company ("**Buyer**"), and, solely for purposes of <u>Section 10.14</u> herein, Vertex Pharmaceuticals Incorporated, a Massachusetts corporation ("**Guarantor**"). Seller and Buyer are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**."

WHEREAS, Seller is a biopharmaceutical company engaged in the synthesis, research and development of compounds as potential therapeutic products for treating cystic fibrosis, including the generation of Intellectual Property associated therewith (the "CF Enterprise").

WHEREAS, upon the terms and subject to the conditions set forth in this Agreement, Seller desires to sell, convey, assign, transfer and deliver to Buyer, and Buyer desires to purchase, acquire and accept from Seller, the Acquired Assets (as defined below), and assume, pay, perform and discharge from Seller certain Liabilities (as defined below) related to the Acquired Assets, upon the terms and subject to the conditions set forth herein.

WHEREAS, Guarantor desires to guaranty certain obligations of Buyer hereunder.

WHEREAS, concurrently with the execution and delivery of this Agreement, Seller and Buyer are entering into that certain Research and Testing Agreement (the "Research and Testing Agreement") dated as of the date hereof.

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants and agreements herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I

ASSET PURCHASE

Section 1.01 Sale of Assets; Assumption of Liabilities.

- (a) <u>Transfer of Assets</u>. On the terms and subject to the conditions of this Agreement, at the Closing, Seller shall sell, convey, assign, transfer and deliver to Buyer and its assignees under <u>Section 10.06</u> hereof (collectively, the "**Buyer Group**"), and Buyer shall, or shall cause the applicable member of the Buyer Group to, purchase, acquire and accept assignment from Seller, all of Seller's right, title and interest in and to those assets used, planned for use or held for use, in each case, in the ownership, operation or conduct of the CF Enterprise as currently, and currently expected to be, owned, operated and conducted (collectively, the "**Acquired Assets**"), free and clear of all Encumbrances (other than Permitted Encumbrances), including the following:
 - (i) all rights to Develop, Manufacture and Commercialize the Transferred Products, including all rights and claims to all clinical study data, reports and analyses to the extent related to the Transferred Products, including those identified on Section $1.01(\underline{a})(\underline{i})$ of the Seller Disclosure Letter;
 - (ii) all Intellectual Property related to the Transferred Products that exists now or as of the Closing anywhere in the world, including: (A) all Intellectual Property claiming any aspect of, or relating to Seller's Development, Manufacturing, and/or Commercialization activities in respect of the Transferred Products on or before the Closing Date, including Transferred Know-How; (B) any rights which an employee, consultant,

agent, inventor, author or third party is obligated by contract, statute or otherwise to assign to Seller; (C) all rights of action arising from the foregoing, including all claims for damages by reason of present, past and future infringement, misappropriation, violation misuse or breach of contract in respect of the foregoing; (D) present, past and future rights to sue and collect damages or seek injunctive relief for any such infringement, misappropriation, violation, misuse or breach; and (E) all income, royalties and any other payments now and hereafter due and/or payable to Seller in respect of the foregoing (collectively, the "**Transferred IP**");

- (iii) all documentation or other tangible embodiments that comprise, embody, disclose or describe the Transferred IP, including engineering drawings, technical documentation, databases, spreadsheets, business records, inventors' notebooks, invention disclosures, digital files, software code and patent, trademark and copyright prosecution files, including any such files in the custody of outside legal counsel (collectively, the "Transferred IP Documentation"); provided, however, that (A) freedom-to-operate opinions of counsel related to the Intellectual Property of Buyer, (B) minutes, consents, resolutions and other materials prepared for or by the Seller Board and (C) documentation and other tangible embodiments covered by the attorney-client privilege associated with the Acquired Assets, including the transactions contemplated by this Agreement, shall each be deemed an Excluded Asset and shall remain with Seller;
- (iv) all rights, title and interest in the Contracts relating to the Transferred Products or Transferred IP, including all Contracts that contain any grant to Seller of any right relating to or under Intellectual Property rights of any Person that is used or held for use by Seller in connection with the Transferred Products, each of which is identified on Section 1.01(a)(iv) of the Seller Disclosure Letter (the "Assigned IP Contracts"), and each other Contract related to the Transferred Products, each of which is identified on Section 1.01(a)(iv) of the Seller Disclosure Letter (together with the Assigned IP Contracts, the "Assigned Contracts");
 - (v) the Transferred Registrations related to the Transferred Products;
- (vi) other than the Transferred Registrations, all qualifications, permits, registrations, clearances, applications, submissions, variances, exemptions, filings, approvals and authorizations which relate primarily to the Transferred Products (collectively, "**Permits**"), including those identified on <u>Section 1.01(a)(vi)</u> of the Seller Disclosure Letter (the "**Transferred Permits**");
- (vii) copies of all customer and supplier lists, marketing studies, consultant reports, books and records (financial, laboratory and otherwise), files, invoices, billing records, distribution lists, manuals (in all cases, in any form or medium), but excluding Tax Returns other than Tax Returns solely related to the Acquired Assets, patient support and market research programs and related databases, and all complaint files and adverse event files, in each case, to the extent (1) related to the Transferred Products and (2) in Seller's or any of its Affiliates' possession or under its control as of the Closing Date;
- (viii) all Transferred Product Records, including Acquired Assets Regulatory Filings, to the extent not covered by any of the foregoing;
- (ix) all third-party warranties, indemnities and guarantees relating to any of the Acquired Assets or the Assumed Liabilities;

- (x) all claims, defenses and rights of offset or counterclaim (at any time or in any manner arising or existing, whether choate or inchoate, known or unknown, contingent or non-contingent) relating to any of the Acquired Assets or the Assumed Liabilities;
- (xi) all goodwill arising from, associated with or relating to the Acquired Assets, including rights under any confidentiality Contracts executed by any third party for the benefit of Seller in connection with the Acquired Assets;
 - (xii) all Transferred Inventory; and
 - (xiii) the Transferred Products.

Notwithstanding anything to the contrary in this Agreement, the Acquired Assets shall not include any Excluded Assets.

(b) Excluded Assets. It is expressly understood and agreed that "Excluded Assets" means all assets, properties and rights of Seller other than the Acquired Assets, including, but not limited to, those set forth on Section 1.01(b) of the Seller Disclosure Letter, the DCE Platform Know-How and the Excluded Therapeutic Products. For the avoidance of doubt, all Transferred Products shall be included in the Acquired Assets.

In the event of any inconsistency or conflict that may arise in the application or interpretation of this definition or the definition of "Acquired Assets," for purposes of determining what is and is not an Excluded Asset or an Acquired Asset, the explicit inclusion of an item on <u>Section 1.01(b)</u> of the Seller Disclosure Letter shall take priority over any textual provision of this definition that would otherwise operate to exclude such asset from the definition of "Excluded Assets" or include such asset in the definition of "Acquired Assets," as applicable.

- (c) <u>DCE Platform Know-How and Non-Exclusive License</u>. Seller hereby grants to Buyer, effective as of the Closing Date, a world-wide, non-exclusive, perpetual, irrevocable, sublicensable, royalty-free, fully-paid license to DCE Platform Know-How for the use in the Development, Manufacture and Commercialization of the Transferred Products and other therapeutic products. Seller shall disclose to Buyer DCE Platform Know-How that is necessary or useful for the ownership, Development, Manufacture and Commercialization of the Transferred Products, and shall have no further disclosure obligation under this Agreement with respect to DCE Platform Know-How.
- (d) <u>Assumed Liabilities</u>. On the Closing Date, Buyer shall, or shall cause the applicable member of the Buyer Group to, deliver to Seller one or more assumption agreements in the form attached hereto as <u>Exhibit A</u> (the "Assumption Agreements"), pursuant to which Buyer, or the applicable member of the Buyer Group, on and as of the Closing Date, shall, among other things, assume and agree to pay, perform and discharge when due only the following Liabilities primarily relating to the Acquired Assets (the "Assumed Liabilities"), and Buyer does not hereby assume or become obligated to pay or perform any other Liabilities of Seller that arise out of or in respect of any of its operations on or prior to the Closing, except for the following:
 - (i) all Liabilities relating to, arising out of, based upon or resulting from the use, ownership, possession or operation of the Acquired Assets by Buyer or its Affiliates after the Closing;
 - (ii) all Liabilities identified on Section 1.01(d) of the Seller Disclosure Letter;

- (iii) all Liabilities under the Assigned Contracts first arising in respect of the period after the Closing (other than any Liability arising out of or relating to a default or breach existing at, prior to, or as a consequence of the Closing); and
 - (iv) all Liabilities for Taxes attributable to a Post-Closing Tax Period.
- (e) Excluded Liabilities. It is expressly understood and agreed that, notwithstanding anything to the contrary in this Agreement, Buyer shall not assume, or cause to be assumed, or be deemed to have assumed or be liable or responsible for any Liabilities (whether now existing or arising after the date hereof) of Seller or any of its Affiliates relating to, arising out of, based upon or resulting from the use, ownership, possession or operation of the Acquired Assets by Seller or its Affiliates on or prior to the Closing, including (i) those Liabilities set forth on Section 1.01(e) of the Seller Disclosure Letter, (ii) any Indebtedness of Seller or any of its Affiliates, (iii) any expenses incurred by, or for the benefit of, Seller or any of its Affiliates in connection with the preparation, execution or consummation or performance of the transactions contemplated by this Agreement and the Related Agreements, including all legal, accounting, Tax advisory, investment banking and other professional fees and expenses, and (iv) any Liability incurred in connection with the open-label Phase 2 clinical trial of CTP-656 in Europe (such Liabilities not assumed hereunder, the "Excluded Liabilities") and the Excluded Liabilities shall remain the sole obligation and responsibility of Seller.

In the event of any inconsistency or conflict that may arise in the application or interpretation of this definition or the definition of "Assumed Liabilities," for purposes of determining what is and is not an Excluded Liability or an Assumed Liability, the explicit inclusion of an item on Section 1.01(d) of the Seller Disclosure Letter shall take priority over any textual provision of this definition that would otherwise operate to exclude such Liability from the definition of "Excluded Liabilities" or include such Liability in the definition of "Assumed Liabilities," as applicable.

Section 1.02 Consideration.

- (a) <u>Upfront Consideration</u>. On the terms, and subject to the conditions, set forth in this Agreement, as partial consideration for the Acquired Assets, and subject to the terms and conditions of this Agreement, at the Closing, Buyer shall, or shall cause the applicable member of the Buyer Group to, (i) assume the Assumed Liabilities, (ii) pay to Seller, by wire transfer of immediately available funds, the Base Purchase Price, less the Escrow Amount, and (iii) pay to the Escrow Agent the Escrow Amount.
- (b) <u>Contingent Consideration</u>. As additional consideration for the Acquired Assets, Buyer shall pay to Seller, pursuant to this <u>Section 1.02(b)</u>, the contingent payment (each a "**Contingent Payment**") set forth below based on the achievement by or on behalf of Buyer or its Affiliates, licensees, sublicensees or transferees of the corresponding Milestone Event set forth below. For the avoidance of doubt, notwithstanding anything to the contrary in this Agreement, a Contingent Payment shall be due and payable only once (and only one Contingent Payment shall be payable with respect to each Milestone Event) and shall be paid by Buyer to Seller promptly, but in no event later than forty-five (45) calendar days following the occurrence of the applicable Milestone Event by wire transfer of immediately available funds to the account designated in writing by Seller to Buyer.

Milestone Event Contingent Payment

Receipt of marketing approval from the FDA of a combination treatment regimen for the treatment of patients with cystic fibrosis that contains CTP-656

\$50,000,000

Completion of a pricing and reimbursement agreement in the United Kingdom, Germany or France with respect to a combination treatment regimen for the treatment of patients with cystic fibrosis that contains CTP-656

\$40,000,000

(c) <u>No Diligence Obligation</u>. From and after the Closing, Buyer shall, in its sole and absolute discretion, make all decisions with respect to the Development, Manufacture and Commercialization of the Acquired Assets and shall have no obligation to undertake any efforts to achieve the Milestone Events.

Section 1.03 The Closing.

(a) <u>Time and Location</u>. The closing of the transactions contemplated by this Agreement (the "**Closing**") shall take place at 9:00 a.m., New York City Time, at the offices of White & Case LLP, 1155 Avenue of the Americas, New York, New York 10036-2787 as soon as possible but in no event later than the third (3rd) Business Day following the satisfaction or waiver of the last of the conditions set forth in <u>Article V</u> to be satisfied or (to the extent permitted) waived (other than any such conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or (to the extent permitted) waiver of such conditions at Closing), unless another time, date or place is agreed to in writing by Seller and Buyer. The date on which the Closing actually occurs will be the "**Closing Date**".

(b) Actions at the Closing. At the Closing:

- (i) Seller shall deliver (or cause to be delivered) to Buyer the various certificates, instruments and documents required to be delivered under Section 5.02 not otherwise listed in this Section 1.03(b);
- (ii) Buyer shall deliver (or cause to be delivered) to Seller the various certificates, instruments and documents required to be delivered under <u>Section 5.03</u> not otherwise listed in this <u>Section 1.03(b)</u>;
- (iii) Seller shall deliver (or cause to be delivered) to Buyer one or more executed Bills of Sale in substantially the form attached hereto as Exhibit B (collectively, the "Bill of Sale"):
- (iv) Seller shall deliver (or cause to be delivered) to Buyer executed Intellectual Property Assignment Agreements, in substantially the form attached hereto as <u>Exhibit C</u> (the "**IP Assignment Agreements**");
- (v) Seller and Buyer shall deliver (or cause to be delivered) to the other one or more executed Assumption Agreements and such other instruments as Seller may reasonably request in order to effect the assignment to, and assumption by, Buyer of certain of the Acquired Assets and the Assumed Liabilities;
 - (vi) Seller shall deliver (or cause to be delivered) to Buyer the Transferred Product Records;
- (vii) Seller and Buyer shall deliver (or cause to be delivered) to the other an executed Transition Services Agreement in substantially the form attached hereto as Exhibit D (the "**Transition Services Agreement**");

- (viii) Seller shall deliver (or cause to be delivered) such other certificates, documents, instruments and writings as shall be reasonably requested by Buyer to effectively vest in Buyer title in and to the Acquired Assets, free and clear of all Encumbrances (other than Permitted Encumbrances), in accordance with the provisions of this Agreement; and
- (ix) Buyer shall pay (or cause to be paid) (A) to Seller, the Base Purchase Price, less the Escrow Amount and (B) to the Escrow Agent, the Escrow Amount, in each case in accordance with <u>Section 1.02(a)</u>.

Consents to Assignment. Notwithstanding anything to the contrary contained in this Agreement, if the sale, assignment, transfer, conveyance or delivery or attempted sale, assignment, transfer, conveyance or delivery to Buyer of any asset that would be an Acquired Asset is (a) prohibited by any applicable Law or (b) would require any authorizations, approvals, consents or waivers from a Third Party or Governmental Entity and such authorizations, approvals, consents or waivers shall not have been obtained prior to the Closing, then in either case the Closing shall proceed without the sale, assignment, transfer, conveyance or delivery of such asset and this Agreement shall not constitute an agreement for the sale, assignment, transfer, conveyance or delivery of such asset; provided, that nothing in this Section 1.04 shall be deemed to waive the rights of Buyer not to consummate the transactions contemplated by this Agreement if the conditions to its obligations set forth in Article V have not been satisfied. In the event that the Closing proceeds without the sale, assignment, transfer, conveyance or delivery of any such asset, then following the Closing, Seller shall use commercially reasonable efforts to obtain promptly such authorizations, approvals, consents or waivers. Pending such authorization, approval, consent or waiver, (i) Seller will comply with the terms of, and will not amend, transfer, let lapse or terminate, its rights with respect to the applicable asset without Buyer's written consent, such consent not to be unreasonably withheld, conditioned or delayed and (ii) the Parties shall cooperate with each other in any mutually agreeable, reasonable and lawful arrangements designed to provide to Buyer the benefits of use of such asset, and to Seller the benefits, including any indemnities, that, in each case, it would have obtained had the asset been conveyed to Buyer at the Closing. To the extent that Buyer is provided the benefits pursuant to this Section 1.04 of any Contract, Buyer shall (x) perform for the benefit of the other parties thereto the obligations of Seller or any affiliate of Seller thereunder and (y) satisfy any related Liabilities with respect to such Contract that, but for the lack of an authorization, approval, consent or waiver to assign such obligations or Liabilities to Buyer, would be Assumed Liabilities. Once authorization, approval, consent or waiver for the sale, assignment, transfer, conveyance or delivery of any such asset not sold, assigned, transferred, conveyed or delivered at the Closing is obtained, Seller shall promptly assign, transfer, convey and deliver such asset to Buyer at no additional cost to Buyer.

Section 1.05 Further Assurances. Subject to the terms and conditions hereof, each of the Parties agrees to use commercially reasonable efforts to execute and deliver, or cause to be executed and delivered, all documents and to take, or cause to be taken, all actions that may be reasonably necessary or appropriate to effectuate the provisions of this Agreement, <u>provided</u>, that all such actions are in accordance with applicable Law. From time to time, whether at or after the Closing, (i) Seller shall execute and deliver such further documents or instruments of conveyance, transfer and assignment and take all such other action as Buyer may reasonably require to more effectively convey, transfer and assign to Buyer any and all ownership, right, title and interest in and to the Acquired Assets, including executing documents or instruments necessary to permit Buyer to record the transfer, conveyance and/or assignment of any and all Transferred IP with any Governmental Entity and (ii) Buyer, and any other member of the Buyer Group, will execute and deliver such further instruments and take all such other action as Seller may reasonably require for such member of the Buyer Group to assume the Assumed Liabilities.

ARTICLE II

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the disclosure schedule provided by Seller to Buyer prior to the date hereof (the "Seller Disclosure Letter"), Seller hereby represents and warrants to Buyer as of the date hereof and as of the Closing Date as follows. The Seller Disclosure Letter shall be arranged in sections corresponding to the Sections contained in this <u>Article II</u>. The disclosures in any section of the Seller Disclosure Letter shall qualify other Sections in this <u>Article II</u> only to the extent it is reasonably clear from a reading of the disclosure that such disclosure is applicable to other Sections.

Section 2.01 Organization, Qualification and Corporate Power. Seller is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware, with all requisite power and authority to own, lease and operate its properties as presently owned, leased and operated and to carry on its business as presently conducted. Seller is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction where the nature of the properties owned, leased or operated by it and the businesses transacted by it require such licensing or qualification. Section 2.01 of the Seller Disclosure Letter lists, as of the date hereof, all jurisdictions in which the property owned, leased or operated by Seller, or the nature of the business conducted by Seller makes such qualification necessary to the extent such qualification relates to any Acquired Asset, except for such failures to be so qualified that would not, individually or in the aggregate, have a Seller Material Adverse Effect. Seller has made available to Buyer prior to the date hereof copies of its organizational documents, in each case, as amended and in full force and effect as of the date hereof.

Section 2.02 Title to Assets. Except as set forth on Section 2.02 of the Seller Disclosure Letter, Seller has good, valid and marketable title to the Acquired Assets, free and clear of any Encumbrances (other than Permitted Encumbrances). Upon the sale, conveyance, transfer, assignment and delivery of the Acquired Assets in accordance with this Agreement, Buyer will acquire good, valid and marketable title to the Acquired Assets, free and clear of any Encumbrances (other than Permitted Encumbrances). Seller has timely paid over to the appropriate Governmental Entity all amounts required to be paid over under all escheat and unclaimed property Laws and has substantially complied with all escheat and unclaimed property Laws.

Section 2.03 Authority. Seller has all requisite corporate power and authority to execute and deliver (or cause to be executed and delivered) this Agreement, the Bill of Sale, the IP Assignment Agreements, the Transition Services Agreement, the Research and Testing Agreement, the Seller FDA Letter, the Seller Orphan Designation Letter and any other agreements, certificates or documents to which Seller is (or will be as of the Closing) a party (collectively, the "Related Agreements") and to perform its obligations hereunder and under each of the Related Agreements to which it is (or will be as of the Closing) a party. The execution and delivery by Seller of this Agreement and each of the Related Agreements to which it is (or will be as of the Closing) a party and the performance by Seller of this Agreement and its obligations hereunder and thereunder, and the consummation by Seller of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action on the part of Seller and, other than the Seller Stockholder Approval, no other corporate or other proceedings or actions on the part of Seller, its board of directors (the "Seller Board") or stockholders are necessary therefor. There are no appraisal or dissenters' rights under applicable Law that are applicable to the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby by Seller. This Agreement has been, and each Related Agreement to which it is (or will be at Closing) a party will be, duly and validly executed and delivered by Seller and (assuming this Agreement and each of the Related Agreements to which Buyer is (or will be at Closing) a party, constitutes the valid and binding obligation of Buyer) constitutes (or will constitute) a valid and binding obligation of Seller, enforceable against Seller in accordance with their

respective terms, except as enforceability may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar Laws relating to or affecting the rights of creditors generally and by general principles of equity.

- **Section 2.04 No Subsidiaries.** Except for Concert Pharmaceuticals Securities Corporation and Concert Pharma U.K. Ltd., Seller has no Subsidiaries.
- **Section 2.05** <u>Non-Contravention; Consents</u>. Neither the execution, delivery or performance of this Agreement by Seller or any of the Related Agreements to which Seller is (or will be at Closing) a party, nor the consummation by Seller of the transactions contemplated hereby or by the Related Agreements, will (with or without the giving of notice or the lapse of time, or both):
 - (a) conflict with or violate any provision of the charter or bylaws or other organizational documents of Seller;
 - (b) create any Encumbrance (other than a Permitted Encumbrance) upon any of the Acquired Assets;
- (c) require on the part of Seller any filing with, notice to, exemption from, or any Permit, authorization, consent or approval of, any Governmental Entity with respect to the Acquired Assets, except for (i) compliance by Seller with the applicable requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") and any other applicable Antitrust Laws, (ii) the Seller Orphan Designation Letter, (iii) the Seller FDA Letter and (iv) the filing of the Proxy Statement with the SEC in preliminary and definitive forms;
- (d) subject to obtaining the Third Party consents or providing the notices set forth on Section 5.02(h) of the Seller Disclosure Letter, conflict with, violate or result in a breach of, constitute a default under, result in the acceleration of, create in any party the right to accelerate, terminate, modify or cancel, require any notice, right of first offer or refusal, consent or waiver under, or result in the loss of any right or privilege under, any Assigned Contract, or other instrument to which Seller is a party or by which any of the Acquired Assets are bound; or
- (e) conflict with or violate any Order or Law or other restriction of any Governmental Entity applicable to Seller, any of the Acquired Assets or any of the Assumed Liabilities,

except, in the case of clauses (b) through (e) above, for such conflicts, breaches, defaults, consents, approvals, authorizations, declarations, filings or notices which would not reasonably be expected to have a Seller Material Adverse Effect.

Section 2.06 Vote Required. The Seller Stockholder Approval is the only vote of the holders of any class or series of Seller's capital stock necessary to consummate the transactions contemplated hereby.

Section 2.07 Absence of Certain Changes. Since January 1, 2016, (a) Seller has owned, developed and operated the Acquired Assets in the Ordinary Course of the CF Enterprise, (b) there has not been any material damage, destruction or other casualty loss with respect to any Acquired Asset, whether or not covered by insurance and (c) there has not been any Effect that has had, or would reasonably be expected to have, individually or in the aggregate, a Seller Material Adverse Effect. Without limiting the generality of the foregoing, except for the transactions contemplated hereby, and except as set forth in Section 4.01(b) Section 4.01(b) of the Seller Disclosure Letter, since January 1, 2016, Seller has not taken any action that, had it been taken after the date of this Agreement, would be prohibited by the terms hereof.

- **Section 2.08 Real Property.** The Acquired Assets do not include any owned or leased real property.
- **Section 2.09** <u>Intellectual Property.</u> (a) <u>Section 2.09(a)(i)</u> of the Seller Disclosure Letter sets forth a complete and correct list of all issued or registered Transferred IP and applications for registration of Transferred IP owned by Seller ("**Registered Business IP**") and, specifying as to each such item, as applicable, the owner(s), jurisdiction of registration or application, the registration and/or application number and the date of registration and/or application.
- (b) The Assigned IP Contracts represent all of the Contracts to which Seller is party and that are related to the Transferred IP and no additional Contracts are necessary or useful for the ownership, Development, Manufacture, Commercialization and operation of the Acquired Assets as currently conducted.
- (c) Except as set forth on <u>Section 2.09(c)</u> of the Seller Disclosure Letter, Seller is the sole owner of all the rights, title and interest in the Transferred IP, free and clear of any and all claims, any requirement of any past (if outstanding), present or future royalty, milestone or other contingent payments, or Encumbrances (other than Permitted Encumbrances) to the Transferred IP. Seller has not transferred ownership of, or granted any license or right to use, or authorized the retention of any right or ownership interest in any Transferred IP to any Person. No Third Party IP is included in or required to exploit the Transferred IP as currently conducted or contemplated by Seller. Seller does not hold any trademarks related to the Transferred Products and, to the knowledge of Seller, there will be no impediment to Buyer's use of the name CTP-656. Seller is entitled to grant all rights that it purports to grant with respect to the DCE Platform Know-How in <u>Section 1.01(c)</u>.
- (d) The Transferred IP is sufficient for the conduct of the Development, Manufacture and Commercialization of CTP-656 after the Closing in substantially the same manner as conducted prior to the Closing and constitutes all the rights, property and assets necessary to conduct in all material respects the Development, Manufacturing and Commercialization activities as currently conducted or contemplated by Seller.
- (e) The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not result in the loss, forfeiture, termination, license, or impairment of, or give rise to any obligation to transfer or to create, change or abolish, or limit, terminate, or consent to the continued use by Buyer of any rights in any Transferred IP or material Third Party IP.
- (f) Except as set forth on <u>Section 2.09(f)</u> of the Seller Disclosure Letter, neither the use or practice of the Transferred IP relating to CTP-656 as currently used or practiced in the Ordinary Course of the ownership, Development and operation of the Acquired Assets infringes or misappropriates or otherwise violates, nor the use or practice of the Transferred IP relating to CTP-656 as used or practiced in the Ordinary Course infringed or misappropriated or otherwise violated any rights, other than rights that would be infringed, misappropriated or otherwise violated if ivacaftor were used or practiced in the same manner as CTP-656, in Intellectual Property of any Third Party ("Third Party IP").
- (g) Except as set forth on <u>Section 2.09(g)</u> of the Seller Disclosure Letter, (i) the use, Manufacture or Commercialization of CTP-656 does not and will not, infringe, misappropriate or otherwise violate or conflict with any Third Party IP, and (ii) no claim, action, investigation or proceeding by or before any Governmental Entity is pending or, has been threatened claiming that the Manufacture or Commercialization of the Transferred Products does or will infringe, misappropriate or otherwise violate or conflict with Third Party IP.

(h) Except as set forth on Section 2.09(h) of the Seller Disclosure Letter, no claim has been asserted in writing to or
pending against Seller or any of its Affiliates and, to the knowledge of Seller, there have not been any threatened claims or demands again
Seller alleging that any aspect of the use or practice of the Transferred IP or the ownership, Development, Manufacture, Commercialization at
operation of the Acquired Assets as currently conducted infringes or misappropriates or would infringe the rights of others in or to any Thi
Party IP, or challenging the validity, enforceability, right to use or ownership of any Transferred IP.

- (i) Seller has not granted to any Third Party any license, ownership interest or right or option to or for the use of or under the Transferred IP.
- (j) Except as set forth on <u>Section 2.09(j)</u> of the Seller Disclosure Letter, there are no settlements, governmental consents or governmental contracts, judgments or governmental orders entered into by Seller or imposed upon Seller that restrict Seller's rights to own or use any Transferred IP or permit any Third Parties to use any Transferred IP.
- (k) Except as set forth on Section 2.09(k) of the Seller Disclosure Letter, no Transferred IP was developed, in whole or in part (i) pursuant to or in connection with the development of any professional, technical or industry standard, (ii) under contract with or using the funding or resources of any Governmental Entity, academic institution or other entity or (iii) under any grants or other funding arrangements with Third Parties, including the Cystic Fibrosis Foundation Therapeutics Incorporated. Except as set forth on Section 2.09(k) of the Seller Disclosure Letter, no current or former employee, consultant or independent contractor of the Seller who was involved in, or who contributed to, the creation or development of any Transferred IP, has performed services for the government, a university, college, or other educational institution, or a research center, during a period of time during which such employee, consultant or independent contractor was also performing services for Seller.
- (l) To the knowledge of Seller, there is no, nor has there been any, infringement, misappropriation, or other violations by any Third Party of any Transferred IP, and no such claims are pending or threatened by Seller against any Person with respect to the Transferred IP.
- (m) Seller has taken commercially reasonable steps and precautions to protect and maintain the Transferred IP, including to establish and preserve the confidentiality, secrecy and ownership of all of the Transferred IP for which it would be commercially reasonable to do so. No such Transferred IP has been disclosed to any Person other than Seller's Representatives who are bound by confidentiality provisions and no employee, officer, director, consultant or advisor of Seller is in violation of any material term of any employment contract or any other Contract, or any restrictive covenant, relating to the right to use confidential information of others.
- (n) Except as indicated in Section 2.09(n) of the Seller Disclosure Letter, all Registered Business IP (i) has been duly maintained and has not been cancelled, allowed to expire, surrendered, or abandoned, and payment of all applicable maintenance fees for such Registered Business IP has been made and is current, (ii) is registered and/or recorded in the name of Seller, is in full force, has been duly applied for, prosecuted and registered in accordance with applicable Laws (including disclosure to the United States Patent and Trademark Office of all material prior art references); (iii) has no filings, payments or similar actions that must be taken within 120 days of the date hereof for the purposes of obtaining, maintaining, perfecting or renewing such registration of Registered Business IP; (iv) has no unsatisfied past or outstanding maintenance or renewal obligation; and (v) has not been and is not involved in any inter partes review, opposition, cancellation, interference, reissue, reexamination or other similar proceeding. All Registered Business IP is subsisting and, except for any Registered Business IP that is a pending patent application, valid and enforceable.

- (o) Except as set forth on <u>Section 2.09(o)</u> of the Seller Disclosure Letter, each Person who has or had access to any trade secrets or confidential information contained in the Transferred IP is subject to a valid and binding written agreement requiring such Person to keep such information confidential. Each Person who has developed or is or was involved in the development of any Transferred IP owned or purported to be owned by Seller has signed a valid and binding agreement confirming that Seller owns such owned Transferred IP.
- (p) Except as set forth on <u>Section 2.09(p)</u> of the Seller Disclosure Letter, Seller has secured valid written present assignments from all consultants and employees who contributed to the creation or development of any Transferred IP owned or purported to be owned by Seller and of the rights to such contributions.
- (q) Section 2.09(q) of the Seller Disclosure Letter sets forth a list of the Transferred Products and the Development status of each such Transferred Product.
- **Section 2.10** <u>Contracts</u>. (a) <u>Section 2.10(a)</u> of the Seller Disclosure Letter sets forth a complete and correct list of each Contract to which Seller or any of its Affiliates is a party that relates to the Acquired Assets and that is (each, a "**Material Contract**"):
 - (i) a Contract providing for payments by or to any Person in excess of \$100,000 over any twelve (12) month period;
 - (ii) a Contract relating to any partnership, commercial collaboration or joint venture or other agreement involving a sharing of profits, losses, costs or Liabilities by Seller or any of its Affiliates with any other Person;
 - (iii) a Contract with any Governmental Entity, other than any MTAs or CTAs;
 - (iv) a Contract relating to the acquisition or disposition of any assets outside the Ordinary Course, including any securities purchase agreements, asset purchase agreements, merger agreements, business combination agreements and any earn-out or agreement for the deferred payment of purchase price entered into in connection therewith;
 - (v) an Assigned Contract;
 - (vi) a Contract relating to the manufacture, storage, distribution or commercialization of the Transferred Products;
 - (vii) a Contract relating to the research or development of the Transferred Products, excluding any NDAs, MTAs and CTAs;
 - (viii) a Contract that is a confidentiality or non-disclosure agreement, other than those related to business development activities ("NDAs"), material transfer (or other similar research) agreement ("MTAs") or clinical trial agreement ("CTAs");
 - (ix) a Contract relating to the testing, auditing or controlling of the Transferred Products, including any pharmacovigilance Contracts and quality Contracts;
 - (x) a Contract that: (A) contains a covenant by Seller not to compete or otherwise limits the freedom of Seller from engaging in the research, ownership, operation, development, manufacture, distribution or commercialization of the Transferred Products; (B) grants any rights of exclusivity to any Person; (C) grants any right of first refusal, first offer, first negotiation or similar preferential right; (D) grants any "most favored customer,"

"most favored supplier" or similar rights to any Person; or (E) contains a "requirements" obligation requiring Seller to purchase a designated portion of any type of material; or

- (xi) a Contract that is otherwise material to the Acquired Assets.
- (b) Each of the Material Contracts is in full force and effect and constitutes a legal, valid and binding agreement of Seller, and to the knowledge of Seller, each other party thereto, enforceable in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors' rights generally, and subject to general principles of equity. Neither Seller, nor, to the knowledge of Seller, any other party thereto is (with or without notice or lapse of time, or both) in material breach or default in the performance, observance or fulfillment of any obligation or covenant contained in any Material Contract, nor does there exist any condition which upon the passage of time or the giving of notice or both, would reasonably be expected to cause such material violation of or material default under or permit the termination or modification of, or acceleration of any obligation under, any Material Contract. Seller has not given or received written or, to the knowledge of Seller, oral notice to or from any Person relating to any such actual or alleged, breach or default. Seller has not received any written or, to the knowledge of Seller, oral notice from a Third Party stating that such Third Party intends to terminate any Material Contract and Seller has not waived any right under the Material Contracts. True and complete copies of all Material Contracts including all schedules, exhibits, appendices, amendments, modifications and waivers relating thereto have been made available to Buyer, except to the extent such Material Contracts have been redacted to (i) enable compliance with Laws relating to antitrust or the safeguarding of data privacy; (ii) comply with confidentiality obligations owed to Third Parties; or (iii) exclude information not related to the Acquired Assets.

Section 2.11 Litigation. There is not, and has never been, a claim, complaint, action, suit, proceeding, hearing or investigation initiated or, to the knowledge of Seller, threatened, before any Governmental Entity or arbitral body relating to the Acquired Assets, Assumed Liabilities, the CF Enterprise, this Agreement or the transactions contemplated hereby (but excluding any claim, complaint, action, suit, proceeding, hearing or investigation solely relating to any Excluded Assets and any sealed qui tam cases). There are no outstanding Orders of any Governmental Entity or arbitral body affecting the Acquired Assets, Assumed Liabilities, the CF Enterprise, this Agreement or the transactions contemplated hereby. No product liability claims have been received in writing by Seller and, to the knowledge of Seller, no such claims have been threatened, in each case, with respect to the Transferred Products.

- Section 2.12 Regulatory Matters. (a) Seller holds all Permits required under the Federal Food, Drug and Cosmetic Act of 1938, as amended (the "FDCA"), the Public Health Service Act of 1944, as amended (the "PHSA"), and the regulations of the United States Food and Drug Administration (the "FDA") promulgated thereunder, and similar Laws of any other similar Governmental Entity (each a "Regulatory Authority") required in connection with the Acquired Assets, including but not limited to the Seller's Development, Manufacture, storage, distribution, import, and export of the Transferred Products (the "Acquired Assets Permits"). Seller is in compliance in all material respects with the terms of the Acquired Assets Permits. Seller has timely filed all material regulatory reports, schedules, statements, documents, filings, submissions, forms, registrations, notices and other documents, together with any amendments required to be made with respect thereto, that each was required to file with any Regulatory Authority related to the Acquired Assets ("Acquired Assets Regulatory Filings"), and has timely paid all Taxes, fees and assessments due and payable in connection therewith. All such Acquired Assets Regulatory Filings complied in all material respects with applicable Law. All such Acquired Assets Regulatory Filings are included within the Acquired Assets.
- (b) All preclinical and clinical studies or tests conducted by or on behalf of Seller related to the Acquired Assets have been conducted in compliance with applicable Law, rules, Regulatory Authority guidance, including the provisions of the FDA's current good clinical practices regulations at 21 C.F.R. Parts 50, 54, 56 and 312 and the FDA's current good laboratory practice regulations at 21 C.F.R. Part 58 and Laws and guidance restricting the use and disclosure of personal information, including but not limited to, individually identifiable health information. No clinical trial conducted by or on behalf of Seller has been terminated or suspended prior to completion for safety or other non-business reasons. Neither Seller nor, to the knowledge of Seller, any Third Party on behalf of Seller, has received any notices (whether in writing or otherwise) or other correspondence (including any warning letter, untitled letter, 483 observations or similar notices) from the FDA, any other Regulatory Authority or any institutional review board or ethics committee (i) requiring the termination, suspension or material modification of any clinical or pre-clinical studies or tests relating to the Transferred Products, or (ii) claiming that the ownership, operation, research, development, manufacture or use of the Acquired Assets is not in compliance with all applicable Laws, and, there is no action, proceeding or suit pending or, to the knowledge of Seller, threatened in writing (including any prosecution, injunction, seizure, civil fine, suspension or recall) relating to the foregoing. Seller has informed Buyer of all serious adverse drug reactions known to Seller and its Affiliates relating to the Transferred Products or their use.
- (c) Seller has not (i) made an untrue statement of a material fact or fraudulent statement to the FDA or any other Regulatory Authority, (ii) failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority or (iii) committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy as set forth in Compliance Policy Guide Sec. 120.100, in each case, related to the Acquired Assets. As of the date of this Agreement, Seller is not the subject of any pending or threatened investigation related to the Acquired Assets by the (x) FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy, or (y) any other Regulatory Authority. None of Seller or any of its officers, employees, agents or clinical investigators has been suspended or debarred or convicted of any crime or engaged in any conduct that would reasonably be expected to result in (A) debarment under 21 U.S.C. § 335a or any similar Law or (B) exclusion under 42 U.S.C. § 1320a-7 or any similar Law, in each case, in connection with activities related to the Acquired Assets.
- (d) Seller's Development, Manufacture, storage, distribution, import, and export of the Transferred Products is, and at all times has been, in compliance in all material respects with all applicable Laws. There has not been any replacement, "dear doctor" letter, investigator notice, safety notice, warning

letter, untitled letter, inspectional observation or other written notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Transferred Products ("Safety Notice") conducted by or on behalf of Seller or, to the knowledge of Seller, any Safety Notice conducted by or on behalf of any Third Party. To the knowledge of Seller, no event has occurred or circumstance exists that (with or without notice or lapse of time) is reasonably likely to give rise to any material actual, alleged, possible or potential action to enjoin Development, Manufacture, storage, distribution, import or export of any Transferred Products. Seller has made available to Buyer copies of material complaints and notices of alleged defect or adverse reaction with respect to the Transferred Products that have been received in writing by Seller.

- (e) Seller is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or other similar written agreements, in each case, entered into with or imposed by any Regulatory Authority and related to the Acquired Assets.
- (f) Seller is, and has been, in compliance with (i) all federal, state and local fraud and abuse laws, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.) and the regulations promulgated pursuant to such statutes; (ii) the FDCA, (iii) the Clinical Laboratory Improvement Amendments of 1988; (iv) the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information and Technology for Economic and Clinical Health Act, and the regulations promulgated pursuant thereto; (v) the PHSA and the regulations of the FDA promulgated thereunder; (vi) laws which are cause for exclusion from any federal health care program; and (vii) applicable requirements under any Permit or Laws, including applicable statutes and implementing regulations administered or enforced by the FDA or other Regulatory Authority, including provisions of the FDA's current good manufacturing practice regulations at 21 C.F.R. Parts 210-211 and those relating to investigational use, premarket approval and applications or abbreviated applications to market the Acquired Assets.
- (g) All reports, documents, claims and notices required to be filed, maintained or furnished to the FDA or any other similar Regulatory Authority by Seller with respect to the Transferred Products have been so filed, maintained or furnished and were complete and correct in all material respects on the date filed (or were corrected in or supplemented by a subsequent filing), except as would not, individually or in the aggregate, reasonably be expected to materially and adversely affect the Acquired Assets, taken together as a whole.
- **Section 2.13** Transferred Inventory. The Transferred Inventory has been manufactured, handled, maintained, packaged and stored, as applicable, at all times in compliance in all material respects with applicable Law. Section 2.13 of the Seller Disclosure Letter contains a complete and accurate list of the Transferred Inventory, including the quantity of each component, and sets forth the applicable shelf life for any active ingredients, and other raw materials included in Transferred Inventory that have a shelf life.
- **Section 2.14 Product Liability**. To the knowledge of Seller, there are no (i) defects in design of CTP-656 which would reasonably be expected to adversely affect performance or create a material risk of injury to persons or property or (ii) citations, decisions, adjudications or statements by any Governmental Entity or consent decrees stating that CTP-656 is defective or unsafe or fail to meet any standards promulgated by any such Governmental Entity.
- **Section 2.15** <u>Compliance with Laws</u>. (a) Seller is, and has been, with respect to the CF Enterprise, Acquired Assets and Assumed Liabilities, in compliance in all material respects with all applicable Laws. Seller is not a party to, nor is subject to, non-compliance proceedings or the provisions of any material Order of any Governmental Entity. No notice, citation, summons or order has been issued to Seller or any of its Affiliates, no complaint has been filed and served, no penalty has been assessed and notice thereof given, and, to the knowledge of Seller, no investigation or review is pending or, to the knowledge of Seller,

threatened against Seller by any Governmental Entity with respect to any alleged, actual, possible or potential violation, or failure to comply with by Seller of any Law applicable to the CF Enterprise, Acquired Assets or Assumed Liabilities.

(b) Set forth on Section 2.15(b) of the Seller Disclosure Letter are all Permits held by Seller that are required in connection with the ownership, operation or Development of the Acquired Assets as currently owned, operated and Developed, each of which is valid and in full force and effect, and none of such Permits will lapse, terminate, expire or otherwise be impaired as a result of the execution or delivery of this Agreement or the Related Agreements by Seller or the consummation of the transactions contemplated hereby and thereby. Except for the Transferred Permits, there are no Permits, whether written or oral, necessary or required in connection with the ownership, operation or Development of the Acquired Assets as currently owned, operated and Developed. No notice, citation, summons or order has been issued, no complaint has been filed and served, no penalty has been assessed and notice thereof given, and no investigation or review is pending or, to the knowledge of Seller, threatened against Seller by any Governmental Entity with respect to any alleged, actual, possible or potential violation, failure to comply with, or failure to have, any Permit required in connection with the Acquired Assets. No event has occurred or circumstance exists that (with or without notice or lapse of time) is reasonably likely to give rise to the loss of or refusal to renew the Transferred Permits.

Section 2.16 Compliance with Anti-Bribery Laws

- (a) Neither Seller nor any its Representatives or Affiliates, or any other Person acting on behalf of Seller, has:
- (i) made, authorized, offered or promised to make any payment, gift or transfer of anything of value, directly, indirectly or through a third party, to or for the use or benefit of any Official for the purpose of (a) unlawfully influencing any act, decision, or failure to act by an Official in his or her official capacity; or (b) inducing such Official to use unlawfully his or her influence with any Governmental Entity to affect any act or decision of the Governmental Entity in order to obtain, retain, or direct business or secure an improper advantage, in each case related to the Acquired Assets;
- (ii) made, authorized, offered or promised to make any payment, gift or transfer of anything of value, directly, indirectly or through a third party, to another individual in exchange for (or as a reward for) improper performance of a relevant function or activity related to the Acquired Assets;
- (iii) requested, accepted or agreed to accept a financial or other advantage, either directly or through a third party, in exchange for (or as a reward for) improper performance of a relevant function or activity related to the Acquired Assets; or
- (iv) made, authorized, offered or promised to make any unlawful bribe, rebate, payoff, influence payment or kickback or has taken any other action related to the Acquired Assets that would violate any Anti-Bribery Law binding on such Person or in effect in any jurisdiction in which such action is taken.
- (b) Seller maintains books, records, and accounts that, in reasonable detail, accurately and fairly reflect in all material respects its transactions and dispositions of its assets, and maintains a system of internal accounting controls sufficient to provide reasonable assurances that:
 - (i) its transactions related to the Acquired Assets are executed and its funds are expended in accordance with its management's authorization;

- (ii) its transactions related to the Acquired Assets are recorded as necessary to permit preparation of its financial statements in conformity with GAAP; and
 - (iii) access to the Acquired Assets is permitted in accordance with its management's authorization.
- (c) The ownership, Development, Manufacture, Commercialization and operation of the Acquired Assets has been in compliance with all Anti-Bribery Laws to which the ownership, Development, Manufacture, Commercialization and operation of the Acquired Assets are subject, as applicable, and Seller has engaged only in lawful business practices, in each case, in all material respects.
- **Section 2.17 Brokers' Fees**. No agent, broker, finder or investment banker other than Aquilo Partners, L.P. is entitled to any brokerage, finder's or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by, or on behalf of, Seller. Seller is solely responsible for the fees and expenses of any such agent, broker, finder or investment banker.
- **Section 2.18** <u>Sufficiency of Assets</u>. The Acquired Assets constitute a conveyance to Buyer, free and clear of any Encumbrance, other than Permitted Encumbrances, of all of the rights, property and assets that are owned, licensed or controlled by Seller or any of its Affiliates as of the Closing Date and that are necessary or useful for the ownership, Development, Manufacture, Commercialization and operation of the CF Enterprise. None of the Excluded Assets (including those set forth in <u>Section 1.01(b)</u> of the Seller Disclosure Letter), other than the DCE Platform Know-How, are necessary or useful for the ownership, Development, Manufacture, Commercialization and operation of the CF Enterprise. Immediately after the Closing, no Person shall have any right, title or interest in or right to use any of the Acquired Assets, other than Buyer. Immediately after the Closing, Buyer will own all assets that are used, held for use or necessary or useful for the ownership, Development, Manufacture, Commercialization and operation of the CF Enterprise, free and clear of any Encumbrance, other than Permitted Encumbrances.
- **Section 2.19** Solvency. Assuming satisfaction of the conditions to this Agreement and after giving effect to the transactions contemplated hereby, the assumption or retention (as applicable) of the Excluded Liabilities by Seller and its Affiliates, payment of all amounts required to be paid in connection with the consummation of the transactions contemplated hereby, and payment of all related fees and expenses, Seller and its Affiliates (on a consolidated basis) are not insolvent as of the Closing Date and the consummation of the transactions contemplated hereby shall not render Seller insolvent. As used herein, "insolvent" means the sum of Seller's debts and other probable Liabilities exceeds the present fair saleable value of Seller's assets. Seller has no current plans to file and prosecute a petition for relief under Chapter 11 or 7 of the United States Bankruptcy Code.
- **Section 2.20 Board Approval**. The Seller Board, by resolutions duly adopted at a meeting duly called and held and not subsequently rescinded or modified in any way (the "**Seller Board Approval**"), has (i) declared that this Agreement and the transactions contemplated hereby are advisable and in the best interests of Seller and the stockholders of Seller, (ii) approved this Agreement and the transactions contemplated hereby, (iii) recommended that the stockholders of Seller approve this Agreement and the transactions contemplated hereby and (iv) directed that this Agreement and the transactions contemplated hereunder be submitted to Seller's stockholders for their approval. No member of the Seller Board has voted against any of the foregoing.
- **Section 2.21 Information Supplied.** The information supplied by Seller for inclusion in the Proxy Statement will not, as of the date the Proxy Statement is first mailed to the stockholders of Seller, and at the time of the Seller Special Meeting, contain any untrue statement of a material fact, or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light

of the circumstances under which they were made, not misleading. Notwithstanding the foregoing sentence, Seller makes no representation or warranty with respect to any information supplied by Buyer or any of its Representatives for inclusion in the Proxy Statement. The Proxy Statement, when filed, will comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act.

Section 2.22 No Misrepresentation. To the knowledge of Seller, no representation or warranty or other statement made by Seller in this Agreement, the Seller Disclosure Letter, the certificates or documents delivered pursuant to Section 1.03(b) or otherwise in connection with the contemplated transactions contains any untrue statement or omits to state a material fact necessary to make any of them, in light of the circumstances in which it was made, not misleading. Seller does not have any knowledge of any fact related to the Acquired Assets that would reasonably be expected to materially adversely affect the assets, business, financial condition, or results of operations of the CF Enterprise that has not been set forth in this Agreement or the Seller Disclosure Letter.

Section 2.23 <u>Disclaimer</u>. Neither Seller nor any of its Affiliates or their respective Representatives has made, or shall be deemed to have made, any representation or warranty, express or implied, at law or in equity, in respect of Seller, the CF Enterprise, the Acquired Assets or the Assumed Liabilities, other than those expressly made by seller in this <u>Article II</u>, the certificate delivered pursuant to <u>Section 5.02(c)</u> or in one of the Related Agreements.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller as of the date hereof and as of the Closing Date that:

Section 3.01 Organization. Buyer is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation.

Section 3.02 Authorization of Transaction. Buyer has all requisite corporate power and authority to execute and deliver (or cause to be executed and delivered) this Agreement and each of the Related Agreements to which Buyer is (or will be as of the Closing) a party and to perform its obligations hereunder and under each of the Related Agreements to which it is (or will be as of the Closing) a party. The execution and delivery by Buyer of this Agreement and each of the Related Agreements to which it is (or will be as of the Closing) a party and the performance by Buyer of this Agreement and its obligations hereunder and thereunder, and the consummation by Buyer of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action on the part of Buyer and no other corporate or other proceedings or actions on the part of Buyer, its board of directors or stockholders are necessary therefor. This Agreement has been, and each Related Agreement to which it is (or will be at Closing) a party will be, duly and validly executed and delivered by Buyer and (assuming this Agreement and each of the Related Agreements to which Seller is (or will be at Closing) a party, constitutes the valid and binding obligation of Seller) constitutes (or will constitute) a valid and binding obligation of Buyer, enforceable against Buyer in accordance with their respective terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, fraudulent transfer, moratorium or other similar Laws relating to or affecting the rights of creditors generally and by general principles of equity.

- **Section 3.03** Noncontravention; Consents. Neither the execution, delivery or performance of this Agreement by Buyer or any of the Related Agreements to which Buyer is (or will be at Closing) a party, nor the consummation by Buyer of the transactions contemplated hereby or by the Related Agreements, will (with or without the giving of notice or the lapse of time, or both):
 - (a) conflict with or violate any provision of the charter or bylaws or other organizational documents of Buyer;
- (b) require on the part of Buyer any filing with, notice to, exemption from, or any Permit, authorization, consent or approval of, any Governmental Entity with respect to the Acquired Assets, except for (i) compliance by Buyer with the applicable requirements of the HSR Act and any other applicable Antitrust Laws, (ii) the Buyer Orphan Designation Letter, and (iii) the Buyer FDA Letter;
- (c) conflict with, violate or result in a breach of, constitute a default under, result in the acceleration of, create in any party any right to accelerate, terminate, modify or cancel, require any notice, right of first offer or refusal, consent or waiver under, or result in the loss of any right or privilege under, any Contract to which Buyer is a party or by which Buyer is bound or to which any of its assets are subject, except which do not, and would not reasonably be expected to, materially and adversely affect Buyer's ability to consummate the transactions contemplated hereby; or
- (d) conflict with or violate any Order or Law or other restriction of any Governmental Entity applicable to Buyer or any of its properties or assets;
 - except, in the case of clauses (b) through (d) of this Section 3.03, for such conflicts, breaches, defaults, consents, approvals, authorizations, declarations, filings or notices which would reasonably be expected to have a Buyer Material Adverse Effect.
- **Section 3.04 Broker's Fees**. No agent, broker, finder or investment banker is entitled to any brokerage, finder's or other similar fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by, or on behalf of, Buyer. Buyer is solely responsible for the fees and expenses of any such agent, broker, finder or investment banker.
- **Section 3.05** <u>Litigation</u>. There is no claim, complaint, action, suit, proceeding, hearing or investigation initiated, or, to the knowledge of Buyer, threatened, before any Governmental Entity or arbitral body against Buyer (but excluding any claim, complaint, action, suit, proceeding, hearing or investigation relating to sealed qui tam cases) which would adversely affect Buyer's performance under this Agreement or any Related Agreement or the consummation of the transactions contemplated by this Agreement or any Related Agreement. There are no outstanding Orders of any Governmental Entity or arbitral body against Buyer which would adversely affect Buyer's performance under this Agreement or any Related Agreement or the consummation of the transactions contemplated by this Agreement or any Related Agreement.
- **Section 3.06** Sufficiency of Funds. As of the date hereof, Buyer has, and at all times until the satisfaction of all of its obligations under this Agreement will have, sufficient cash, available lines of credit or other sources of immediately available funds on hand to enable it perform all of its obligations under this Agreement.
- **Section 3.07** Information Supplied. The information supplied by Buyer for inclusion in the Proxy Statement will not, as of the date the Proxy Statement is first mailed to the stockholders of Seller, and at the time of the Seller Special Meeting, contain any untrue statement of a material fact, or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing sentence, Buyer makes no representation or warranty with respect to any information supplied by Seller or any of its

Representatives for inclusion in the Proxy Statement. The information supplied by Buyer for inclusion in the Proxy Statement will comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act.

Section 3.08 Solvency. Assuming satisfaction of the conditions to this Agreement and after giving effect to the transactions contemplated hereby, the assumption or retention (as applicable) of the Assumed Liabilities by Buyer, payment of all amounts required to be paid in connection with the consummation of the transactions contemplated hereby, and payment of all related fees and expenses, neither the Buyer nor the Guarantor will be insolvent as of the Closing Date and the consummation of the transactions contemplated by this Agreement and the Related Agreements shall not render Buyer or the Guarantor insolvent. As used herein, "insolvent" means the sum of the debts and other probable Liabilities of the Buyer exceeds the present fair saleable value of the assets of the Buyer. Neither Buyer nor the Guarantor has current plans to file and prosecute a petition for relief under Chapter 11 or 7 of the United States Bankruptcy Code or any similar foreign Laws.

Section 3.09 Limited Representations. Buyer acknowledges, for itself and on behalf of its Affiliates, that none of Seller, its Affiliates or their respective Representatives or any other Person acting on their behalf has made any representation or warranty regarding the CF Enterprise, the Acquired Assets, the Assumed Liabilities or the transactions contemplated by this Agreement, except as expressly set forth in <u>Article II</u>, the certificate delivered pursuant to <u>Section 5.02(c)</u> or in one of the Related Agreements. Buyer acknowledges that, to the extent provided by Seller, none of Seller, its Affiliates or their respective Representatives thereof makes any representation or warranty with respect to any estimates, projections, forecasts or business plans (including the reasonableness of the assumptions underlying such estimates, projections, forecasts or plans).

ARTICLE IV

PRE-CLOSING COVENANTS

Section 4.01 **Operation of Business**.

- (a) Except as otherwise consented to in writing by Buyer, as set forth on <u>Section 4.01</u> of the Seller Disclosure Letter, the Research and Testing Agreement or as required by applicable Law or Order, or as expressly contemplated by this Agreement, during the period from the date of this Agreement until the Closing Date or the date, if any, on which this Agreement is earlier validly terminated pursuant to <u>Section 7.01</u> (the "**Pre-Closing Period**"), Seller shall:
 - (i) use commercially reasonable efforts to preserve the CF Enterprise and operate the Acquired Assets in the Ordinary Course; and
 - (ii) not materially deviate from the planned re-stocking of Transferred Inventory summarized on Section 4.01(a)(ii) of the Seller Disclosure Letter unless such material deviation is the result of a circumstance outside of Seller's control and to which Seller did not contribute. Seller shall promptly notify Buyer once it becomes aware of any actual or expected material deviation.

- (b) Except (1) as set forth on <u>Section 4.01(b)</u> of the Seller Disclosure Letter or as required by this Agreement, (2) as required by applicable Law or Order, or (3) with the written consent of Buyer, such consent not to unreasonably be withheld, conditioned or delayed, Seller shall not:
 - (i) sell, lease, abandon or otherwise dispose of or permit any Encumbrance (other than Permitted Encumbrances) on any Acquired Asset, except inventory in the Ordinary Course;
 - (ii) acquire any properties or assets that constitute Acquired Assets, either tangible or intangible, other than in the Ordinary Course;
 - (iii) (A) settle or commence any claim, complaint, action, suit, proceeding, hearing or investigation; or (B) waive any claims or rights, in either case in a manner that would constitute an Assumed Liability or with respect to the Acquired Assets, except, after reasonable consultation with Buyer, claims or rights relating to any Transaction Litigation that would not reasonably be expected to impair or adversely affect the Acquired Assets;
 - (iv) fail to pay in the Ordinary Course all payables and other Liabilities, in each case, that would constitute Assumed Liabilities, when due;
 - (v) (A) enter into, extend, modify, amend, terminate or renew or waive any right or remedy under any Assigned Contract (or any Contract that would be an Assigned Contract if entered into prior to the date hereof) or (B) knowingly take, or fail to take, any action that would constitute a breach, violate the terms, conditions or provisions of, or result in a default under, or give to others any rights of termination, amendment, acceleration or cancellation of any Assigned Contract;
 - (vi) except as otherwise expressly permitted or required under this Agreement, terminate or materially modify any ongoing clinical trial with respect to the Transferred Products;
 - (vii) take any action which would reasonably be likely to impair Buyer's rights in the Acquired Assets;
 - (viii) fail to maintain material insurance policies currently maintained by or on behalf of Seller or covering the Acquired Assets or the Assumed Liabilities unless comparable replacement policies with substantially similar coverage areas and amounts are procured;
 - (ix) fail to comply with all Laws applicable to the Acquired Assets and the Assumed Liabilities in all material respects;
 - (x) terminate or fail to maintain or renew any Transferred Permits;
 - (xi) dispose of or permit to lapse any Transferred IP; or
 - (xii) enter into any agreement, or otherwise become obligated, to do any action prohibited under <u>clauses (i)</u> (\underline{xi}) of this <u>Section 4.01(b)</u>.

Section 4.02 Access. During the Pre-Closing Period, Seller shall keep Buyer informed of all material developments relevant to the ownership, Development, Manufacture, Commercialization and operation of the Acquired Assets and its ability to consummate the transactions contemplated hereby, including with respect to the items set forth on Section 4.02 of the Seller Disclosure Letter. During the

Pre-Closing Period, subject to (a) compliance with applicable Laws and (b) any established legal privilege, Seller shall permit (or cause to be permitted) the Representatives of Buyer, at Buyer's expense, to have reasonable access (at reasonable times, on reasonable prior written notice and in a manner so as not to unreasonably disrupt the normal business operations of Seller or its Affiliates) to the premises, properties, financial and accounting records, employees, Contracts, and other records and documents, of or pertaining to the CF Enterprise, the Acquired Assets and the Assumed Liabilities, and such other relevant information and materials as may be reasonably requested. Buyer acknowledges that it remains bound by the amended and restated mutual confidentiality agreement, dated August 5, 2016, entered into between Buyer and Seller (the "Confidentiality Agreement"), provided that Buyer shall be authorized to engage in discussions with, and disclose confidential information (as defined in the Confidentiality Agreement) to, (i) Regulatory Authorities in connection with its post-closing integration planning and (ii) such other third-parties as may be required in connection with the conduct of activities under the Research and Testing Agreement. Prior to the Closing, except as contemplated by the Research and Testing Agreement, Buyer shall not, and shall cause each member of the Buyer Group and their respective Representatives not to, contact or communicate with the employees, customers and suppliers of Seller or any of their respective Affiliates in connection with the transactions contemplated by this Agreement without the prior written consent of Seller.

Section 4.03 Governmental Approvals and Consents.

Subject to the terms and conditions of this Agreement (including Section 4.03(f)), each Party will use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under this Agreement and applicable Laws to satisfy the conditions to Closing set forth herein and consummate the transactions contemplated hereby as soon as practicable after the date of this Agreement and in any event no later than the Outside Date, including (x) preparing and filing, in consultation with the other Party and as promptly as practicable and advisable after the date of this Agreement, all documentation (A) to effect all necessary applications, notices, petitions and other filings and (B) to obtain all waiting period expirations or terminations, registrations, permits and authorizations necessary or advisable to be obtained from any Governmental Entity in order to consummate the transactions contemplated hereby and (y) taking all steps as may be necessary to obtain all waiting period expirations or terminations, registrations, permits and authorizations, including defending or contesting any suit, action, legal proceeding or claim brought by a Third Party, including any Governmental Entities, that would otherwise prevent or materially impede, interfere with, hinder or delay the consummation of the transactions contemplated hereby. In furtherance and not in limitation of the foregoing, each Party agrees (i) to make all necessary applications, notices, petitions and filings required (and thereafter make any other required submissions and respond as promptly as practicable to any requests for additional information or documentary material) with respect to this Agreement or the transactions contemplated hereby with the Antitrust Division of the Department of Justice (the "DOJ") and the Federal Trade Commission (the "FTC") on a Notification and Report Form pursuant to the HSR Act with respect to the transactions contemplated hereby as promptly as practicable, and in any event within ten (10) Business Days after the execution of this Agreement (unless another date is mutually agreed between the Parties), and any other Governmental Entity under any other applicable Antitrust Law and (ii) to promptly determine whether any other filings are required to be made with, and whether any other consents, approvals, Permits or authorizations are required to be obtained from, any Governmental Entity under any other applicable Law in connection with the transactions contemplated hereby, and if so, to promptly prepare and file any such filings and to seek any such other consents, approvals, permits or authorizations (the filings described in the foregoing <u>clauses (i)</u> and <u>(ii)</u> collectively, "**Regulatory Filings**"). All filing fees required in connection with the Regulatory Filings shall be borne by Buyer.

(b) In connection with, and without limiting, the efforts or the obligations of the Parties under <u>Section 4.03(a)</u> but subject to <u>Section 4.03(f)</u>, each of Buyer and Seller shall, to the extent permitted

by applicable Law and not prohibited by the applicable Governmental Entity, (i) cooperate and coordinate in all respects with the other in the making of Regulatory Filings (including, to the extent permitted by applicable Law, providing copies, or portions thereof, of all such documents to the non-filing Parties prior to filing and considering all reasonable additions, deletions or changes suggested by the non-filing Parties in connection therewith) and in connection with resolving any investigation, request or other inquiry of any Governmental Entity under any applicable Law with respect to any such filing, (ii) supply the other Party and its counsel, as applicable, with any information and reasonable assistance that may be required or reasonably requested in connection with the making of such filings, including, within the time allowed by the relevant Governmental Entity and under applicable Law, any additional or supplemental information that may be required or reasonably requested by the FTC, the DOJ and the relevant Governmental Entities in any applicable jurisdiction in which any such filing is made under any other applicable Law and (iii) use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other Parties in doing, all things necessary, proper or advisable to obtain the expiration or termination of the applicable waiting periods (and any extension thereof) under the HSR Act or any other Antitrust Law (the "Antitrust Approvals"), in each case as soon as practicable, and to avoid any impediment to the consummation of the transactions contemplated hereby under any applicable Law, including using commercially reasonable efforts to take all such action as reasonably may be necessary to resolve such objections, if any, as the FTC, the DOJ or any other Governmental Entity or Person may assert with respect to the transactions contemplated hereby. Notwithstanding anything to the contrary in this Section 4.03(b), none of Buyer, on the one hand, or Seller, on the other hand, shall be required to agree to any term or take or refrain from taking any action in connection with obtaining the Antitrust Approvals that is not conditioned upon the consummation of the transactions contemplated hereby.

Each of Buyer, on the one hand, and Seller, on the other hand, shall, to the extent practicable and unless prohibited by applicable Law or by the applicable Governmental Entity, promptly inform the other of any material communication from any Governmental Entity regarding any of the transactions contemplated hereby in connection with any Regulatory Filings or investigations with, by or before any Governmental Entity relating to this Agreement or the transactions contemplated hereby, including any claims, complaints, actions, suits, proceedings, hearings or investigations initiated by a private party. If any Party or affiliate thereof shall receive a request for additional information or documentary material from any Governmental Entity with respect to a Regulatory Filing, then such Party shall, subject to <u>Section 4.03(f)</u>, use its commercially reasonable efforts to make, or cause to be made, as soon as reasonably practicable, an appropriate response in compliance with such request. In connection with and without limiting the foregoing, to the extent reasonably practicable and unless prohibited by applicable Law or by the applicable Governmental Entity, the Parties will (i) give each other reasonable advance notice of all meetings with any Governmental Entity relating to the transactions contemplated hereby, (ii) give each other an opportunity to participate in each of such meetings, (iii) keep the other Party reasonably apprised with respect to any material communications with any Governmental Entity regarding the transactions contemplated hereby, (iv) cooperate in the filing of any analyses, presentations, memoranda, briefs, arguments, opinions or other written communications explaining or defending the transactions contemplated hereby, articulating any regulatory or competitive argument or responding to requests or objections made by any Governmental Entity, (v) provide each other with a reasonable advance opportunity to review and comment upon, and consider in good faith the views of the other with respect to, all material written communications (including applications, analyses, presentations, memoranda, briefs, arguments and opinions) with a Governmental Entity regarding the transactions contemplated hereby and (vi) provide each other (or counsel of each Party, as appropriate) with copies of all material written communications to or from any Governmental Entity relating to the transactions contemplated hereby. Any such disclosures, rights to participate or provisions of information by one Party to the other may be made on a counsel-only basis to the extent required under applicable Law. It is acknowledged and agreed that, subject to the provisions of this Section 4.03(c) and except where

prohibited by applicable Law, Buyer shall have sole responsibility for determining strategy with respect to the Antitrust Approvals.

- (d) Buyer will not extend any waiting period under the HSR Act (by pull and refile, or otherwise) or any other Antitrust Laws or enter into any agreement with the FTC, the DOJ or any other Governmental Entity not to consummate the transactions contemplated hereby, except with the prior written consent of Seller. Neither Buyer nor Seller shall, nor shall they permit their respective Subsidiaries to, acquire or agree to acquire any business, Person or division thereof, or otherwise acquire or agree to acquire any assets, if the entering into of a definitive agreement relating to, or the consummation of, such acquisition could reasonably be expected to increase the risk of not obtaining the applicable consent, clearance, approval, authorization or waiver under the HSR Act or any Antitrust Law with respect to the transactions contemplated hereby.
- (e) Subject to Section 4.03(f), each of Buyer and Seller shall use its commercially reasonable efforts to obtain all of its respective consents, waivers, authorizations and approvals of all Third Parties (other than Governmental Entities, which are the subject of clauses (a)-(d) above) necessary, proper or advisable for the consummation of the transactions contemplated hereby and to provide any notices to Third Parties required to be provided by it prior to the Closing.
- (f) Nothing contained in this Section 4.03 or in any other provision of this Agreement shall be construed as requiring Buyer to agree to any terms or conditions as a condition to, or in connection with, obtaining any Antitrust Approval that would (i) impose any limitations on Buyer's ownership or operation of all or any portion of the Acquired Assets or all or any portion of its or its Subsidiaries', businesses or assets, or compel Buyer or any of its Subsidiaries to dispose of or hold separate all or any portion of the Acquired Assets or any portion of its or its Subsidiaries', businesses or assets, (ii) impose any limitations on the ability of Buyer to acquire or hold or to exercise full rights of ownership of the Acquired Assets, (iii) impose any obligations on Buyer or any of its Subsidiaries in respect of or relating to Buyer's or any of its Subsidiaries' facilities, operations, places of business, employment levels, products or businesses, (iv) require Buyer or any of its Subsidiaries to make any payments or (v) impose any other obligation, restriction, limitation, qualification or other condition on Buyer or any of its Subsidiaries (other than, with respect to clauses (iii), (iv) and (v), such terms or conditions as are reasonable and relate to the Ordinary Course and that are imposed by a Governmental Entity with power and authority to grant the Antitrust Approvals, and which, individually or in the aggregate, do not competitively disadvantage Buyer or any of its Subsidiaries) (any such term or condition in (i) through (v) being referred to herein as a "Burdensome Term or Condition").
- (g) Notwithstanding anything herein to the contrary, in no event shall Seller or any of its Subsidiaries agree to any obligation, restriction, requirement, limitation, qualification, condition, remedy or other action relating to the Antitrust Approvals without the prior written consent of Buyer; provided, that notwithstanding the foregoing (i) it is understood and agreed that any failure by Seller to agree to any such obligation, restriction, requirement, limitation, qualification, condition, remedy or other action by reason of Buyer's withholding its written consent from Seller to do so shall not constitute a breach of this Section 4.03 by Seller and (ii) Buyer shall be required to provide its written consent to Seller agreeing to any such obligation, restriction, requirement, limitation, qualification, condition, remedy or other action to the extent it would not, individually, or together with any other such obligation, restriction, requirement, limitation, qualification, condition, remedy or other action, impose a Burdensome Term or Condition.

- **Section 4.04** Notices of Certain Events. During the Pre-Closing Period, Seller and Buyer shall promptly notify the other Party of any of the following after gaining knowledge thereof:
- (a) any material actions, suits, claims or proceedings in connection with the transactions contemplated by this Agreement commenced or threatened against Seller relating to the Acquired Assets or the Assumed Liabilities, or Buyer, as the case may be;
- (b) the occurrence or non-occurrence of any fact or event which would be reasonably likely to cause any condition set forth in Article V of this Agreement not to be satisfied;
- (c) the occurrence or existence of any fact, circumstance or event which could result in any representation or warranty made by Seller in this Agreement or any exhibit, schedule or certificate or delivered herewith, to be untrue or inaccurate in any material respect;
- (d) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement;
- (e) any oral or written communication Seller receives from any Governmental Entity with respect to the Acquired Assets, the Assumed Liabilities or the transactions contemplated hereby;
- (f) the occurrence of any event, circumstance, development, state of facts, occurrence, change or Effect which has had a Seller Material Adverse Effect or the occurrence or non-occurrence of any event, circumstance, development, state of facts, occurrence, change or effect which would reasonably be expected, individually or in the aggregate to result in a Seller Material Adverse Effect; and
- (g) any filings, payments or similar actions that must be taken within 120 days of the Closing Date for the purposes of obtaining, maintaining, perfecting or renewing registration of Registered IP.

If Seller provides a notification pursuant to this <u>Section 4.04(a)</u>, (b), (c), (f) and (g) prior to the Closing, Seller shall also, by notice in accordance with the terms of this Agreement, supplement or amend the Seller Disclosure Letter (each, a "**Supplement**"), in order to correct any matter that first arises after the date hereof which may constitute a breach of any representation, warranty, agreement or covenant contained herein. If Buyer does not provide a written termination notice pursuant to <u>Section 7.01(h)</u> within five (5) Business Days after the expiration of the thirty (30) day cure period set forth in <u>Section 7.01(b)</u>, Buyer shall be deemed to have waived its rights (i) to terminate this Agreement pursuant to <u>Section 7.01(b)</u> and (ii) to seek indemnification from Seller in accordance with <u>Section 6.02</u>, in each case, solely with respect to the subject matter of such Supplement.

Section 4.05 Release of Encumbrances. Seller shall take all actions required of Seller to cause any Encumbrance, other than Permitted Encumbrances, on the Acquired Assets to be terminated and released as of the Closing. For the avoidance of doubt, nothing in this Section 4.05 modifies Seller's obligation to deliver the Acquired Assets free and clear of all Encumbrances, other than Permitted Encumbrances.

Section 4.06 No Solicitation by Seller; Seller Board Recommendation.

(a) During the Pre-Closing Period, Seller shall not, and shall cause its Subsidiaries and their respective Representatives not to, directly or indirectly, solicit, initiate, knowingly encourage or knowingly facilitate, or furnish or disclose non-public information in furtherance of, any inquiries that would reasonably be expected to lead to, or the making of any proposal or offer to implement, any Alternative Transaction, or negotiate or otherwise engage in discussions with any Person (other than Buyer or its Representatives) with respect to any Alternative Transaction, or approve, recommend or authorize any

Alternative Transaction, or enter into any agreement, arrangement or understanding with respect to any Alternative Transaction or requiring it to abandon, terminate or fail to consummate the sale of the Acquired Assets in accordance with the terms hereof; <u>provided</u>, that at any time prior to receipt of the Seller Stockholder Approval (and in no event after receipt of the Seller Stockholder Approval), Seller may furnish information or afford access to, and negotiate or otherwise engage in discussions with, any Third Party who delivers a bona fide written proposal for an Alternative Transaction that was not solicited after the date of this Agreement or in violation of this <u>Section 4.06</u>, if and so long as the Seller Board determines in good faith after consultation with its outside legal counsel that failure to take such action would be reasonably likely to be inconsistent with the Seller Board's fiduciary duties under Delaware Law and determines in good faith that such a proposal is, or would reasonably be expected to lead to, a Superior Proposal.

- (b) During the Pre-Closing Period, Seller shall notify Buyer promptly (but in any event within 24 hours) of any inquiries, proposals or offers received by, or any discussions or negotiations sought to be initiated or continued with, Seller or any of its Representatives, in each case relating to an Alternative Transaction, indicating the name of such Person and providing to Buyer a summary of the material terms of such proposal or offer for an Alternative Transaction. Prior to providing any information or data to, or entering into any negotiations or discussions with, any Person in connection with a proposal or offer for an Alternative Transaction, Seller shall receive from such Person an executed confidentiality agreement containing confidentiality terms and provisions at least as restrictive as those contained in the Confidentiality Agreement (which shall not preclude discussions or negotiations relating to the proposal or offer from such Person and which shall not contain any exclusivity provision or other term that would restrict, in any manner, Seller's ability to consummate the transactions contemplated by this Agreement). Seller agrees that it will keep Buyer reasonably informed, on a reasonably prompt basis, of the status and material terms of any such proposals or offers (including any material developments) in respect of any such discussions or negotiations and that it will deliver to Buyer a summary of any material changes to any such proposals or offers and all nonpublic information being furnished to such Person not previously provided to Buyer.
- (c) Seller agrees that it will immediately cease and cause to be terminated any existing activities, discussions or negotiations with any Third Parties conducted prior to the date of this Agreement with respect to any Alternative Transaction (and promptly terminate all physical and electronic data room access previously granted to any such Third Party) and will not terminate, amend, modify or waive any provision of any confidentiality or standstill agreement to which it is a party and shall enforce, to the fullest extent permitted under applicable Law, the provisions of any such agreement.
- (d) Notwithstanding anything in this Section 4.06 or Section 4.07 to the contrary, at any time prior to the receipt of the Seller Stockholder Approval (and in no event after the receipt of the Seller Stockholder Approval), the Seller Board may (i) effect a Seller Change of Recommendation in response to a Seller Intervening Event or (ii) effect a Seller Change of Recommendation and, subject to compliance with this Section 4.06 and Section 7.01(g), terminate this Agreement in accordance with Section 7.01(g), following receipt of an unsolicited bona fide written proposal for an Alternative Transaction after the date of this Agreement, which the Seller Board determines in good faith by resolution duly adopted after consultation with its outside legal counsel is a Superior Proposal, in each case with respect to clauses (i) and (ii), if and only if the Seller Board determines in good faith after consultation with its outside legal counsel that such action would be reasonably likely to be inconsistent with the Seller Board's fiduciary duties under Delaware Law and Seller has complied in all material respects with the applicable provisions of this Section 4.06 with respect thereto. Prior to effecting a Seller Change of Recommendation or Seller Change of Recommendation and termination of this Agreement in accordance with Section 7.01(g) as provided above, Seller shall provide Buyer with five (5) Business Days' prior written notice (it being understood and agreed that any amendment to the financial terms or any other material term of such applicable Alternative Transaction or any change to the material facts or circumstances relating to such Seller Intervening Event shall, in each case, require a

new written notice and a new three (3) Business Day period commencing at the time of such new notice) advising Buyer of Seller's intention to effect a Seller Change of Recommendation or Seller Change of Recommendation and termination of this Agreement in accordance with Section 7.01(g) as provided above, and specifying in reasonable detail (i) in the case of an Alternative Transaction, the material terms and conditions of, and the identity of any Person proposing, such Alternative Transaction or (ii) in the case of a Seller Intervening Event, the material facts and circumstances relating to such Seller Intervening Event, and that Seller shall, during such time and if requested by Buyer, engage in good faith negotiations with Buyer (including by making its officers and its legal advisors reasonably available to negotiate) to amend this Agreement (x) such that the proposed Alternative Transaction would no longer constitute a Superior Proposal or (y) in a manner that obviates the need to effect a Seller Change of Recommendation, as applicable. The Parties agree that nothing in this Section 4.06 shall in any way limit or otherwise affect Buyer's right to terminate this Agreement pursuant to Section 7.01(c) at such time as the requirements of such subsection have been met. Any such Seller Change of Recommendation shall not change the approval of this Agreement or any other approval of the Seller Board in any respect that would have the effect of causing any state corporate takeover statute or other similar statute to be applicable to the transactions contemplated hereby. Notwithstanding any Seller Change of Recommendation, if this Agreement is not otherwise terminated by either Party in accordance with the terms hereof, this Agreement shall be submitted to the stockholders of Seller at the Seller Special Meeting for the purpose of voting on the authorization of this Agreement and the transactions consummated hereby, and nothing contained herein, including any rights of Seller to take certain actions pursuant to Section 4.06, shall be deemed to relieve Seller of such obligation. Nothing contained in this Agreement shall prohibit Seller from (A) complying with Rule 14a-9, Rule 14d-9 and Rule 14e-2(a) promulgated under the Exchange Act; provided, that any such action made that relates to an Alternative Transaction shall be deemed to be a Seller Change of Recommendation unless the Seller Board recommends against the Alternative Transaction and reaffirms the Seller Board Recommendation in connection with such action, (B) making any disclosure to the stockholders of Seller if the Seller Board determines in good faith, after consultation with its outside legal counsel, that failure to take such action would be reasonably likely to be inconsistent with the Seller Board's fiduciary duties under Delaware Law or (C) informing any Person of the existence of the provisions contained in this Section 4.06; provided, however, that neither the Seller Board nor any committee thereof shall, except as expressly permitted by this Section 4.06(d), effect any Seller Change of Recommendation, it being understood that a "stop, look and listen" communication to the stockholders of Seller pursuant to Rule 14d-9(f) under the Exchange Act (or any similar communication to the stockholders of Seller) shall not be deemed to be or constitute a Seller Change of Recommendation.

Section 4.07 Preparation of the Proxy Statement; Seller Stockholders' Meeting.

(a) As promptly as reasonably practicable following the date of this Agreement (but in any event, no more than twenty (20) days following the date of this Agreement), Seller shall prepare and cause to be filed with the SEC the Proxy Statement in preliminary form, in such form and substance as Seller shall determine and providing Buyer with an opportunity to review (and Seller will give reasonable and due consideration to all comments by Buyer) and in compliance as to form in all material respects with the applicable provisions of the Securities Act and the rules and regulations thereunder. Each of Seller and Buyer shall furnish all information concerning itself, its Affiliates and the holders of its Common Stock to the other and provide such other assistance as may be reasonably requested by such other Party in connection with the preparation, filing and distribution of the Proxy Statement. Seller shall promptly notify Buyer upon the receipt of any comments from the SEC or any request from the SEC for amendments or supplements to the Proxy Statement, and shall, as promptly as reasonably practicable after receipt thereof, provide Buyer with copies of all correspondence related to the Proxy Statement between it and its Representatives, on one hand, and the SEC, on the other hand, and all written comments with respect to the Proxy Statement received from the SEC, and advise Buyer of any oral comments with respect to the Proxy Statement received from the SEC with respect

to the Proxy Statement. Notwithstanding the foregoing, no filing of any amendment or supplement to the Proxy Statement or response to any comments of the SEC with respect to the Proxy Statement or any amendment or supplement thereof shall be made by Seller without providing Buyer with an opportunity to review (and Seller will give reasonable and due consideration to all comments by Buyer), except to the extent such amendment, supplement or response are made in connection with an Alternative Transaction as permitted by Section 4.06.

- (b) Without limiting the generality of the foregoing, the information supplied or to be supplied by either Party for inclusion or incorporation by reference in the Proxy Statement shall not, on the date the Proxy Statement (or any amendment thereof or supplement thereto) is first mailed to stockholders of Seller, at the time of the Seller Special Meeting, or as of the Closing Date, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. If, at any time prior to the Closing Date, any information relating to Seller or Buyer, or any of their respective Affiliates, should be discovered by Seller or Buyer that, in the reasonable judgment of Seller or Buyer, should be set forth in an amendment of, or a supplement to, the Proxy Statement, so that the Proxy Statement would not include any misstatement of a material fact or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Party that discovers such information shall promptly notify the other Party, and Seller and Buyer shall cooperate in the prompt filing with the SEC of any necessary amendment of, or supplement to, the Proxy Statement and, to the extent required by Law, in disseminating the information contained in such amendment or supplement to stockholders of Seller. Nothing in this Section 4.07(b) shall limit the obligations of any Party under Section 4.07(a). For purposes of this Section 4.07, any information concerning or related to Buyer or its Affiliates or their respective Representatives will be deemed to have been provided by Buyer.
- (c) Subject to the provisions of Section 4.06, Seller shall, in accordance with applicable Law and Seller's charter and bylaws, establish a record date for, duly call, give notice of, convene and hold the Seller Special Meeting as promptly as reasonably practicable after the date hereof, for the purpose of obtaining the Seller Stockholder Approval; provided, that the Seller Special Meeting shall occur no more than thirty (30) Business Days after the date that the SEC has advised that it will not provide further comments on the Proxy Statement (or the date on which the ten-day period referred to in Rule 14a-6 under the Exchange Act has expired without receipt of SEC comments or notice from the SEC that it will provide comments). Subject to the provisions of <u>Section 4.06</u> and compliance with applicable Law, Seller shall, as promptly as reasonably practicable on or after the date that the SEC has advised that it will not provide further comments on the Proxy Statement (or the date on which the ten-day period referred to in Rule 14a-6 under the Exchange Act has expired without receipt of SEC comments or notice from the SEC that it will provide comments) (but it any event no more than five (5) Business Days thereafter), mail the Proxy Statement to the stockholders of Seller. Subject to the provisions of Section 4.06, Seller (i) shall include in the Proxy Statement the Seller Board Recommendation, (ii) shall use its reasonable best efforts to solicit and obtain the Seller Stockholder Approval, and (iii) shall not withhold, withdraw, amend, modify or qualify (or publicly propose to or publicly state that it intends to withdraw, amend, modify or qualify) in any manner adverse to Buyer the Seller Board Recommendation (it being understood that publicly taking a neutral position or no position with respect to an Alternative Transaction (other than a "stop, look and listen" communication to the stockholders of Seller pursuant to Rule 14d-9(f) under the Exchange Act (or any similar communication to the stockholders of Seller) shall be considered a modification to the Seller Board Recommendation in a manner adverse to Buyer) (collectively, a "Seller Change of Recommendation"), except to the extent permitted by Section 4.06. Notwithstanding the foregoing provisions of this Section 4.07(c), Seller shall be permitted to recess, adjourn, postpone or delay the Seller Special Meeting without the prior consent of Buyer if and solely to the extent

that: (i) there are holders of an insufficient number of Common Stock present or represented by a proxy at the Seller Special Meeting to constitute a quorum at the Seller Special Meeting, <u>provided</u>, that any such recesses, adjournments, postponements or delays shall not cause the Seller Special Meeting to be recessed, adjourned, postponed or delayed by more than fifteen (15) days after the initial date established for the Seller Special Meeting; (ii) Seller has not received proxies representing a sufficient number of Common Stock to obtain the Seller Stockholder Approval, <u>provided</u>, that any such adjournments, postponements or delays shall not cause the Seller Special Meeting to be adjourned, postponed or delayed by more than more than fifteen (15) days after the initial date established for the Seller Special Meeting; (iii) such adjournment, postponement, delay or cancellation is required by applicable Law or a request from the SEC or its staff; or (iv) in the good faith judgment of the Seller Board (after consultation with its outside legal advisors), the failure to adjourn, postpone or delay the Seller Special Meeting would be reasonably likely to not allow sufficient time under applicable Laws for the distribution and review of any required or appropriate supplement or amendment to the Proxy Statement by Seller's stockholders prior to the Seller Special Meeting as then-scheduled.

ARTICLE V

CONDITIONS PRECEDENT TO CLOSING

- **Section 5.01** Conditions to the Obligations of Each Party. The respective obligations of Buyer and Seller to consummate the transactions contemplated hereby are subject to the satisfaction or waiver (if permissible under applicable Law) by Buyer or Seller, as appropriate, at or before the Closing Date, of each of the following conditions:
 - (a) the Seller Stockholder Approval shall have been obtained;
- (b) no Order, stipulation or injunction by any Governmental Entity of competent jurisdiction shall be in effect which prevents, makes illegal, or limits the consummation of any of the transactions contemplated by this Agreement, and no action, suit or proceeding shall be pending by or before any Governmental Entity of competent jurisdiction seeking an Order, stipulation or injunction seeking to enjoin, restrain or otherwise prevent or prohibit the consummation of, or limit, any of the transactions contemplated by this Agreement;
- (c) no Law shall have been enacted, promulgated or deemed applicable to the transactions contemplated hereby by any Governmental Entity that prevents the consummation of such transactions or has the effect of making such consummation thereof illegal or otherwise prohibiting, restraining or enjoining the consummation of such transactions;
- (d) all waiting periods under the HSR Act and any other applicable Antitrust Laws (and any extensions thereof) shall have been terminated or shall have expired; and
 - (e) the Escrow Agreement shall have been duly executed and delivered by the Escrow Agent.
- **Section 5.02** <u>Conditions to Obligations of Buyer</u>. In addition to the satisfaction or waiver, as applicable, of the conditions under <u>Section 5.01</u>, the obligation of Buyer to consummate the transactions to be consummated at the Closing is subject to the satisfaction (or waiver (if permissible under applicable Law) in writing by Buyer) of the following conditions:
- (a) (i) each of the Fundamental Representations of Seller set forth in <u>Article II</u> shall be true and correct (disregarding all qualifications and exceptions as to materiality or Seller Material Adverse Effect contained therein) in all material respects on and as of the date of this Agreement and on and as of

the Closing Date (except with respect to representations and warranties that address matters only as of a particular date, in which case, as of such other date); and (ii) each of the representations and warranties of Seller set forth in Article II (other than the Fundamental Representations) shall be true and correct (disregarding all qualifications and exceptions as to materiality or Seller Material Adverse Effect contained therein) on and as of the date of this Agreement and on and as of the Closing Date (except with respect to representations and warranties that address matters only as of a particular date, in which case, as of such other date), except for failures of such representations and warranties to be true and correct as to matters that would not reasonably be expected to have a Seller Material Adverse Effect;

- (b) Seller shall have performed or complied in all material respects with the agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Closing;
- (c) Seller shall have delivered to Buyer a certificate, validly executed by a duly authorized officer of Seller, dated as of the Closing Date, certifying that each of the conditions specified in <u>clauses (a)</u>, (b) and (h) of this <u>Section 5.02</u> is satisfied;
- (d) Seller shall have delivered a certificate of non-foreign status satisfying the requirements of Treasury Regulation <u>Section</u> <u>1.1445-2(b)</u> in a form reasonably acceptable to Buyer;
- (e) Seller shall have delivered to Buyer all other items listed in <u>Section 1.03(b)</u> not otherwise delivered under this <u>Section 5.02</u>;
- (f) Seller shall have delivered to Buyer letters from Seller to the FDA transferring to Buyer or any of its designees ownership of (i) Investigational New Drug Application # 12855 (and any additional applications with the FDA) in substantially the form attached hereto as <u>Exhibit E-1</u> (the "Seller FDA Letter") and (ii) the orphan drug designation of CTP-656 in substantially the form attached hereto as <u>Exhibit E-2</u> (the "Seller Orphan Designation Letter");
 - (g) Seller shall have delivered a counterpart to the Escrow Agreement, duly executed by Seller;
- (h) All Third Party consents and notices set forth on <u>Section 5.02(h)</u> of the Seller Disclosure Letter shall have been obtained or delivered, as applicable, in form and substance reasonably satisfactory to Buyer;
 - (i) Since the date of this Agreement, there shall not have occurred a Seller Material Adverse Effect;
 - (j) No Antitrust Approval shall, individually or in the aggregate, impose any Burdensome Term or Condition; and
- (k) Seller shall have in its inventory, a minimum quantity of Transferred Inventory with respect to CTP-656 Free Base equal to forty (40) kilograms.
- **Section 5.03 Conditions to Obligations of Seller.** The obligation of Seller to consummate (or cause to be consummated) the transactions to be consummated at the Closing are subject to the satisfaction (or waiver in writing by Seller) of the following conditions:
- (a) (i) each of the Fundamental Representations of Buyer set forth in <u>Article III</u> shall be true and correct (disregarding all qualifications and exceptions as to materiality or Buyer Material Adverse Effect contained therein) in all material respects on and as of the date of this Agreement and on and as of the Closing Date (except with respect to representations and warranties that address matters only as of a particular date, in which case, as of such other date); and (ii) each of the representations and warranties of

Buyer set forth in <u>Article III</u> (other than the Fundamental Representations) shall be true and correct (disregarding all qualifications and exceptions as to materiality or Buyer Material Adverse Effect contained therein) on and as of the date of this Agreement and on and as of the Closing Date (except with respect to representations and warranties that address matters only as of a particular date, in which case, as of such other date), except for failures of such representations and warranties to be true and correct as to matters that would not reasonably be expected to have a Buyer Material Adverse Effect;

- (b) Buyer shall have performed or complied with in all material respects its agreements and covenants required to be performed or complied with by it under this Agreement at or prior to the Closing;
- (c) Buyer shall have delivered to Seller a certificate, validly executed by a duly authorized officer of Buyer, dated as of the Closing Date, certifying that each of the conditions specified in <u>clauses (a)</u> and <u>(b)</u> of this <u>Section 5.03</u> is satisfied;
 - (d) Buyer shall have delivered a counterpart to the Escrow Agreement, duly executed by Buyer;
- (e) Buyer shall have delivered to Seller letters from Buyer or any of its designees to the FDA accepting ownership of (i) Investigational New Drug Application # 12855 (and any additional applications with the FDA) issued by the FDA in substantially the form attached hereto as Exhibit F-1 (the "Buyer FDA Letter") and (ii) the orphan drug designation of CTP-656 in substantially the form attached hereto as Exhibit F-2 (the "Buyer Orphan Designation Letter"); and
- (f) Buyer shall have delivered to Seller all other items listed in $\underline{\text{Section } 1.03(\underline{b})}$ not otherwise delivered under this $\underline{\text{Section}}$ 5.03.

ARTICLE VI

INDEMNIFICATION

Section 6.01 Survival.

- (a) Other than claims alleging fraud or willful or intentional misconduct or breach of this Agreement, the representations and warranties of Seller and Buyer set forth in this Agreement and the certificates delivered at Closing pursuant to Sections 5.02(c) and 5.03(c) shall survive the Closing for a period of eighteen (18) months from the Closing Date, other than for the representations and warranties of Seller contained in Section 2.01 (Organization, Qualification and Corporate Power), Section 2.02 (Title to Assets), Section 2.03 (Authority), Section 2.05 (Non-Contravention; Consents) and Section 2.17 (Brokers' Fees), and of Buyer contained in Sections 3.01 (Organization), Section 3.02 (Authorization of Transaction) and Section 3.04 (Brokers' Fees), (collectively, the "Fundamental Representations"), which shall survive the Closing until the date that is sixty (60) days after the expiration of the applicable statute of limitations.
- (b) The covenants and agreements to be performed by or on behalf of a Party prior to the Closing shall survive the Closing for a period of twenty four (24) months from the Closing Date. The covenants or other agreements contained in this Agreement that by their terms are to be performed by or on behalf of a Party after the Closing shall survive until the date that such covenants and agreements are fully performed.
- (c) No Person shall be liable for any claim for indemnification under this <u>Article VI</u> unless a Claim Notice is delivered by the Person seeking indemnification to the Person from whom indemnification is sought prior to the expiration of the applicable survival period, in which case the representation, warranty, covenant or agreement which is the subject of such claim shall survive, to the extent

of the claims described in such Claim Notice only, until such claim is resolved, whether or not the amount of the Damages resulting from such breach has been finally determined at the time the notice is given.

- (d) The right of a Person to any remedy pursuant to this <u>Article VI</u> shall not be affected by any investigation or examination conducted, or any knowledge possessed or acquired (or capable of being possessed or acquired), by such Person at any time concerning any circumstance, action, omission or event relating to the accuracy or performance of any representation, warranty, covenant or obligation.
- **Section 6.02** Indemnification by Seller. Subject to the terms and conditions of this Article VI, from and after the Closing, Seller shall defend, indemnify and hold harmless Buyer and its Subsidiaries and their respective officers, directors, Affiliates, stockholders, members, partners and each of the heirs, executors, successors and assigns of any of the foregoing (collectively, the "Buyer Indemnified Parties") in respect of any and all Damages incurred as a result or arising out of:
- (a) any (i) breach of any representation or warranty of Seller in this Agreement or the certificate of Seller delivered at the Closing pursuant to Section 5.02(c) (without giving effect to any "Seller Material Adverse Effect" or other materiality threshold or qualifier contained therein, except in the case of the representation contained in Section 2.07(c)), or (ii) failure to perform any covenant or agreement of Seller contained in this Agreement or the Related Agreements;
 - (b) Seller's and its Affiliates' failure, fully or timely, to pay, satisfy or perform the Excluded Liabilities;
 - (c) any Tax for which Seller is responsible pursuant to Section 8.01;
 - (d) any Tax imposed on or relating to Acquired Assets that is attributable to any Pre-Closing Tax Period;
- (e) any failure by Seller, or claim by a creditor of Seller that Seller has failed to comply with the provisions of any applicable bulk sales, bulk transfer or similar Laws; or
- (f) all costs and Liabilities, including product Liability, associated with the open-label Phase 2 clinical trial of CTP-656 in Europe, including all costs associated with termination of such clinical trial.
- **Section 6.03** <u>Indemnification by Buyer</u>. Subject to the terms and conditions of this <u>Article VI</u>, from and after the Closing, Buyer shall indemnify Seller and its Subsidiaries and their respective officers, directors, Affiliates, stockholders, members, partners and each of the heirs, executors, successors and assigns of any of the foregoing (collectively, the "**Seller Indemnified Parties**") in respect of, and hold the Seller Indemnified Parties harmless against, any and all Damages incurred as a result or arising out of:
- (a) any (i) breach of any representation or warranty of Buyer contained in <u>Article III</u> of this Agreement or the certificate of Buyer delivered at the Closing pursuant to <u>Section 5.03(c)</u> (without giving effect to any "Buyer Material Adverse Effect" or other materiality threshold or qualifier contained therein), or (ii) failure to perform any covenant or agreement of Buyer contained in this Agreement or the Related Agreements;
 - (b) Buyer's and its Affiliates' failure, fully or timely, to pay, satisfy or perform the Assumed Liabilities;
 - (c) any Tax for which Buyer is responsible pursuant to Section 8.01; or

(d) any Tax imposed on or relating to Acquired Assets that is attributable to any Post-Closing Tax Period.

Section 6.04 Claims for Indemnification.

(a) Third Party Claims.

- (i) All claims for indemnification made under this Agreement resulting from, related to or arising out of a Third Party claim, action, suit or proceeding (a "Third Party Claim") against an Indemnified Party shall be made in accordance with the following procedures. A Person entitled to indemnification under this Article VI (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any Third Party Claim for which indemnification may be sought or, if earlier, upon the written assertion of any such Third Party Claim; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party of any Liability hereunder, except to the extent that the Indemnifying Party has been materially prejudiced thereby, and then only to such extent. Within twenty (20) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim, so long as prior to the Indemnifying Party assuming control of such defense, it has provided reasonable assurance to the Indemnified Party (A) of its financial ability to assume the cost of such Third Party Claim and (B) that, as between the Indemnifying Party and the Indemnified Party, any Damages related to such Third Party Claim shall be the responsibility of the Indemnifying Party (subject to any applicable limitations provided in <u>Section 6.05</u>); <u>provided</u>, that the Indemnifying Party shall not be entitled to assume control of such defense and shall pay the fees and expenses of counsel retained by the Indemnified Party if (i) the Third Party Claim seeks an injunction or other equitable or non-monetary relief, (ii) the maximum amount the Indemnified Party would be entitled to recover under this Article VI in respect of such Third Party Claim is anticipated to be more than the Cap, (iii) the Indemnified Party has been advised in writing by its counsel that a reasonable likelihood exists of a conflict of interest between the Indemnifying Party and the Indemnified Party, and (iv) upon petition by the Indemnified Party, the appropriate court rules that the Indemnifying Party failed or is failing to vigorously prosecute or defend such Third Party Claim. If the Indemnifying Party does not assume control of such defense in accordance with the terms hereof, the Indemnified Party shall control such defense.
- (ii) The Party not controlling such defense may participate therein at its own expense and may retain separate co-counsel at its own expense; <u>provided</u>, that if (A) the Indemnifying Party shall have failed, or is not entitled, to assume the defense of such Third Party Claim in accordance with <u>Section 6.04(a)(i)</u>, (B) the employment of such counsel has been specifically authorized in writing by the Indemnifying Party, which authorization shall not be unreasonably withheld, conditioned or delayed, or (C) the named parties to any such action (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party and such Indemnified Party shall have been advised in writing by such counsel that there may be one (1) or more legal defenses available to the Indemnified Party which are not available to the Indemnifying Party, or are available to the Indemnifying Party but the assertion of which would be adverse to the interests of the Indemnified Party, the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith shall be considered Damages for purposes of this Agreement; <u>provided</u>, <u>however</u>,

that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one (1) counsel for all Indemnified Parties. The Party controlling such defense shall keep the other Party advised of the status of such Third Party Claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto.

- (iii) The Indemnified Party shall not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed so long as the Indemnifying Party is actively and diligently defending in good faith any such Third Party Claim. The Indemnifying Party shall not agree to any settlement of (y) such Third Party Claim that (A) does not include a complete and unconditional release of the Indemnified Party from all Liability with respect thereto, (B) has a finding or admission of any violation of Law or any violation of the rights of any Person, (C) imposes any injunctive relief or other restrictions of any kind or nature on any Indemnified Party or (D) imposes any Liability on the Indemnified Party, or (z) any matters with respect to Taxes that could reasonably be expected to adversely impact Buyer or the Acquired Assets in any Post-Closing Tax Period, in each case without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld, conditioned or delayed. Each of the Indemnifying Party and the Indemnified Party shall direct their respective counsel to reasonably cooperate with the other.
- (b) Procedure for Other Claims. An Indemnified Party wishing to assert a claim for indemnification under this Article VI which is not subject to Section 6.04(a) shall deliver to the Indemnifying Party a written notice (a "Claim Notice") which contains (i) a description and, if then known, the amount (the "Claimed Amount") of any Damages incurred by the Indemnified Party or the method of computation of the amount of such claim of any Damages, (ii) a statement that the Indemnified Party is entitled to indemnification under this Article VI and a reasonable explanation of the basis therefor, and (iii) a demand for payment in the amount of such Damages (including wire instructions if payment is requested to be made by wire transfer). Within twenty (20) days after delivery of a Claim Notice, the Indemnifying Party shall deliver to the Indemnified Party a written response in which the Indemnifying Party shall (A) agree that the Indemnified Party is entitled to receive all of the Claimed Amount (in which case, within five (5) Business Days of such response, the Indemnifying Party shall, as applicable, pay to the Indemnified Party by check or by wire transfer, or Seller and Buyer shall deliver joint written instructions to the Escrow Agent to release to the Indemnified Party from the Escrow Amount an amount equal to the Claimed Amount to the bank account or accounts designated by the Indemnified Party in a notice to the Indemnifying Party not less than two (2) Business Days prior to such payment), (B) agree that the Indemnified Party is entitled to receive part, but not all, of the Claimed Amount (the "Agreed Amount") (in which case, within five (5) Business Days of such response, the Indemnifying Party shall, as applicable, pay to the Indemnified Party by check or by wire transfer, or Seller and Buyer shall deliver joint written instructions to the Escrow Agent to release to the Indemnified Party from the Escrow Amount an amount equal to the Agreed Amount to the bank account or accounts designated by the Indemnified Party in a notice to the Indemnifying Party not less than two (2) Business Days prior to such payment), or (C) contest that the Indemnified Party is entitled to receive any of the Claimed Amount including the reasons therefor. If the Indemnifying Party in such response contests the payment of all or part of the Claimed Amount, the Indemnifying Party and the Indemnified Party shall use commercially reasonable efforts to resolve such dispute. If such dispute is not resolved within sixty (60) days following the delivery by the Indemnifying Party of such response, the Indemnifying Party and the Indemnified Party shall each have the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 10.09.

- **Section 6.05 Limitations**. (a) Subject to Section 10.13, from and after the Closing, the rights of the Indemnified Parties under this Article VI shall be the sole and exclusive remedies of the Indemnified Parties with respect to claims resulting from any breach of warranty or failure to perform any covenant or agreement contained in this Agreement or any Related Agreement or otherwise relating to the transactions that are the subject of this Agreement. Notwithstanding the foregoing or anything in this Agreement to the contrary, nothing contained in this Agreement shall relieve or limit the Liability of any Party or any officer or director of such Party from any liability arising out of or resulting from fraud or intentional or willful misconduct in connection with the transactions contemplated by this Agreement or the Related Agreement, or in connection with the delivery of any of the documents referred to herein or therein.
 - (b) Notwithstanding anything to the contrary contained in this Agreement, each of the following limitations shall apply:
 - (i) the aggregate liability of Seller for all Damages (y) under <u>Section 6.02(a)(i)</u> (other than in respect of fraud or intentional or willful misconduct by Seller or in respect of any Fundamental Representation of Seller) shall not exceed an amount equal to the Escrow Amount (the "Cap"); and (z) other than in respect of fraud or intentional or willful misconduct by Seller, under <u>Section 6.02(a)</u> shall not exceed an amount equal to the sum of the Base Purchase Price and any Contingent Payment paid pursuant to <u>Section 1.02(b)</u>;
 - (ii) a Buyer Indemnified Party shall have no right to indemnification under <u>Section 6.02(a)(i)</u> (other than in respect of fraud or intentional or willful misconduct by Seller or in respect of any Fundamental Representation of Seller, in each case, as to which the limitation shall not apply) unless and until the amount of Damages suffered by such Buyer Indemnified Party with respect to an individual claim under such sections exceeds \$50,000 (it being stated for the avoidance of doubt that Damages arising from any potential indemnification claims that arise out of or involve or relate to similar facts or are based on related or similar occurrences, events or circumstances will be aggregated and treated as an individual claim for this purpose) and the aggregate amount of Damages suffered by such Buyer Indemnified Party under such section exceeds \$1,600,000 (the "Aggregate Threshold"), whereupon the Buyer Indemnified Parties shall be indemnified for all Damages (including Damages up to the Aggregate Threshold), subject to the limitations contained in Section 6.05(b)(i);
 - (iii) the aggregate liability of Buyer for all Damages (y) under $\underline{Section~6.03(a)(i)}$ (other than on account of fraud or intentional or willful misconduct by Buyer or in respect of any Fundamental Representation of Buyer) shall not exceed an amount equal to the Cap; and (z) other than on account of fraud or willful misconduct by Buyer, under $\underline{Section~6.03(a)}$ shall not exceed an amount equal to the sum of the Base Purchase Price and any Contingent Payment paid pursuant to $\underline{Section~1.02(b)}$; and
 - (iv) a Seller Indemnified Party shall have no right to indemnification under Section 6.03(a)(i) (other than on account fraud or intentional or willful misconduct by Buyer or in respect of any Fundamental Representation of Buyer, in each case, as to which the limitation shall not apply) unless and until the amount of Damages suffered by such Seller Indemnified Party with respect to an individual claim under such sections exceeds \$50,000 (it being stated for the avoidance of doubt that Damages arising from any potential indemnification claims that arise out of or involve or relate to similar facts or are based on related or similar occurrences, events or circumstances will be aggregated and treated as an individual claim for this purpose) and the aggregate amount of Damages suffered by such

Seller Indemnified Party under such sections exceeds the Aggregate Threshold, whereupon the Seller Indemnified Parties shall be indemnified for all Damages (including Damages up to the Aggregate Threshold), subject to the limitations contained in Section 6.05(b)(iii).

- (c) In no event shall any Indemnifying Party be responsible and liable under this <u>Article VI</u> for special or punitive Damages, except to the extent that any of the foregoing are awarded to a Third Party against any Indemnified Party in circumstances in which such Indemnified Party is entitled to indemnification hereunder. In no event shall any Indemnifying Party be responsible and liable under this <u>Article VI</u> for indirect, consequential or incidental Damages except to the extent that (i) such Damages are awarded to a Third Party against any Indemnified Party in circumstances in which such Indemnified Party is entitled to indemnification hereunder, or (ii) such Damages are a reasonably foreseeable result of the event that gave rise thereto or the matter for which indemnification is sought hereunder.
- (d) The amount of any Damages for which indemnification is provided under this Article VI shall be computed net of any Third Party insurance proceeds actually received by the Indemnified Party (net of any retroactive premium adjustments and any other costs of collection), each Party agreeing (i) to use commercially reasonable efforts to recover all available insurance proceeds and (ii) to the extent any indemnity payment under this Agreement has been paid by the Indemnifying Party to or on behalf of the Indemnified Party prior to the receipt, directly or indirectly by the Indemnified Party of any net insurance proceeds under Third Party insurance policies on account of such Damages which duplicate, in whole or in part, the payment by the Indemnifying Party to or on behalf of the Indemnified Party, the Indemnified Party on account of such Damages which duplicate, in whole or in part, the payment made by the Indemnifying Party to or on behalf of the Indemnified Party. No Party shall be entitled to recover more than once for the same Damages.
- **Section 6.06** Manner of Payment. Subject to the limitations set forth in Section 6.05(b), any indemnification of Buyer pursuant to Section 6.02 shall be effected (i) first, by release of funds held by the Escrow Agent with respect to indemnification of Buyer pursuant to Section 6.02 for any Damages incurred up to an amount equal to the Escrow Amount pursuant to the terms of the Escrow Agreement and (ii) second, to the extent of any difference, by wire transfer of immediately available funds from Seller to an account designated in writing by Buyer. In the event any payment is to be made from the Escrow Account in accordance with this Section 6.06, Seller and Buyer shall deliver joint written instructions to the Escrow Agent to release to the Indemnified Party from the Escrow Account the appropriate amount by wire transfer in immediately available funds to the bank account or accounts designated by the Indemnified Party in a notice to the Indemnifying Party not less than two (2) Business Days prior to such payment.
- **Section 6.07** Right of Setoff. Upon notice to Seller specifying in reasonable detail the basis therefor, Buyer may, at its sole discretion, set off any amount to which it may be entitled under this Article VI that is the subject of a final, non-appealable decision from a court of competent jurisdiction against amounts otherwise payable pursuant to Section 1.02.
- **Section 6.08** Adjustment to Purchase Price. Any payment by Buyer or Seller, as the case may be, pursuant to this Article VI shall be treated as an adjustment to the Base Purchase Price for Tax purposes unless otherwise required by applicable Law.
- **Section 6.09** Release of the Escrow Account. On the eighteen (18) month anniversary of the Closing Date, to the extent the amount remaining in the Escrow Account exceeds any amounts which are the subject of any unresolved or unsatisfied claims for indemnifiable Damages pursuant to Section 6.02 that were properly made on or prior to the eighteen (18) month anniversary of the Closing Date in accordance with the provisions of this Article VI, Buyer and Seller shall deliver to the Escrow Agent a joint written

instruction in accordance with the terms of the Escrow Agreement to the effect that the Escrow Agent release any such excess amount to Seller as of such date. To the extent any amounts are retained in the Escrow Account pursuant to the immediately preceding sentence, Buyer and Seller shall instruct the Escrow Agent to release such funds, following the resolution of each such claim, to Buyer or to Seller in accordance with the resolution of the applicable claim, as appropriate.

ARTICLE VII

TERMINATION

Section 7.01 Termination of Agreement. The Parties may terminate this Agreement prior to the Closing as provided below:

- (a) by mutual written agreement of Seller and Buyer;
- (b) by Buyer if a breach of any representation or warranty or failure to perform any covenant or agreement on the part of Seller set forth in this Agreement shall have occurred that would cause any of the conditions set forth in Section 5.02(a) or (b) not to be satisfied, and such breach is incapable of being cured or not cured within thirty (30) days following Buyer's delivery of notice to Seller of such breach or failure to perform, provided, that Buyer may terminate this Agreement pursuant to this Section 7.01(b) only if, at the time of termination, Buyer is not in material breach of any of its representations, warranties, covenants or agreements contained in this Agreement;
- (c) by Seller if a breach of any representation or warranty or failure to perform any covenant or agreement on the part of Buyer set forth in this Agreement shall have occurred that would cause any of the conditions set forth in Section 5.03(a) or (b) not to be satisfied, and such breach is incapable of being cured or not cured within thirty (30) days following Seller's delivery of notice to Buyer of such breach or failure to perform, provided, that Seller may terminate this Agreement pursuant to this Section 7.01(c) only if, at the time of termination, Seller is not in material breach of any of its representations, warranties, covenants or agreements contained in this Agreement;
- (d) by Buyer, if the Seller Board (i) fails to make the Seller Board Recommendation referred to in <u>Section 4.06(d)</u> or shall fail to include in the Proxy Statement the Seller Board Recommendation, (ii) effects a Seller Change of Recommendation, (iii) authorizes, approves or recommends to Seller's stockholders, or otherwise authorizes, approves or publicly recommends, an Alternative Transaction or (iv) fails to publicly confirm the Seller Board Recommendation within ten (10) Business Days after a written request (which request must be reasonable under the circumstances) by Buyer that it do so following Seller's receipt of an Alternative Transaction;
 - (e) by Buyer, if there shall have been a material breach by Seller of Section 4.06 or Section 4.07;
 - (f) by Buyer or Seller by written notice to the other if;
 - (i) the condition set forth in $\underbrace{Section 5.01(b)}_{5.01(c)}$ or $\underbrace{Section 5.01(c)}_{5.01(c)}$ is not satisfied and the Order, stipulation or injunction giving rise to such non-satisfaction has become final and non-appealable; $\underbrace{provided}_{5.01(c)}$, that the right to terminate this Agreement pursuant to this $\underbrace{Section 7.01(f)(i)}_{5.01(c)}$ shall not be available to any party that has failed to perform fully its obligations under this Agreement in any manner that shall have proximately caused or resulted in the imposition of such Order, stipulation or injunction or the failure of such Order, stipulation or injunction to be resisted, resolved or lifted;

- (i) the Closing shall not have occurred on or before October 31, 2017 (the "**Outside Date**"); <u>provided</u>, <u>however</u>, that no Party may terminate this Agreement pursuant to this <u>Section 7.01(f)(ii)</u> if such Party's material breach of any representation, warranty, covenant or other obligation under this Agreement shall have proximately caused or resulted in the Closing not having occurred on or prior to the Outside Date; or
- (ii) the Seller Stockholder Approval is not obtained at the Seller Special Meeting or at any adjournment or postponement thereof, in each case at which a vote on such approval was taken; or
- (g) by Seller, <u>provided</u>, that it has complied with its obligations under <u>Section 4.06</u> and <u>Section 4.07</u>, at any time prior to obtaining the Seller Stockholder Approval at the Seller Special Meeting or at any adjournment or postponement thereof, in order to concurrently enter into a binding agreement for an Alternative Transaction that constitutes a Superior Proposal, if prior to or concurrently with such termination, Seller pays the Termination Fee (<u>as defined in Section 7.02(b</u>)); or
- (h) by Buyer within five (5) Business Days following the cure period set forth in <u>Section 7.01(b)</u> upon receipt by Buyer of a Supplement pursuant to <u>Section 4.04</u>, if the Supplement gives rise to a breach that is not cured within the cure period.

Section 7.02 Effect of Termination.

- (a) To terminate this Agreement as provided in <u>Section 7.01</u> (except in the case of termination pursuant to <u>Section 7.01(a)</u>), the terminating party shall have given written notice to the other Party specifying the subsection of <u>Section 7.01</u> pursuant to which such termination is made, and this Agreement shall forthwith become null and void and there will be no liability of any Party (or any stockholder or Representative of such Party) to each other Party hereto, except with respect to the Confidentiality Agreement, this <u>Section 7.02</u>, <u>Section 9.04</u> and <u>Article X</u>; <u>provided</u>, that no such termination shall relieve any Party from liability for any damages resulting from fraud or a willful breach of its representations, warranties or covenants set forth in this Agreement prior to such termination and any aggrieved Party will be entitled to all rights and remedies under applicable Law or in equity.
 - (b) <u>Seller Termination Fee</u>. (i) If this Agreement is terminated pursuant to:
 - (A) <u>Section 7.01(d)</u> or <u>Section 7.01(e)</u>;
 - (B) Section 7.01(f)(ii) and (x) a vote of the stockholders of Seller contemplated by this Agreement at the Seller Special Meeting to obtain the Seller Stockholder Approval has not occurred and (y) a proposal with respect to an Alternative Transaction shall have been publicly proposed or announced or otherwise publicly disclosed and not withdrawn after the date of this Agreement and prior to the date of termination of this Agreement;
 - (C) <u>Section 7.01(b)</u> or <u>Section 7.01(f)(iii)</u>, and, in either case, a proposal with respect to an Alternative Transaction shall have been publicly proposed or announced or otherwise publicly disclosed and not withdrawn after the date of this Agreement and prior to the date of the Seller Special Meeting; or

(D) <u>Section 7.01(g)</u>;

then (x) in the case of a termination contemplated by $\underline{\text{Section 7.02(b)(i)(A)}}$, Seller shall pay or cause to be paid to Buyer within two (2) Business Days following the termination of this

Agreement, a fee, by wire transfer in immediately available funds to an account specified by Buyer, equal to \$6,400,000 (the "**Termination Fee**"); (y) in the case of termination contemplated by $\underline{Section 7.02(b)(i)(D)}$, Seller shall pay or cause to be paid to Buyer the Termination Fee on the date of termination of this Agreement; and (z) in the case of a termination contemplated by $\underline{Section 7.02(b)(i)(B)}$ or $\underline{Section 7.02(b)(i)(C)}$, if Seller, within twelve (12) months after such termination either consummates an Alternative Transaction or enters into a definitive agreement to implement an Alternative Transaction, Seller shall pay to Buyer the Termination Fee simultaneously with such consummation or entering into such definitive agreement, as the case may be. For purposes of clause (z) of this $\underline{Section 7.02(b)(i)}$, each reference to "15%" in the definition of "Alternative Transaction" shall be deemed to be a reference to "50%."

- (ii) If Buyer or Seller terminates this Agreement pursuant to <u>Section 7.01(f)(iii)</u>, then Seller shall reimburse Buyer, or cause Buyer to be reimbursed, for Buyer's reasonable, documented out-of-pocket expenses incurred in connection with this Agreement and the transactions contemplated hereby, <u>provided</u>, <u>however</u>, Seller's aggregate liability under this <u>Section 7.02(b)</u> (<u>ii)</u> shall not exceed an amount equal to \$500,000.
 - (iii) In no event shall Seller be obligated to pay the Termination Fee on more than one occasion.
- (c) Seller acknowledges that (i) the agreements contained in this Section 7.02 are an integral part of the transactions contemplated by this Agreement and that without this Section 7.02 Buyer would not have entered into this Agreement and (ii) the Termination Fee is not a penalty, but rather is liquidated damages in a reasonable amount that will compensate Buyer in the circumstances in which the Termination Fee is payable for the efforts and resources expended and opportunities foregone while negotiating this Agreement and in reliance on this Agreement and on the expectation of the consummation of the transactions contemplated hereby. If Seller fails to promptly pay any amount due pursuant to this Section 7.02, Seller shall pay to Buyer all reasonable fees, costs and expenses of enforcement (including reasonable attorney's fees as well as reasonable expenses incurred in connection with any action initiated by Buyer), together with interest on the amount of the Termination Fee at the prime lending rate as published in *The Wall Street Journal*, Eastern Edition, in effect on the date such payment is required to be made.
- (d) If Seller becomes obligated to pay the Termination Fee pursuant to Section 7.02(b), Buyer agrees that Buyer's right to receive the Termination Fee from Seller shall be Buyer's sole and exclusive remedy against Seller, its Subsidiaries, Affiliates and their respective Representatives and, upon payment of the Termination Fee, neither Seller, its Subsidiaries, Affiliates nor their respective Representatives shall have any Liability or obligation to Buyer relating to or arising out of this Agreement or the transactions contemplated hereby.
- (e) In the event that this Agreement is terminated (i) by either Buyer or Seller pursuant to Section 7.01(f)(ii), and at the time of such termination any of the conditions set forth in Section 5.01(b) or (c) (under conditions attributable to one or more Antitrust Laws) or Section 5.01(d) shall not have been satisfied or waived or (ii) by either Buyer or Seller pursuant to Section 7.01(f)(i) (under conditions attributable to one or more Antitrust Laws), and at the time of such termination under either Section 7.01(f)(i) or Section 7.01(f)(ii), all conditions set forth in Article 5 other than those attributable to Antitrust Laws have been satisfied or waived by the party or parties then entitled to give such waiver (other than those conditions that by their terms are to be satisfied as of the Closing, provided, that each such condition is then capable of being satisfied), then Buyer shall reimburse Seller, or cause Seller to be reimbursed, for Seller's reasonable, documented out-of-pocket expenses incurred in connection with this Agreement and the transactions

contemplated hereby, provided, however, that Buyer's aggregate liability under this <u>Section 7.02(e)</u> shall not exceed an amount equal to \$500,000.

ARTICLE VIII

TAX MATTERS

Section 8.01 <u>Certain Tax Matters</u>. Buyer shall be responsible for the payment of any transfer, sales, use, stamp, conveyance, value added, recording, registration, documentary, filing and other non-income Taxes and administrative fees (including notary fees) arising in connection with the consummation of the transactions contemplated by this Agreement ("**Transfer Taxes**"). Buyer shall, at its own expense, timely file any Tax Return or other document with respect to such Taxes or fees (and Seller shall cooperate with respect thereto as necessary). Buyer and Seller shall use commercially reasonable efforts to cooperate with each other to minimize any Transfer Taxes.

Section 8.02 <u>Withholding Taxes</u>. Each of Buyer and Escrow Agent shall be entitled to deduct and withhold from any consideration payable or otherwise deliverable to Seller or any other Person pursuant to this Agreement (including the Contingent Payments, if any) all Taxes that Buyer or the Escrow Agent, as the case may be, are required to deduct or withhold therefrom under any applicable provision of Tax Law with respect to the making of such payment. All such withheld amounts shall be treated as delivered to Seller; <u>provided</u>, that Buyer or the Escrow Agent shall remit or cause to be remitted to the applicable Governmental Entity the amounts withheld as required under any applicable provision of Tax Law. Buyer shall, to the extent reasonable, notify Seller if any such withholding is required.

ARTICLE IX

FURTHER AGREEMENTS

Section 9.01 <u>Post-Closing Information</u>. After the Closing, Buyer shall respond to reasonable, written requests for information and assistance by Seller in connection with Seller completing the audit of its accounts and preparation of its required federal, state and local Tax Returns.

Section 9.02 Wrong Pockets. If either Buyer, on the one hand, or Seller, on the other hand, becomes aware that any of the Acquired Assets has not been transferred to Buyer or that any of the Excluded Assets has been transferred to Buyer, Buyer or Seller, as applicable, shall promptly notify the other and the Parties shall, as soon as reasonably practicable, ensure that such property is transferred, with any necessary prior Third Party consent or approval, to (a) Buyer, in the case of any Acquired Asset which was not transferred to Buyer at the Closing; or (b) Seller, in the case of any Excluded Asset which was transferred to Buyer at the Closing.

Section 9.03 <u>Use of Names</u>. After the Closing Date, Seller shall, and shall cause its Affiliates to, cease to use the names set forth on Section 9.03 of the Seller Disclosure Letter and any name confusingly similar thereto (collectively, the "Restricted Names") and any trademarks, trade names, trade dress, service marks and logos that use or incorporate any Restricted Name. Seller agrees that from and after the Closing, Seller shall not have any right, title, interest, license or other right whatsoever in the Restricted Names. Seller shall, and shall cause its Affiliates to, remove, strike over or obliterate all Restricted Names and any trademarks, trade names, trade dress, service marks and logos that use or incorporate any Restricted Name from the Excluded Assets (it being understood that this requirement shall not apply to fair use of any Restricted Name, including, but not limited to, in documents and materials kept as records that are maintained for

internal use only and not publicly disseminated, or to be archived as such records, for historical purposes or as required by applicable Law). Any use of the Restricted Names by Seller as permitted in this Section 9.03 is subject to its use of each Restricted Name in the same form and manner as, to the same extent as (without an increase in extent or type of uses of each Restricted Name) and subject to the same standards of quality that are in effect for each Restricted Name as of the Closing Date. All goodwill arising from any such use shall inure to the benefit of Buyer or an applicable Affiliate of Buyer owning the Restricted Name so used. Seller shall not to use any Restricted Name in any manner that may reflect negatively on such name and mark or on Buyer or any of its Affiliates.

Section 9.04 Confidentiality.

- (a) From and after the date of this Agreement until the Closing, Buyer and Seller each agree they will be bound by and comply with the obligations of the Confidentiality Agreement. After the Closing Date, Buyer's obligations with respect to Confidential Material under the Confidentiality Agreement shall be deemed to have been terminated by and the Confidentiality Agreement shall no longer be binding upon Buyer.
- (b) Seller acknowledges that it is in possession of Confidential Material. Seller shall, and shall cause each of its Affiliates and their respective Representatives to, (i) treat confidentially and not disclose all or any portion of such Confidential Material and use such Confidential Material solely for the purpose of fulfilling its obligations under this Agreement and the Related Agreements and for no other purpose, in each case, following the Closing Date and (ii) from the date hereof and until the Closing Date, use Confidential Material for the sole purpose of developing and operating the Acquired Assets in the Ordinary Course and to consummate the transactions contemplated by this Agreement. Seller acknowledges and agrees that such Confidential Material is proprietary and confidential in nature and may be disclosed to its Representatives only to the extent necessary for Seller to consummate the transactions contemplated by this Agreement (it being understood that Seller shall be responsible for any disclosure by any such Representative not permitted by this Agreement). If, following the Closing Date, Seller or any of its Affiliates or their respective Representatives are requested or required to disclose (after Seller has used its commercially reasonable efforts to avoid such disclosure and after promptly advising and consulting with Buyer about Seller's intention to make, and the proposed contents of, such disclosure) any of the Confidential Material (whether by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process), Seller shall, or shall cause such Affiliate or Representative, to provide Buyer with prompt written notice of such request so that Buyer may seek an appropriate protective order or other appropriate remedy. At any time that such protective order or remedy has not been obtained, Seller or such Affiliate or Representative may disclose only that portion of the Confidential Material which such Person is legally required to disclose or of which disclosure is required to avoid sanction for contempt or any similar sanction, and Seller shall exercise its commercially reasonable efforts to obtain assurance that confidential treatment will be accorded to such Confidential Material so disclosed. Seller further agrees that, from and after the Closing Date, Seller and its Affiliates and Representatives, upon the request of Buyer, promptly will deliver to Buyer all documents, or other tangible embodiments, constituting Confidential Material or other information with respect to the Acquired Assets, without retaining any copy thereof, and shall promptly destroy all other information and documents constituting or containing Confidential Material; provided, however, that Seller or its Representatives shall be permitted to retain one archival copy of any Confidential Material for record purposes and to evidence Seller's compliance with this Agreement or applicable Law, and in addition, nothing in this Agreement shall require the alteration, modification, deletion or destruction of back-up tapes or other media made in the ordinary course of business.

Section 9.05 Restrictive Covenants. (a) During the period beginning on the Closing Date and ending on the fifth (5th) anniversary of the Closing Date (the "Non-Compete Period"), Seller covenants

and agrees not to, and shall cause its Affiliates not to, directly or indirectly anywhere in the world, acquire or Develop, Manufacture or Commercialize any compound or product or file any Intellectual Property related thereto, in each case with the intention of treating cystic fibrosis, and shall not control, advise, enable, provide services to, fund or guarantee the obligations of, any Third Party engaged in, or planning to engage in, any of the foregoing. Notwithstanding the foregoing, nothing in this Section 9.05 shall restrict, place conditions on or impede Seller from the current or planned (each as of the Closing Date) Development, Manufacturing, or Commercialization of any Excluded Therapeutic Products.

- (b) During the period beginning on the date of this Agreement and ending on the date that is twelve (12) months after the earlier of (i) termination of this Agreement in accordance with its terms and (ii) the Closing Date, each of Buyer and Seller shall not, and shall cause their respective Affiliates not to, directly or indirectly, solicit for employment or employ or cause to leave the employ of the other Party or any of its Affiliates, any employee of the other Party or its Affiliates, without obtaining the prior written consent of the other Party; provided that each Party may make general solicitations for employment not specifically directed at the other Party or any of its Affiliates or their respective employees and employ any person who responds to such solicitations.
- (c) Seller shall instruct its officers and directors, and shall cause its Affiliates to instruct their officers and directors, not to directly or indirectly through any other Person (whether as an officer, manager, director, employee, partner, consultant, holder of equity or debt investment, lender or in any other manner or capacity), engage in conduct, oral or otherwise, that disparages or damages or would reasonably be expected to disparage or damage any of Buyer, its Affiliates or any of their respective current or former Representatives, holders of equity or debt investments, lenders, businesses, activities, operations or reputations.
- (d) As a material inducement to Buyer's execution of this Agreement (without such inducement Buyer would not have entered into this Agreement), Seller acknowledges and agrees that the provisions of this Section 9.05 are reasonable and necessary to protect the legitimate business interests of Buyer and its acquisition of the Acquired Assets. Seller shall not contest that Buyer's remedies at law for any breach or threat of breach by Seller or any of its Affiliates of the provisions of this Section 9.05 will be inadequate, and that Buyer shall be entitled to an injunction or injunctions to prevent breaches or threatened breaches of the provisions of this Section 9.05 and to enforce specifically such terms and provisions, in addition to any other remedy to which Buyer may be entitled at Law or equity, as well as the reasonable costs and attorneys' fees it incurs in enforcing the provisions contained in this Section 9.05. The covenants contained in this Section 9.05 are covenants independent of any other provision of this Agreement or any other agreement between the Parties hereunder, and the existence of any claim Seller may have against Buyer under any other provision of this Agreement or otherwise, shall not constitute a defense to the enforcement of the provisions contained in this Section 9.05. Seller further agrees that should it violate any provisions contained in this Section 9.05, the Non-Compete Period shall extend for an additional time period that is equal to the term of such violation so that Buyer is provided with the full benefit of the restrictive period set forth in this Section 9.05.
- (e) If any of the provisions contained in this <u>Section 9.05</u> shall for any reason be held by a court of competent jurisdiction to be excessively broad as to duration, scope, activity or subject, then such provision shall be construed by limiting and reducing it with respect to such jurisdiction, only to the extent necessary so as to be valid and enforceable to the extent compatible with the applicable Law of such jurisdiction.

Section 9.06 <u>FDA Letters</u>. Promptly after the Closing (but in no event later than two (2) Business Days following the Closing), Seller shall file, or cause to be filed, with the FDA the Seller FDA Letter, the

Buyer FDA Letter, the Seller Orphan Designation Letter and the Buyer Orphan Designation Letter and shall provide an as-filed copy of each such letter to Buyer.

ARTICLE X

MISCELLANEOUS

Section 10.01 Certain Definitions. For the purposes of this Agreement, the term:

"Affiliates" has the meaning set forth in Rule 12b-2 of the Exchange Act.

"Alternative Transaction" means, whether or not proposed in writing, any of the following events (in each case in a single transaction or series of related transactions): (i) any sale, lease, contribution or other disposition, directly or indirectly (including by way of merger, consolidation, share exchange, tender offer, exchange offer, other business combination, partnership, joint venture, sale of capital stock of or other equity interests in Subsidiaries or otherwise) to any Third Party of (A) Acquired Assets (other than sales, dispositions or transfers in the Ordinary Course), or (B) beneficial ownership of fifteen percent (15%) or more of the combined voting securities of Seller or of any resulting parent company of Seller (excluding voting securities acquired in open market purchases), or (ii) any issuance, sale or other disposition, directly or indirectly, to any Third Party (or the shareholders of any Third Party) of securities (or options, rights or warrants to purchase, or securities convertible into or exchangeable for, such securities) representing fifteen percent (15%) or more of the combined voting securities of Seller (excluding voting securities acquired in open market purchases), in each case other than transactions contemplated by this Agreement.

"Anti-Bribery Law" means (i) the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations issued thereunder, and (ii) any law, rule, regulation, or other legally binding measure of any jurisdiction including, without limitation, the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or that otherwise relates to bribery or corruption.

"Antitrust Laws" means the Sherman Act, 15 U.S.C. §§ 1-7, as amended; the Clayton Act, 15 U.S.C. §§ 12-27, 29 U.S.C. §§ 52-53, as amended; the HSR Act; the Federal Trade Commission Act, 15 U.S.C. § 41-58, as amended; and all other Laws and Orders that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization, restraint of trade, or lessening of competition through merger or acquisition.

"Base Purchase Price" means \$160,000,000.

"Business Day" means any day that is not a Saturday or Sunday or a day on which banking institutions located in New York, New York or Boston, Massachusetts are required by Law to remain closed.

"Buyer Material Adverse Effect" means any Effect that is materially adverse to the ability of Buyer to consummate the transactions contemplated by this Agreement.

"Commercialize" or "Commercialization" means all activities related to importing, storing, transporting, distributing, marketing, detailing, and selling a medicinal product or any such use with a view to sale of a medicinal product; and "Commercialization" shall be construed accordingly. Commercialization shall not include Development or Manufacturing.

"Common Stock" means the common stock of Seller, par value \$0.001 per share.

"Confidential Material" means all data and information (whether written or oral) that is confidential, proprietary or is not otherwise generally available to the public regarding the Acquired Assets or the Assumed Liabilities. Notwithstanding the foregoing, the restrictions set forth in Section 9.04 shall not apply to data

or information (a) that is or becomes generally available to the public, other than as a result of disclosure by Seller, its Affiliates or their respective Representatives in violation of this Agreement, (b) becomes available to Seller its Affiliates or their respective Representatives from a Person other than a member of the Buyer Group or their respective Representatives on a non-confidential basis, <u>provided</u>, that such Person was not bound by a confidentiality agreement with or other contractual, legal or fiduciary obligation of confidentiality to the Buyer Group or such Representatives with respect to such materials or (c) to the extent not severable, that primarily relates to the Excluded Assets and Excluded Liabilities.

"Contract" means any contract, agreement, license, sublicense, indenture, instrument, commitment and any other legally binding agreement, whether written or oral.

"Damages" means, without duplication, (a) any and all claims, actions, causes of action, judgments, awards, penalties, Liabilities, losses, costs or damages (of any kind including economic, consequential, special, indirect, incidental, punitive, or exemplary losses, costs or damages, including without limitation, lost profits), including reasonable fees and expenses of attorneys, accountants and other professional advisors, whether involving a dispute solely between the parties hereto or otherwise, and (b) any losses or costs incurred in investigating, defending or settling any claim, action or cause of action described in clause (a).

"DCE Platform Know-How" means Seller's Know-How, other than Transferred Know-How that has specific application to the ownership, operation or conduct of the CF Enterprise, to Develop, Manufacture or Commercialize deuterium-substituted therapeutic agents, including Know-How to (i) assess compounds as suitable targets for deuterium substitution; (ii) synthesize a wide range of chemical compounds that incorporate deuterium selectively at specific positions and accurately analyze deuterium content at those positions; (iii) optimize assays to evaluate the metabolic stability and metabolite profile of deuterated compounds; (iv) identify deuterated compounds that possess improved in vitro or in vivo metabolic or pharmacokinetic properties relative to the corresponding non-deuterated compound; (v) develop and apply bioanalytical methods to identify and measure metabolites formed by the in vitro and in vivo metabolism of deuterated compounds; (vi) understand how the effects of selective deuterium substitution may translate from in vitro to in vivo systems and from non-human models to humans, and how deuterium substitution affects individual and population-based ADME parameters; (vii) manufacture, analyze, and formulate deuterated compounds, including development of analytical methods for determining level of deuterium incorporation; and (viii) sourcing deuterium reagents, starting materials, and intermediates, and developing and utilizing a supply chain of multiple vendors.

"Developed" or "Development" means all activities related to research and development of a medicinal product including, all testing and studies (non-clinical, preclinical and clinical), toxicology testing, pharmacology, statistical analysis, and reporting, together with all other activities with respect to the product useful for the preparation and submission of applications or other filings to a Regulatory Authority to obtain Regulatory Approval for the product and in support of obtaining Regulatory Approval. Development shall not include Manufacturing or Commercialization.

"Effect" means any event, occurrence, change, development or effect.

"EMA" means the European Medicines Agency or any successor agency that is responsible for reviewing applications seeking approval for the sale of pharmaceuticals in the European Union.

"Encumbrance" means any charge, claim, condition, equitable interest, lien, encumbrance, option, pledge, security interest, hypothecation, mortgage, right of first refusal, or any restriction on use, voting, transfer, receipt of income, right of set-off, title retention, or exercise of any other attribute of ownership.

"Escrow Agent" means Citibank, N.A.

"Escrow Agreement" means the Escrow Agreement to be entered into on the Closing Date in substantially the form attached hereto as Exhibit G.

"Escrow Account" means the escrow account to be established and maintained pursuant to the terms of the Escrow Agreement for the Escrow Amount.

"Escrow Amount" means, initially, \$16,000,000, which amount shall be adjusted to reflect any earnings thereon and any amounts released pursuant to the terms and subject to the conditions set forth in this Agreement and the Escrow Agreement.

"Exchange Act" means the Securities Exchange Act of 1934.

"Excluded Therapeutic Product" means any product of Seller that is not a Transferred Product, including compounds that are solely intended for use as a treatment of antibacterial infections in patients with cystic fibrosis.

"GAAP" means generally accepted accounting principles in the United States.

"Governmental Entity" means any United States or non-United States federal, state, provincial or local court, tribunal, arbitrator or arbitral body, the United States Congress or other state or local legislative body, administrative agency or commission or other governmental or regulatory agency or authority or any securities exchange.

"Indebtedness" means, with respect to any Person, any principal, interest, premiums or other obligations of such Person (excluding accrued expenses and trade payables), whether or not contingent: (a) in respect of notes payable, accrued interest payable or other obligations for borrowed money, whether secured or unsecured; (b) evidenced by bonds, notes, debentures or similar instruments or letters of credit (or reimbursement agreements in respect thereof); (c) in respect of banker's acceptances; (d) representing capital lease obligations; (e) representing the balance deferred and unpaid of the purchase price of any property or services; (f) representing any hedging obligations, if and to the extent any of the preceding items (other than letters of credit and hedging obligations) would appear as a liability upon a balance sheet of the specified Person prepared in accordance with GAAP; (g) in respect of accrued bonuses owed to any employees of such Person with respect to the 2016 calendar year; (h) any Liability of such Person in respect of banker's acceptances or letters of credit (but solely to the extent drawn and not paid), (i) all prepayment premiums, penalties, costs and/or expenses related to any items of Indebtedness of the type referred to in clauses (a) through (i) above that would be required to be paid as a result of the transactions contemplated hereby or to extinguish the Indebtedness as of immediately prior to the Closing or (j) direct or indirect guarantees or other contingent Liabilities (including so called "make-whole", "take-or-pay" or "keep-well" agreements) with respect to any indebtedness, obligation, claim or Liability of any other Person of a type described in clauses (a) through (i) above. In addition, the term "Indebtedness" includes all Indebtedness of others secured by a lien on any asset of the specified Person (whether or not such Indebtedness is assumed by the specified Person) and, to the extent not otherwise included, the guarantee by the specified Person of any Indebtedness of a

"Intellectual Property" means any and all intellectual property rights or similar proprietary rights and description throughout the world, whether registered or unregistered, including all rights pertaining to or deriving from: (a) Patents, inventions, invention disclosures, discoveries and improvements, whether or not patentable; (b) trademarks, trade dress, service marks, certification marks, logos, brands, slogans, design rights, names, corporate names, trade names, Internet domain names, social media accounts and addresses and other similar designations of source or origin, together with the goodwill symbolized by any of the

foregoing; (c) copyrights and copyrightable subject matter; (d) rights in any computer software or firmware (whether in source code, object code or other form), algorithms, data files, databases, compilations and data technology supporting the foregoing, and all documentation, including user manuals and training materials, related to any of the foregoing; (e) trade secrets (including those trade secrets defined in the Uniform Trade Secrets Act and under corresponding foreign Law), and all other non-public confidential or proprietary information, Know-How, clinical data, non-clinical data, pre-clinical data, in-vitro data, inventions, processes, formulae, models, and methodologies, excluding Patents, and rights to limit the use or disclosure thereof by any Person; and (f) all applications, registrations, and renewals for the foregoing in any jurisdiction throughout the world.

"Know-How" means any know-how, trade secret, proprietary invention, discovery, data, information, process, method, technique, material, technology, result or other know-how, whether or not patentable, and all other non-public confidential or proprietary information.

"knowledge" means (i) with respect to Seller, the knowledge, within the scope of his or her responsibility assuming reasonable inquiry of those employees known to such persons to have specialized knowledge of the subject matter of the representation and warranty, of the individuals listed in <u>Section 10.01(a)</u> of the Seller Disclosure Letter and (ii) with respect to Buyer, the knowledge, within the scope of his or her responsibility assuming reasonable inquiry of those employees known to such persons to have specialized knowledge of the subject matter of the representation and warranty, of the Chief Legal and Administrative Officer.

"Law" means (i) any statute, code, rule, regulation, ordinance, rule of common law, requirement or other pronouncement of any Governmental Entity having the effect of law and (ii) any binding guidance document with regard to drug approval requirements.

"Liability" means any debt, Indebtedness, obligation, Tax, duty or liability of any nature (including known, unknown, fixed, absolute, disclosed, undisclosed, matured, unmatured, accrued, unaccrued, asserted, unasserted, determined, determinable, contingent, indirect, conditional, implied, vicarious, derivative, joint, several or secondary liability), regardless of whether such debt, Indebtedness, obligation, Tax, duty or liability would be required to be disclosed on a balance sheet prepared in accordance with GAAP and regardless of whether such debt, obligation, duty or liability is immediately due and payable.

"Manufacture" or "Manufacturing" shall mean any and all activities related to making, producing, processing, filling, finishing, packaging, labeling or quality assurance testing and releasing of a medicinal product (or any ingredient thereof). Manufacturing shall not include Development or Commercialization.

"Milestone Event" means each of the events set forth in Section 1.02(b).

"Official" means any official, employee or representative of, or any other person acting in an official capacity for or on behalf of, any (i) Governmental Entity, including any entity owned or controlled thereby, (ii) political party, party official or political candidate, or (iii) public international organization.

"**Orders**" means all orders, rulings, judgments, settlements, arbitration awards or decrees of any Governmental Entity (or any agreement entered into or any administrative, judicial or arbitration award with any Governmental Entity).

"**Ordinary Course**" means the ordinary course of the ownership, operation, Development, Manufacture and Commercialization of the Acquired Assets consistent with past practice.

"Patents" means patents, including utility and design patents, patent applications, including provisionals, non-provisionals, utility models and any and all related national or international counterparts

thereto, including any divisional, continuation, continuation-in-part applications, reissues, reexaminations, substitutions and extensions thereof (including supplementary protection certificates, requests for, and grants of, continued examination, post-grant confirmations or amendments, counterparts claiming priority from any of the foregoing; and any patents or patent applications that claim priority to or from any of the foregoing) and all rights associated with any of the foregoing, including the right to claim priority arising from or related to any of the foregoing.

"**Permitted Encumbrance**" means: (i) Encumbrances for Taxes, assessments and governmental charts or levies either not yet due and payable or which are being contested in good faith by appropriate proceedings and for which adequate reserves have been established in accordance with GAAP; (ii) Encumbrances incurred in the Ordinary Course for mechanics, carriers', workmen's, warehouseman's, repairmen's, materialmen's or other similar liens that are not yet due and payable or that are being contested in good faith by appropriate proceedings; and (iii) Encumbrances incurred in the Ordinary Course for pledges and deposits to secure the performance of bids, trade Contracts, surety and appeal bonds, performance bonds and other obligations of a similar nature, in each case in the Ordinary Course.

"**Permits**" means any and all federal, state, local and foreign qualifications, permits, registrations, clearances, certificates, rights, applications, submissions, variances, exemptions, filings, approvals and authorizations from Governmental Entities.

"**Person**" means any individual, corporation, limited liability company, partnership, joint venture, estate, trust, association, unincorporated organization, other form of entity, of whatever nature, or Governmental Entity.

"**Post-Closing Tax Period**" means a Tax period that begins after the Closing Date and the portion of a Straddle Period that begins after the Closing Date.

"**Pre-Closing Tax Period**" means a Tax period that ends on or before the Closing Date and the portion of a Straddle Period ending on and including the Closing Date.

"Proxy Statement" means a proxy statement to be sent to the stockholders of Seller (together with any amendments or supplements thereto) with respect to the Seller Special Meeting.

"Regulatory Approval" means any and all registration, clearance, license permit, approval, concession, variance, waiver, or other authorization of any national, regional, state, or regulatory authority, department, bureau, commission, council or other Governmental Entity that is necessary for any activities in relation to or with a medicinal product in a given country, jurisdiction, or region (including for the Development, Manufacture, supply, and Commercialization of such medicinal product) in such country or jurisdiction.

"Regulatory Documentation" means with respect to any Transferred Products, the regulatory documentation, or portion thereof, related to each such product, including (as applicable) all applications for Transferred Registrations and renewals thereof (including investigational new drug applications, orphan designations, new drug applications, abbreviated new drug applications and marketing authorization applications), and the safety reports, information on adverse events, and copies of all correspondence, reports, or minutes with any Governmental Entity, and all data submitted to Governmental Entities in connection with Transferred Registrations, pricing studies, and documents (including, without limitation, laboratory, clinical and pre-clinical animal study data) relating to the Transferred Registrations or to the subject matter of the Transferred Registrations to the extent relating to the Transferred Products. For the avoidance of doubt, Regulatory Documentation shall not include laboratory notebooks, internal audit reports or batch records (other than those batch records contained in Transferred Registrations).

"Representatives" means, when used with respect to Buyer or Seller, the directors, officers, employees, consultants, financial advisors, accountants, legal counsel, investment bankers, lenders and other agents, advisors and representatives of Buyer or Seller, as applicable, and their respective Subsidiaries.

"SEC" means the United States Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933, as amended.

"Seller Board Recommendation" means the recommendation of the Seller Board that the stockholders of Seller vote in favor of approval of the sale of the Acquired Assets pursuant to this Agreement and the transaction contemplated hereby.

"Seller Intervening Event" means an Effect that affects or would reasonably be expected to affect the Acquired Assets, taken as a whole, that (a) is material, (b) was not known to the Seller Board as of the date of this Agreement (and which could not have become known through any further reasonable investigation, discussion, inquiry or negotiation with respect to any event, fact, circumstance, development or occurrence known to Seller as of the date of this Agreement), (c) becomes known to the Seller Board prior to obtaining the Seller Stockholder Approval (d) does not relate to or involve any Alternative Transaction and (e) is not the result of a material breach of this Agreement by Seller.

"Seller Material Adverse Effect" means any Effect that is materially adverse to (i) the ability of Seller to consummate the transactions contemplated by this Agreement or (ii) the condition (financial or otherwise) or ownership, operation or development of the Acquired Assets, taken as a whole; provided, however, that a "Seller Material Adverse Effect" shall not include, either alone or in combination, any Effect resulting from or arising out of (and the following will not be taken into account when determining whether a "Seller Material Adverse Effect" has occurred): (A) the announcement, pendency or consummation of this Agreement or the transactions contemplated hereby, including the identity of, or any facts or circumstances relating to, Buyer or any of its Affiliates to the extent resulting from the public announcement of this Agreement or the pendency of the transactions contemplated hereby; (B) any action taken by Seller at the written request of Buyer or with Buyer's written consent, or the failure of Seller to take an action that Seller is specifically prohibited from taking by the terms of this Agreement; (C) any event or occurrence generally affecting the industries in which Seller operates relating to the Acquired Assets or in the economy generally or other general business, financial or market conditions; (D) changes affecting the national or international general economic, political, legal or regulatory conditions; (E) changes in Laws after the date hereof applicable to the Acquired Assets; or (F) national or international political conditions or instability, including the engagement by the United States in hostilities, whether or not pursuant to a declaration of emergency or war, or the occurrence of any military or terrorist attack upon the United States or any other nation, except, in each of clauses (C), (D), (E), or (F) above, to the extent such Effects have a disproportionate impact on the Acquired Assets and the Assumed Liabilities, taken as a whole, relative to other Persons owning assets similar to the Acquired Assets, in the industry or markets in which Seller operates.

"Seller Special Meeting" means the meeting of the holders of Common Stock for the purpose of seeking the Seller Stockholder Approval, including any postponement or adjournment thereof.

"Seller Stockholder Approval" means the affirmative vote of the holders of a majority of the outstanding Common Stock entitled to vote upon the authorization of this Agreement and the transactions contemplated hereby at the Seller Special Meeting.

"Straddle Period" means a taxable period that begins before the Closing Date and ends after the Closing Date

"Subsidiaries" means all those corporations, associations or other business entities of which the entity in question (a) owns or controls a majority of the outstanding equity securities either directly or through an unbroken chain of entities as to each of which a majority of the outstanding equity securities is owned directly or indirectly by its parent (<u>provided</u>, there shall not be included any such entity the equity securities of which are owned or controlled in a fiduciary capacity), (b) in the case of partnerships, serves as a general partner, (c) in the case of a limited liability company, serves as a managing member, or (d) otherwise has the ability to elect a majority of the directors, trustees or managing members thereof.

"Superior Proposal" means any bona fide written proposal made to Seller by any Third Party which did not result from a breach of Section 4.06 with respect to any Alternative Transaction or any purchase or acquisition (a) involving the Acquired Assets or more than 50% of the voting power of the Common Stock, (b) that is on terms that the Seller Board determines in good faith (after consultation with its financial advisors and outside legal counsel) would result in a transaction that, if consummated, is more favorable to Seller's stockholders from a financial point of view than the transactions contemplated by this Agreement (taking into account any proposal by Buyer to amend the terms of this Agreement); (c) with respect to which the cash consideration and other amounts (including costs associated with the proposed acquisition) payable at closing are subject to fully committed financing from recognized financial institutions; and (d) that is reasonably likely to receive all required governmental approvals on a timely basis and otherwise reasonably capable of being completed within a reasonable period of time on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal.

"**Tax Returns**" means all reports, returns, declarations, statements, forms or other information required to be supplied to a Governmental Entity in connection with Taxes, including amendments thereto.

"Taxes" means (a) all taxes, including income, gross receipts, capital gain, ad valorem, value-added, goods and services, excise, real property, personal property, sales, use, transfer, withholding, employment and franchise taxes or other similar charges imposed by the United States of America or any state, local or foreign government, or any agency thereof, or other political subdivision of the United States or any such government, and any interest, penalties, assessments or additions to tax resulting from, attributable to or incurred in connection with any tax or any contest or dispute thereof and (b) any liability for any item described in clause (a) of another natural person, corporation, limited liability company, association, partnership, not for profit entity, other form of business, or Governmental Entity, whether by Contract (other than any Contract entered into in the Ordinary Course the principal purpose of which is not related to taxes) or express or implied agreement, pursuant to any applicable Law, as a transferee or successor, or otherwise.

"Third Party" means any Person other than the Parties or any of their respective Subsidiaries and Affiliates.

"Transaction Litigation" means any claim or legal proceeding (including any class action or derivative litigation) not involving a Governmental Entity asserted or commenced by, on behalf of or in the name of, against or otherwise involving Seller and/or any of its directors or officers relating directly or indirectly to this Agreement, the sale of the Acquired Assets or any of the other transactions contemplated by this Agreement (including any such claim or legal proceeding based on allegations that Seller's entry into the Agreement or the terms and conditions of the Agreement constituted a breach of the fiduciary duties of Seller's Board or any officer of Seller).

"Transferred Inventory" means all inventory of Transferred Products and reference standards, retains and intermediates related thereto, ingredients and any other raw materials, work-in-progress materials, package inserts, packaging and labeling materials, supplies and other inventories used in the manufacturing or production of any Transferred Products, but specifically excluding such quantity of

CTP-656 as may be required by Seller prior to Closing in the Ordinary Course, including material required for Seller to support and conduct its clinical trials.

"**Transferred Know-How**" means Know-How (other than DCE Platform Know-How) that is necessary or useful for the ownership, Development, Manufacture and Commercialization of the CF Enterprise.

"Transferred Products" means (i) all deuterated ivacaftor, including the deuterated form of ivacaftor having a chemical formula as set forth on Section 10.01(b) of the Seller Disclosure Letter, including the compound coded by Seller as CTP-656, and (ii) any other compounds used, planned for use or held for use, in each case, in the ownership, operation or conduct of the CF Enterprise (including deuterated tezacaftor) as of the date hereof and the Closing Date, in each of cases (i) and (ii), including any derivatives, combinations, or other forms thereof; provided, that compounds that are (a) solely intended for use as a treatment of antibacterial infections in patients with cystic fibrosis or (b) listed on Section 10.01(c) of the Seller Disclosure Letter shall not be considered Transferred Products.

"Transferred Product Records" (i) written records lab notebooks, accounts, notes, reports, batch records and data, (ii) Regulatory Documentation, (iii) Development data (of any kind) from discovery through to submission (raw data, stability, validation, quality by design work), all analytical methods development and validation, (iv) Manufacturing data (of any kind), batch records, Manufacturing facility, quality control lab commissioning, validation protocols, testing protocols, and reports, (v) facility and equipment detailed drawings, all equipment maintenance and calibration data, and (vi) records relating to the filing, prosecution, issuance, maintenance, enforcement or defense of the Transferred IP, in the case of clauses (i) - (vi) that are owned or controlled by or otherwise in the possession of Seller as of the Closing Date and related to the Transferred Products.

"Transferred Registrations" any and all Regulatory Approvals granted or issued by, or applied for to a national, regional, state, or regulatory authority, department, bureau, commission, council or other Governmental Entity for any activities in relation to or with a medicinal product in a given country, jurisdiction, or region (including for the Development, Manufacture, supply, and Commercialization of such medicinal product).

Section 10.02 Terms Defined Elsewhere. The following terms are defined elsewhere in this Agreement, as indicated below:

Acquired Assets	<u>Section 1.01(a)</u>
Acquired Assets Permits	<u>Section 2.12(a)</u>
Acquired Assets Regulatory Filings	<u>Section 2.12(a)</u>
Aggregate Threshold	<u>Section 6.05(b)(ii)</u>
Agreed Amount	<u>Section 6.04(b)</u>
Agreement	<u>Preamble</u>
Antitrust Approvals	<u>Section 4.03(b)</u>
Assigned Contracts	<u>Section 1.01(a)(iv)</u>
Assigned IP Contracts	<u>Section 1.01(a)(iv)</u>
Assumed Liabilities	<u>Section 1.01(d)</u>
Assumption Agreements	<u>Section 1.01(d)</u>
Bill of Sale	<u>Section 1.03(b)(iii)</u>
Burdensome Term or Condition	<u>Section 4.03(f)</u>

Buyer	<u>Preamble</u>
Buyer FDA Letter	Section 5.03(e)
Buyer Group	Section 1.01(a)
Buyer Indemnified Parties	Section 6.02
Buyer Orphan Designation Letter	<u>Section 5.03(e)</u>
Cap	<u>Section 6.05(b)(i)</u>
CF Enterprise	Recitals
Claim Notice	Section 6.04(b)
Claimed Amount	Section 6.04(b)
Closing	<u>Section 1.03(a)</u>
Closing Date	<u>Section 1.03(a)</u>
Confidentiality Agreement	Section 4.02
Contingent Payment	<u>Section 1.02(b)</u>
CTAs	Section 2.10(a)(viii)
DOJ	<u>Section 4.03(a)</u>
Electronic Delivery	Section 10.07
Excluded Assets	<u>Section 1.01(b)</u>
Excluded Liabilities	<u>Section 1.01(e)</u>
FDA	Section 2.12(a)
FDCA	<u>Section 2.12(a)</u>
FTC	<u>Section 4.03(a)</u>
Fundamental Representations	<u>Section 6.01(a)</u>
Guarantor	<u>Preamble</u>
HSR Act	<u>Section 2.05(c)</u>
Indemnified Party	<u>Section 6.04(a)</u>
Indemnifying Party	<u>Section 6.04(a)</u>
IP Assignment Agreements	Section 1.03(b)(iv)
Material Contract	<u>Section 2.10(a)</u>
MTAs	Section 2.10(a)(viii)
NDAs	Section 2.10(a)(viii)
Non-Compete Period	<u>Section 9.05(a)</u>
Outside Date	<u>Section 7.01(f)(ii)</u>
Parties	<u>Preamble</u>
Party	<u>Preamble</u>
PHSA	<u>Section 2.12(a)</u>
Pre-Closing Period	<u>Section 4.01(a)</u>
Research and Testing Agreement	Recitals
Registered Business IP	Section 2.09(a)
Regulatory Authority	<u>Section 2.12(a)</u>
Regulatory Filings	<u>Section 4.03(a)</u>

Section 2.03 Section 9.02

Section 2.12(d)

Related Agreements

Restricted Names Safety Notice

Seller **Preamble** Seller Board Section 2.03 Seller Board Approval Section 2.20 Seller Change of Recommendation Section 4.07(c) Seller Disclosure Letter Article II Seller FDA Letter Section 5.02(f) Section 6.03 Seller Indemnified Parties Seller Orphan Designation Letter <u>Section 5.02(f)</u> Supplement Section 4.04 Termination Fee Section 7.02(b) Third Party Claim Section 6.04(a) Third Party IP <u>Section 2.09(f)</u> **Transfer Taxes** Section 8.01(a) Transferred IP Section 1.01(a)(ii) Transferred IP Documentation Section 1.01(a)(iii) **Transferred Permits** Section 1.01(a)(vi) Transition Services Agreement Section 1.03(b)(vii)

Section 10.03 Press Releases and Announcements. Each Party shall consult with the other Party and give the other Party a reasonable opportunity to comment on such Party's press release announcing the execution and delivery of this Agreement. No Party shall issue (and each Party shall cause its Affiliates not to issue) any press release or public disclosure relating to the subject matter of this Agreement, or its terms, without the prior written approval of the other Party; provided, however, that nothing in this Section 10.03 shall prevent any Party from (a) making any public disclosure it believes in good faith is required by Law, regulation or stock exchange rule (in which case the disclosing Party shall use its commercially reasonable efforts to advise the other Party prior to making disclosure and the other Party shall have the right to review such press release or announcement prior to its publication) or (b) enforcing its rights hereunder.

Section 10.04 No Third Party Beneficiaries. Except as provided by applicable Law, this Agreement shall not confer any rights or remedies upon any Person other than each Party and its respective successors and permitted assigns and, to the extent specified herein, its respective Affiliates; provided, however, that the provisions of Article VI and Article VII are intended for the benefit of the entities and individuals specified therein and their respective legal representatives, successors and assigns.

Section 10.05 Entire Agreement. This Agreement (including the documents referred to herein), the Related Agreements, the Confidentiality Agreement and the Escrow Agreement constitute the entire agreement between the Parties with respect to the subject matters hereof and supersede all other prior agreements (except that the Confidentiality Agreement shall be deemed amended hereby so that until the termination of this Agreement in accordance with Section 7.01, Buyer shall be permitted to take the actions contemplated by this Agreement) and understandings, both written and oral, between the Parties or any of them with respect to the subject matter hereof and thereof.

Section 10.06 <u>Succession and Assignment</u>. This Agreement shall be binding upon and inure to the benefit of and be enforceable by each of the Parties named herein and its respective successors and permitted assigns. No Party may assign either this Agreement or any of its rights, interests, or obligations hereunder (whether by operation of Law or otherwise) without the prior written consent of the other Party; provided, that (i) Seller may assign all of its rights and obligations hereunder to any successor or assign of

Seller's business through the acquisition (whether by operation of Law or otherwise) of more than 50% of the voting power of Common Stock and/or substantially all of Seller's assets and (ii) Buyer may assign the right to acquire certain of the Acquired Assets to one or more of its Affiliates prior to the Closing (provided, that in connection with any such assignment, Buyer shall remain primarily liable for such assigned obligations); provided, however, following the Closing, Buyer may assign and delegate, in whole or in part, its rights and obligations hereunder to either (i) a wholly-owned Subsidiary of Buyer, (ii) an Affiliate under common control with Buyer or (iii) in connection with the transfer by Buyer of all or substantially all of the Acquired Assets; and provided, further, however, that no such assignment shall relieve Buyer of any obligation or liability under this Agreement.

Section 10.07 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but both of which together shall constitute one and the same instrument. This Agreement may be executed and delivered by e-mail of a .pdf, .tif, .jpeg or similar attachment ("**Electronic Delivery**"), and any such counterparty delivered using Electronic Delivery shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

Section 10.08 Notices. All written notices that are required or permitted hereunder will be in writing and sufficient if delivered personally or sent by nationally-recognized overnight courier, addressed as follows:

if to Buyer, to:

Vertex Pharmaceuticals Incorporated Attention: Business Development 50 Northern Avenue Boston, MA 02110

with a copy (which shall not constitute notice) to:

Vertex Pharmaceuticals Incorporated Attention: Corporate Legal 50 Northern Avenue Boston, MA 02110 Email: Legal_Notice@vrtx.com

and

White & Case LLP 1155 Avenue of the Americas New York, New York 10036

Attn: Daniel G. Dufner, Jr., Esq. Michael A. Deyong, Esq.

Email:

If to Seller, to:

Concert Pharmaceuticals, Inc. 99 Hayden Avenue, Suite 500

Lexington, MA 02421 Attn: Chief Executive Officer and General Counsel

Email: rtung@concertpharma.com rsilverman@concertpharma.com

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP 100 Northern Ave Boston, MA 02210

Attn: John M. Mutkoski, Esq.

Andrew H. Goodman, Esq.

Email: JMutkoski@goodwinlaw.com AGoodman@goodwinlaw.com

or to such other address as the Party to whom written notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such written notice will be deemed to have been given and received by the other Party: (a) when delivered if personally delivered; or (b) on receipt if sent by overnight courier.

Section 10.09 Governing Law; Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the Laws of the State of Delaware, without giving effect to conflicts of laws principles that would result in the application of the Law of any other state. Each of the Parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the Court of Chancery of the State of Delaware, or, if such court finds it lacks subject matter jurisdiction, the federal court of the United States of America sitting in Delaware, and any appellate court from any thereof, in any suit, action, legal proceeding or claim arising out of or relating to this Agreement or the agreements delivered in connection herewith or the transactions contemplated hereby or thereby or for recognition or enforcement of any judgment relating thereto, and each of the Parties hereby irrevocably and unconditionally (i) agrees not to commence any such suit, action, legal proceeding or claim except in the Court of Chancery of the State of Delaware, or, if such court finds it lacks subject matter jurisdiction, the federal court of the United States of America sitting in Delaware, and any appellate court from any thereof, (ii) agrees that any claim in respect of any such suit, action, legal proceeding or claim may be heard and determined in the Court of Chancery of the State of Delaware, or, if such court finds it lacks subject matter jurisdiction, the federal court of the United States of America sitting in Delaware, and any appellate court from any thereof, (iii) waives, to the fullest extent it may legally and effectively do so, any objection that it may now or hereafter have to the laying of venue of any such suit, action, legal proceeding or claim in such courts and (iv) waives, to the fullest extent permitted by Law, the defense of an inconvenient forum to the maintenance of such suit, action, legal proceeding or claim in such courts. Each of the Parties hereto (A) agrees that a final judgment in any such suit, action, legal proceeding or claim shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law and (B) waives any objection to the recognition and enforcement by a court in other jurisdictions of any such final judgment. Each Party to this Agreement irrevocably consents to service of process inside or outside the territorial jurisdiction of the courts referred to in this <u>Section 10.09</u> in the manner provided for notices in <u>Section</u> 10.08. Nothing in this Agreement will affect the right of any Party to this Agreement to serve process in any other manner permitted by Law.

Section 10.10 Amendments and Waivers. The Parties may mutually amend or waive any provision of this Agreement at any time. No amendment or waiver of any provision of this Agreement shall be valid unless the same shall be in writing and signed by each of the Parties. No waiver by either Party of any default, misrepresentation, or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof.

Section 10.11 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the Parties agree that the body making the determination of invalidity or unenforceability shall have the power to reduce the scope, duration or area of the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified after the expiration of the time within which the judgment may be appealed.

Section 10.12 Expenses. Except as otherwise specifically provided to the contrary in this Agreement or any of the Related Agreements, each of the Parties shall bear its own costs and expenses (including legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby, whether or not the Closing takes place.

Section 10.13 Specific Performance. Each Party acknowledges and agrees that the other Party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or are threatened to be breached, and that money damages or other legal remedies would not be an adequate remedy for any such damages. It is accordingly agreed that prior to the valid termination of this Agreement in accordance with Section 7.01, (i) the Parties shall be entitled to seek (in a court of competent jurisdiction as set forth in Section 10.09) an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement (including Buyer's obligation to effect the Closing), without bond or other security being required, this being in addition to any remedy to which they are entitled under this Agreement, and (ii) the right of specific enforcement is an integral part of the transactions contemplated by this Agreement and without that right, neither Seller nor Buyer would have entered into this Agreement. Without limiting the generality of the foregoing, it is explicitly agreed that Seller shall be entitled to an injunction, specific performance or other equitable remedy to specifically enforce Buyer's obligation to effect the Closing on the terms and conditions set forth herein in the event that all conditions in Sections 5.01 and 5.02 have been satisfied (other than those conditions that by their nature are to be satisfied by actions taken at the Closing, each of which is then capable of being satisfied at a Closing on such date) at the time when the Closing would have occurred but for the failure of Buyer to comply with its obligations to effect the Closing pursuant to the terms of this Agreement. Each of Seller and Buyer acknowledges and agrees that following a valid termination of this Agreement in accordance with <u>Section</u> 7.01, each Party shall be entitled to seek monetary damages for a willful or intentional breach of this Agreement in accordance with Section 7.02(a).

Section 10.14 Guaranty. Guarantor irrevocably guarantees each and every covenant and obligation of Buyer and the full and timely performance of Buyer's obligations under the provisions of this Agreement. This is a guaranty of payment and performance, and not of collection, and Guarantor acknowledges and agrees that this guaranty is full and unconditional, and no release or extinguishments of

Buyer's Liabilities (other than in accordance with the terms of this Agreement), whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guaranty. Guarantor hereby waives, for the benefit of Seller, (i) any right to require Seller as a condition of payment or performance of Guarantor to proceed against Buyer or pursue any other remedies whatsoever and (ii) to the fullest extent permitted by Law, any defenses or benefits that may be derived from or afforded by Law that limit the liability of or exonerate guarantors or sureties, except to the extent that any such defense is available to Buyer. Guarantor understands that Seller is relying on this guaranty in entering into this Agreement. Under no circumstances shall the maximum amount payable by Guarantor hereunder for any reason and under any legal theory in law or at equity exceed an amount equal to the Base Purchase Price and any Contingent Payment that becomes payable pursuant to Section 1.02(b).

Section 10.15 <u>Construction</u>. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) "either" and "or" are not exclusive and "include", "includes" and "including" are not limiting; (b) "hereof", "hereto", "hereby", "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) the word "will" shall be construed to have the same meaning as the word "shall"; (d) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if"; (e) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (f) references to any Law, Contract, instrument or other document shall mean such Law. Contract, instrument or other document as amended, supplemented or otherwise modified from time to time, including by succession of comparable successor Laws; (g) references to a person or entity are also to its permitted successors and assigns; (h) references to an "Article", "Section", "Exhibit", "Annex" or "Schedule" refer to an Article or Section of, or an Exhibit, Annex or Schedule to, this Agreement; (i) references to "\$" or otherwise to dollar amounts refer to the lawful currency of the United States; (j) unless the context so requires, references to any Laws or specific provisions of Laws shall include any rules, regulations and delegated legislation issued thereunder; (k) references to any pronoun shall include the corresponding masculine, feminine and neuter forms; (l) the table of contents and headings set forth in this Agreement are for convenience of reference purposes only and shall not affect or be deemed to affect in any way the meaning or interpretation of this Agreement or any term or provision hereof; and (m) references herein to "primarily" shall include "primarily" as well as any other standard that reflects a majority or more of the matter addressed, including "exclusively" or any similar term. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified, and if any action is to be taken or given on or by a particular calendar day, and such calendar day is not a Business Day, then such action may be deferred until the next Business Day. The language used in this Agreement shall be deemed to be the language chosen by the Parties hereto to express their mutual intent, and no rule of strict construction shall be applied against either Party. The Parties agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any Law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

Section 10.16 <u>Waiver of Jury Trial</u>. EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY OF THE AGREEMENTS DELIVERED IN CONNECTION HEREWITH AND THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE EITHER OF SUCH WAIVERS, (B) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVERS, (C) IT MAKES

SUCH WAIVERS VOLUNTARILY, AND (D) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS <u>SECTION 10.16</u>.

[Remainder of page intentionally left blank]

The Parties hereto have executed this Agreement as of the date first above written.

CONCERT PHARMACEUTICALS, INC.

By: /s/ Roger Tung

Name: Roger Tung
Title: President & CEO

VERTEX PHARMACEUTICALS (EUROPE) LIMITED

By: /s/ Ian Smith

Name: Ian Smith
Title: Director

Solely with respect to Section 10.14 herein:

VERTEX PHARMACEUTICALS INCORPORATED

By: /s/ Ian Smith

Name: Ian Smith

Executive Vice President, Chief Operating Officer and Chief Financial

Title: Officer

FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "First Amendment") is made as of March 1, 2017, by and between ARE-SD REGION NO. 23, LLC, a Delaware limited liability company ("Landlord"), and VERTEX PHARMACEUTICALS INCORPORATED, a Massachusetts corporation ("Tenant").

RECITALS

- **A.** Landlord and Tenant are parties to that certain Lease Agreement dated as of December 2, 2015 (the "**Lease**"). Pursuant to the Lease, Tenant leases certain premises containing approximately 170,523 rentable square feet of space in that certain to be constructed building to be known as 3215 Merryfield Row, San Diego, California ("**Building**"). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.
- **B.** Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease as provided in this First Amendment.
- **NOW, THEREFORE,** in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:
- **1.** <u>Dates and Schedule.</u> Notwithstanding anything to the contrary contained in the Lease:
 - **a.** The Target Commencement Date as defined on page 1 of the Lease is hereby amended to be August 1, 2017; provided, however, that in no event may such date be extended by any Force Majeure events whether occurring before or after the date of this First Amendment, but such date may be extended on a day-for-day basis for any Tenant Delays first occurring after the date of this First Amendment;
 - **b.** The reference to the Outside Delivery Date as "May 1, 2017" in the fifth paragraph of <u>Section 2</u> of the Lease is hereby deleted and replaced with "January 3, 2018"; provided, however, that in no event may such date be extended by any Force Majeure events whether occurring before or after the date of this First Amendment, but such date may be extended on a day-for-day basis for any Tenant Delays first occurring after the date of this First Amendment;
 - c. Schedule 2 to the Work Letter is hereby deleted in its entirety and replaced with the schedule attached here to as Exhibit A; and
 - d. Landlord and Tenant agree that neither party shall claim Landlord Delay or Tenant Delay with respect to any period prior to the date of this First Amendment.
- 2. <u>Budget for Tenant's Work</u>. The third sentence of <u>Section 7(a)</u> of the Work Letter, Budget For Tenant's Work, is deleted and replaced with the following:

The Budget shall include a payment to Landlord of administrative rent ("Administrative Rent") of \$15,000 per month, which amount shall be payable on the first of each month commencing on the first day of the full month following Landlord's delivery of the Building to Tenant in Tenant Improvements Work Readiness Condition through date of completion of Tenant's Work but in no event shall such Administrative Rent exceed \$150,000. There shall be no other payment of Administrative Rent related to Tenant Work.

- **3.** Right to Expand. Section 39 of the Lease is hereby deleted in its entirety and replaced with the following:
 - "39. Right to Expand; Right of First Refusal.
 - Expansion in the Project. Landlord, in Landlord's sole discretion, may at any time construct a second building at the Project (the "Spectrum 3 Building"). Without limiting the foregoing, Landlord shall, in the exercise of its sole and absolute discretion, make the decisions as to all matters regarding the Spectrum 3 Building including, without limitation, the size thereof. Tenant acknowledges that, if Landlord so elects in its sole and absolute discretion, all or a portion of the Spectrum 3 Building may consist of small suites (e.g., a science hotel). Subject to the terms of this Section 39, each time that Landlord intends to accept a written proposal (the "Pending Deal") to lease all or a portion of the ROFR Space (as hereinafter defined) to a third party, Landlord shall deliver to Tenant written notice (the "Pending Deal Notice") of the existence and the material terms of such Pending Deal. For purposes of this Section 39(a), "ROFR Space" shall mean any space in the Spectrum 3 Building so long as Landlord has not previously provided Tenant with Pending Deal Notice(s) which in the aggregate cover fifty percent (50%) or more of the total rentable square footage in the Spectrum 3 Building. Tenant shall be entitled to exercise its right under this Section 39(a) only with respect to the entire ROFR Space described in such Pending Deal Notice (the "Identified Space"). Within 5 business days after Tenant's receipt of the Pending Deal Notice, Tenant shall deliver to Landlord written notice (the "Space Acceptance Notice") if Tenant elects to lease the Identified Space. Tenant's right to receive the Pending Deal Notice and election to lease or not lease the Identified Space pursuant to this Section 39(a) is hereinafter referred to as the "Right of Refusal." Notwithstanding any provision to the contrary in this Lease, once Landlord has provided Tenant with Pending Deal Notice(s) which in the aggregate cover fifty percent (50%) or more of the total rentable square footage in the Spectrum 3 Building, Tenant shall have no further Right(s) of First Refusal. If Tenant elects to lease the Identified Space by delivering the Space Acceptance Notice within the required 5 business day period, Tenant shall be deemed to agree to lease the Identified Space on the same general terms and conditions as this Lease except that the terms of the Lease shall be modified to reflect the terms of the Pending Deal Notice for the rental of the Identified Space, provided, however, that (i) if the term of the lease with respect to the Identified Space would pursuant to the Pending Deal expire prior to the term of the Lease with respect to the then-existing Premises, then the term of the Lease with respect to the Identified Space shall be modified to be co-

terminous with the Term of this Lease with respect to the then-existing Premises, and (ii) if the term of the lease with respect to the Identified Space is modified to be co-terminous with the term of the then-existing Premises pursuant to subsection (i), then the economic terms set forth in the Pending Deal Notice shall be equitably adjusted to account for such extension of the term with respect to the Identified Space, provided that such adjustment of the economic terms shall be no less favorable to Landlord on an annual basis than the economic terms set forth in the Pending Deal (and with market rate annual increases in base rent for the Identified Space for that portion of the lease term for the Identified Space beyond the term provided for in the Pending Deal), as reasonably determined by Landlord and Tenant. If the term of the lease with respect to the Identified Space would pursuant to the Pending Deal expire after the term of this Lease with respect to the then-existing Premises, then the term of the lease with respect to the Identified Space shall be as provided in the Pending Deal (and, for the avoidance of any doubt, no adjustment shall be made to the term of this Lease for the then-existing Premises). Notwithstanding anything to the contrary contained herein, in no event shall the Work Letter or the TI Allowance (as defined in the Work Letter) apply to the Identified Space, as the terms and conditions of the Pending Deal Notice (as may be equitably adjusted by Landlord), including any tenant improvement allowance provided for in the Pending Deal Notice, shall apply. If Tenant fails to deliver a Space Acceptance Notice to Landlord within the required 5 business day period, Tenant shall be deemed to have waived its rights under this Section 39(a) to lease the Identified Space identified in the applicable Pending Deal Notice, and Landlord shall have the right to lease such Identified Space to the third party subject to the Pending Deal (or an affiliate of such third party) ("Pending Deal Party"). Provided Tenant has not already waived or exercised its rights under this Section 39(a) to space which in the aggregate constitutes 50% or more of the total rentable square footage in the Building, Tenant's Right of First Refusal with respect to such Identified Space shall be restored if Landlord fails to enter into an agreement to lease the Identified Space to the Pending Deal Party within 6 months after Landlord's deliver of the Pending Deal Notice to Tenant.

(b) Furthermore, for the avoidance of any doubt, Tenant shall in no event be entitled to a second Pending Deal Notice with respect to any space in the Spectrum 3 Building once Landlord has entered into a lease with a Pending Deal Party with respect to such space in the Spectrum 3 Building.

If Tenant leases a portion of the Spectrum 3 Building and a portion of the Spectrum 3 Building is leased to a third party, the following Lease provisions shall also apply to Tenant's leasing of the Identified Space (and in the event of any conflict between the provisions of this paragraph and the other provisions of the this Lease with respect to the leasing of the Identified Space, the provisions of this paragraph shall govern): (i) Tenant shall not, without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed, use the Identified Space in any manner which will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Spectrum 3 Building as proportionately allocated to the Identified Space based upon Tenant's share of the Spectrum 3 Building or the Building Systems serving the Spectrum 3 Building shall require Landlord's consent which consent may be given or withheld in Landlord's sole discretion, (iii) Landlord may equitably increase, in Landlord's reasonable discretion, Tenant's share of Operating Expenses for any item of expense or cost reimbursable by Tenant that relates to a repair, replacement, or service that benefits only the Identified Space or only a portion of the Spectrum 3 Building that includes the Identified Space or that varies with occupancy or use. Also, so long as Tenant leases any portion of the Spectrum 3 Building, Section 5(hh) shall be deleted in its entirety.

- (c) **Amended Lease**. If: (i) Tenant fails to timely deliver a Space Acceptance Notice, or (ii) after the expiration of a period of 20 days from the date Landlord delivers to Tenant a lease amendment or lease agreement for the Identified Space no lease amendment or lease agreement for the Identified Space acceptable to both parties each in their reasonable discretion has been executed and delivered by Tenant to Landlord, Tenant shall be deemed to have waived its right to lease the Identified Space subject to the applicable Pending Deal, subject to terms of <u>Section 39(a)</u>.
- (d) **Exceptions**. Notwithstanding the above, the Right of First Refusal shall, at Landlord's option, not be in effect and may not be exercised by Tenant:
 - (i) during any period of time that Tenant is in Default under any provision of the Lease; or
 - (ii) if Tenant has been in Default under any provision of the Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Right of First Refusal.
- (e) **Termination**. The Right of First Refusal shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Right of First Refusal, if, after such exercise, but prior to the commencement date of the lease of such Right of First Refusal, (i) Tenant fails to timely cure any default by Tenant under the Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of the Right of First Refusal to the date of the commencement of the lease of the Identified Space, whether or not such Defaults are cured.
- (f) **Subordinate**. Tenant hereby acknowledges and agrees that, notwithstanding anything to the contrary contained in this Lease, Tenant's Right of First Refusal shall be subject and subordinate to any expansion rights granted in the Spectrum 3 Building to any Pending Deal Party with whom Landlord enters into a lease for space in the Spectrum 3 Building.
- (g) **Rights Personal**. The Right of First Refusal is personal to Vertex Pharmaceuticals Incorporated and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease, except that it may be assigned in connection with any Permitted Assignment of this Lease.

- (h) **No Extensions**. The period of time within which the Right of First Refusal may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Right of First Refusal."
- **Fence**. Landlord hereby approves Tenant's installation, at Tenant's sole cost and expense, of a fence adjacent to the meadow area of the Project, in a location reasonably agreed to by the parties (the "**Fence Installation**"), which Fence Installation shall be performed using materials of a quality and design reasonably acceptable to Landlord, subject to the terms of <u>Section 12</u> of the original Lease and any other conditions that Landlord may reasonably impose.
- **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this First Amendment and that no Broker brought about this transaction. Landlord and Tenant each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this First Amendment.
- **Disclosure.** For purposes of Section 1938 of the California Civil Code, as of the date of this First Amendment, Tenant acknowledges having been advised by Landlord that the project in which the Building is located has not been inspected by a certified access specialist.
- 7. OFAC. Tenant and Landlord are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

8. <u>Miscellaneous</u>

- **a.** This First Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This First Amendment may be amended only by an agreement in writing, signed by the parties hereto.
- **b.** This First Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective their successors and assigns.
- **c.** This First Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this First Amendment attached thereto.
- **d.** Except as amended and/or modified by this First Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this First Amendment. In the event of any conflict between the provisions of this First Amendment and the provisions of the Lease the provisions of this First Amendment shall prevail. Whether or not specifically amended by this First Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this First Amendment.

[Signatures are on the next page]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment as of the day and year first above written.

TENANT:

VERTEX PHARMACEUTICALS INCORPORATED,

a Massachusetts corporation

By: Charles E. Pappalardo

Its: Vice President, Real Estate and Operations

LANDLORD:

ARE-SD REGION NO. 23, LLC,

a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P., a Delaware limited partnership, managing member

By: ARE-QRS CORP., a Maryland corporation, general partner

By: Michael Budewitz

Its: Vice President RE Legal Affairs

CERTIFICATION

I, Jeffrey M. Leiden, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Vertex Pharmaceuticals Incorporated;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 28, 2017 /s/ Jeffrey M. Leiden

Jeffrey M. Leiden

Chief Executive Officer and President

CERTIFICATION

I, Ian F. Smith, certify that:

- 1. I have reviewed this Ouarterly Report on Form 10-O of Vertex Pharmaceuticals Incorporated:
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 28, 2017 /s/ Ian F. Smith

Ian F. Smith

Executive Vice President, Chief Operating Officer and Chief Financial Officer

SECTION 906 CEO/CFO CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) each of the undersigned officers of Vertex Pharmaceuticals Incorporated, a Massachusetts corporation (the "Company"), does hereby certify, to such officer's knowledge, that the Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 28, 2017

/s/ Jeffrey M. Leiden

Jeffrey M. Leiden

Chief Executive Officer and President

Date: April 28, 2017

/s/ Ian F. Smith

Ian F. Smith

Executive Vice President, Chief Operating Officer and Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.