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
	FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

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

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

Large accelerated filer x

and post such files). Yes x No o

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

244,655,527

Class

Outstanding at July 24, 2015

VERTEX PHARMACEUTICALS INCORPORATED FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2015

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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.

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Part I. Financial Information

Item 1. Financial Statements

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except per share amounts)

Royally revenues 5,077 13,015 11,860 23,03 Collaborative revenues 611 3,067 1,453 7.5 Total revenues 166,076 138,421 304,585 25,68 Custs and expenses: 15,409 9,655 24,700 148,28 Royally expenses 15,409 7,645 43,977 14,63 Research and development expenses 223,858 224,407 439,457 43,937 14,63 Research and development expenses 23,359 77,446 180,554 151,53 161,40 15,53 161,40 15,53 161,74 163,53 161,73 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 161,74 163,53 163,74 163,53 163,43 163,43 163,43 163,43 163,43 163,43 163,43 163,43 163,43 163,43 163,43 163,43 </th <th></th> <th>Three Months</th> <th>Ende</th> <th>d June 30,</th> <th></th> <th>Six Months E</th> <th>nded</th> <th>June 30,</th>		Three Months	Ende	d June 30,		Six Months E	nded	June 30,
Product revenues S 160,388 S 122,319 S 291,263 S 225, Royalty revenues 5,077 13,015 11,868 32,7 13,015 11,868 32,7 13,015 11,868 32,7 13,015 11,868 32,7 13,015 13,087 14,633 7, Total revenues 166,076 133,421 304,585 226,6 13,600 133,421 304,585 226,6 13,600 133,421 304,585 226,6 13,600 13,60		2015		2014		2015		2014
Royalty revenues 5.077 13.015 11.69 2.32 Collaborative revenues 611 3.097 1.453 7.7 Total revenues 166,076 138,421 304,535 2.56 Costs and expenses: 15.690 9.655 2.479 1.84 Royalty expenses 1.451 7.645 4.377 1.43 Research and development expenses 23,358 224,487 439,457 433 Sales, general and administrative expenses 94,394 77,46 180,254 153 Sales, general and administrative expenses 337,240 180,922 433,419 633 Loss from operations (171,164) 180,522 433,419 363 Loss from operations (171,164) 115,585 44,774 633 Interest expenses, net (2111) 1,5585 42,418 333 Interest expenses, net (2111) 1,5583 339,269 338 Interest expense, net (211) 1,5393 339,269 338 Loss from cont	Revenues:							
Collaborative revenues	Product revenues, net	\$ 160,388	\$	122,319	\$	291,263	\$	225,780
Total revenues 166,076 138,421 304,595 256, Costs and expenses: Cost of product revenues 15,409 9,655 24,790 18, Royalty expenses 1,1451 7,645 43,77 14, Research and development expenses 223,858 224,487 439,457 463, Sales, general and administrative expenses 94,394 77,46 180,254 151, Restructuring expenses (1,1451 16,146) 16,155, Guilland 16,165, Guilland 16,1	Royalty revenues	5,077		13,015		11,869		23,748
Costs and expenses: Costs for product revenues 15,409 9,655 24,790 18.8 Royalty expenses 1,451 7,645 4,377 14.4 Research and development expenses 223,838 224,487 439,457 463, 363, 363, 363, 363, 363, 363, 363,	Collaborative revenues	611		3,087		1,453		7,344
Cost of product revenues	Total revenues	 166,076		138,421		304,585		256,872
Royalty expenses	Costs and expenses:							
Research and development expenses 223,881 224,487 439,457 403,53 Sales, general and administrative expenses 94,394 77,466 180,254 151,53 Restructuring expenses (income) 21,28 2700 (1,144) 55,53 Total costs and expenses 337,240 318,933 647,734 633,63 Loss from operations (171,164) (180,542) (343,149) 308,63 Loss from contentions operations before provision for income taxes (190,661) (185,365) (342,48) 33,63 Loss from continuing operations before provision for income taxes (190,661) (185,365) (389,66) 389,61 Loss from continuing operations before provision for income taxes (190,661) (185,365) (389,66) 389,61 Provision for income taxes (190,661) (185,963) (419,695) 389,61 389,61 Loss from continuing operations text benefit of \$0 2,092 (159,089) (419,695) 389,1 Loss startibutable to Vertex \$1,888,48 (159,089) 387,454 389,2 Loss from continuing operations	Cost of product revenues	15,409		9,655		24,790		18,227
Sales, general and administrative expenses 94,394 77,466 180,254 151, Restructuring expensess (income) 2,128 270 (1,144) 5, 5 Total costs and expenses 337,240 318,963 647,734 633, 63 Loss from operations (17,164) (180,542) (343,149) (396, 143,149) Loss from continuing operations peters provision for income texes (19,164) 37,731 (3,699) 38, 18, 18, 18, 18, 18, 18, 18, 18, 18, 1	Royalty expenses	1,451		7,645		4,377		14,549
Restructuring expenses (income) 2,128 270 (1,144) 5 Total costs and expenses 337,244 318,963 647,734 633 Loss from operations (171,164) (180,542) (34,149) (366,30) Interest expense, net (21,111) (15,555) (42,418) (318,03) Other income (expenses), net (141,414) 37,731 (3,699) 38,030 Loss from continuing operations before provision for income taxes (190,861) (155,396) (389,266) (389,261) Loss from continuing operations (220,992) (159,089) (419,696) (391,416) Loss from continuing operations (220,992) (159,089) (419,696) (391,416) Loss from discontinued operations (220,992) (159,089) (419,696) (391,416) Loss from discontinued operations (220,992) (159,089) (387,454) (391,416) Loss from discontinued operations (188,848) (159,089) (387,454) (391,416) Loss from continuing operations (188,848) (159,089) (387,454)	Research and development expenses	223,858		224,487		439,457		463,104
Total costs and expenses 337,240 318,963 647,734 633 Loss from operations (171,164 (180,542 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645 (343,149) (396, 161,645	Sales, general and administrative expenses	94,394		77,446		180,254		151,658
Content Cont	Restructuring expenses (income)	2,128		(270)		(1,144)		5,918
Interest expense, net	Total costs and expenses	337,240		318,963		647,734		653,456
Other income (expenses), net 1,414 37,731 (3,699) 38, Loss from continuing operations before provision for income taxes (190,861) (158,396) (389,266) (391,266)	Loss from operations	(171,164)		(180,542)		(343,149)		(396,584)
Loss from continuing operations before provision for income taxes (190,861) (158,396) (389,266) (389, 266) (38	Interest expense, net	(21,111)		(15,585)		(42,418)		(31,302)
Provision for income taxes 30,131 693 30,430 1 Loss from continuing operations (220,992) (159,089) (419,696) (391, 10, 10, 10, 10, 10, 10, 10, 10, 10, 1	Other income (expenses), net	1,414		37,731		(3,699)		38,182
Case from continuing operations Case C	Loss from continuing operations before provision for income taxes	(190,861)		(158,396)	-	(389,266)		(389,704)
Loss from discontinued operations, net of tax benefit of \$0	Provision for income taxes	30,131		693		30,430		1,496
Net loss (220,992) (159,382) (419,696) (391, 150, 150, 150, 150, 150, 150, 150, 15	Loss from continuing operations	(220,992)	-	(159,089)	-	(419,696)		(391,200)
Loss attributable to noncontrolling interest 32,144	Loss from discontinued operations, net of tax benefit of \$0	_		(293)		_		(639)
Net loss attributable to Vertex \$ (188,848) \$ (159,382) \$ (387,454) \$ (391,494) Amounts attributable to Vertex: Loss from continuing operations (188,848) (159,089) (387,454) (391,494) Loss from discontinued operations — (293) —	Net loss	(220,992)		(159,382)		(419,696)		(391,839)
Amounts attributable to Vertex: Loss from continuing operations (188,848) (159,089) (387,454) (391, 491) Loss from discontinued operations — (293) — 0 Net loss attributable to Vertex (188,848) (159,382) (387,454) (391, 491) Amounts per share attributable to Vertex common shareholders: Vertical State of Common Shareholders: Net loss from continuing operations: State of Colors o	Loss attributable to noncontrolling interest	32,144		_		32,242		_
Loss from continuing operations (188,848) (159,089) (387,454) (391, 491) Loss from discontinued operations — (293) — <td>Net loss attributable to Vertex</td> <td>\$ (188,848)</td> <td>\$</td> <td>(159,382)</td> <td>\$</td> <td>(387,454)</td> <td>\$</td> <td>(391,839)</td>	Net loss attributable to Vertex	\$ (188,848)	\$	(159,382)	\$	(387,454)	\$	(391,839)
Loss from discontinued operations	Amounts attributable to Vertex:							
Net loss attributable to Vertex (188,848) (159,382) (387,454) (391,454) Amounts per share attributable to Vertex common shareholders: S (0.78) \$ (0.68) \$ (1.61) \$ (0.62) \$ (0.68) \$ (1.61) \$ (0.68) \$ (1.61) \$ (0.68) \$ (1.61) \$ (0.68) \$ (1.61) \$ (0.68) \$ <td>Loss from continuing operations</td> <td>(188,848)</td> <td></td> <td>(159,089)</td> <td></td> <td>(387,454)</td> <td></td> <td>(391,200)</td>	Loss from continuing operations	(188,848)		(159,089)		(387,454)		(391,200)
Amounts per share attributable to Vertex common shareholders: Net loss from continuing operations: Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (1	Loss from discontinued operations	_		(293)		_		(639)
Net loss from continuing operations: \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Net loss from discontinued operations: \$ - \$ - \$ - \$ - \$ - \$ Diluted \$ - \$ - \$ - \$ - \$ - \$ Net loss: \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.68) \$ Shares used in per share calculations:	Net loss attributable to Vertex	(188,848)		(159,382)		(387,454)		(391,839)
Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Net loss from discontinued operations: Basic \$ - \$ - \$ - \$ - \$ Diluted \$ - \$ - \$ - \$ Net loss: Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Shares used in per share calculations:	Amounts per share attributable to Vertex common shareholders:							
Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (Net loss from continuing operations:							
Net loss from discontinued operations: Basic \$ - \$ <td>Basic</td> <td>\$ (0.78)</td> <td>\$</td> <td>(0.68)</td> <td>\$</td> <td>(1.61)</td> <td>\$</td> <td>(1.68)</td>	Basic	\$ (0.78)	\$	(0.68)	\$	(1.61)	\$	(1.68)
Basic \$ - \$ - \$ - \$ Diluted \$ - \$ - \$ - \$ Net loss: Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.78) \$ (0.68) \$ (1.61) \$ (0.78) \$ (0.68) \$ (0.61) \$ (0.68) \$ (0.68) \$ (0.68) \$ (0.61) \$ (0.68)	Diluted	\$ (0.78)	\$	(0.68)	\$	(1.61)	\$	(1.68)
Diluted \$ - \$ - \$ - \$ Net loss: - \$ (0.78) \$ (0.68) \$ \$ (1.61) \$ (2.61) \$ (2.61) \$ (3	Net loss from discontinued operations:							
Net loss: Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (2.50) Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (2.50) Shares used in per share calculations:	Basic	\$ _	\$	_	\$	_	\$	_
Basic \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (1.61) \$ Shares used in per share calculations:	Diluted	\$ _	\$	_	\$	_	\$	_
Diluted \$ (0.78) \$ (0.68) \$ (1.61) \$ (2.55) Shares used in per share calculations:	Net loss:							
Shares used in per share calculations:	Basic	\$ (0.78)	\$	(0.68)	\$	(1.61)	\$	(1.68)
Shares used in per share calculations:	Diluted	\$ (0.78)	\$	(0.68)	\$	(1.61)	\$	(1.68)
Paris 240.757 222.900 240.120 222	Shares used in per share calculations:							
Edsic 240,737 253,000 240,125 253,	Basic	240,757		233,808		240,129		233,353
Diluted 240,757 233,808 240,129 233,	Diluted	240,757		233,808		240,129		233,353

Comprehensive loss attributable to Vertex

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

Three Months Ended June 30, Six Months Ended June 30, 2015 2014 2015 2014 Net loss \$ (220,992)(159,382)(419,696) \$ (391,839)Changes in other comprehensive loss: Unrealized holding (losses) gains on marketable securities (46) 82 130 55 Unrealized losses on foreign currency forward contracts (4,280)(89) (3,974)(125)Foreign currency translation adjustment 1,828 281 1,220 353 Total changes in other comprehensive loss (2,498)274 (2,624)283 (223,490)(159,108)(422, 320)(391,556) Comprehensive loss Comprehensive loss attributable to noncontrolling interest 32,144 32,242

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

(191,346)

\$

(159,108)

\$

(390,078)

\$

(391,556)

\$

VERTEX PHARMACEUTICALS INCORPORATED Condensed Consolidated Balance Sheets

Condensed Consolidated Balance Sheets (unaudited)

(in thousands, except share and per share amounts)

		June 30,	D	ecember 31,
Assets		2015		2014
Current assets:	¢	070 540	¢.	C25 250
Cash and cash equivalents	\$	870,543	\$	625,259
Marketable securities, available for sale		145,907		761,847
Restricted cash and cash equivalents (VIE)		88,318		8,418
Accounts receivable, net		94,519		75,964
Inventories		42,113		30,848
Prepaid expenses and other current assets		53,289		44,175
Total current assets		1,294,689		1,546,511
Property and equipment, net		713,378		715,812
Intangible assets		284,340		29,000
Goodwill		50,384		39,915
Restricted cash		22,146		176
Other assets	<u></u>	9,136	Φ.	3,265
Total assets	\$	2,374,073	\$	2,334,679
Liabilities and Shareholders' Equity				
Current liabilities:				
Accounts payable	\$	72,703	\$	71,194
Accrued expenses		206,030		209,676
Deferred revenues, current portion		14,930		17,468
Accrued restructuring expenses, current portion		10,166		33,107
Capital lease obligations, current portion		13,921		17,806
Senior secured term loan, current portion		42,873		14,206
Other liabilities, current portion		13,200		4,797
Total current liabilities		373,823		368,254
Deferred revenues, excluding current portion		21,019		27,808
Accrued restructuring expenses, excluding current portion		9,677		12,748
Capital lease obligations, excluding current portion		42,900		39,293
Deferred tax liability		112,413		15,044
Fan Pier lease obligation, excluding current portion		472,834		473,073
Senior secured term loan, excluding current portion		251,939		280,569
Other liabilities, excluding current portion		41,252		21,707
Total liabilities		1,325,857		1,238,496
Commitments and contingencies				
Shareholders' equity:				
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding at June 30, 2015 and December 31, 2014		_		_
Common stock, \$0.01 par value; 500,000,000 and 300,000,000 shares authorized at June 30, 2015 and December 31, 2014, respectively; 244,341,701 and 241,764,398 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively		2,406		2,385
Additional paid-in capital		5,987,169		5,777,154
Accumulated other comprehensive (loss) income		(1,707)		917
Accumulated deficit		(5,092,904)		(4,705,450)
Total Vertex shareholders' equity		894,964		1,075,006
Noncontrolling interest		153,252		21,177
Total shareholders' equity		1,048,216		1,096,183
Total liabilities and shareholders' equity	\$	2,374,073	\$	2,334,679

VERTEX PHARMACEUTICALS INCORPORATED

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

_	Comm	Common Stock		Common Stock			Common Stock			Common Stock				Accumulated Other									
	Shares		Amount]	Additional Paid-in Capital	Comprehensive Income (Loss)		Accumulated Deficit		Total Vertex Shareholders' Equity		Noncontrolling Interest		Total Shareholders' Equity									
Balance at December 31, 2013	233,789	\$	2,320	\$	5,321,286	\$	(306)	\$	(3,966,895)	\$	1,356,405	\$		\$	1,356,405								
Other comprehensive income, net of tax							283				283				283								
Net loss									(391,839)		(391,839)		_		(391,839)								
Issuance of common stock under benefit plans	3,542		27		117,920						117,947				117,947								
Stock-based compensation					89,473						89,473				89,473								
Balance at June 30, 2014	237,331	\$	2,347	\$	5,528,679	\$	(23)	\$	(4,358,734)	\$	1,172,269	\$	_	\$	1,172,269								
•																							
Balance at December 31, 2014	241,764	\$	2,385	\$	5,777,154	\$	917	\$	(4,705,450)	\$	1,075,006	\$	21,177	\$	1,096,183								
Other comprehensive loss, net of tax							(2,624)				(2,624)				(2,624)								
Net loss									(387,454)		(387,454)		(32,242)		(419,696)								
Issuance of common stock under benefit plans	2,578		21		87,333						87,354				87,354								
Stock-based compensation					122,682						122,682				122,682								
Noncontrolling interest upon consolidation											_		164,317		164,317								
Balance at June 30, 2015	244,342	\$	2,406	\$	5,987,169	\$	(1,707)	\$	(5,092,904)	\$	894,964	\$	153,252	\$	1,048,216								

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

	Six Months E	ided June 30,		
	2015	2014		
Cash flows from operating activities:				
Net loss	\$ (419,696)	\$ (391,839)		
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization expense	30,428	29,960		
Stock-based compensation expense	120,645	89,024		
Deferred income taxes	6,346	_		
Other non-cash items, net	6,045	22		
Changes in operating assets and liabilities:				
Accounts receivable, net	(21,197)	2,518		
Inventories	(9,426)	1,194		
Prepaid expenses and other assets	(15,397)	(17,538)		
Accounts payable	(3,033)	7,671		
Accrued expenses and other liabilities	38,206	(9,459)		
Accrued restructuring expense	(26,012)	(9,369)		
Deferred revenues	(9,303)	(5,866)		
Net cash used in operating activities	(302,394)	(303,682)		
Cash flows from investing activities:				
Purchases of marketable securities	(125,655)	(703,977)		
Sales and maturities of marketable securities	741,725	801,206		
Payment for acquisition of variable interest entity	(80,000)	_		
Expenditures for property and equipment	(23,978)	(27,227)		
(Increase) decrease in restricted cash and cash equivalents	(21,975)	1		
Decrease in restricted cash and cash equivalents (VIE)	2,277	_		
Decrease (increase) in other assets	87	(528)		
Net cash provided by investing activities	492,481	69,475		
Cash flows from financing activities:				
Issuances of common stock under benefit plans	87,850	117,947		
Payments on capital lease obligations	(14,441)	(11,884)		
Proceeds from capital lease financing	13,386	(11,004)		
Payments on Fan Pier lease obligation	(30,292)	(30,292)		
Payments returned related to Fan Pier lease obligation	(50,232)	8,050		
Net cash provided by financing activities	56,503	83,821		
Effect of changes in exchange rates on cash				
5 5	(1,306)	1,645		
Net increase (decrease) in cash and cash equivalents	245,284	(148,741)		
Cash and cash equivalents—beginning of period Cash and cash equivalents—end of period	625,259 \$ 870,543	\$ 420,558		
Cash and Cash equivalents—end of period	ψ 070,343	420,530		
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$ 12,777	\$ 31,933		
Cash paid for income taxes	\$ 1,022	\$ 798		
Capitalization of costs related to Fan Pier lease obligation	\$ —	\$ 25,564		
Assets acquired under capital lease	\$ —	\$ 8,985		
Issuances of common stock exercises from employee benefit plans receivable	\$ 166	\$ -		

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 June 30, 2015 and 2014.

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, 2014, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 that was filed with the Securities and Exchange Commission (the "SEC") on February 13, 2015 (the "2014 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, noncontrolling interest, the consolidation of VIEs, leases 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 2014 Annual Report on Form 10-K.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements please refer to Note A, "Nature of Business and Accounting Policies—Recent Accounting Pronouncements," in the 2014 Annual Report on Form 10-K. The Company did not adopt any new accounting pronouncements during the six months ended June 30, 2015 that had a material effect on its condensed consolidated financial statements.

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 Customer's 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 incentives offered to certain indirect customers, including patients. 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.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2015:

			Rebates,				
		Trade	Chargebacks		Product	Other	
	A	llowances	and Discounts		Returns	Incentives	Total
				(in t	thousands)		
Balance at December 31, 2014	\$	1,463	\$ 29,102	\$	4,713	\$ 745	\$ 36,023
Provision related to current period sales		2,865	20,305		181	1,251	24,602
Adjustments related to prior period sales		(86)	(5,958)		(975)	(235)	(7,254)
Credits/payments made		(2,985)	(13,654)		(3,194)	(1,105)	(20,938)
Balance at June 30, 2015	\$	1,257	\$ 29,795	\$	725	\$ 656	\$ 32,433

C. Collaborative Arrangements

Cystic Fibrosis Foundation Therapeutics Incorporated

In April 2011, the Company entered into an amendment (the "April 2011 Amendment") to its existing collaboration agreement with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") pursuant to which CFFT agreed to provide financial support for (i) development activities for VX-661, a compound that targets the processing and trafficking defect of the F508del CFTR proteins discovered under the collaboration, and (ii) additional research and development activities directed at discovering new compounds targeting the processing and trafficking defect of the F508del protein.

Under the April 2011 Amendment, CFFT agreed to provide the Company with up to \$75.0 million in funding over approximately five years for research and development activities. The Company retains the right to develop and commercialize KALYDECO (ivacaftor), ORKAMBI (lumacaftor in combination with ivacaftor), lumacaftor, VX-661 and any other compounds discovered during the course of the research collaboration with CFFT. The Company recognized no collaborative revenues from this collaboration during the three and six months ended June 30, 2015 and \$1.6 million and \$4.5 million of collaborative revenues from this collaboration during the three and six months ended June 30, 2014, respectively.

In the original agreement, as amended prior to the April 2011 Amendment, the Company agreed to pay CFFT tiered royalties calculated as a percentage, ranging from single digits to sub-teens, of annual net sales of any approved drugs discovered during the research term that ended in 2008, including KALYDECO, ORKAMBI, lumacaftor and VX-661. The April 2011 Amendment provides for a tiered royalty in the same range on net sales of compounds targeting the processing and trafficking defect of F508del CFTR proteins discovered during the research term that began in 2011 and ended in February 2014. In each of the third quarter of 2012 and the first quarter of 2013, CFFT earned a commercial milestone payment of \$9.3 million from the Company upon achievement of certain sales levels for KALYDECO. These milestones were reflected in the Company's cost of product revenues. There are no additional commercial milestone payments payable by the Company to CFFT related to sales levels for KALYDECO. The Company also is obligated to make up to two one-time commercial milestone payments to CFFT upon achievement of certain sales levels for ORKAMBI.

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 July 2015. The Company has royalty obligations to CFFT for each compound commercialized pursuant to this collaboration until the expiration of patents covering that compound. 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 life 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 patent life extensions. CFFT may terminate its funding obligations under the collaboration, as amended, in certain circumstances, in which case there will be a proportional adjustment to the royalty rates and commercial milestone payments for certain compounds. The collaboration also may be terminated by either party for a material breach by the other, subject to notice and cure provisions.

Janssen Pharmaceutica NV

The Company has a collaboration agreement (the "Janssen HCV Agreement") with Janssen Pharmaceutica NV ("Janssen NV") for the development, manufacture and commercialization of telaprevir, which Janssen NV began marketing under the brand name INCIVO in certain of its territories in September 2011. Pursuant to the Janssen HCV Agreement, as amended, Janssen NV has a fully-paid license to manufacture and commercialize INCIVO in its territories including Europe, South America, the Middle East, Africa and Australia, subject to the payment of third-party royalties on net sales of INCIVO. In addition to the collaborative revenues, the Company recorded royalty revenues and corresponding royalty expenses related to third-party royalties that Janssen NV remains responsible for based on INCIVO net sales.

During the three and six months ended June 30, 2015 and 2014, the Company recognized the following revenues attributable to the Janssen NV collaboration:

	Three Months Ended June 30,					Six Months I	Ended	ded June 30,	
	2015	;		2014		2015		2014	
				(in thou	ısands)				
Royalty revenues (INCIVO)	\$	59	\$	5,698	\$	1,584	\$	10,633	
Collaborative revenues (telaprevir)		537		1,483		1,179		2,872	
Total revenues attributable to the Janssen NV collaboration	\$	596	\$	7,181	\$	2,763	\$	13,505	

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 milestone and royalty 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 regarding the time to develop the drug candidates, 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 milestone and royalty payments. The following collaborations are, or were previously, reflected in the Company's financial statements for being consolidated as VIEs:

Parion Sciences, Inc.

License and Collaboration Agreement

On June 4, 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 P-1055, for the

potential treatment of cystic fibrosis, or CF, and other pulmonary diseases. The Company is leading development activities for VX-371 and P-1055 in CF and other pulmonary diseases 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 P-1055, 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 P-1055 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 such point. Parion may terminate upon 30 days' notice if the Comapny experiences a change of control prior to the initiation of the first Phase 3 clinical trial for a licensed product, 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 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 Parion is a VIE based on, among other factors, the significance to Parion of the ENaC inhibitors licensed to the Company pursuant to the Parion Agreement and on the Company's power to direct the activities that most significantly impact the economic performance of 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. In particular, the Company did not acquire any equity interest in Parion, any interest in Parion's cash and cash equivalents or any control over Parion's activities that do not relate to the Parion Agreement.

Consideration for the Parion Agreement

The Company determined that the fair value of the consideration from the Company to Parion was \$255.3 million as of June 4, 2015, which consisted of (i) an \$80.0 million up-front payment, (ii) the estimated fair value of the contingent research and development milestones potentially payable by the Company to Parion and (iii) the estimated fair value of potential royalty payments payable by the Company to Parion. The Company valued the contingent milestone and royalty payments using (a) discount rates ranging from 4.1% to 5.9% for the development milestones and (b) a discount rate of 6.6% for royalties. The consideration paid and the preliminary fair value of the contingent milestone and royalty payments payable by the Company pursuant to the agreement are set forth in the table below:

	Jun	e 4, 2015
	(in tl	nousands)
Up-front payment	\$	80,000
Fair value of contingent milestone and royalty payments		175,340
Total	\$	255,340

Preliminary Allocation of Assets and Liabilities

For the purposes of the condensed consolidated balance sheets at June 4, 2015 and June 30, 2015, the Company preliminarily allocated the total consideration, which is comprised of the up-front payment and the fair value of the contingent milestone and royalty payments, intangible assets, goodwill, deferred tax liability, net and net other assets and liabilities.

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 P-1055, that are licensed by the Company from Parion. The difference between the preliminary fair value of the consideration and the fair value of Parion's assets (including the fair value of intangible assets) and liabilities was allocated to goodwill.

The following table summarizes the preliminary fair values of the assets and liabilities recorded on the effective date of the agreement:

	Jui	ne 4, 2015
	(in t	housands)
Intangible assets	\$	255,340
Goodwill		10,468
Deferred tax liability		(91,023)
Net other assets (liabilities)		(10,468)
Net assets attributable to noncontrolling interests	\$	164,317

BioAxone Biosciences, Inc.

In October 2014, the Company entered into a license and collaboration agreement (the "BioAxone Agreement") with BioAxone Biosciences, Inc. ("BioAxone"), a privately-held biotechnology company, 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 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.

Alios BioPharma, Inc.

In 2011, the Company entered into a license and collaboration agreement (the "Alios Agreement") with Alios BioPharma, Inc. ("Alios"), a privately-held biotechnology company, which resulted in the consolidation of Alios as a VIE through December 31, 2013. Pursuant to the Alios Agreement, the Company and Alios collaborated on the research, development and commercialization of HCV nucleotide analogues discovered by Alios through April 2014. In December 2014, the Alios Agreement terminated in accordance with its terms pursuant to a termination notice delivered by the Company in October 2014. As of September 30, 2014, the Company concluded that it no longer had significant continuing involvement with Alios due to its intent and ability to terminate the Alios Agreement, among other factors; therefore, the operations of Alios are presented as discontinued operations in these condensed consolidated financial statements.

Aggregate VIE Financial Information

The Company did not have any consolidated VIEs for the three and six months ended June 30, 2014. An aggregate summary of net loss attributable to noncontrolling interest related to the Company's VIEs for the three and six months ended June 30, 2015 is as follows:

	Three Months Ended Jo 30, 2015	une	Six Months Ended June 30, 2015				
	(in thousands)						
Loss attributable to noncontrolling interest before provision for income taxes	\$ (1,	,293)	\$ (1,579)				
Income tax provision	(29,	,653)	(29,590)				
Decrease in fair value of contingent milestone and royalty payments	(1,	,198)	(1,073)				
Net loss attributable to noncontrolling interest	\$ (32,	,144)	\$ (32,242)				

During the three and six months ended June 30, 2015, the fair value of the contingent milestone and royalty payments related to the BioAxone collaboration increased by \$0.4 million and \$0.5 million, respectively. During the three months ended June 30, 2015, the fair value of the contingent milestone and royalty payments related to the Parion collaboration decreased by \$1.6 million. The changes in the fair value of the contingent milestone and royalty payments was primarily due to the changes in market interest rates. As of June 30, 2015, the fair value of the contingent milestone and royalty payments related to the BioAxone collaboration and the Parion collaboration was \$27.6 million and \$173.7 million, respectively.

The following 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:

	J	une 30, 2015	Decem	ber 31, 2014					
		(in thousands)							
Restricted cash and cash equivalents (VIE)	\$	88,318	\$	8,418					
Prepaid expenses and other current assets		895		268					
Intangible assets		284,340		29,000					
Goodwill		19,391		8,923					
Other assets		508		42					
Accounts payable		823		189					
Accrued expenses and other current liabilities		34,254		3,891					
Deferred tax liability, net		108,913		11,544					
Other liabilities		6,068		300					
Noncontrolling interest		153,252		21,177					

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 our 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.

Outlicense Arrangements

In the ordinary course of the Company's business, the Company has entered into various agreements pursuant to which it has outlicensed rights to certain drug candidates to third-party collaborators. Although the Company does not consider any of these outlicense arrangements to be material, the most notable of these outlicense arrangements is described below. Pursuant to these outlicense arrangements, our collaborators are responsible for all costs related to the continued development of such drug candidates. Depending on the terms of the arrangements, the Company's collaborators may be required to make upfront payments, milestone payments upon the achievement of certain product research and development objectives and/or pay royalties on future sales, if any, of commercial products resulting from the collaboration.

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. is responsible for costs related to the development and commercialization of the compounds. During the three and six months ended June 30, 2015, the Company recorded reimbursement for these development activities of \$7.1 million and \$14.7 million, respectively. During the three and six months ended June 30, 2014, the Company recorded no reimbursement for these development activities. 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. Janssen Inc. may terminate the Janssen Influenza Agreement, subject to certain exceptions, upon six months' notice.

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 Company did not include the securities described in the following table in the computation of the net loss from continuing operations per share attributable to Vertex common shareholder calculations because the effect would have been anti-dilutive during each period:

	Three Months En	ded June 30,	Six Months Ended June 30,						
	2015	2014	2015	2014					
		(in thousands)							
Stock options	11,933	14,549	11,933	14,549					
Unvested restricted stock and restricted stock units	3,355	2,584	3,355	2,584					

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 June 30, 2015, the Company's investments were in money market funds, corporate debt securities and commercial paper.

As of June 30, 2015, 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. The Company's financial assets valued based on Level 2 inputs consisted of corporate debt securities and commercial paper, which consist of investments in highly-rated investment-grade corporations.

The following table sets forth the Company's financial assets and liabilities subject to fair value measurements:

	Fair Value Measurements as of June 30, 2015									
				Fair	Value Hierarchy	7				
	Total		Level 1		Level 2		Level 3			
			(in tho	usand	s)					
Financial assets carried at fair value:										
Cash equivalents:										
Money market funds	\$ 518,084	\$	518,084	\$	_	\$	_			
Marketable securities:										
Corporate debt securities	120,408		_		120,408		_			
Commercial paper	25,499		_		25,499		_			
Prepaid and other current assets:										
Foreign currency forward contracts	1,087		_		1,087		_			
Total financial assets	\$ 665,078	\$	518,084	\$	146,994	\$	_			
Financial liabilities carried at fair value:										
Other liabilities, current portion:										
Foreign currency forward contracts	\$ (2,737)	\$	_	\$	(2,737)	\$	_			
Other liabilities, excluding current portion:										
Foreign currency forward contracts	(313)		_		(313)		_			
Total financial liabilities	\$ (3,050)	\$	_	\$	(3,050)	\$	_			

The Company's VIEs invested in cash equivalents consisting of money market funds of \$84.4 million as of June 30, 2015, 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 milestone and royalty payments, which are valued based on Level 3 inputs. Please refer to Note C, "Collaborative Arrangements," for further information.

As of June 30, 2015, the fair value and carrying value of the Company's Term Loan was \$294.8 million. The fair value of the Company's Term Loan was estimated based on Level 3 inputs computed using the effective interest rate of the Term Loan. The effective interest rate considers the timing and amount of estimated future interest payments. Please refer to Note K, "Long-term Obligations" for further information regarding the Company's Term Loan.

F. Marketable Securities

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

	Am	ortized Cost	τ	Gross Inrealized Gains		Gross Unrealized Losses	Fair Value
			(in thousands)				
As of June 30, 2015							
Cash and cash equivalents:							
Cash and money market funds	\$	870,543	\$	_	\$	_	\$ 870,543
Total cash and cash equivalents	\$	870,543	\$	_	\$	_	\$ 870,543
Marketable securities:							
Commercial paper (due within 1 year)	\$	25,470	\$	29	\$	_	\$ 25,499
Corporate debt securities (due within 1 year)		120,430		12		(34)	120,408
Total marketable securities	\$	145,900	\$	41	\$	(34)	\$ 145,907
Total cash, cash equivalents and marketable securities	\$	1,016,443	\$	41	\$	(34)	\$ 1,016,450
As of December 31, 2014							
Cash and cash equivalents:							
Cash and money market funds	\$	625,259	\$	_	\$	_	\$ 625,259
Total cash and cash equivalents	\$	625,259	\$	_	\$	_	\$ 625,259
Marketable securities:							
Government-sponsored enterprise securities (due within 1 year)	\$	463,788	\$	14	\$	(52)	\$ 463,750
Commercial paper (due within 1 year)		51,674		72		_	51,746
Corporate debt securities (due within 1 year)		196,065		2		(66)	196,001
Corporate debt securities (due after 1 year through 5 years)		50,443		_		(93)	50,350
Total marketable securities	\$	761,970	\$	88	\$	(211)	\$ 761,847
Total cash, cash equivalents and marketable securities	\$	1,387,229	\$	88	\$	(211)	\$ 1,387,106

The Company has a limited number of marketable securities in insignificant loss positions as of June 30, 2015, 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 and six months ended June 30, 2015 and 2014.

G. Accumulated Other Comprehensive (Loss) Income

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

	Foreign Currency Translation Adjustment		Ga	realized Holding nins (Losses) on ketable Securities	Unrealized Gains (Losses) on Foreign Currency Forward Contracts			Total
				(in thou	sands)	1		
Balance at December 31, 2014	\$	(971)	\$	(123)	\$	2,011	\$	917
Other comprehensive (loss) income before reclassifications		1,220		130		(1,370)		(20)
Amounts reclassified from accumulated other comprehensive loss		_		_		(2,604)		(2,604)
Net current period other comprehensive (loss) income	\$	1,220	\$	130	\$	(3,974)	\$	(2,624)
Balance at June 30, 2015	\$	249	\$	7	\$	(1,963)	\$	(1,707)

	Foreign Currency Translation Adjustment			nrealized Holding ains on Marketable Securities	Unrealized Losses on Foreign Currency Forward Contracts			Total
Balance at December 31, 2013	\$	(325)	\$	42	\$	(23)	\$	(306)
Other comprehensive income (loss) before reclassifications		353		55		(108)		300
Amounts reclassified from accumulated other comprehensive loss		_		_		(17)		(17)
Net current period other comprehensive income (loss)	\$	353	\$	55	\$	(125)	\$	283
Balance at June 30, 2014	\$	28	\$	97	\$	(148)	\$	(23)

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. To date, the existence of operational sites in countries outside the United States has decreased the degree to which the Company has sought to hedge its revenues in certain foreign currencies.

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 June 30, 2015, all hedges were determined to be highly effective and the Company has 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 June 30, 2015	As of Dec	ember 31, 2014
Foreign Currency	(in tho	usands)	
Euro	\$ 102,796	\$	20,209
British pound sterling	82,960		13,515
Australian dollar	25,993		_
Total foreign currency forward contracts	\$ 211,749	\$	33,724

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 June 30, 2015

Assets			Liabilities						
Classification	Fa	ir Value	Classification]	Fair Value				
(in thousands)									
Prepaid and other current assets	\$	1,087	Other liabilities, current portion	\$	(2,737)				
Other assets		_	Other liabilities, excluding current portion		(313)				
Total assets	\$	1,087	Total liabilities	\$	(3,050)				

As of December 31, 2014

Assets		Liabilities						
Classification	F	air Value	Classification	Fair Value				
Prepaid and other current assets	\$	2,011	Other liabilities, current portion	\$	_			
Total assets	\$	2,011	Total liabilities	\$	_			

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

			P	As of June 30, 201	5			
	s Amounts cognized	Gross Amour Offset	nts	Gross Amount Presented	(Gross Amount Not Offset	I	egal Offset
Foreign currency forward contracts				(in thousands)				
Total assets	\$ 1,087	\$	_ 5	\$ 1,087	\$	(1,087)	\$	_
Total liabilities	\$ (3,050)	\$	_ 5	\$ (3,050)	\$	1,087	\$	(1,963)

					As of I	December 31, 20	14			
	Gross An Recogn		Gr	oss Amounts Offset	G	Presented		ross Amount Not Offset	I	Legal Offset
Foreign currency forward contracts					(i	n thousands)				
Total assets	\$	2 011	\$	_	\$	2 011	\$	_	\$	2 011

I. Inventories

Inventories consisted of the following:

	As of June 30, 2015		December 31, 2014						
	(in thousands)								
Raw materials	\$ 8,147	\$	8,506						
Work-in-process	30,989		20,508						
Finished goods	2,977		1,834						
Total	\$ 42,113	\$	30,848						

J. Intangible Assets and Goodwill

Intangible Assets

As of June 30, 2015, in-process research and development intangible assets of \$284.3 million were recorded on the Company's condensed consolidated balance sheet. The increase of \$255.3 million as compared to the \$29.0 million recorded as of December 31, 2014 is due to the Company's collaboration with Parion.

In June 2015, in connection with entering into the Parion Agreement, the Company recorded an in-process research and development intangible asset of \$255.3 million based on the Company's estimate of the fair value of Parion's lead investigational ENaC inhibitors, including VX-371 and P-1055, that were licensed by the Company from Parion. The Company aggregated the fair value of the ENaC inhibitors into a single intangible asset because the phase, nature and risks of development as well as the amount and timing of benefits associated with the assets were similar. In October 2014, the Company recorded an inprocess research and development intangible asset of \$29.0 million based on the Company's estimate of the fair value of VX-210, a drug candidate for patients with spinal cord injuries that was licensed by the Company from BioAxone. The Company used discount rates of 7.1% and 7.5% in the present-value models to estimate the fair values of the ENaC inhibitors and VX-210 intangible assets, respectively.

The Company also conducted an evaluation of Parion and BioAxone's other programs at the effective date of the Parion Agreement and BioAxone Agreement, respectively, and determined that market participants would not have ascribed value to those programs because of the stage of development of the assets in each program and uncertainties related to the potential clinical development and commercialization of the programs.

Goodwill

As of June 30, 2015, goodwill of \$50.4 million was recorded on the Company's condensed consolidated balance sheet. The Company allocated \$10.5 million to goodwill related to the Parion Agreement during the six months ended June 30, 2015. This goodwill relates to the potential synergies between licensed drug candidates and the Company's CF drugs and drug candidates. None of the goodwill related to the Parion Agreement is expected to be deductible for income tax purposes. As of December 31, 2014, \$39.9 million of goodwill was recorded on the Company's 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 and determined that the Fan Pier Leases did not meet the criteria for "sale-leaseback" treatment upon completion of the Buildings, the Company recorded project construction costs incurred by the landlord as an asset and a related financing obligation during the construction period and 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

Property and equipment, net, included \$508.9 million and \$515.0 million as of June 30, 2015 and December 31, 2014, respectively, related to construction costs for the Buildings. The carrying value of the Company's lease agreement liability for the Buildings was \$473.2 million and \$473.4 million as of June 30, 2015 and December 31, 2014, respectively.

Term Loan

On July 9, 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 provides for a \$300.0 million senior secured term loan ("Term Loan"). The credit agreement also provides that, subject to satisfaction of certain conditions, the Company may request that the lenders establish an incremental senior secured term loan facility in an aggregate amount not to exceed \$200.0 million. The Term Loan initially bore interest at a rate of 7.2% per annum, which will be reduced to 6.2% per annum based on the FDA's approval of ORKAMBI. The Term Loan will bear interest at a rate of LIBOR plus 5.0% per annum during the third year of the term.

The maturity date of all loans under the facilities is July 9, 2017. Interest is payable quarterly and on the maturity date. The Company is required to repay principal on the Term Loan in installments of \$15.0 million per quarter from October 1, 2015 through July 1, 2016 and in installments of \$60.0 million per quarter from October 1, 2016 through the maturity date. The Company may prepay the Term Loan, in whole or in part, at any time; provided that prepayments prior to the July 9, 2016 are subject to a make-whole premium to ensure Macquarie receives approximately the present value of two years of interest payments over the life of the loan.

The Company's obligations under the facilities are unconditionally guaranteed by certain of its domestic subsidiaries. All obligations under the facilities, and the guarantees of those obligations, are secured, subject to certain exceptions, by substantially all of the Company's assets and the assets of all guarantors, including the pledge of all or a portion of the equity interests of certain of its subsidiaries.

The credit agreement requires that the Company maintain, on a quarterly basis, a minimum level of KALYDECO net revenues. Further, the credit agreement includes negative covenants, subject to exceptions, restricting or limiting the Company's ability and the ability of its subsidiaries to, among other things, incur additional indebtedness, grant liens, engage in certain investment, acquisition and disposition transactions, pay dividends, repurchase capital stock and enter into transactions with affiliates. The credit agreement also contains customary representations and warranties, affirmative covenants and events of default, including payment defaults, breach of representations and warranties, covenant defaults and cross defaults. If an event of default occurs, the administrative agent would be entitled to take various actions, including the acceleration of amounts due under outstanding loans. There have been no events of default as of or during the period ended June 30, 2015.

Based on the Company's evaluation of the Term Loan, the Company determined that the Term Loan contains several embedded derivatives. These embedded derivatives are clearly and closely related to the host instrument because they relate to the Company's credit risk; therefore, they do not require bifurcation from the host instrument, the Term Loan.

The Company incurred \$5.3 million in fees paid to Macquarie that were recorded as a discount on the Term Loan and are being recorded as interest expense using the effective interest method over the term of the loan in the Company's condensed consolidated statements of operations. As of June 30, 2015, the unamortized discount associated with the Term Loan that was embedded in the senior secured term loan caption on the Company's condensed consolidated balance sheet was \$5.2 million.

L. Stock-based Compensation Expense

The Company issues stock options, restricted stock and restricted stock units with service conditions, which are generally the vesting periods of the awards. The Company also has issued, to certain members of senior management, restricted stock and restricted stock units that vest upon the earlier of the satisfaction of (i) a performance condition or (ii) a service condition and stock options that vest upon the earlier of the satisfaction of (a) performance conditions or (b) a service condition. In addition, the Company issued pursuant to a retention program restricted stock awards to certain members of senior management that will vest upon the satisfaction of both (i) a performance condition and (ii) a service condition. The Company also issues shares pursuant to an employee stock purchase plan ("ESPP").

In the second quarter of 2015, the Company's shareholders approved an amendment and restatement of the 2013 Stock and Option Plan that, among other things, increased the number of shares of common stock available for issuance under the

plan by 7,800,000 shares, plus the number of shares that remained available for issuance under our 2006 Stock and Option Plan, which rolled-over into the 2013 Stock and Option Plan.

During the three and six months ended June 30, 2015 and 2014, the Company recognized the following stock-based compensation expense included in loss from continuing operations:

	Three Months Ended June 30,					Six Months Ended June 30,				
		2015		2014		2015		2014		
				(in thou	ısands)		_		
Stock-based compensation expense by type of award:										
Stock options	\$	37,687	\$	26,985	\$	66,646	\$	52,112		
Restricted stock and restricted stock units		24,902		14,020		52,071		33,013		
ESPP share issuances		1,825		1,681		3,965		4,348		
Less stock-based compensation expense capitalized to inventories		(1,153)		(242)		(2,037)		(449)		
Total stock-based compensation included in costs and expenses	\$	63,261	\$	42,444	\$	120,645	\$	89,024		
Stock-based compensation expense by line item:										
Research and development expenses	\$	41,632	\$	27,253	\$	79,849	\$	60,153		
Sales, general and administrative expenses		21,629		15,191		40,796		28,871		
Total stock-based compensation included in costs and expenses	\$	63,261	\$	42,444	\$	120,645	\$	89,024		

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

	As of June 3	0, 2015
	Unrecognized Expense, Net of Estimated Forfeitures	Weighted-average Recognition Period
	 (in thousands)	(in years)
Type of award:		
Stock options	\$ 169,671	2.22
Restricted stock and restricted stock units	\$ 175,285	2.73
ESPP share issuances	\$ 3,953	0.59

The following table summarizes information about stock options outstanding and exercisable at June 30, 2015:

		Options Outstanding		Options Exercisable							
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)				
\$17.16-\$20.00	147	2.52	\$	18.87	147	\$	18.87				
\$20.01-\$40.00	2,888	4.04	\$	34.82	2,534	\$	34.60				
\$40.01-\$60.00	3,015	7.12	\$	48.32	1,534	\$	49.67				
\$60.01-\$80.00	1,705	8.60	\$	75.99	539	\$	74.93				
\$80.01-\$100.00	2,108	8.57	\$	90.22	621	\$	86.72				
\$100.01-\$120.00	1,868	9.58	\$	109.24	113	\$	109.25				
\$120.01-\$127.54	202	9.92	\$	127.31	165	\$	127.54				
Total	11.933	7.22	\$	66.92	5,653	\$	52.06				

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 June 30, 2015, the Company had \$35.4 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.

Other income (expense), net

In April 2014, the Company received a one-time cash payment of \$36.7 million from its landlord pursuant to the Fan Pier Leases. This payment related to bonds issued pursuant to an Infrastructure Development Assistance Agreement between The Commonwealth of Massachusetts and the Company's landlord. The bonds were issued in connection with the landlord's contribution to infrastructure improvements and also were dependent upon employment levels at the Company through the bond issuance date. The Company accounted for the cash payment as a government grant as it was provided in part related to the Company's employment level in Massachusetts. Such grants are recognized as income in the period in which the conditions of the grant are met and there is reasonable assurance that the grant will be received, provided it is not subject to refund. In the second quarter of 2014, the Company recorded \$36.7 million as a credit to other income (expense), net in its consolidated statements of operations because the Company's employment obligations related to these funds were satisfied as of the date of issuance of the bonds and the payment received was not subject to refund.

N. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. For the three and six months ended June 30, 2015, the Company recorded a provision for income taxes of \$30.1 million and \$30.4 million, respectively. The provision for income taxes recorded in the three and six months ended June 30, 2015 included \$29.7 million related to the estimated income tax effect on Parion of the Company's \$80.0 million up-front payment to Parion in June 2015. The Company has no liability for taxes payable by Parion and the income tax provision and related liability have been allocated to noncontrolling interest (VIE). For the three and six months ended June 30, 2014, the Company recorded a provision for income taxes of \$0.7 million and \$1.5 million, respectively, related to state income taxes and income earned in various foreign jurisdictions.

As of June 30, 2015 and December 31, 2014, the Company had unrecognized tax benefits of \$0.9 million. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of June 30, 2015, 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 June 30, 2015 and December 31, 2014. In 2015, it is reasonably possible that the Company will reduce the balance of its unrecognized tax benefits by approximately \$0.5 million due to the application of statute of limitations and settlements with taxing authorities, all of which would reduce the Company's effective tax rate.

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.

The Company files U.S. 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 before 2010 or any other major taxing jurisdiction for years before 2009, except where the Company has net operating losses or tax credit carryforwards that originated before 2009. The Company currently is under examination by the Internal Revenue Service, Pennsylvania, Delaware, New York and Texas for the year ended December 31, 2011. No adjustments have been reported. The Company is not under examination by any other jurisdictions for any tax year. The Company concluded audits with Massachusetts and Revenue Quebec during 2015 and the Canada Revenue Agency and Revenue Quebec during 2014 with no material adjustments.

The Company currently intends to reinvest the total amount of its unremitted earnings. At June 30, 2015, 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 U.S. federal income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries.

O. Restructuring Liabilities

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 and six months ended June 30, 2015 and 2014 were as follows:

		Three Months	End	ed June 30,		Six Months E	ndec	l June 30,
	2015 2014					2015		2014
				(in thou	sands)	1		
Liability, beginning of the period	\$	9,506	\$	18,324	\$	11,596	\$	19,115
Cash payments		(2,584)		(3,960)		(6,569)		(7,822)
Cash received from subleases		2,799		2,689		5,275		5,378
Restructuring expense (income)		203		(2,117)		(378)		(1,735)
Liability, end of the period	\$	9,924	\$	14,936	\$	9,924	\$	14,936

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 and six months ended June 30, 2015 and 2014 were as follows:

	Three Months	Ende	d June 30,	Six Months Ended June 30,					
	 2015		2014		2015		2014		
			(in thou	ısands)					
Liability, beginning of the period	\$ 11,137	\$	3,722	\$	33,390	\$	797		
Cash payments	(3,095)		(2,143)		(22,351)		(4,377)		
Restructuring expense (income)	975		1,677		(2,022)		6,836		
Liability, end of the period	\$ 9,017	\$	3,256	\$	9,017	\$	3,256		

Other Restructuring Activities

The Company has incurred several other restructuring activities that are unrelated to its 2003 Kendall Restructuring and the Fan Pier Move Restructuring. In October 2013, 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 cystic fibrosis and other research and development programs.

The activities related to the Company's other restructuring liabilities for the three and six months ended June 30, 2015 and 2014 were as follows:

	Three	e Months	End	ed June 30,	Six Months Ended June 30,					
	2015	;		2014		2015		2014		
				(in thou	ısands)					
Liability, beginning of the period	\$	845	\$	1,821	\$	869	\$	8,441		
Cash payments		(893)		(1,199)		(1,223)		(8,466)		
Restructuring expense		950		170		1,256		817		
Liability, end of the period	\$	902	\$	792	\$	902	\$	792		

P. Commitments and Contingencies

Financing Arrangements

As of June 30, 2015, the Company had irrevocable stand-by letters of credit outstanding that were issued in connection with property leases and other similar agreements totaling \$21.9 million that are cash collateralized. The cash used to support these letters of credit is included in restricted cash, as of June 30, 2015, on the Company's condensed consolidated balance sheet.

Litigation

On May 28, 2014, a purported shareholder class action *Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharmaceuticals Incorporated, et al.* was filed in the United States District Court for the District of Massachusetts, naming the Company and certain of the Company's current and former officers and directors as defendants. The lawsuit alleged that the Company made material misrepresentations and/or omissions of material fact in the Company's disclosures during the period from May 7, 2012 through May 29, 2012, all in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The purported class consists of all persons (excluding defendants) who purchased the Company's common stock between May 7, 2012 and May 29, 2012. The plaintiffs seek unspecified monetary damages, costs and attorneys' fees as well as disgorgement of the proceeds from certain individual defendants' sales of the Company's stock. On October 8, 2014, the Court approved Local No. 8 IBEW Retirement Fund as lead plaintiff, and Scott and Scott LLP as lead counsel for the plaintiff and the putative class. On February 23, 2015, the Company filed a reply to the plaintiffs' opposition to its motion to dismiss. The court heard oral argument on the motion to dismiss on March 6, 2015 and took the motion under advisement. The Company believes the claims to be without merit and intends to vigorously defend the litigation. As of June 30, 2015, the Company has not recorded any reserves for this purported class action.

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 June 30, 2015 or December 31, 2014.

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 early-stage development programs in other indications, while maintaining our financial strength.

We market KALYDECO (ivacaftor) for the treatment of certain patients with CF who have specific genetic mutations in their cystic fibrosis transmembrane conductance regulator, or *CFTR*, gene. In July 2015, ORKAMBI (lumacaftor in combination with ivacaftor) was approved by the United States Food and Drug Administration, or FDA, as a treatment for patients with CF twelve years of age and older who have two copies (homozygous) of the F508del mutation in their *CFTR* gene, which is the most prevalent form of CF. We also are seeking approval to market lumacaftor in combination with ivacaftor for this patient population in Europe, Canada and Australia.

Cystic Fibrosis

Ivacaftor

KALYDECO was approved in 2012 in the United States and European Union as a treatment for patients with CF six years of age and older who have the G551D mutation in their *CFTR* gene. Our KALYDECO net product revenues have been increasing over the last several years due to the increased number of patients who are being treated with KALYDECO in the United States and ex-U.S. markets as we have expanded the label for KALYDECO and obtained reimbursement for additional patients eligible for treatment with KALYDECO in ex-U.S markets.

Lumacaftor in Combination with Ivacaftor

In July 2015, the FDA approved ORKAMBI for the treatment of patients with CF twelve years of age and older who are homozygous for the F508del mutation in their *CFTR* gene. We have begun marketing ORKAMBI in the United States and will recognize our first net product revenues from ORKAMBI in the third quarter of 2015. We have established a wholesale acquisition cost for ORKAMBI in the United States of \$259,000 on an annual basis. Our future ORKAMBI net product revenues in the United States will reflect the number of patients for whom ORKAMBI is prescribed, the level of rebates, chargebacks, discounts and other adjustments to our ORKAMBI gross product revenues and patient adherence to the recommended treatment regimen. We believe that there currently are approximately 8,500 patients in the United States who are eligible for treatment with ORKAMBI.

We submitted a Marketing Authorization Application, or MAA, for ORKAMBI for the treatment of patients with CF twelve years of age and older who are homozygous for the F508del mutation in their *CFTR* gene to the European Medicines Agency, or EMA, in November 2014. We do not expect significant net product revenues from ORKAMBI from ex-U.S. markets in 2015 due to the reimbursement discussions that will be required in these markets following its potential approval by the European Commission in the fourth quarter of 2015. We believe that there are approximately 12,000 patients with CF twelve years of age and older who are homozygous for the F508del mutation in Europe.

We are currently conducting two Phase 3 clinical trials to evaluate lumacaftor in combination with ivacaftor for the treatment of patients with CF six to eleven years of age who are homozygous for the F508del mutation in their CFTR gene. The first clinical trial will evaluate approximately 50 patients in the United States to support potential FDA approval in patients with CF six to eleven years of age. The primary endpoint of the first six-month clinical trial is safety. This clinical trial is fully enrolled and if this trial is successful, we plan to submit a supplemental New Drug Application to the FDA in the first half of 2016. In the European Union, a clinical trial with a primary endpoint evaluating efficacy will be required to support approval of lumacaftor in combination with ivacaftor for patients with CF six to eleven years of age who are homozygous for the F508del mutation in their *CFTR* gene. We recently initiated a second clinical trial to evaluate lumacaftor in combination with ivacaftor in approximately 200 patients within this patient population. The primary endpoint of this second clinical trial is absolute change in lung clearance index.

VX-661 in Combination with Ivacaftor

In the first quarter of 2015, we initiated a Phase 3 development program for VX-661 in combination with ivacaftor in multiple CF patient populations who have at least one copy of the F508del mutation. We have initiated four clinical trials as part of this Phase 3 development program as follows:

- Two Copies of the F508del Mutation. A Phase 3 clinical trial evaluating the combination of VX-661 and ivacaftor in patients with CF twelve years of age and older who have two copies of the F508del mutation in their CFTR gene. Enrollment of approximately 500 patients in this clinical trial in North America and Europe is ongoing.
- One Copy of the F508del Mutation and a Second Mutation That Results in a Gating Defect in the CFTR Protein. A Phase 3 clinical trial evaluating the combination of VX-661 and ivacaftor in patients with CF who have one copy of the F508del mutation in their CFTR gene and a second mutation in their CFTR gene that results in a gating defect in the CFTR protein. Enrollment of approximately 200 patients in this clinical trial in North America and Europe is ongoing.
- One Copy of the F508del Mutation and a Second Mutation That Results in Residual CFTR Function. A Phase 3 clinical trial evaluating the combination of VX-661 and ivacaftor in patients with CF who have one copy of the F508del mutation in their CFTR gene and a second mutation in their CFTR gene that results in residual CFTR function. This clinical trial also will evaluate ivacaftor dosed without VX-661. Enrollment of approximately 300 patients in this clinical trial in North America and Europe is ongoing.
- One Copy of the F508del Mutation and A Second Mutation That Results in Minimal CFTR Function. We have initiated a Phase 3 clinical trial evaluating the combination of VX-661 and ivacaftor in patients who have one copy of the F508del mutation in their CFTR gene and a second mutation in their CFTR gene that results in minimal CFTR function. The clinical trial will enroll approximately 150 patients and expansion of the clinical trial to an additional approximately 150 patients will depend on an interim futility analysis of efficacy data from the initial approximately 150 patients.

ENaC Inhibition

In June 2015, we entered into a collaboration with Parion Sciences, Inc., or Parion, to develop investigational epithelial sodium channel, or ENaC, inhibitors, including VX-371 (formerly P-1037), for the potential treatment of CF and other pulmonary diseases. VX-371 is currently being evaluated in an exploratory Phase 2a clinical trial in approximately 120 patients with CF with any mutation in their *CFTR* gene, including those who have mutations not expected to respond to ivacaftor alone. We expect data from this clinical in mid-2016. We expect to initiate a Phase 2a clinical trial of VX-371 in early 2016, that evaluates that addition of VX-371 to treatment with ORKAMBI for patients with CF who are homozygous for the F508del mutation in their *CFTR* gene.

Next-generation CFTR Corrector Compounds

We also are seeking to identify and develop next-generation *CFTR* corrector compounds that could be evaluated in future dual- and/or triple-combination treatment regimens with the potential to provide additional benefits to patients with CF. We have multiple next-generation correctors in the lead-optimization stage of research and expect to begin clinical development of a next-generation corrector in 2015.

Research and Early-Stage Development

We are engaged in a number of other research and early-stage development programs, including programs in the areas of oncology and neurology. We plan to continue investing in our research programs and fostering scientific innovation in order to identify and develop transformative medicines with a focus on CF and other genetic diseases, oncology and neurology. 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.

HCV Infection

Prior to 2014, we recognized significant net product revenues based on sales of INCIVEK (telaprevir), a product for the treatment of genotype 1 HCV infection that we marketed in North America. In October 2013, in response to declining sales of INCIVEK and increased competition, we reduced our focus on marketing INCIVEK and eliminated the U.S. field-based sales force that had been promoting INCIVEK. We have withdrawn INCIVEK from the market in the United States, and we expect to wind-down any remaining activities relating to the field of HCV infection in 2015.

In the fourth quarter of 2014, we terminated our collaboration with Alios BioPharma, Inc., or Alios, related to the development of HCV nucleotide analogues. Our financial statements reflect the activities related to Alios as discontinued operations.

Drug Discovery and Development

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.

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 will be 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. Following the FDA's July 2015 approval of ORKAMBI in the United States, we are engaging 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. If ORKAMBI is approved in Europe and other foreign countries, we will need to focus on obtaining and maintaining 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. 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 following obtaining any marketing approvals for ORKAMBI in ex-U.S. markets.

RESULTS OF OPERATIONS

	T	Three Months Ended June 30,				Increase/(Dec	Six Months Ended June 30,					Increase/(Decrease)		
		2015		2015 2014		\$	%	2015			2014		\$	%
		(in thousands)								(ir	thousands)			
Revenues	\$	166,076	\$	138,421	\$	27,655	20%	\$	304,585	\$	256,872	\$	47,713	19 %
Operating costs and expenses		337,240		318,963		18,277	6%		647,734		653,456		(5,722)	(1)%
Other items, net		(17,684)		21,160		N/A	N/A		(44,305)		4,745		N/A	N/A
Net loss attributable to Vertex	\$	(188,848)	\$	(159,382)	\$	29,466	18%	\$	(387,454)	\$	(391,839)	\$	(4,385)	(1)%

Net Loss Attributable to Vertex

Net loss attributable to Vertex was \$188.8 million in the second quarter of 2015 compared to a net loss attributable to Vertex of \$159.4 million in the second quarter of 2014. Our revenues increased in the second quarter of 2015 as compared to the second quarter of 2014 due to increased KALYDECO net product revenues, partially offset by decreased royalty revenues and collaborative revenues. Our operating costs and expenses increased in the second quarter of 2015 as compared to the second quarter of 2014 primarily due to increases in sales, general and administrative expenses and cost of product revenues, partially offset by decreased royalty expenses. The change in other items, net in the second quarter of 2015 as compared to the second quarter of 2014 was principally due to a \$36.7 million credit to other income (expense) resulting from a one-time payment to us relating to our headquarters lease that we recorded in the second quarter of 2014 for which there was no corresponding credit in the second quarter of 2015.

Net loss attributable to Vertex was \$387.5 million in the first half of 2015 compared to a net loss attributable to Vertex of \$391.8 million in the first half of 2014. Our revenues increased in the first half of 2015 as compared to the first half of 2014 due to increased KALYDECO net product revenues, partially offset by decreased royalty revenues and collaborative revenues. Our operating costs and expenses in the first half of 2015 were consistent with our operating expenses in the first half of 2014, with increased sales, general and administrative expenses being offset by decreases in research and development expenses and royalty expenses. The change in other items, net in the first half of 2015 as compared to the first half of 2014 was principally due to a \$36.7 million credit to other income (expense) resulting from a one-time payment to us relating to our headquarters lease that we recorded in the first half of 2014 for which there was no corresponding credit in the first half of 2015.

We expect that our net loss attributable to Vertex in the second half 2015 will be largely dependent on our ability to successfully commercialize ORKAMBI in the United States following our receipt of FDA approval for this combination therapy in July 2015.

Diluted Net Loss Per Share Attributable to Vertex Common Shareholders

Diluted net loss per share attributable to Vertex common shareholders was \$0.78 in the second quarter of 2015 as compared to a diluted net loss per share attributable to Vertex common shareholders of \$0.68 in the second quarter of 2014. Diluted net loss per share attributable to Vertex common shareholders was \$1.61 in the first half of 2015 as compared to a diluted net loss per share attributable to Vertex common shareholders of \$1.68 in the first half of 2014.

Revenues

	T	Three Months Ended June 30,				Increase/(Dec	Six Months Ended June 30,					Increase/(Decrease)		
		2015 2014				\$	%		2015		2014		\$	%
			(in	thousands)						(in	thousands)			
Product revenues, net	\$	160,388	\$	122,319	\$	38,069	31 %	\$	291,263	\$	225,780	\$	65,483	29 %
Royalty revenues		5,077		13,015		(7,938)	(61)%		11,869		23,748		(11,879)	(50)%
Collaborative revenues		611		3,087		(2,476)	(80)%		1,453		7,344		(5,891)	(80)%
Total revenues	\$	166,076	\$	138,421	\$	27,655	20 %	\$	304,585	\$	256,872	\$	47,713	19 %

Product Revenues, Net

	Tl	Three Months Ended June 30,				Increase/(Dec	Six Months Ended June 30,					Increase/(Decrease)		
		2015		2014		\$	%		2015		2014		\$	%
			(in	thousands)						(in	thousands)			
KALYDECO	\$	154,888	\$	113,055	\$	41,833	37 %	\$	285,062	\$	212,570	\$	72,492	34 %
INCIVEK		5,500		9,264		(3,764)	(41)%		6,201		13,210		(7,009)	(53)%
Total product revenues, net	\$	160,388	\$	122,319	\$	38,069	31 %	\$	291,263	\$	225,780	\$	65,483	29 %

Our total net product revenues increased in the second quarter and the first half of 2015 as compared to the second quarter and the first half of 2014 due to increased KALYDECO net product revenues. KALYDECO net product revenues were \$154.9 million in the second quarter of 2015, including \$61.2 million of net product revenues from international markets. The increase in KALYDECO net product revenues in the first half and second quarter of 2015, as compared to the first half and second quarter of 2014, was primarily due to additional patients being treated with KALYDECO as we completed reimbursement discussions in various jurisdictions and increased the number of patients eligible to receive KALYDECO through multiple label expansions that were approved by regulatory authorities in the United States and Europe during 2014 and 2015.

We have withdrawn INCIVEK from the market in the United States. We may continue to recognize small incremental INCIVEK revenues over the next several quarters as we adjust our INCIVEK reserves for rebates, chargebacks and discounts.

We believe our total net product revenues for the remainder of 2015 will be dependent on our ability to successfully commercialize ORKAMBI in the United States following our receipt of FDA approval for this combination therapy in July 2015. We do not expect significant net product revenues from ORKAMBI in 2015 from ex-U.S. markets due to the reimbursement discussions that will be required in these markets following the potential approval of ORKAMBI by the European Commission in the fourth quarter of 2015.

Royalty Revenues

Our royalty revenues were \$5.1 million and \$11.9 million in the second quarter and the first half of 2015, respectively, as compared to \$13.0 million and \$23.7 million in the second quarter and the first half of 2014, respectively. Since the beginning of 2014, our royalty revenues have consisted 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. The decreased royalty revenues in the second quarter and the first half of 2015 as compared to the second quarter and the first half of 2014 were primarily due to the continued decline in net sales of INCIVO (telaprevir) by our collaborator Janssen NV.

Collaborative Revenues

Our collaborative revenues were \$0.6 million and \$1.5 million in the second quarter and the first half of 2015, respectively, as compared to \$3.1 million and \$7.3 million in the second quarter and the first half of 2014, respectively. The decrease during the second quarter and the first half of 2015 as compared to the second quarter and the first half of 2014 was primarily attributable to the fact that we did not receive any research funding from CFFT during the second quarter and the first half of 2015, as compared to \$1.6 million and \$4.5 million in research funding provided by CFFT in the second quarter and the first half of 2014, respectively.

Operating Costs and Expenses

	Three Months Ended June 30,				Increase/(Decrease)				Six Months Ended June 30,				Increase/(Decrease)			
		2015 2014			\$	%	2015		2014			\$	%			
			(in	thousands)						(iı	n thousands)					
Cost of product revenues	\$	15,409	\$	9,655	\$	5,754	60 %	\$	24,790	\$	18,227	\$	6,563	36 %		
Royalty expenses		1,451		7,645		(6,194)	(81)%		4,377		14,549		(10,172)	(70)%		
Research and development expenses		223,858		224,487		(629)	—%		439,457		463,104		(23,647)	(5)%		
Sales, general and administrative expenses		94,394		77,446		16,948	22 %		180,254		151,658		28,596	19 %		
Restructuring expenses (income)		2,128		(270)		N/A	N/A		(1,144)		5,918		N/A	N/A		
Total costs and expenses	\$	337,240	\$	318,963	\$	18,277	6 %	\$	647,734	\$	653,456	\$	(5,722)	(1)%		

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 CFFT, our tiered third-party royalties on KALYDECO and on future sales of ORKAMBI following FDA approval in July 2015, calculated as a percentage of net sales, range from the single digits to the sub-teens. We expect our cost of product revenues to continue to increase in the second half of 2015 due to increased net product revenues, together with an expected increase in the third-party royalty rate payable to CFFT as we begin to pay royalties at the top end of the royalty range, and the potential payment of commercial milestones to CFFT based on sales of ORKAMBI.

Royalty Expenses

Royalty expenses include third-party royalties payable upon net sales of telaprevir by our collaborators in their territories and expenses related to a subroyalty payable to a third party on net sales of an HIV protease inhibitor sold by GlaxoSmithKline. Royalty expenses in the second quarter of 2015 decreased by \$6.2 million, or 81%, as compared to the second quarter of 2014 and decreased by \$10.2 million, or 70%, in the first half of 2015 as compared to the first half of 2014, primarily as a result of decreased INCIVO (telaprevir) sales by our collaborator Janssen NV.

Research and Development Expenses

	T	Three Months Ended June 30,				Increase/(De	Six Months Ended June 30,					Increase/(Decrease)		
		2015		2014		\$	%		2015		2014		\$	%
			(in	thousands)						(in	thousands)			
Research expenses	\$	65,195	\$	65,342	\$	(147)	— %	\$	130,757	\$	132,365	\$	(1,608)	(1)%
Development expenses		158,663		159,145		(482)	—%		308,700		330,739		(22,039)	(7)%
Total research and development expenses	\$	223,858	\$	224,487	\$	(629)	—%	\$	439,457	\$	463,104	\$	(23,647)	(5)%

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, 2012, we have incurred \$2.9 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 and clinical 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 2014 and the first half of 2015, 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. Obtaining regulatory approval can be a lengthy, time-consuming and uncertain process. In November 2014, we submitted an MAA to the EMA for lumacaftor in combination with ivacaftor. Even if we are successful in obtaining marketing approval from the European Commission in the fourth quarter of 2015, we currently do not expect to recognize significant revenues from ORKAMBI in 2015 from ex-U.S. markets due to the reimbursement discussions that will be required in these markets following the potential approval. 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 June 30,				Increase/(Decrease)				Six Months Ended June 30,				Increase/(De	crease)
	2015 2014			\$	%	2015		2014			\$	%		
			(in	thousands)						(i	n thousands)			
Research Expenses:														
Salary and benefits	\$	19,798	\$	21,015	\$	(1,217)	(6)%	\$	40,254	\$	41,442	\$	(1,188)	(3)%
Stock-based compensation expense		13,081		8,837		4,244	48 %		26,857		20,891		5,966	29 %
Laboratory supplies and other direct expenses		10,416		10,696		(280)	(3)%		19,584		19,975		(391)	(2)%
Outsourced services		4,947		4,850		97	2 %		9,505		9,334		171	2 %
Infrastructure costs		16,953		19,944		(2,991)	(15)%		34,557		40,723		(6,166)	(15)%
Total research expenses	\$	65,195	\$	65,342	\$	(147)	—%	\$	130,757	\$	132,365	\$	(1,608)	(1)%

We maintain a substantial investment in research activities. Our research expenses in the second quarter and the first half of 2015 were consistent with our research expenses in the second quarter and the first half of 2014. We expect to continue to invest in our research programs with a focus on identifying drug candidates for specialty markets.

Development Expenses

	Three Months Ended June 30,				Increase/(Decrease)				Six Months Ended June 30,				Increase/(Decrease)		
		2015		2014		\$	%		2015		2014		\$	%	
			(in	thousands)						(i	in thousands)				
Development Expenses:															
Salary and benefits	\$	39,427	\$	38,829	\$	598	2 %	\$	81,622	\$	80,840	\$	782	1 %	
Stock-based compensation expense		28,551		18,416		10,135	55 %		52,992		39,262		13,730	35 %	
Laboratory supplies and other direct expenses		8,473		11,017		(2,544)	(23)%		15,417		19,649		(4,232)	(22)%	
Outsourced services		56,303		58,340		(2,037)	(3)%		106,397		123,531		(17,134)	(14)%	
Drug supply costs		2,702		1,558		1,144	73 %		4,285		4,527		(242)	(5)%	
Infrastructure costs		23,207		30,985		(7,778)	(25)%		47,987		62,930		(14,943)	(24)%	
Total development expenses	\$	158,663	\$	159,145	\$	(482)	—%	\$	308,700	\$	330,739	\$	(22,039)	(7)%	

Our development expenses in the second quarter of 2015 were consistent with development expenses in the second quarter of 2014. Our development expenses decreased by \$22.0 million, or 7%, in the first half of 2015 as compared to the first half of 2014, primarily due to a reduction in outsourced services expenses and infrastructure costs, partially offset by an increase in stock-based compensation expense. The decrease in outsourced services expenses in the first half of 2015 as compared to the first half of 2014 was largely attributable to reduced clinical trial expenses following the completion of the TRAFFIC and TRANSPORT clinical trials in the first half of 2014. We expect our development expenses for outsourced activities to increase during the second half of 2015 as compared to the first half of 2015 due to activities related to clinical trials we have initiated or plan to initiate in 2015, including our Phase 3 development program for VX-661 in combination with ivacaftor. The decrease in infrastructure costs in the first half of 2015 as compared to the first half of 2014 was largely

attributable to the relocation of our corporate headquarters in Massachusetts from Cambridge to Boston in the first half of 2014.

Sales, General and Administrative Expenses

	Three Months Ended June 30,				į	Increase/(Decrease)			Six Months Ended June 30,			Increase/(Decrease)		
	201	15	2	2014		\$	%		2015		2014		\$	%
	(in thousands)							(in thousands)						
Sales, general and administrative expenses	\$!	94,394	\$	77,446	\$	16,948	22%	\$	180,254	\$	151,658	\$	28,596	19%

Sales, general and administrative expenses increased by 22% in the second quarter of 2015 as compared to the second quarter of 2014 and increased by 19% in the first half of 2015 as compared to the first half of 2014, primarily due to increased investment in commercial support for KALYDECO and costs incurred to prepare for the launch of ORKAMBI in the United States and the potential launch of lumacaftor in combination with ivacaftor in ex-U.S. markets.

Restructuring Expense

We recorded restructuring expenses of \$2.1 million in the second quarter of 2015 as compared to restructuring credits of \$0.3 million in the second quarter of 2014 and recorded restructuring credits of \$1.1 million in the first half of 2015 as compared to restructuring expenses of \$5.9 million in the first half of 2014. Our restructuring expenses (credits) in the three and six months ended June 30, 2015 and 2014 have related primarily to adjustments to our restructuring liability resulting from the relocation of our corporate headquarters to Boston, Massachusetts and the early termination of our leases in Cambridge, Massachusetts.

Other Items

Interest Expense, Net

Interest expense, net was \$21.1 million and \$42.4 million in the second quarter and the first half of 2015, respectively, compared to \$15.6 million and \$31.3 million in the second quarter and the first half of 2014, respectively. The increase during the second quarter and the first half of 2015 compared to the second quarter and the first half of 2014 was primarily due to interest expense associated with the \$300 million we borrowed in July 2014 pursuant to our credit agreement. During the second half of 2015, we expect to incur approximately \$30 million of interest expense associated with the leases for our corporate headquarters and approximately \$11 million of interest expense related to the credit agreement that we entered into in July 2014.

Other Income (Expense), Net

Other income (expense), net was income of \$1.4 million in the second quarter and an expense of \$3.7 million in the first half of 2015, compared to income of \$37.7 million and \$38.2 million in the second quarter and the first half of 2014, respectively. Other income (expense), net in the second quarter and first half of 2014 was primarily due to a credit of \$36.7 million related to a one-time cash payment in the second quarter of 2014 from our landlord pursuant to leases for our corporate headquarters.

Income Taxes

We recorded a provision for income taxes of \$30.1 million and \$30.4 million in the second quarter and the first half of 2015, respectively, compared to \$0.7 million and \$1.5 million in the second quarter and the first half of 2014, respectively. The provision for income taxes in the second quarter and first half of 2015 was principally due to the consolidation of Parion as a VIE into our condensed consolidated financial statements. The provision for income taxes in the second quarter and first half of 2014 related to state income taxes and income earned in various foreign jurisdictions.

Discontinued Operations, Net of Tax

Our loss from discontinued operations was \$0.3 million and \$0.6 million in the second quarter and the first half of 2014, respectively, related to Alios BioPharma, Inc., a variable interest entity that we consolidated from June 2011 through December 2013. As of September 30, 2014, we concluded that we no longer had significant continuing involvement with Alios. As a result, the effect of the Alios collaboration is presented as discontinued operations in our condensed consolidated statements of operations.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2015, we had cash, cash equivalents and marketable securities of \$1.02 billion, which represented a decrease of \$371 million from \$1.39 billion as of December 31, 2014. This decrease was primarily due to cash expenditures we made during the first half of 2015 related to, among other things, research and development expenses and sales, general and administrative expenses and an \$80 million payment made in connection with entry into our collaboration agreement with Parion, partially offset by cash receipts from product sales and \$87.9 million in cash we received from issuances of common stock pursuant to our employee benefit plans. We also incurred \$25.0 million in costs for capital expenditures including net cash flows from capital leases during the first half of 2015. Our future cash flows will be substantially dependent on our success in commercializing ORKAMBI, which was approved by the FDA in July 2015, and on obtaining approval and government reimbursement for ORKAMBI in ex-U.S. markets.

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. In the near-term, we expect cash flows from product revenues to increase due to sales of ORKAMBI in the United States following receipt of FDA approval in July 2015. We do not expect significant net product revenues from ORKABMI in 2015 from ex-U.S. markets due to the reimbursement discussions that will be required in these markets following the potential approval of ORKAMBI by the European Commission in the fourth quarter of 2015.

We have borrowed \$300.0 million under a credit agreement that we entered into in July 2014 and, subject to certain conditions, we may request up to an additional \$200.0 million pursuant to that credit agreement. In recent periods, we also have received significant proceeds from the issuance of common stock under our employee benefit plans, but 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 operate our organization. We must repay the principal amount on the \$300.0 million we borrowed in June 2014 as follows: \$15.0 million in the second half of 2015, \$105.0 million in 2016 and \$180.0 million in 2017. We also have substantial facility and capital lease obligations, including leases for two buildings in Boston, Massachusetts that continue through 2028. 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 pre-established developmental and regulatory targets. We expect that cash flows from KALYDECO and ORKAMBI, 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 KALYDECO and ORKAMBI 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

In July 2014, we borrowed \$300.0 million pursuant to a credit agreement. In addition, subject to certain conditions, we may request that the lenders loan us up to an additional \$200.0 million under the credit agreement. 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, 2014, which was filed with the Securities and Exchange Commission, or SEC, on February 13, 2015. 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 the second quarter of 2015 we entered into a collaboration agreement with Parion pursuant to which Parion is eligible to receive milestone and royalty payments, including up to \$490 million in development and regulatory milestone payments for the development of VX-371 (formerly P-1037) and/or P-1055 in CF.

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 first half of 2015, 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, 2014, which was filed with the SEC on February 13, 2015.

RECENT ACCOUNTING PRONOUNCEMENTS

For a discussion of recent accounting pronouncements please refer to Note A, "Nature of Business and Accounting Policies—Recent Accounting Pronouncements," in the 2014 Annual Report on Form 10-K. There were no new accounting pronouncements adopted during the six months ended June 30, 2015 that had a material effect on our financial statements.

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

As of June 30, 2015, we invest our cash in a variety of financial instruments, principally money market funds, investment-grade corporate bonds and commercial paper. 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.

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 maintain a foreign currency management program with the objective of reducing the impact of exchange rate fluctuations on our operating results and forecasted revenues and expenses denominated in foreign currencies.

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 June 30, 2015 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 June 30, 2015 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

Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharmaceuticals Incorporated, et al.

On May 28, 2014, a purported shareholder class action *Local No. 8 IBEW Retirement Plan & Trust v. Vertex Pharmaceuticals Incorporated, et al.* was filed in the United States District Court for the District of Massachusetts, naming us and certain of our current and former officers and directors as defendants. The lawsuit alleged that we made material misrepresentations and/or omissions of material fact in our disclosures during the period from May 7, 2012 through May 29, 2012, all in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The purported class consists of all persons (excluding defendants) who purchased our common stock between May 7, 2012 and May 29, 2012. The plaintiffs seek unspecified monetary damages, costs and attorneys' fees as well as disgorgement of the proceeds from certain individual defendants' sales of our stock. On

October 8, 2014, the Court approved Local No. 8 IBEW Retirement Fund as lead plaintiff, and Scott and Scott LLP as lead counsel for the plaintiff and the putative class. We filed a motion to dismiss the complaint on December 8, 2014 and the plaintiffs filed their opposition to our motion to dismiss on January 22, 2015. On February 23, 2015, we filed a reply to the plaintiffs' opposition to our motion to dismiss. The court heard oral argument on our motion to dismiss on March 6, 2015 and took the motion under advisement. We believe the claims to be without merit and intend to vigorously defend the litigation.

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, 2014, which was filed with the SEC on February 13, 2015. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K.

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 and regulatory authority filings and submissions for ivacaftor, lumacaftor and VX-661;

- expectations regarding potential marketing approvals for ORKAMBI in ex-U.S. markets;
- · our ability to successfully market KALYDECO and ORKAMBI or any of our other drug candidates for which we obtain regulatory approval;
- our expectations regarding the timing and structure of clinical trials of our drugs and drug candidates, including, ivacaftor, lumacaftor and VX-661, and the expected timing of our receipt of data from our ongoing and planned clinical trials;
- 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;
- 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, 2014, which was filed with the SEC on February 13, 2015. 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 June 30, 2015:

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
April 1, 2015 to April 30, 2015	53,044	\$0.01	_	_
May 1, 2015 to May 31, 2015	28,047	\$0.01	_	_
June 1, 2015 to June 30, 2015	16,132	\$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 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
3.1	Restated Articles of Organization of Vertex Pharmaceuticals Incorporated, as amended.
10.1	Amended and Restated 2013 Stock and Option Plan (1) *
10.2	Strategic Collaboration and License Agreement, dated as of June 4, 2015, by and among Parion Sciences, Inc., Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited.†
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

- (1) Incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 30, 2015.
 - * Management contract, compensatory plan or agreement.
- † Confidential portions of this document have been filed separately with the Securities and Exchange Commission pursuant to a request for confidential 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

August 4, 2015 By: /s/ Ian F. Smith

Ian F. Smith

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

Federal Identification No. 04-3039129

The Commonwealth of Massachusetts

MICHAEL JOSEPH CONNOLLY Secretary of State ONE ASHBURTON PLACE, BOSTON, MASS: 02108

RESTATED ARTICLES OF ORGANIZATION

General Laws, Chapter 156B, Section 74

This certificate must be submitted to the Secretary of the Commonwealth within sixty days after the date of the vote of stockholders adopting the restated articles of organization. The fee for filing this certificate is prescribed by General Laws, Chapter 156B Section 114. Make check payable to the Commonwealth of Massachusetts.

We, Joshua Boger, President Richard H. Aldrich, Clerk of

Vertex Pharmaceuticals Incorporated

(Name of Corporation)

located at 40 Allston Street, Cambridge, Massachusetts 02139 do hereby certify that the following restatement of the articles of organization of the corporation was duly adopted at a meeting held on May 24, 1991, by vote of

1,080,000 shares of common out of 2,702,500 shares outstanding, (Class of Stock)

5,051,955 shares of Series A Convertible Preferred Stock out of 5,279,227 shares outstanding, and (Class of Stock)

1,343,655 shares of Series B Convertible Preferred Stock out of 1,404,000 shares outstanding, (Class of Stock)

being at least two-third of each class of stock outstanding and entitled to vote and of each class or series of stock adversely affected thereby:

1. The name by which the corporation shall be known is:

Vertex Pharmaceuticals Incorporated

2. The purpose for which the corporation is formed are as follows:

To develop, manufacture, market, and sell pharmaceutical products.

To carry on any business or other activity which may be lawfully carried on by a corporation organized under the Business Corporation Law of the Commonwealth of Massachusetts whether or not related to those referred to in the foregoing paragraph.

* 571,429 shares of Series C Convertible Preferred Stock out of 571,429 shares outstanding

Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on separate 8 1/2 x 11 sheets of paper leaving a left hand margin of at least 1 inch for binding. Additions to more than one article may be continued on a single sheet so long as each article requiring each such addition is clearly indicated.

3. The total number of shares and the par value, if any, of each class of stock which the corporation is authorized to issue is as follows:

Class of St	ock W	ithout Par Value	With Par Value		
		N	umber of Shares	Number of Shares	Par Value
Preferred	None	1,000,000 \$.01			
Common	None	25,000,000 \$ 0	1		

*4. If more than one class is authorized, a description of each of the different classes of stock with, if any, the preferences, voting powers, qualifications, special or relative rights or privileges as to each class thereof and any series now established:

See Attached.

*5. The restrictions, if any, imposed by the articles of organization upon the transfer of shares of stock of any class are as follows:

None.

*6. Other lawful provisions, if any, for the conduct and regulation of the business and affairs of the corporation, for its voluntary dissolution, or for limiting, defining, or regulating the powers of the corporation, or of its directors or stockholders, or of any class of stockholders:

See Attached.

*If there are no such provisions, state "None".

AMENDMENTS

1. Article 3 is amended as follows:

- (i) Every three shares of the Common Stock, \$.01 par value, of the Corporation outstanding on the effective date of these Restated Articles of Organization shall on such effective date be combined into two shares of Common Stock, \$.01 par value; <u>provided</u>, that no fractional shares shall be issued in connection with such combination and the fair value of fractional shares resulting therefrom shall be paid in cash to holders who would otherwise have received such fractional shares; and <u>provided</u>, <u>further</u>, that in connection with the foregoing, no changes shall be made in the capital or surplus account of the Corporation.
- (ii) In connection and simultaneously with the combination described above, the authorized Common Stock, \$.01 par value, of the Corporation shall be reduced from 11,024,000 shares to 7,349,333 shares; provided, that in connection with the foregoing, no changes shall be made in the capital or surplus account of the Corporation.
- (iii) Every three shares of each series of the Convertible Preferred Stock, \$.01 par value, of the Corporation outstanding on the effective date of these Restated Articles of Organization shall on such effective date, pursuant to the terms of such Convertible Preferred Stock, be automatically converted into two shares of Common Stock, \$.01 par value; <u>provided</u>, that no fractional shares shall be issued in connection with said conversion and the fair value of fractional shares resulting therefrom shall be paid in cash to holders who would have otherwise received such fractional shares.
- (iv) In connection and simultaneously with the conversion described above, the entire class, including each series of such class, of Convertible Preferred Stock, \$.01 par value, of the Corporation shall be cancelled and withdrawn from the authorized capital stock of the Corporation.
- (v) Immediately following the foregoing, the amount of the authorized capital stock of the Corporation shall be increased to 26,000,000 shares, consisting of 25,000,000 shares of Common Stock, \$.01 par value, and 1,000,000 shares of Preferred Stock, \$.01 par value.
- 2. Article 4 is amended as follows:
- (i) The class of Preferred Stock, \$.01 par value, authorized pursuant to Article 3 is authorized to be issued by the Board of Directors, in one or more series, as set forth in Article 4 of these Restated Articles of Organization.

- 3. Article 6 is amended as follows:
- (i) The first paragraph, relating to Amendment of the By-Laws, is designated as Part A.
- (ii) The second paragraph, relating to Meetings of Stockholders, is designated as Part B.
- (iii)The third paragraph, relating to Partnership Agreements, is designated as Part C.
- (iv) The fourth paragraph, relating to liability of Directors, is designated as Part D.
- (v) There is added as a new Part E provisions relating to (a) the election of a classified Board of Directors, (b) nomination of directors, (c) filling of newly created directorships and vacancies, (d) removal of directors, (e) election of directors by holders of Preferred Stock, and (f) amendment or repeal of the provisions set forth in Part E.

ARTICLE 4

A. Common Stock

The holders of shares of Common Stock of the Corporation shall be entitled to one vote for each share of such stock held by them, respectively, upon all matters presented to the stockholders. The Common Stock shall be subject to the special provisions applicable to any series of Preferred Stock issued by the Board of Directors, as hereinafter provided.

B. Preferred Stock.

The Preferred Stock may be issued by the Board of Directors, in one or more series and with such rights, powers, preferences, and terms and at such times and for such consideration as the Board of Directors shall determine, without further stockholder action. With respect to any such series of Preferred Stock, prior to issuance, the Board of Directors by resolution shall designate that series to distinguish it from other series and classes of stock of the Corporation, shall specify that number of shares to be included in the series, and shall fix the rights, powers, preferences, and terms of the shares of the series, including but without limitation: (i) the dividend rate, its preference as to any other class or series of capital stock, and whether dividends will be cumulative or non cumulative; (ii) whether the shares are to be redeemable and, if so, at what times and prices and on what other terms and conditions; (iii) the terms and amount of any sinking fund provided for the purchase of redemption for the shares; (iv) whether the shares shall be convertible or exchangeable and, if so, the times, prices, rates, adjustments, and other terms of such conversion or exchange; (v) the voting rights, if any, applicable to the shares in addition to those prescribed by law; (vi) the restrictions and conditions, if any, on the issue or reissue of any additional shares of such series or of any other series of Preferred Stock ranking on a parity with or prior to the shares of such series; and (vii) the rights of the holders of such shares upon voluntary or involuntary liquidation, dissolution, or winding up of the Corporation.

ARTICLE 6

A. Amendment of By-Laws

To the extent and the manner provided in the By-Laws, the Board of Directors may make, amend, or repeal the By-Laws in whole or in part, except with respect to any provision thereof which by law or by the By-Laws requires action by the stockholders.

B. Meetings of Stockholders

To the extent and in the manner provided in the By-Laws, meetings of the stockholders may be held anywhere within the Commonwealth of Massachusetts or elsewhere in the United States.

C. Partnership Agreements

The Corporation may enter into partnership agreements (general or limited) and joint ventures with any person, firm, association, or corporation engaged in carrying on any business in which the Corporation is authorized to engage, or in connection with carrying out all or any of the purposes of the Corporation.

D. Liability of Directors

No director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director; provided, however, that this provision shall not eliminate or limit the liability of a director to the extent provided by applicable law (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of laws, (iii) under Section 61 or 62 of the Business Corporation Law, Chapter 156B, of the Commonwealth of Massachusetts, or (iv) for any transactions from which the director derived an improper personal benefit. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal.

E. Board of Directors

1. Number, Election and Terms. Subject to the rights of the holders of any series of Preferred Stock to elect directors who shall serve for such term and have such voting powers as shall be provided in Article 4 of these Articles, the Board of Directors shall consist of such number of persons as shall be provided in the Corporation's By-Laws. The Board of Directors shall be classified with respect to the time for which its members shall severally hold office by dividing them into three classes, as nearly equal in number as possible, with the term of office of one class expiring at the annual meeting of stockholders each year. At each annual meeting of the stockholders of the Corporation, the successors to the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders held in the third year following the year of their election. If the number of directors

is changed, any increase or decrease shall be apportioned by the Board of Directors among the classes so as maintain the number of directors in each class as nearly equal as possible. Each director shall hold office until the annual meeting for the year in which such director's term expires and until such director's successor shall be elected and shall qualify. No director need be a stockholder.

- 2. <u>Nomination</u>. Advance notice of nominations for the election of directors, other than by the Board of Directors or a committee thereof, shall be given within the time and in the manner provided in the By-Laws.
- 3. Newly Created Directorships and Vacancies. Newly created directorships resulting from any increase in the number of directors and any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal, or other cause shall be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor shall have been elected and qualified. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.
- 4. <u>Removal of Directors</u>. Any director may be removed from office by stockholder vote at any time, but only for cause, by the affirmative vote of the holders of a majority of the voting power of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class. Any director may also be removed from office for cause by vote of a majority of the directors then in office.
- 5. <u>Directors Elected by Holders of Preferred Stock</u>. Whenever the holders of any class or series of Preferred Stock or of any other class or series of shares issued by the Corporation shall have the right, voting separately as a class or series, to elect one or more directors under specified circumstances, the election, term of office, filling of vacancies, and other features of such directorships shall be governed by the terms of these Articles applicable to such class or series, and none of the provisions of this Part E shall apply with respect to directors so elected.
- 6. <u>Amendment, Repeal, etc.</u> Notwithstanding any other provision of these Articles to the contrary, the affirmative vote of the holders of at least 80% of the voting power of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend, adopt any provision inconsistent with, or repeal this Part E or any provision thereof.

*We further certify that the foregoing restated articles of organization effect no amendments to the articles of organization of the corporation as heretofore amended, except amendments to the following articles 3, 4 and 6.
(*If there are no such amendments, state "None".)
Briefly describe amendments in space below:
See Attached.
IN WITNESS WHEREOF AND UNDER THE PENALTIES OF PERJURY, we have hereto signed our names this 30th day of July in the year 1991
/S/ Joshua Boger
Joshua Boger President
/S/ Richard H. Aldrich
Richard H. Aldrich Clerk

THE COMMONWEALTH OF MASSACHUSETTS

RESTATED ARTICLES OF ORGANIZATION (General Laws, Chapter 156B, Section 74)

I hereby approve the within restated articles of organization and, the filing fee in the amount of \$19,150.67 having been paid, said articles are deemed to have been filed with me this 31st day of July, 1991

/S/ MICHAEL JOSEPH CONNOLLY

MICHAEL JOSEPH CONNOLLY Secretary of State

TO BE FILLED IN BY CORPORATION

PHOTOCOPY OF RESTATED ARTICLES OF ORGANIZATION TO BE SENT TO: Timothy B. Bancroft, Esq. Warner & Stackpole 75 State Street, Boston, MA 02109 Telephone (617) 951-9000

Copy Mailed

The Commonwealth of Massachusetts

OFFICE OF THE MASSACHUSETTS SECRETARY OF STATE MICHAEL JOSEPH CONNOLLY, Secretary ONE ASHBURTON PLACE, BOSTON, MASS. 02108

CERTIFICATE OF VOTE OF DIRECTORS ESTABLISHING A SERIES OF A CLASS OF STOCK

General Laws, Chapter 156B, Section 26

We, Joshua Boger, President and Richard H. Aldrich, Clerk of

Vertex Pharmaceuticals Incorporated

(Name of Corporation)

located at 40 Allston Street, Cambridge, Massachusetts 02139 do hereby certify that by unanimous written consent of the Board of Directors as of July 1, 1991, the following vote establishing and designating a series of class of stock and determining the relative rights and preferences thereof was duly adopted.

See attached.

Note: Votes for which the space provided above is not sufficient should be set out on continuation sheets to be numbered 2A, 2B etc. Continuation sheets must have a left-hand margin 1 inch wide for binding and shall be 8 1/2" x 11". Only one side should be used.

VOTED, that pursuant to the authority granted to and vested in the Board of Directors of this Corporation (hereinafter called the "Board of Directors" or the "Board") by the provisions of the Restated Articles of Organization of the Corporation approved by the Board on May 23, 1991 and approved by the stockholders of the Corporation on May 24, 1991, the Board of Directors hereby establishes a series of Preferred Stock (the "Preferred Stock") of the Corporation, effective as of the date of the filing of the Restated Articles of Organization with the Secretary of the Commonwealth of Massachusetts, and hereby states the designation and number of shares, and prescribes the relative rights and preferences thereof as follows:

Series A Junior Participating Preferred Stock:

Section 1. <u>Designation and Amount</u>. The shares of such series shall be designated as "Series A Junior Participating Preferred Stock" (the "Series A Preferred Stock") and the number of shares constituting the Series A Preferred Stock shall be 250,000. Such number of shares may be increased or decreased by resolution of the Board of Directors; provided, that no decrease shall reduce the number of shares of Series A Preferred Stock to a number less than the number of shares then outstanding plus the number of shares reserved for issuance upon the exercise of outstanding options, rights or warrants, or the conversion of any outstanding securities, issued by the Corporation exercisable for or convertible into Series A Preferred Stock.

Section 2. Dividends and Distributions.

(A) Subject to the rights of the holders of any shares of any series of Preferred Stock (or any similar stock) ranking prior and superior to the Series A Preferred Stock with respect to dividends, the holders of shares of Series A Preferred Stock, in preference to the holders of Common Stock, par value \$.01 per share (the "Common Stock"), of the Corporation, and of any other junior stock, shall be entitled to receive, when, as and if declared by the Board of Directors out of funds legally available for the purpose, quarterly dividends payable in cash on the first day of March, June, September and December in each year (each such date being referred to herein as a "Quarterly Dividend Payment Date"), commencing on the first Quarterly Dividend Payment Date after the first issuance of a share or fraction of a share of Series A Preferred Stock, in an amount per share (rounded to the nearest cent) equal to the greater of (a) \$1 or (b) subject to the provisions for adjustment hereinafter set forth, 100 times the aggregate per share amount of all cash dividends, and 100 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions, other than a dividend payable in shares of Common Stock or a subdivision of the outstanding shares of Common Stock (by reclassification or otherwise), declared on the Common Stock since the immediately preceding Quarterly

Continuation Sheet 2A

Dividend Payment Date or, with respect to the first Quarterly Dividend Payment Date, since the first issuance of any share or fraction of a share of Series A Preferred Stock. In the event the Corporation shall at any time declare or pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision or combination or consolidation of the outstanding shares of Common Stock (by reclassification or otherwise than by payment of a dividend in shares of Common Stock) into a greater or lesser number of shares of Common Stock, then in each such case the amount to which holders of shares of Series A Preferred Stock were entitled immediately prior to such event under clause (b) of the preceding sentence shall be adjusted by multiplying such amount by a fraction, the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

- (B) The Corporation shall declare a dividend or distribution on the Series A Preferred Stock as provided in paragraph (A) of this Section immediately after it declares a dividend or distribution on the Common Stock (other than a dividend payable in shares of Common Stock); provided, that, in the event no dividend or distribution shall have been declared on the Common Stock during the period between any Quarterly Dividend Payment Date and the next subsequent Quarterly Dividend Payment Date, a dividend of \$1 per share on the Series A Preferred Stock shall nevertheless be payable on such subsequent Quarterly Dividend Payment Date.
- (C) Dividends shall begin to accrue and be cumulative on outstanding shares of Series A Preferred Stock from the Quarterly Dividend Payment Date next preceding the date of issue of such shares, unless the date of issue of such shares is prior to the record date for the first Quarterly Dividend Payment Date, in which case dividends on such shares shall begin to accrue from the date of issue of such shares, or unless the date of issue is a Quarterly Dividend Payment Date or is a date after the record date for the determination of holders of shares of Series A Preferred Stock entitled to receive a quarterly dividend and before such Quarterly Dividend Payment Date, in either of which events such dividends shall begin to accrue and be cumulative from such Quarterly Dividend Payment Date. Accrued but unpaid dividends shall not bear interest. Dividends paid on the shares of Series A Preferred Stock in an amount less than the total amount of such dividends at the time accrued and payable on such shares shall be allocated pro rata on a share-by-share basis among all such shares at the time outstanding. The Board of Directors may fix a record date for the determination of holders of shares of Series A Preferred Stock entitled to receive payment of a dividend or distribution declared thereon, which record date shall be

Continuation Sheet 2B

not more than 60 days prior to the date fixed for the payment thereof.

Section 3. Voting Rights. The holders of shares of Series A Preferred Stock shall have the following voting rights:

- (A) Each share of Series A Preferred Stock shall entitle the holder thereof to 100 votes on all matters submitted to a vote of the stockholders of the Corporation.
- (B) Except as otherwise provided herein, in any other Certificate of Vote of Directors establishing a series of Preferred Stock or any similar stock, or by law, the holders of shares of Series A Preferred Stock and the holders of shares of Common Stock and any other capital stock of the Corporation having general voting rights shall vote together as one class on all matters submitted to a vote of the stockholders of the Corporation.
- (C) Except as otherwise provided herein, or by law, holders of shares of Series A Preferred Stock shall have no special voting rights and their consent shall not be required (except to the extent they are entitled to vote with holders of shares of Common Stock as set forth herein) for taking any corporate action.

Section 4. Certain Restrictions.

- (A) Whenever quarterly dividends or other dividends or distributions payable on the Series A Preferred Stock as provided in Section 2 are in arrears, thereafter and until all accrued and unpaid dividends and distributions, whether or not declared, on shares of Series A Preferred Stock outstanding shall have been paid in full, the Corporation shall not:
- (i) declare or pay dividends, or make any other distributions, on any shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Preferred Stock;
- (ii) declare or pay dividends, or make any other distributions, on any shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Preferred Stock, except dividends paid ratably on the Series A Preferred Stock and all such parity stock on which dividends are payable or in arrears in proportion to the total amounts to which the holders of all such shares are then entitled;
- (iii) redeem or purchase or otherwise acquire for consideration any shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Preferred Stock; provided,

Continuation Sheet 2C

that the Corporation may at any time redeem, purchase or otherwise acquire shares of such junior stock in exchange for shares of stock of the Corporation ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A-Preferred Stock; or

- (iv) redeem or purchase or otherwise acquire for consideration any shares of Series A Preferred Stock, or any shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Preferred Stock, except-in accordance with a purchase offer made in writing or by publication (as determined by the Board of Directors) to all holders of such shares upon such terms as the Board of Directors, after consideration of the respective annual dividend rates and other relative rights and preferences of the respective series and classes, shall determine in good faith will result in fair and equitable treatment among the respective series or classes.
- (B) The Corporation shall not permit any subsidiary of the Corporation to purchase or otherwise acquire for consideration any shares of stock of the Corporation unless the Corporation could, under paragraph (A) of this Section, purchase or otherwise acquire such shares at such time and in such manner.

Section 5. <u>Reacquired Shares</u>. Any shares of Series A Preferred Stock purchased or otherwise acquired by the Corporation in any manner whatsoever shall be retired and cancelled promptly after the acquisition thereof. All such shares shall upon their cancellation become authorized but unissued shares of Preferred Stock and may be reissued as part of a new series of Preferred Stock subject to the conditions and restrictions on issuance set forth herein, in the Restated Articles of Organization, or in any other Certificate of Vote of Directors establishing a series of Preferred Stock or any similar stock or as otherwise required by law.

Section 6. <u>Liquidation</u>, <u>Dissolution or Winding Up</u>. Upon any liquidation, dissolution or winding up of the Corporation, no distribution shall be made (1) to the holders of shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Preferred Stock unless, prior thereto, the holders of shares of Series A Preferred Stock shall have received \$100 per share, plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment; provided, that the holders of shares of Series A Preferred Stock shall be entitled to receive an aggregate amount per share, subject to the provision for adjustment hereinafter set forth, equal to 100 times the aggregate amount to be distributed per share to holders of shares

Continuation Sheet 2D

of Common Stock, or (2) to the holders of shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Preferred Stock, except distributions made ratably on the Series A Preferred Stock and all such parity stock-in proportion to the total amounts to which the holders of all such shares are entitled upon such liquidation, dissolution or winding up. In the event the Corporation shall at any time declare or pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision or combination or consolidation of the outstanding shares of Common Stock (by reclassification or otherwise than by payment of a dividend in shares of Common Stock) into a greater or lesser number of shares of Common Stock, then in each such case the amount to which holders or shares of Series A Preferred Stock were entitled immediately prior to such event under the proviso to clause (1) of the preceding sentence shall be adjusted by multiplying such amount by a fraction, the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

Section 7. Consolidation, Merger, etc. In case the Corporation shall enter into any consolidation, merger, combination or other transaction in which the shares of Common Stock are exchanged for or changed into other stock or securities, cash and/or any other property, then in any such case each share of Series A Preferred Stock shall at the same time be similarly exchanged for or changed into an amount per share, subject to the provision for adjustment hereinafter set forth, equal to 100 times the aggregate amount of stock, securities, cash and/or any other property (payable in kind), as the case may be, into which or for which each share of Common Stock is changed or exchanged. In the event the Corporation shall at any time declare or pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision or combination or consolidation of the outstanding shares of Common Stock (by reclassification or otherwise than by payment of a dividend in shares of Common Stock) into a greater or lesser number of shares of Common Stock, then in each such case the amount set forth in the preceding sentence with respect to the exchange or change of shares of Series A Preferred Stock shall be adjusted by multiplying such amount by a fraction, the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock prior to such event.

Section 8. No Redemption. The shares of Series A Preferred Stock shall not be redeemable.

Section 9. Rank. The Series A Preferred Stock shall rank, with respect to the payment of dividends and the distribution of assets, junior to all series of any other class of the Corporation's Preferred Stock.

Continuation Sheet 2E

Section 10. <u>Amendment</u>. The Restated Articles of Organization of the Corporation shall not be amended in any manner which would materially alter or change the powers, preferences or special rights of the Series A Preferred Stock so as to affect them adversely without the affirmative vote of the holders of at least two-thirds of the outstanding shares of Series A Preferred Stock, voting together as a single class.

Continuation Sheet 2F

IN WITNESS WHEREOF AND UNDER THE PENALTIES OF PERJURY, we have hereto signed our names this 30th day of July in the year 1991.

/S/ Joshua Boger

Joshua Boger, President

/S/ Richard H. Aldrich

Richard H. Aldrich, Clerk

THE COMMONWEALTH OF MASSACHUSETTS

Certificate of Vote of Directors Establishing A Series of a Class of Stock (General Laws, Chapter 156B, Section 26)

I hereby approve the within certificate and, the filing fee in the amount of \$100.00 having been paid, said certificate is hereby filed this 31st day of July, 1991

/S/ MICHAEL JOSEPH CONNOLLY

MICHAEL JOSEPH CONNOLLY Secretary of State

TO BE FILLED IN BY CORPORATION Photo copy of certificate to be sent TO:

Timothy B. Bancroft, Esq. Warner & Stackpole 75 State Street, Boston, MA 02109 Telephone: (617) 951-9000

THE COMMONWEALTH OF MASSACHUSETTS

WILLIAM FRANCIS GALVIN Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

(General Laws, Chapter 156B, Section 72)

We, Joshua S. Boger, President and Richard H. Aldrich, Clerk of

 $\label{lem:vertex_power} \textbf{Vertex Pharmaceuticals Incorporated} \ ,$

(EXACT NAME OF CORPORATION)

located at 40 Allston Street, Cambridge, Massachusetts 02139,
(STREET ADDRESS OF CORPORATION IN MASSACHUSETTS) certify that these Articles of Amendment affecting articles numbered: 3
(NUMBER THOSE ARTICLES 1, 2, 3, 4, 5 AND/OR 6 BEING AMENDED) of the Articles of Organization were duly adopted at a meeting held on May 11, 1995, by vote of:
11,800,239 shares of Common Stock of 17,189,713 shares outstanding,
shares of of shares outstanding, and (TYPE, CLASS & series, if any)
shares of of shares outstanding (TYPE, CLASS & series, if any)

being at least a majority of each type, class or series outstanding and entitled to vote thereon:

VOTED: To increase the number of shares of Common Stock, \$.01 par value per share that the Corporation shall have authority to issue from 25,000,000 shares to

50,000,000 shares; and that Article 3 of the

Corporation's Restated Articles of Organization be, and hereby is, amended to read as follows:

3. The total number of shares and the par value, if any, of each class of stock which the Corporation shall be authorized to issue is as follows: 1,000,000

shares of Preferred Stock, \$.01 par value per share and 50,000,000 shares of Common Stock, \$.01 par value per share.

To CHANGE the number of shares and the par value (if any) of any type, class or series of stock which the corporation is authorized to issue, fill in the following:

The total PRESENTLY authorized is:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 25,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

CHANGE the total authorized to:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 50,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

The foregoing amendment will become effective when these Article of Amendments are filed in accordance with General Laws, Chapter 156B, Section 6 unless the articles specify, in accordance with the vote adopting the amendment, a later effective date not more than thirty days after such filing, in which event the amendment will become effective on such later date.
EFFECTIVE DATE:
IN WITNESS WHEREOF AND UNDER THE PENALTIES OF PERJURY, we have hereunto signed our names this 15th day of May, in the year 1995,

our names this 15th day of May, in the year 1999
/s/ Joshua S. Boger , President

/s/ Richard H. Aldrich , Clerk

3

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT (GENERAL LAWS, CHAPTER 156B, SECTION 72)

I hereby approve the within Articles of Amendment and, the filing fee in the amount of \$25,000.00 having been paid, said articles are deemed to have been filed with me this 17th day of May 1995.

/s/ William Francis Galvin WILLIAM FRANCIS GALVIN

SECRETARY OF THE COMMONWEALTH

TO BE FILLED IN BY CORPORATION

PHOTOCOPY OF DOCUMENT TO BE SENT TO:

KENNETH S. BOGER, ESQUIRE WARNER & STACKPOLE 75 STATE STREET BOSTON, MA 02109 617-951-9000

The Commonwealth of Massachusetts

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

(General laws, Chapter 156B, Section 72)

We, Thomas G. Auchincloss, Jr.	Vice President,
and Richard H. Aldrich , Clerk, of	

(see page 2)

Vertex Pharmaceuticals Incorporated

(1) For amendments adopted pursuant to Chapter 156B, Section 70. (2) For amendments adopted pursuant to Chapter 156B, Section 71. Note: if the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate 8-1/2 x 11 sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

To change the number of shares and the par value (if any) of any type, class or series of stock which the corporation is authorized to issue, fill in the following:

The total presently authorized is:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 50,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

Change the total authorized to:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 100,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

VOTED: To increase the number of shares of Common Stock, \$.01 par value per share that the Corporation shall have authority to issue from 50,000,000 shares to 100,000,000 shares; and that Article 3 of the Corporation's Restated Articles of Organization be, and hereby is, amended to read as follows:

3. The total number of shares and the par value, if any, of each class of stock which the Corporation shall be authorized to issue is as follows: 1,000,000 shares of Preferred Stock, \$.01 par value per share and 100,000,000 shares of Common Stock, \$.01 par value per share.

articles specify, in accordance with the vote adopting the amendment, a later effective date not more than thirty days after such filing, in which event the amendment will become effective on such later date.
Later effective date:
SIGNED UNDER THE PENALTIES OF PERJURY, this 30th day of May, 1997.
/s/ Thomas G. Auchincloss, Jr., Vice President,
Thomas G. Auchincloss, Jr.

/s/ Richard H. Aldrich. Clerk

Richard H. Aldrich

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT (General Laws, Chapter 156B, Section 72)

I hereby approve the within Articles of Amendment, and the filing fee in the amount of \$50,000 having been paid, said article is deemed to have been filed with me this 4th day of June, 1997.

Effective date:

/S/ WILLIAM FRANCIS GALVIN

WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

TO BE FILLED IN BY CORPORATION Photocopy of document to be sent to:

Sarah P. Cecil Vertex Pharmaceuticals Incorporated 130 Waverly Street Cambridge, MA 02139-4242

The Commonwealth of Massachusetts

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

(General Laws, Chapter 156B, Section 72)

We, Vicki L. Sato, PH.D., President,
and Sarah P. Cecil, Clerk,
of

VERTEX PHARMACEUTICALS INCORPORATED,

(Exact name of corporation)

ocated at 130 WAVERLY STREET, CAMBRIDGE, MASSACHUSETTS 02139-4242, (Street address of corporation in Massachusetts)		
certify that these Articles of Amendment affecting articles numbered: 3 (Number those articles 1, 2, 3, 4, 5 and/or 6 being amended)		
of the Articles of Organization were duly adopted at a meeting held on MAY 8, 2001, by vote of:		
40,020,139 shares of Common Stock of 60,150,471 shares outstanding, (type, class & series, if any)		
shares of of shares outstanding, and (type, class & series, if any)		
shares of of shares outstanding, (type, class & series, if any)		

being at least a majority of each type, class or series outstanding and entitled to vote thereon:

Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate $8\ 1/2\ x\ 11$ sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

To change the number of shares and the par value (if any) of any type, class or series of stock which the corporation is authorized to issue, fill in the following:

The total presently authorized is:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 100,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

Change the total authorized to:

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS

NUMBER OF NUMBER OF

TYPE SHARES TYPE SHARES PAR VALUE

Common: 0 Common: 200,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

VOTED: To increase the number of shares of Common Stock, \$.01 par value per share that the Corporation shall have authorized to issue from 100,000,000 shares to 200,000,000 shares; and that ARTICLE 3 of the Corporation's Restated Articles of Organization be, and hereby is, amended to read as follows:

3. The total number of shares and the par value, if any, of each class of stock which the Corporation shall be authorized to issue is as follows: 1,000,000 shares of Preferred Stock, \$.01 par value per share and 200,000,000 shares of Common Stock, \$.01 par value per share.

The foregoing amendment(s) will become effective when these Articles of Amendment are filed in accordance with General Laws, Chapter 156B, Section 6 unless these articles specify, in accordance with the vote adopting the amendment, a <i>later</i> effective date not more than <i>thirty days</i> after such filing, in which event the amendment will become effective on such later date.
Later effective date:
SIGNED UNDER THE PENALTIES OF PERJURY, this 16TH day of May, 2001,
/s/ Vicki L. Sato, Ph.D., President,
Vicki L. Sato, Ph.D.
/s/ Sarah P. Cecil. Clerk

Sarah P. Cecil

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT (General Laws, Chapter 156B, Section 72)

I hereby approve the within Articles of Amendment and, the filing fee in the amount of \$100,000 having been paid, said articles are deemed to have been filed with me this $21^{\rm st}$ day of May, 2001.

Effective date:		

/S/ WILLIAM FRANCIS GALVIN

 $\label{eq:WILLIAM FRANCIS GALVIN} WILLIAM FRANCIS GALVIN Secretary of the Commonwealth$

TO BE FILLED IN BY CORPORATION Photocopy of document to be sent to:

Sarah P. Cecil, Esq. Vertex Pharmaceuticals Incorporated 130 Waverly Street Cambridge, MA 02139-4242

Telephone: (617) 577-6000

(1) Exact name of corporation: Vertex Pharmacouticals Incorporated

The Commonwealth of Massachusetts

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

(General Laws, Chapter 156D, Section 10.06; 950 CMR 113.34)

(2) Exact limit of corporation. Active a manufacture of the second of th
(2) Registered office address: 130 Waverly Street, Cambridge, Massachusetts 02139 (number, street, city or town, state, zip code)
(3) These articles of amendment affect article(s): 3 (specify the number(s) of article(s) being amended (I-VI))
(4) Date adopted: May 15, 2008
(5) Approved by:
(check appropriate box)
o the incorporation
o the board of directors without shareholder approval and shareholder approval was not required.
☑ the board of directors and the shareholders in the manner required by law and the articles of organization.
(6) State the article number and the text of the amendment. Unless contained in the text of the amendment, state the provisions for implementing the exchange, reclassification or cancellation of issued shares.

VOTED: To increase the number of shares of Common Stock, \$.01 par value per share, that the Corporation shall have authorized to issue from 200,000,000 shares to

3. The total number of shares and the par value, if any, of each class of stock that the Corporation shall be authorized to issue is as follows: 1,000,000 shares of Preferred Stock,

300,000,000 shares; and that ARTICLE 3 of the Corporation's Restated Articles of Organization be, and hereby is, amended to read as follows:

\$.01 par value per share, and 300,000,000 shares of Common Stock, \$.01 par value per share.

To change the number of shares and the par value, *if any, of any type, or to designate a class or series, of stock, or change a designation of class or series of stock, which the
corporation is authorized to issue, complete the following:

Total authorized prior to amendment:

Common: 0

WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS	
NUMBER OF NUMBER OF TYPE SHARES TYPE SHARES PAR VALUE	
Common: 0 Common: 200,000,000 \$ 0.01	
Preferred: 0 Preferred: 1,000,000 \$ 0.01	
Total authorized after amendment:	
WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS	
NUMBER OF NUMBER OF TYPE SHARES TYPE SHARES PAR VALUE	

Common: 300,000,000 \$ 0.01

Preferred: 0 Preferred: 1,000,000 \$ 0.01

(7) The amendment shall be effective at the time and on the date approved by the Division, unless a later effective date not more than 90 days from the date and time of filing is specified:

*G.L. Chapter 156D eliminates the concept of par value, however a corporation may specify par value in Article III. See G.L. Chapter 156D, Section 6.21, and the comments relative thereto.

Signed by: <u>/s/ Joshua Boger</u>
o Chairman of the board of directors, ☑ President, o Other officer,

- o Court-appointed fiduciary,

on this <u>15th</u> day of <u>May</u>, <u>2008</u>.

THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT (General Laws, Chapter 156D, Section 10.06;950 CMR 113.34)

I hereby certify that upon examination of these articles of amendment, it appears that the provision of the General Laws relative thereto have been compiled with, and the filing fee in the amount of \$100,000 having been paid, said articles are deemed to have been filed with me this 20th day of May, 2008, at 12:24 p.m.

Effective date: _ (must be within 90 days of date submitted)

/S/ WILLIAM FRANCIS GALVIN

WILLIAM FRANCIS GALVIN Secretary of the Commonwealth

> Filing fee: Minimum filing fee \$100 per article amended, stock increases \$100 per 100,000 shares, plus \$100 for each additional 100,000 shares or any fraction thereof.

> > TO BE FILLED IN BY CORPORATION **Contact Information**

KENNETH S. BOGER SENIOR VICE PRESIDENT AND GENERAL COUNSEL 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242 Telephone: (617) 444-6417

Email: KEN_BOGER@VRTX.COM

Upon filing, a copy of this filing will be available at www.sec.state.ma.us/cor. If the document is rejected, a copy of the rejection sheet and rejected document will be available in the rejected queue.

(1) Exact name of corporation: Vertex Pharmaceuticals Incorporated

The Commonwealth of Massachusetts

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

(General Laws, Chapter 156D, Section 10.06;950 CMR 113.34)

(2) Registered office address: 155 Federal Street, Suite 700, Boston MA 02110 (number, street, city or town, state, zip code)
(3) These articles of amendment affect article(s): 3 (specify the number(s) of article(s) being amended (I-VI))
(4) Date adopted: <u>June 4, 2015</u>
(5) Approved by:
(check appropriate box)
o the incorporation
o the board of directors without shareholder approval and shareholder approval was not required.
oxtimes the board of directors and the shareholders in the manner required by law and the articles of organization.
(6) State the article number and the text of the amendment. Unless contained in the text of the amendment, state the provisions for implementing the exchange, reclassification or cancellation of issued shares.

3. The total number of shares and the par value, if any, of each class of stock that the Corporation shall be authorized to issue is as follows: 1,000,000 shares of Preferred Stock, \$0.01 par value per share, and 500,000,000 shares of Common Stock, \$0.01 par value per share.

ARTICLE 3 of the Corporation's Restated Articles of Organization be, and hereby is, amended to read as follows:

To change the number of shares and the par value, *if any, of any type, or to designate a class or series, of stock, or change a designation of class or series of stock, which the corporation is authorized to issue, complete the following:
Total authorized prior to amendment:

WITH PAR VALUE STOCKS

WITHOUT PAR VALUE STOCKS

relative thereto.

NUMBER OF NUMBER OF TYPE SHARES TYPE SHARES PAR VALUE
Common: 0 Common: 300,000,000 \$ 0.01
Preferred: 0 Preferred: 1,000,000 \$ 0.01
Total authorized after amendment:
WITHOUT PAR VALUE STOCKS WITH PAR VALUE STOCKS
NUMBER OF NUMBER OF TYPE SHARES TYPE SHARES PAR VALUE
Common: 0 Common: 500,000,000 \$ 0.01
Preferred: 0 Preferred: 1,000,000 \$ 0.01
(7) The amendment shall be effective at the time and on the date approved by the Division, unless a later effective date not more than 90 days from the date and time of filing is specified:

*G.L. Chapter 156D eliminates the concept of par value, however a corporation may specify par value in Article III. See G.L. Chapter 156D, Section 6.21, and the comments

Signed by: /s/ Jeffrey M. Leiden

- ☑ Chairman of the board of directors,☑ President,o Other officer,o Court-appointed fiduciary,

on this 10^{th} day of June , 2015 .

THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin Secretary of the Commonwealth One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT (General Laws, Chapter 156D, Section 10.06;950 CMR 113.34)

I hereby certify that upon examination of these articles of amendment, it appears that the provision of the General Laws relative thereto have been compiled with, and the filing fee in the amount of \$200,000 having been paid, said articles are deemed to have been filed with me this 11th day of June, 2015, at 2:21 p.m. time

Effective date: (must be within 90 days of date submitted)

/S/ WILLIAM FRANCIS GALVIN

WILLIAM FRANCIS GALVIN Secretary of the Commonwealth

> Filing fee: Minimum filing fee \$100 per article amended, stock increases \$100 per 100,000 shares, plus \$100 for each additional 100,000 shares or any fraction thereof.

> > TO BE FILLED IN BY CORPORATION **Contact Information**

MICHAEL J. LACASCIA 50 NORTHERN AVENUE BOSTON, MASSACHUSETTS 02210 Telephone: (617) 961-7018

Email: MICHAEL_LACASCIA@VRTX.COM

Upon filing, a copy of this filing will be available at www.sec.state.ma.us/cor. If the document is rejected, a copy of the rejection sheet and rejected document will be available in the rejected queue.

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

STRATEGIC COLLABORATION AND LICENSE AGREEMENT

by and among

VERTEX PHARMACEUTICALS INCORPORATED

VERTEX PHARMACEUTICALS (EUROPE) LIMITED

and

PARION SCIENCES, INC.

ActiveUS 144208420v.18

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STRATEGIC COLLABORATION AND LICENSE AGREEMENT

This Strategic Collaboration and License Agreement (this "Agreement") is entered into as of June 4, 2015 ("Effective Date") by and among Parion Sciences, Inc., a corporation duly organized and validly existing under the laws of the state of Delaware (hereinafter referred to as "Parion") and Vertex Pharmaceuticals Incorporated, a corporation duly organized and existing under the laws of The Commonwealth of Massachusetts ("Vertex Parent"), and Vertex Pharmaceuticals (Europe) Limited, a private limited company organized under the laws of England and Wales ("Vertex UK" and, together with, Vertex Parent "Vertex"). Parion and Vertex are each referred to herein by name or, individually, as a "Party" or, collectively, as "Parties."

BACKGROUND

WHEREAS, Parion is engaged in the research and development of ENaC inhibitors, including P-1037 and P-1055;

WHEREAS, Parion controls the Parion Technology and desires to advance the development and commercialization of the Parion Technology via a transaction with a company that is able to effectively develop and commercialize CF and other specialty pulmonary products incorporating ENaC inhibitors in the Territory;

WHEREAS, Vertex is engaged in the research, development and commercialization of pharmaceutical products and desires to secure rights to develop pharmaceutical products associated with the Parion Technology in all pulmonary indications, including cystic fibrosis ("CF"), primary ciliary dyskinesia ("PCD"), chronic obstructive pulmonary disease ("COPD") and non-CF Bronchiectasis ("NCFB");

WHEREAS, Vertex and Parion have engaged in discussions regarding the further development and potential commercialization of the Parion Technology and have agreed to pursue a licensing and development transaction with a goal of increasing the value of the Parion Technology for the benefit of both of the Parties, including allowing Parion to increase its expertise in the development and commercialization of pharmaceutical products; and

WHEREAS, Parion and Vertex desire to proceed with such licensing and development pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein below and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Parion and Vertex hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 Definitions.

The following capitalized terms and derivations thereof shall have the meanings given in this Article 1 when used in this Agreement:

"Affiliate" means, as to a Person, any other Person that controls, is controlled by or is under common control with such Person, for so long as such control exists. For purposes of this definition only, "control" shall mean (i) possession, directly or indirectly, of the power to direct the management and policies of the

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controlled Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance or otherwise. Control shall be presumed where there is beneficial ownership (direct or indirect) of more than 50% of the shares of the controlled Person that are entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, in the election of the corresponding managing authority). For the avoidance of doubt, a corporation or other business entity that is controlled by a group of unaffiliated financial investors (e.g., venture capital investors) who also control Parion shall not be deemed to be an Affiliate of Parion as long as no single investor controls both Parion and such entity.

- "Applicable Laws" means any federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, guidance, guidelines or requirements of Regulatory Authorities, national securities exchanges or securities listing organizations, that are in effect from time to time during the Term and applicable to a particular activity hereunder.
- "Back-Up Compound" means a Licensed Compound selected by the JSC to be developed as a back-up to any Lead Compound for an Indication.
- "Business Day" means each Monday, Tuesday, Wednesday, Thursday and Friday that is not a calendar day on which banking institutions in Boston, Massachusetts are authorized or obligated to close by law or executive order.
- "Calendar Quarter" means a period of three consecutive months during a Calendar Year beginning on and including 1st January, 1st April, 1st July or 1st October, or the applicable part thereof during the first or last quarter of the Term.
- "Calendar Year" means a period of twelve consecutive months beginning on and including 1st January, or the applicable part thereof during the Term.

"CFFT Agreements" means [***].

"Change of Control" means with respect to an entity that:

- (a) any "person" or "group" as such terms are used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Act"), becomes a beneficial owner, as such term is used in Rule 13d-3 promulgated under the Act, of securities of such entity representing more than 50% of the combined voting power of the outstanding securities of such entity having the right to vote in the election of directors; or
- **(b)** all or substantially all the business or assets of such entity are sold or disposed of, or such entity merges with and into another entity pursuant to a merger, consolidation, or other similar transaction, other than (i) a transaction solely for the purpose of reincorporating the entity or one of its subsidiaries in a different jurisdiction or recapitalizing or reclassifying such entity's stock; or (ii) a merger or consolidation in which the shareholders of such entity immediately prior to such merger or consolidation continue to own at least a majority of the outstanding voting securities of such entity or the surviving entity immediately after the merger or consolidation.
- **(c)** Notwithstanding the foregoing, the term "Change of Control," with respect to Parion, does not include: (i) an underwritten public offering of Parion's common stock pursuant to a Registration Statement on Form S-1 under the Securities Act of 1933, as amended; or (ii) any sale of shares of capital stock of Parion, in a single transaction or series of related transactions, principally for bona fide equity financing purposes in which Parion issues new securities solely to institutional investors for cash or the

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cancellation or conversion of indebtedness of Parion or a combination thereof for the purpose of financing the operations and business of Parion.

"Clinical Trial" means any research study of a therapeutic product administered to human subjects designed to provide specific data to determine the safety, efficacy and/or other properties of such product.

"CMC Activities" means activities related to chemistry, manufacturing, and controls, including production of registration batches, validation and other similar pre-commercial manufacturing activities.

"Collaboration Expenses" means the FTE Costs and out-of-pocket costs that are paid or incurred by Parion or any of its Affiliates after the Effective Date that are directly attributable to the conduct of activities under the Development Plan. Subject to the foregoing, Collaboration Expenses shall include: (a) the FTE Costs and out-of-pocket costs incurred in connection with the planning, conduct, statistical analysis and reporting of Clinical Trials pursuant to the Development Plan, including the cost of Clinical Trial subject recruitment and monitoring initiatives; (b) the FTE Costs and out-of-pocket costs incurred in connection with regulatory activities in support of Clinical Trials pursuant to the Development Plan; and (c) other FTE Costs and out-of-pocket costs incurred in connection with Parion's performance of other activities in accordance with the terms of the Development Plan, including any manufacturing costs.

"Combination Product" shall have the meaning stated in the definition of "Net Sales."

"Commercially Reasonable Efforts" means, with respect to the performing Party, the carrying out of obligations of such Party [***] that such Party [***] the Licensed Compound or Licensed Product, [***] Licensed Compound or Licensed Product, [***] Party of the Licensed Compound or Licensed Product [***].

"Completion" means, with respect to any Clinical Trial, the date following final Database Lock on which the final tables, listing and figures, together with any additional post-hoc analyses needed to support the interpretation of the clinical results from such Clinical Trial have been compiled (ignoring for this purpose, any roll-over study conducted to collect additional data regarding the patients in such Clinical Trial after the collection of the data that will be used to evaluate the primary and secondary endpoints of the Clinical Trial).

"Control" or "Controlled" means, with respect to particular Know-How or a particular Patent, possession by the Person granting the applicable right, license or sublicense (or by an Affiliate controlled by such Person) to another Person as provided herein of the power and authority, whether arising by ownership, license, or other authorization (other than pursuant to a license granted under this Agreement), to disclose and deliver the particular Know-How to the other Person and to grant under such Know-How, or to grant under such Patent, a right, license or sublicense, as applicable, as provided in this Agreement without violating the terms of any written agreement with any Third Party.

"Data" means any and all research and development data, such as preclinical data, pharmacology data, chemistry data (including analytical, product characterization, manufacturing, and stability data), toxicology data, clinical data (including statistical analyses and reports, safety and other electronic databases, clinical specimen analyses and reports), together with supporting data, in each case generated in the course of Development of, a Licensed Compound or Licensed Product and Controlled by a Party during the Term (including previously generated Parion data that Parion possesses as of the Effective Date).

"**Database Lock**" means, with respect to any Clinical Trial, the date on which the database(s) containing the applicable clinical trial data is determined to be complete and locked in order to permit the analysis of the primary and secondary endpoints of such Clinical Trial.

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"Develop" or "Development" means, with respect to any compound, any and all processes and activities conducted to file for, obtain, and maintain Marketing Approval in the Field for such Licensed Compound or Licensed Product, which may involve preclinical testing, CMC Activities, ADME (absorption, distribution, metabolism and excretion) and toxicology studies, clinical trials, quality of life assessments, pharmacoeconomics, post-marketing studies, label expansion studies, regulatory affairs, and further activities related to development of such Licensed Compound or Licensed Product.

"Development Milestones" means the milestones as set forth in Section 6.4.1, as applicable.

"**Drug Approval Application**" means a New Drug Application or Supplemental New Drug Application as defined in the FFDCA or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

[***]

"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.

"ENaC Inhibitors" means [***] (which, for the avoidance of doubt, includes any [***].

"EU" or "European Union" means the European Union member states as then constituted and Switzerland.

"Executive Officer" with respect to Parion shall mean Parion's Chief Executive Officer, or such other executive officer of Parion as shall be designated by Parion from time to time, and with respect to Vertex shall mean Vertex's Chief Financial Officer, or such other officer of Vertex as shall be designated by Vertex from time to time.

"Existing Regulatory Documentation" means the Regulatory Filings Controlled by Parion or any of its Affiliates as of the Effective Date, including that certain U.S. IND having the following number: 115168.

"FDA" means the United States Food and Drug Administration or any successor entity that is responsible for reviewing applications seeking approval for the sale of pharmaceuticals in the United States.

"FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

"Field" means all pulmonary therapeutic, pulmonary prophylactic and pulmonary diagnostic uses in humans, including but not limited to the treatment of CF, COPD, PCD, asthma and NCFB.

"First Commercial Sale" means, with respect to any Licensed Product, the first arms-length sale of such Licensed Product by Vertex or its Affiliate or sublicensee to a Third Party in a country of the Territory for use or consumption in such country following Marketing Approval. For the avoidance of doubt, sales prior to receipt of Marketing Approval, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales" and any sales to any government, foreign or domestic, including purchases for immediate sale and/or stockpiling purposes, shall not be considered a First Commercial Sale in that country.

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"FTE" means one employee full-time for one year or more than one person working the equivalent of a full-time person, working directly on performing development activities according to the Development Plan, where "full-time" is considered [***] for one Calendar Year.

"FTE Costs" shall be calculated by multiplying (a) the total number of FTEs performing relevant activities pursuant to this Agreement by (b) the FTE Rate.

"FTE Rate" means the agreed rate of [***] to be used by each Party in determining the cost of an FTE in the applicable functional area. For clarity, the FTE Rate includes (i) wages and salaries, employee benefits, bonus, travel and entertainment, supplies and other direct expenses and (ii) indirect allocations including, but not limited to, human resources, finance, occupancy or depreciation and administrative support.

"GAAP" means then-current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles, in each case consistently applied.

"Generic Product" shall mean, with respect to a Licensed Product, on a country-by-country basis, a pharmaceutical product being sold by a Third Party(ies) not acting on behalf of Vertex in such country, that: (i) has received marketing approval from the Regulatory Authorities in such country through an abbreviated regulatory approval process (e.g., an ANDA in the U.S., and its foreign equivalent in other countries), (ii) contains the same or similar active pharmaceutical ingredient as such Licensed Product and (iii) satisfies the applicable therapeutic equivalence requirement, if any, for approval under the applicable abbreviated regulatory approval process in the applicable country.

"Gilead Agreement" means, [***].

"Hatch-Waxman Act" means the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984, as set forth at 21 U.S.C. §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) and any amendments thereto.

"**Indication**" means a separately-defined, well-categorized class of disease or medical condition in humans (a) that a Licensed Product is being evaluated for, or (b) for which a Licensed Product has received Marketing Approval, and shall include any disease or medical condition contained in the Licensed Product's labeling as part of the Marketing Approval for such Licensed Product. For the avoidance of doubt, each of CF, COPD, NCFB and PDC are separate Indications.

"IND" means an Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 C.F.R. §312 for authorization to initiate clinical studies, or any comparable filings with any Regulatory Authority in any other jurisdiction.

"**Initiate**" or "**Initiation**" shall mean, with respect to a Clinical Trial, the administration of the first dose to the first human in that Clinical Trial.

"Inventory Maintenance Period" means the period beginning on the Effective Date and ending on [***].

"Joint Know-How" means Know-How that is jointly developed by the Parties.

"Joint Patents" means Patents that disclose or claim Joint Inventions.

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"Key Results Memorandum" means a high level summary of results of a Clinical Trial (containing tables, listings and figures, together with any additional post-hoc analysis needed to support the interpretation of the clinical results), which is prepared (following the date on which the database(s) containing the applicable data is determined to be completed in order to permit the analysis of the primary and secondary endpoints of such Clinical Trial) to help guide decision making regarding the design of future Clinical Trials of the applicable drug candidate.

"Know-How" means information, Data, tangible materials, trade secrets, techniques, methods, formulae and processes. Know-How shall not include Patent rights.

"Knowledge" means actual knowledge of (i) the executive officers and members of the board of directors of a Party and (ii) solely with respect to [***], in each case after making reasonable inquiry.

"Lead Compound" means a Licensed Compound selected by the JSC as the lead compound to develop for an Indication, which initially shall be P-1037 for all Indications.

"LIBOR" means the London Interbank Offered Rate for deposits having a maturity of one month published by the British Bankers' Association.

"Licensed Compound" means (i) P-1037, (ii) P-1055, (iii) any Vertex Selected Compound, and (iv) following any exercise of the Option by Vertex pursuant to Section 2.8, the applicable Option Compound, and in each case, references to any such Licensed Compound shall include [***]. For clarity, if an Option Compound becomes a Licensed Compound, and such Option Compound is comprising an ENaC Inhibitor that, alone, is a Licensed Compound, such Option Compound and such ENaC Inhibitor shall be two separate and distinct Licensed Compounds.

"Licensed Product" means any pharmaceutical product that contains a Licensed Compound. For avoidance of doubt, except as otherwise expressly set forth in this Agreement, Licensed Product includes any Shared Product.

"Major EU Country" means any one of the [***].

"Major Market" means: (a) the [***] and (b) the [***].

"Marketing Approval" means, with respect to a Licensed Product in a particular jurisdiction, approval by the applicable Regulatory Authority of an NDA, MAA or similar filing for authorization to market a Licensed Product in a jurisdiction other than the United States or the European Union for such Licensed Product in the Field.

"Marketing Approval Application" or "MAA" shall mean a marketing authorization application, or similar application, submitted to (i) the EMA, for authorization to initiate marketing activities in the European Union through the centralized process, or (ii) the Regulatory Authority in a Major EU Country for authorization to initiate marketing activities in such Major EU Country.

"NDA" means a "New Drug Application" as defined in 21 C.F.R. §314.3.

"Net Sales" shall mean the gross invoiced price for Licensed Products sold by Vertex, its Affiliates or permitted sublicensees (the "Selling Party") to Third Parties, less the following deductions from such gross amounts:

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- **(a)** credits or allowances, if any are actually allowed, 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;
- **(b)** import taxes, export taxes, excise taxes (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48)), sales taxes, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined and/or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind), to the extent not reimbursed by a non-related party;
- **(c)** insurance, customs charges, freight, shipping and other transportation costs incurred in shipping product to such non-related parties, to the extent not reimbursed by a non-related party;
- (d) discounts (including trade, quantity, cash discounts and fees for services) actually allowed, cash and non-cash coupons, 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, 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)) which effectively reduce the selling price or gross sales of the Licensed Product. Rebates paid on Licensed Product(s) shall not be negotiated by Vertex in order to obtain preferential treatment for other Vertex products.

Generally, only items that are deducted from the Selling Party's gross sales of Licensed Product(s), as included in the Selling Party's published financial statements and that are in accordance with GAAP, applied on a consistent basis, shall be deducted from such gross sales for purposes of the calculation of Net Sales. However, compulsory payments required by federal or state governments based upon sales volume or market share of Licensed Products (but for clarity excluding taxes on the Selling Party's net income), to the extent borne by the Selling Party, shall be deducted from "Net Sales" regardless of its classification in the Selling Party's published financial statements; provided that any such deduction shall be limited to that share of such compulsory payment proportional to the share of the total sales volume or market share of the Selling Party used to compute the compulsory payment represented by applicable Net Sales of Licensed Products; and provided further that, Vertex shall include in each report provided to Parion pursuant to Section 6.7 for any Calendar Quarter in which such deduction is taken an explanation of how the share of such compulsory payment allocated to applicable Net Sales of Licensed Products was calculated.

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 shall be reported with the next quarterly report. Sales between or among Vertex, its Affiliates and sublicensees shall be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales shall include the subsequent final sales to Third Parties by Vertex or any such Affiliates or sublicensees. A Licensed Product shall not be deemed to be sold if the Licensed Product is provided free of charge to a Third Party in reasonable quantities as a sample consistent with industry standard promotional and sample practices. For clarity, [***].

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If a sale, transfer or other disposition with respect to Licensed Products involves consideration other than cash or is not at arm's length, then the Net Sales from such sale, transfer or other disposition shall be calculated [***] during the same Calendar Quarter as such sale, transfer or other disposition.

Solely for purposes of calculating Net Sales, if Vertex or its Affiliates or any permitted sublicensee sells a Licensed Product in the form of a combination product containing a Licensed Compound (which may include a [***]) and one or more other therapeutically or prophylactically active ingredients (whether combined in a single formulation or package, as applicable, or formulated separately but packaged under a single label approved by a Regulatory Authority and sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), Net Sales of such Combination Product for the purpose of determining the payments due to Parion pursuant to this Agreement will be calculated by multiplying actual Net Sales of such Combination Product as determined in the first paragraph of the definition of "Net Sales" by the fraction A/(A+B) [***]. If it is not possible to determine the fraction A/(A+B) based on the criteria specified in the preceding sentence [***]. In such event, the Parties shall discuss the amount to be included in Net Sales, based on the foregoing, [****].

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"P-321" means the compound as described in <u>Schedule A</u>, and [***].
"P-552" means the compound as described in <u>Schedule A</u>, and [***].
"P-1037" means the compound as described in <u>Schedule A</u>, and [***].
"P-1046" means the compound as described in <u>Schedule A</u>, and [***].
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"P-1055" means the compound as described in Schedule A, and [***].

"Parion Compound Pool" means (i) [***] and (ii) all ENaC Inhibitors first synthesized by Parion during the Inventory Maintenance Period and in each case [***], excluding in each case the Licensed Compounds and Parion Selected Compounds; provided, however, if, subsequent to the Effective Date, there is a Change of Control involving Parion (where Parion is the acquired entity), the following compounds (to the extent not included in the Parion Compound Pool prior to such Change of Control) shall not be included in the Parion Compound Pool for purposes of this Agreement (even if any such compound otherwise satisfies the definition of being an ENaC Inhibitor):

- (a) any compounds claimed in a Valid Claim owned by or exclusively licensed to the acquirer or its Affiliates existing immediately prior to the Change of Control (other than Parion and any of its Affiliates); and
- **(b)** any compounds identified by the acquirer or its Affiliates [***] (the "Parion Exempt Compounds"); provided that the acquirer or its Affiliates existing immediately prior to the Change of Control (other than Parion and any of its Affiliates) promptly following the effective date of such Change of Control, establish and enforce internal processes, policies, procedures and systems to (i) segregate information relating to any such Parion Exempt Compounds from any Confidential Information related to the Parion Compound Pool, Licensed Compounds and Licensed Products, (ii) prevent the personnel of the acquirer and its Affiliates existing immediately prior to the Change of Control (other than Parion and any of its Affiliates) that provide services to or are involved in the research or development of such Parion Exempt Compounds from accessing any personnel data, files, systems, information or other data related to the Parion Technology or the Confidential Information of Vertex; and (iii) prevent the personnel of Parion and any of its Affiliates that provide services to or are involved in the collaboration established under this Agreement from accessing any

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personnel data, files, systems, information or other data related to the research or development of such Parion Exempt Compounds.

"Parion ENaC Inhibitors" means the Parion Compound Pool, Parion Selected Compounds and all ENaC Inhibitors first synthesized by Parion after last calendar day of the Inventory Maintenance Period and in each case [***].

"Parion Exempt Compounds" shall have the meaning stated in the definition of "Parion Compound Pool."

"Parion Agreements" means (a) the Gilead Agreement, and (b) the CFFT Agreements.

"Parion Know-How" means any and all Know-How Controlled by Parion (or by any such Affiliate controlled by Parion) on or after the Effective Date that is necessary or useful for the Development, manufacture, or commercialization of Licensed Compounds or Licensed Products in the Field.

"Parion Patents" means any and all Patents (including Patents based on Parion Inventions and Parion's interest in any Joint Patents) Controlled by Parion on or after the Effective Date that cover the keeping, making, using, selling, offering for sale or import of Licensed Compounds or Licensed Products in the Field. An initial list of Parion Patents shall be set forth in Exhibit A to this Agreement. Exhibit A will be updated by Parion during the Term, as specified in Section 2.4.

"Parion Selected Compounds" means (i) P-321, P-552 and P-1046 [***], and (ii) compounds selected by Parion for development from the Parion Compound Pool pursuant to Section 2.7.2 and, to the extent not comprising Licensed Compound, [***].

"Parion Technology" means the Parion Patents and Parion Know-How.

"Patent" means any of the following, whether existing now or in the future anywhere in the world: (i) any issued patent, including inventor's certificates, substitutions, extensions, confirmations, reissues, re-examination, renewal or any like governmental grant for protection of inventions; and (ii) any pending application for any of the foregoing, including any addition, continuation, divisional, substitution, continuations-in-part, provisional and converted provisional applications.

"Person" means any individual, corporation or other entity.

"**Phase I Clinical Trial**" means any human clinical study as described in 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, a similar clinical study.

"**Phase II Clinical Trial**" means any human clinical study as described in 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the United States, a similar clinical study.

"Phase IIa Clinical Trial" means, as to a particular Licensed Product, a Phase II Clinical Trial of pharmacological or clinical activity of the Licensed Product in a target patient population. This study may include safety, dose ranging, duration of effect or kinetic/dynamic relationship assessments.

"**Phase IIb Clinical Trial**" means, as to a particular Licensed Product, a Phase II Clinical Trial conducted in a sufficient number of patients to generate sufficient data efficacy and safety, if successful, to commence a Phase III Clinical Trial of such Licensed Product.

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"Phase III Clinical Trial" means any human clinical study as described in 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, a similar clinical study.

"**Pricing Approval**" means the governmental approval, agreement, determination or decision establishing the price and approving reimbursement for a Licensed Product in a regulatory jurisdiction.

"Profit-Share Term" means, as to each Shared Product, the period commencing upon the date of Parion's exercise of the applicable Profit/Loss-Sharing Option and continuing until the earlier of (a) such time as [***], or (b) such time as [***].

"Regulatory Authority" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the Development, manufacture, commercialization or other use (including the granting of Marketing Approvals) of any Licensed Product in any jurisdiction, including the FDA, EMA, European Commission, and the Ministry of Health, Labor and Welfare in Japan.

"Regulatory Filing" means all (i) applications (including all INDs and applications for Marketing Approvals, including NDAs and MAAs), registrations, licenses, authorizations and approvals (including regulatory approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (iii) clinical and other data, including study data, contained or relied upon in any of the foregoing; in each case ((i), (ii) and (iii)) relating to the Licensed Compound or a Licensed Product.

"Royalty Term" means, with respect to a Licensed Product in a country, the period commencing on the first sale of such Licensed Product in such country and ending upon the later of: (a) the expiration of the last Valid Claim of a Parion Patent, which, but for the licenses granted herein, would be infringed by such Licensed Product in such country; [***] after the First Commercial Sale of such Licensed Product in such country.

"Selling Party" shall have the meaning set forth in the definition of "Net Sales."

"Territory" means all countries and territories of the world.

"Third Party" means any Person other than a Party or an Affiliate of a Party.

"U.S." or "United States" means the United States of America.

"Valid Claim" means a claim: (i) in any issued, unexpired Patent that has not been donated to the public, revoked nor held unenforceable or invalid by a governmental agency or court of competent jurisdiction by a decision from which there is no appeal or (if there is a right to appeal) from which the period for appeal has expired without such appeal, and that has not been disclaimed or admitted to be invalid, or unenforceable through reissue, disclaimer or otherwise, or (ii) in any patent application among the Patents, which has not been finally cancelled, withdrawn or abandoned by any administrative agency or other body of competent jurisdiction and is not pending without issuing for more than seven years subsequent to the earliest filing date from which such application claims priority.

"Vertex Patents" means Patents that are Controlled by Vertex or its Affiliate(s).

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"**Vertex Selected Compounds**" means the compounds selected by Vertex for development from the Parion Compound Pool pursuant to Section 2.7.1 and [***].

1.2 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

<u>Definitions</u>	<u>Location</u>			
[***]	Section 1.1 ([***] definition)			
[***]	Section 6.5.4(a)			
[***]	Section 6.5.4(b)			
Act	Section 1.1 (Change of Control definition)			
Alliance Manager	Section 3.6.8			
Agreement	Preamble			
Audited Party	Section 6.13(e)			
Auditing Party	Section 6.13(e)			
Baseline Net Sales	Section 6.5.4(a)			
Breaching Party	Section 12.3			
CF	Background			
Co-Development Election	Section 3.2.6(f)			
Co-Development Percentage	Section 3.2.6(g)			
Confidential Information	Section 8.1			
COPD	Background			
COPD Co-Development Election	Section 3.2.6(c)			
COPD Pre-Option Costs	Section 3.2.6(d)			
Development Plan	Section 3.2.1			
Development Reconciliation Payment	Section 6.13(d)			
Development Reconciliation Report	Section 6.13(d)			
Development Report	Section 6.13(b)			
Dollars	Section 6.8			
Effective Date	Preamble			
Enforcement Action	Section 7.4			
Event Notice	Section 12.4			
Exercise Notice	Section 5.1.1			
Existing Patents	Section 9.2.2			
HS	Exhibit E			
Indemnify	Section 10.1			
Infringing Product	Section 7.4			
Inventor Personnel	Section 9.2.11			
Joint Commercialization Agreement	Section 5.2.2			
Joint Inventions	Section 7.1.2			
JSC	Section 3.6.1			
Losses	Section 10.1			

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NCFB Background NCFB Co-Development Election Section 3.2.6(b) NCFB Development Termination Notice Section 3.2.6(d) Non-Breaching Party Section 12.3 Northern Trial Section 3.2.3(a) Option Section 2.8.2 Option Compound Section 2.8.2 Section 6.2 Option Fee Section 2.8.2 Option Notice Option Period Section 2.8.2 Option Compound Licensed Product Section 6.4.1(d) Orange Book and Equivalents Section 7.8 **Outside Scope Claims** Section 7.2.3 P-1055 Development Notice Section 3.2.6(a) P-1055 Lead Compound Section 3.2.6(a) P-1055 Lead Compound Licensed Product Section 3.2.6(a) Preamble Parion COPD Opt-in Section 3.2.6(e) Parion Indemnitees Section 10.2 Parion Inventions Section 7.1.1 Preamble Party Patent Term Extensions Section 7.2.5 **PCD** Background **Product Trademarks** Section 7.9 Profit/Loss-Sharing Option Section 5.1.1 Prosecution and Maintenance Section 7.2.4 Section 4.5 Safety Data Exchange Agreement Second Compound Licensed Product Section 6.4.1(c) Section 2.7.1 Selection Period **Shared Development Cost** Section 3.2.6(g)**Shared Product** Section 5.2.1 Southern Trial Section 3.2.3(b) Subcommittee Section 3.6.9 Supplemental Royalty Rate Section 6.5.1(b) Section 12.1 Term Third-Party Claim Section 10.1 Third-Party Infringement Claim Section 7.3.1 Vertex Preamble Vertex Indemnitees Section 10.1 Vertex Inventions Section 7.1.3 Vertex UK Preamble

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ARTICLE 2 LICENSES; EXCLUSIVITY

- **2.1** <u>License Grants To Vertex</u>. Subject to the terms and conditions of this Agreement, Parion hereby grants to Vertex an exclusive license under the Parion Patents and the Parion Know-How and Parion's interest in Joint Know-How and Joint Patents to make, have made, use, sell, keep, offer for sale, and import Licensed Compounds and Licensed Products in the Field in the Territory.
- **2.2** <u>Sublicenses</u>. Each Party has the right to grant sublicenses or licenses, as applicable, of its rights under Section 2.1 and Section 2.6, as applicable, hereof to its Affiliates and to Third Parties, provided that any such Affiliate or Third Party agrees in writing to terms and conditions consistent with the terms of this Agreement applicable to sublicensees and that the Party granting such sublicense remains responsible for the compliance of such sublicensee with the applicable terms and conditions of this Agreement.
- **2.3 No Additional Rights.** No other license, either express or implied, is granted hereunder with respect to any Patent, Know-How, Joint Patent, Joint Know-How or other intellectual property rights of either Party except as expressly stated in this Agreement.
- **2.4 Updates.** At the request of Vertex, which may be made not more than once per Calendar Year, Parion shall update the listing of Parion Patents set forth in Exhibit A so as to include information with respect to additional patent application filings, issuances, grants, continuations, divisionals, substitutions, continuations-in-part, provisional and converted provisional applications, reissues, reexaminations, extensions, inventor's certificates, renewals, or any like governmental grant or application for protection of inventions of the Parion Patents, or any abandonment or lapse thereof. At the request of Vertex, which may be made not more than once per Calendar Quarter, Parion shall provide Vertex with written reports relative to any and all Parion Know-How generated or obtained by Parion during the Term.
- 2.5 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Vertex or Parion are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Vertex, and to the extent applicable, Parion, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding 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 the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.
- **2.6 Parion Retention of Rights.** Vertex acknowledges that Parion retains, subject to Section 2.9, the right, under Parion Patents, Parion Know-How and Parion's interest in Joint Patents and Joint Know-How:

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- **2.6.1** to make, have made, use, sell, keep, offer for sale, and import (a) [***] and (b) [***], in each case ((a) and (b)) [***];
- **2.6.2** to conduct research with [***], unless and until (a) [***] in which case such [***], or (b) [***], in which case [***];

and

2.6.3 solely to the extent necessary to discharge its obligations under this Agreement.

2.7 <u>Selection of Additional Compounds</u>.

- **2.7.1** During the Inventory Maintenance Period, Parion shall maintain an inventory list of all compounds in the Parion Compound Pool and shall make available to Vertex all Data and information reasonably requested by Vertex regarding each such compound in the Parion Compound Pool. Subject to Section 2.7.3, Vertex, may, in its discretion, select one or more additional compounds from the Parion Compound Pool to be Vertex Selected Compounds for development as a Licensed Compound under this Agreement by written notice to Parion (which written notice must be provided during the period from the Effective Date until the date that is [***] after the end of the Inventory Maintenance Period (the "Selection Period") (each, a "Vertex Selected Compound"); provided that Vertex shall select such Vertex Selected Compounds only to the extent Vertex has the good faith intention of conducting preclinical Development activities with a view toward Development of such Licensed Compound in the Field in the Territory.
- **2.7.2** During the Selection Period, subject to Section 2.7.3, Parion, may, in its discretion, select one or more additional compounds from the Parion Compound Pool to be Parion Selected Compounds for development outside the Field in the Territory by written notice to Vertex together with such Data as Parion possesses relating to such compound; provided that Parion shall select such Parion Selected Compounds only to the extent Parion has the good faith intention of conducting preclinical Development activities with a view toward Development of such Parion Selected Compound in a non-inhalable form outside the Field in the Territory. For the avoidance of doubt, after the end of the Selection Period, Parion shall have no restrictions on use of the Parion Compound Pool other than as necessary to comply with other provisions of this Agreement, including Section 2.9.
- 2.7.3 If Vertex provides notice to Parion, pursuant to Section 2.7.1, that it is selecting a compound from the Parion Compound Pool, or if Parion provides notice to Vertex, pursuant to Section 2.7.2, that it is selecting a compound from the Parion Compound Pool, the recipient of such notice shall have [***] to consider whether it wishes to select such compound. If during such [***] period, the recipient of such notice advises the provider of such notice that it also wishes to select such compound, the Parties shall negotiate in good faith for any additional [***] regarding which Party shall have the right to select such compound, taking into consideration the properties of such compound and the relative potential of such compound in the Field and outside the Field. If the Parties do not reach an agreement with respect to such compound, then neither Party shall have the right to select such compound from the Parion Compound Pool except as provided in the following sentence. If the Party that initially selected such compound from the Parion Compound Pool selects another compound from the Parion Compound Pool within [***] thereafter to replace such compound, it shall provide notice to the other Party that it is selecting such compound from the Parion Compound Pool, but such selection shall not be subject to the review period provided in this Section 2.7.3. In such case, such replacement compound shall be immediately included as a Vertex Selected Compound (if Vertex was the provider of such notice) or a Parion Selected Compound (if Parion was the provider of such notice), and the other Party (the recipient of such notice) may select the initially selected compound from the Parion Compound Pool within [***] after notice of the replacement compound by providing notice to the other Party that it is selecting such compound from the Parion Compound Pool. In

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such case, such initially selected compound shall be immediately included as a Vertex Selected Compound (if Vertex was the provider of such notice) or a Parion Selected Compound (if Parion was the provider of such notice).

- **2.7.4** If Vertex terminates, or does not commence, preclinical Development or Development activities with respect to a Vertex Selected Compound selected pursuant to Section 2.7.1 during the Term, Vertex shall provide written notice to Parion of same, and the applicable Vertex Selected Compound shall be returned to the Parion Compound Pool and such Vertex Selected Compound shall no longer be considered a Licensed Compound hereunder. If Parion terminates, or does not commence, preclinical Development or Development activities with respect to a Parion Selected Compound selected pursuant to Section 2.7.2 during the Inventory Maintenance Period, Parion shall provide written notice to Vertex of same, and the applicable Parion Selected Compound shall be returned to the Parion Compound Pool.
- **2.7.5** During the relevant period as provided in Section 2.7.4, in the event that (a) if Vertex does not commence a multi-day toxicology study in the Field, or (b) if Parion does not commence a multi-day toxicology study outside the Field, as applicable, within [***] after the selection of a compound from the Parion Compound Pool, such Party shall be deemed to have determined to return such compound to the Parion Compound Pool.

2.8 **Option for** [***].

- **2.8.1** Pursuant to the rights retained by Parion pursuant to Section 2.6.2, Parion may conduct, in its sole discretion, preclinical research activities in the Field with respect to [***] not comprising any Licensed Compound, subject to Vertex's option rights under this Section 2.8. Any such preclinical research activities must include [***] and a [***]. From the Effective Date through the expiration of the Option Period, Parion shall not grant any rights to any Third Party with respect to any [***].
- **2.8.2** Upon the completion of the study report for the validated therapeutic ratio consisting of [***] and a [***] with respect to a [***] (each, an "**Option Compound**"), Parion shall provide written notice of such event to Vertex, together with a copy of such study report(s) and any such other relevant data and information as may be reasonably necessary to allow Vertex to assess such Option Compound (each, an "**Option Notice**"). Upon receipt of an Option Notice, Vertex shall have [***] (each, an "**Option Period**") to exercise an option to include such Option Compound as a Licensed Compound pursuant to this Agreement (each, an "**Option**"). Vertex may exercise the Option with respect to such Option Compound during the Option Period by sending written notice to Parion of its election to exercise the Option, together with a payment of the Option Fee with respect to such Option Compound. Upon the exercise of the Option with respect to such Option Compound, the applicable Option Compound shall immediately be deemed to be a Licensed Compound under this Agreement, and any Patents and Know-How covering or claiming such Option Compound shall be included in the Parion Patents and Parion Know-How licensed to Vertex under this Agreement.
- **2.8.3** If Vertex does not exercise the Option with respect to any [***] during the relevant Option Period, then such [***] shall become a Parion ENaC Inhibitor and Parion shall have no further obligation to Vertex with respect to such [***] except as provided in Sections 2.6 and 2.9.

2.9 Exclusivity by Parion.

2.9.1 Except pursuant to this Agreement or any Joint Commercialization Agreement, and subject to Section 2.9.2, during the Term, Parion and its Affiliates (i) shall not [***], (ii) shall not [***], and (iv) shall not [***]; or grant any rights to any Third Party (other than Vertex) of any

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ENaC Inhibitor (including any [***]) to engage in any of the activities within the foregoing clauses (i), (ii), (iii) or (iv) with respect to any such ENaC Inhibitor (including any such [***]); provided, however, that Parion [***].

2.9.2 If there is a Change of Control involving Parion (where Parion is the acquired entity), the obligations of Section 2.9.1 shall not apply to any ENaC Inhibitor program of the acquirer or its Affiliates that exists prior to the effective time of such Change of Control; provided that (a) Parion and the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control (other than Parion and its Affiliates) establish and enforce internal processes, policies, procedures and systems to segregate information relating to any such program from any Confidential Information related to the Parion Compound Pool, Licensed Compounds and Licensed Products, (b) the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control (other than Parion and its Affiliates) do not use, directly or indirectly, any Confidential Information of Vertex in such program, and (c) no personnel who were employees or consultants of Parion or its Affiliates at any time prior to or after the Change of Control shall conduct any activities under such program.

2.10 Exclusivity by Vertex.

- **2.10.1** Except pursuant to this Agreement or any Joint Commercialization Agreement, and subject to Section 2.10.3, during [***], in the Territory or grant any rights to any Third Party of any ENaC Inhibitor (including any [***]) to engage in any of the foregoing activities with respect to any such ENaC Inhibitor (including any such [***]).
- **2.10.2** Except pursuant to this Agreement or any Joint Commercialization Agreement, and subject to Section 2.10.3, during [***], or grant any rights to any Third Party of any ENaC Inhibitor (including any such [***]) to engage in any of the foregoing activities with respect to any such ENaC Inhibitor (including any [***]).
- **2.10.3** If there is a Change of Control involving Vertex (where Vertex is the acquired entity) and this Agreement does not terminate pursuant to Section 12.4 based on such Change of Control, the obligations of Sections 2.10.1 and 2.10.2 shall not apply to any ENaC Inhibitor program of the acquirer or its Affiliates that exists prior to the effective time of such Change of Control; provided that (a) Vertex and the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control (other than Vertex and its Affiliates) establish and enforce internal processes, policies, procedures and systems to segregate information relating to any such program from any Confidential Information related to the Parion Compound Pool, Licensed Compounds and Licensed Products, (b) the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control (other than Vertex and its Affiliates) do not use, directly or indirectly, any Parion Technology or Confidential Information of Parion in such program, and (c) no personnel who were employees or consultants of Vertex or its Affiliates at any time prior to or after the Change of Control shall conduct any activities under such program.

ARTICLE 3 DEVELOPMENT PROGRAM

3.1 Development.

3.1.1 The Parties shall each use Commercially Reasonable Efforts, subject to the oversight of the JSC, to conduct Development activities as set forth in the Development Plan, as it may be amended from time to time in accordance with Section 3.2.1 and 3.2.4. Subject to Section 3.2.6, Vertex shall be solely

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responsible for all costs of the Development of Licensed Products and Licensed Compounds incurred after the Effective Date in accordance with the Development Plan and shall reimburse Parion for Parion's Collaboration Expenses incurred after the Effective Date in accordance with the Development Plan.

3.1.2 Subject to Sections 3.2.3 and 3.2.4, Vertex shall use Commercially Reasonable Efforts to Develop and obtain Marketing Approvals for a Lead Compound as a treatment for CF [***].

3.2 <u>Development Plan</u>.

- **3.2.1 Establishment.** The initial plan for the Development of Licensed Products in the Field in the Territory is attached as <u>Exhibit B</u> to this Agreement (the "**Development Plan**"). The Development Plan shall be updated from time to time, upon review and approval by the JSC as set forth in Section 3.2.4.
- **3.2.2 Development Activities.** All Development by the Parties will be overseen by the JSC. The JSC will allocate clinical and non-clinical Development activities to each Party in an effort to share the Development burden and ensure each Party is contributing to the Development Plan, subject to Sections 3.2.3 and 3.2.5.

3.2.3 Clinical Trials.

- (a) Parion will be responsible for conducting (i) the first Phase IIa Clinical Trial in CF (the "Northern Trial") to evaluate P-1037 pursuant to the protocol which is identified in the cover page of such protocol attached hereto as Exhibit C (which, if feasible and mutually agreed by the Parties, shall be amended to [***], (ii) the Phase IIa Clinical Trials to evaluate P-1037 as a treatment for (x) PCD and NCFB[***] and (y) COPD, [***], in each case in accordance with protocols to be approved by the JSC and (iii) the Phase I Clinical Trial in healthy volunteers of P-1055 (and preclinical activities to support such Phase I Clinical Trial).
- **(b)** Vertex will be responsible for conducting the second Phase IIa Clinical Trial in CF (the "**Southern Trial**") to evaluate P-1037 in accordance with the description attached hereto as <u>Exhibit D</u>; provided that the Southern Trial may be modified by the JSC. Vertex shall, if feasible, conduct an interim analysis of the data from the Southern Trial in order to support the accelerated design and potential initiation of Phase IIb Clinical Trials of P-1037.
- **(c)** Vertex will be responsible for conducting all other Clinical Trials of Licensed Compounds and Licensed Products for all Indications, [***] pursuant to the Development Plan for Licensed Products.

3.2.4 Modification of the Development Plan.

- (a) <u>Exhibit E</u> sets forth the currently anticipated design of the [***]. Based on data from the Northern Trial and Southern Trial, the JSC will consider carefully the clinical and non-clinical data generated as of the relevant date of determination, as well as the evolving treatment landscape, in order to design any additional Phase I Clinical Trial(s), Phase II Clinical Trial(s) and/or pivotal Phase III Clinical Trials to evaluate P-1037 and will supplement the Development Plan accordingly, provided that:
 - (i) Development in specific patient populations, including [***], may be conducted on a background of medicines that are then approved and commonly used by physicians (or which are reasonably

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expected to be approved)			

- (ii) [***] P-1037 in patients with CF [***] as set forth on Exhibit E;
- (iii) Vertex shall use Commercially Reasonable Efforts to submit to Regulatory Authorities [***];
- (iv) Vertex shall use Commercially Reasonable Efforts to submit [***]; and
- (v) [***] in the Development Plan [***]in each population of CF patients [***].

In addition, the Development Plan shall be supplemented, updated or otherwise modified regularly by the JSC as and when additional relevant data and information become available during the Development of Licensed Products (but in any event no less frequently than once per Calendar Year by November 15 of such Calendar Year, with the first such update to be provided on or before November 15, 2015).

- **(b)** If the JSC determines the Development or commercialization of P-1037 is not commercially viable or feasible, P-1055 shall (to the extent supported by then existing data regarding P-1055), or another Licensed Compound shall, become the Lead Compound for patients with CF pursuant to the Development Plan, as determined by the JSC, and the JSC shall modify the Development Plan accordingly.
- **(c)** Following the later of Completion of (i) the initial Phase IIa Clinical Trials evaluating P-1037 as a potential treatment for PCD, NCFB and COPD, and (ii) the multi-day ([***]) dose-ranging Phase I Clinical Trial of P-1055, (A) the JSC may decide to progress Development of P-1037 in any, all or none of those Indications, (B) the JSC may decide to progress Development of P-1055 in any, all or none of those Indications, and (C) the JSC may decide whether or not to progress the Development of any other Licensed Compound as a Lead Compound or a Back-Up Compound for any, all or none of these Indications.
- **(d)** If Vertex (i) selects a compound from the Parion Compound Pool as a Vertex Selected Compound pursuant to Section 2.7.1, or (ii) exercises the Option for an Option Compound pursuant to Section 2.8, then the JSC shall modify the Development Plan to include such Development activities to be undertaken with respect to such Licensed Compound(s).
- **(e)** If Parion exercises any Co-Development Election pursuant to Section 3.2.6, then the JSC shall modify the Development Plan to include such Development activities to be undertaken with respect to such Licensed Compound(s) that is the subject of such Co-Development Election.
- **(f)** The Development Plan with respect to each Licensed Compound shall be modified from time to time by the JSC as deemed appropriate for the Development of such Licensed Compound for the relevant Indication(s).
- **3.2.5 Parion Development Activities.** Parion shall have no obligation to conduct Clinical Trials of Licensed Compounds other than the Clinical Trials described in Section 3.2.3, without Parion's consent, which may be withheld at Parion's sole discretion, and Parion shall have no right to conduct Clinical

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Trials of Licensed Compounds other than the Clinical Trials described in Section 3.2.3, without Vertex's prior consent, which may be withheld at Vertex's sole discretion. Parion shall maintain accurate and reasonably complete records of all results of any Clinical Trials of Licensed Compounds and other activities under this Agreement conducted by or on behalf of Parion and shall promptly disclose to Vertex all progress, interim data, final results and safety findings from (i) each Clinical Trial of Licensed Compounds conducted by or on behalf of Parion, and (ii) all other activities conducted by or on behalf of Parion under this Agreement, in each case in order to facilitate the advancement of the Development Plan.

3.2.6 Co-Development Option.

- (a) Promptly following the Completion of each of the Phase IIa Clinical Trials of P-1037 in NCFB and COPD, and the multi-day ([***]) dose-ranging Phase I Clinical Trial of P-1055 (or such other Licensed Compound selected by Vertex for such Phase I Clinical Trial), Parion shall deliver to Vertex a Key Results Memorandum from each such Clinical Trial. Within [***] after the delivery of the last of the foregoing Key Results Memoranda, Vertex shall notify Parion in writing (the "P-1055 Development Notice") that (A) Vertex intends to continue Development of P-1055 or any other Licensed Compound (a "P-1055 Lead Compound") as a proposed treatment for NCFB (whether or not Vertex intends to continue Development of a P-1055 Lead Compound as a treatment for COPD but not NCFB, or (C) based on the data, Vertex does not intend to continue Development of P-1055 or any other Licensed Compound as a potential treatment for NCFB or COPD. If Vertex intends to continue Development of any P-1055 Lead Compound for NCFB and/or COPD, Vertex shall (concurrently with the delivery of the P-1055 Development Notice) provide Parion (1) [***] (the "P-1055 Lead Compound Licensed Product") as a proposed treatment for NCFB and/or COPD, as applicable, and (2) [***] as a proposed treatment for NCFB or COPD, as applicable, [***]. The Parties shall meet within [***] after receipt of such information to discuss [***].
- **(b)** If Vertex notifies Parion that it intends to continue Development of the P-1055 Lead Compound for NCFB in the P-1055 Development Notice, Parion shall have the option, exercisable by written notice from Parion to Vertex on or before the [***] following Parion's receipt of the P-1055 Development Notice, to exercise an option to jointly Develop the P-1055 Lead Compound (the "NCFB Co-Development Election") as a potential treatment for patients with NCFB. If Parion exercises its NCFB Co-Development Election pursuant to this Section 3.2.6(b), Parion shall contribute to the Shared Development Cost of Developing the P-1055 Lead Compound as a potential treatment for patients with NCFB as described in Section 3.2.6(g).
- (c) If Vertex notifies Parion that it intends to continue Development of the P-1055 Lead Compound for COPD but not NCFB in the P-1055 Development Notice, Parion shall have the option, exercisable by written notice from Parion to Vertex on or before the [***] following Parion's receipt of the P-1055 Development Notice, to exercise an option to jointly Develop the P-1055 Lead Compound (the "COPD Co-Development Election") as a potential treatment for patients with COPD. If Parion exercises its COPD Co-Development Election pursuant to this Section 3.2.6(c), Parion shall contribute to the Shared Development Cost of Developing the P-1055 Lead Compound as a potential treatment for patients with COPD as described in Section 3.2.6(g).
- **(d)** If Parion exercises its NCFB Co-Development Election and thereafter the JSC determines that the Development of the P-1055 Lead Compound as a proposed treatment for NCFB shall cease prior to the receipt of Marketing Approval in the U.S. for the P-1055 Lead Compound Licensed Product, Vertex shall advise Parion in writing of the status, if any, of its Development of the P-1055 Lead

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Compound (a "NCFB Development Termination Notice"). If Vertex is currently Developing, or plans to commence Development of, the P-1055 Lead Compound as a potential treatment for COPD, but Parion has either not exercised, or has not been offered the opportunity to exercise, the COPD Co-Development Election, then Vertex shall provide Parion (concurrently with the NCFB Development Termination Notice) (A) a current summary of the clinical Data regarding the P-1055 Lead Compound as a potential treatment for COPD, (B) [***] as a proposed treatment for COPD, and (C) [***] as a potential treatment for COPD [***], together with, if applicable, (D) a detailed report of out-of-pocket costs and FTE Costs of Development of the P-1055 Lead Compound as a proposed treatment for COPD incurred by Vertex since the Completion of the Phase IIa Clinical Trial of P-1055 as a treatment for COPD, calculated as of the most recent practicable date ("COPD Pre-Option Costs"). The Parties shall meet within [***] after receipt of such information to discuss the Development Plan and budget.

- **(e)** Parion shall have the option, exercisable by written notice from Parion to Vertex on or before the [***] following Parion's receipt of the NCFB Development Termination Notice, to opt-in to the joint Development of the P-1055 Lead Compound as a potential treatment for patients with COPD (the "**Parion COPD Opt-in**"); provided that Parion previously exercised the NCFB Co-Development Election and Parion pays an opt-in fee to Vertex equal to the Co-Development Percentage of the COPD Pre-Option Costs within [***] of Parion's exercise of the Parion COPD Opt-in; provided further, Parion shall pay its share of the Shared Development Cost of Developing the P-1055 Lead Compound as a proposed treatment for patients with COPD as described in Section 3.2.6(g) incurred on or after the last day included in the calculation of the COPD Pre-Option Costs.
- **(f)** Each of the NCFB Co-Development Election, the COPD Co-Development Election and the Parion COPD Opt-in shall be referred to herein as a "Co-Development Election." Failure by Parion to provide Vertex a notice with respect to a Co-Development Election within the applicable times above shall result in the expiration of the applicable option with respect to the potential joint Development of the P-1055 Lead Compound.
- **(g)** If Parion makes a Co-Development Election, Parion shall [***] (the "Co-Development Percentage"), of Development of the P-1055 Lead Compound for NCFB or COPD, as applicable, incurred after the Completion of the applicable Phase IIa Clinical Trial pursuant to the Development Plan, as such Development Plan may be amended, for the P-1055 Lead Compound Licensed Product for such Indication (the "Shared Development Cost"), including [***]. Notwithstanding the foregoing, in the case of a Parion COPD Opt-in, the Co-Development Percentage shall remain unchanged from the Co-Development Percentage specified in Parion's prior NCFB Co-Development Election. Vertex shall perform a reconciliation of Shared Development Costs incurred by each Party beginning after Parion's Co-Development Election as set forth in Section 6.13.
- **(h)** If Parion fails to pay its share of the Shared Development Cost for Development of the P-1055 Lead Compound for NCFB or COPD, as applicable, in accordance with Section 3.2.6(g) and Section 6.13, in each case within [***] receipt of notice of failure to pay such share within the time period provided in Section 6.13(d) after Vertex's delivery of the applicable Development Reconciliation Report, then:
 - (i) Parion shall have no right to elect to jointly commercialize the P-1055 Lead Compound for such Indication pursuant to Section 5.1;

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- (ii) Vertex [***], either (A) [***], or (B) [***] the P-1055 Lead Compound [***];
- (iii) [***] Vertex as set forth in [***]
- (iv) [***].
- (v) Within [***] after the end of each Calendar Quarter thereafter, Vertex shall provide to Parion an itemized report of Vertex's Shared Development Costs for such Calendar Quarter, including reasonable supporting documentation, which report shall be subject to Parion's audit right set forth in Section 6.13.

3.3 <u>Technology Transfer</u>.

- **3.3.1 Initial Transfer.** Parion shall transfer to Vertex a copy of all Parion 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 (including e-mails, documents, spreadsheets, copies of standard operating procedures or technical specifications). Unless otherwise agreed by Parion and Vertex in writing, Parion shall provide such Parion Know-How to Vertex within [***] after the Effective Date. Notwithstanding the foregoing, Parion shall use Commercially Reasonable Efforts to proceed with transfers to Vertex of certain of such information and materials as reasonably agreed by the Parties within [***] after the Effective Date.
- **3.3.2** Additional Transfers. Following the initial transfer described in Section 3.3.1, annually during the Term Parion shall provide updates to Vertex regarding any newly acquired or generated Parion Know-How, including information concerning any Licensed Products or Licensed Compounds, and improved procedures for synthesis or manufacture of Licensed Compounds and/or Licensed Products. The Parties shall also respond promptly to any requests from the other Party regarding the availability of specified information that is required by the other Party in connection with the Development or commercialization of Licensed Products in the Field.
 - **3.4** Third Party Vendors or Contractors. Exhibit F attached hereto identifies the Third Party vendors and contractors that Parion has involved, or Parion anticipates will be involved, in the Development or manufacture of the Licensed Products and Licensed Compounds. At Vertex's request to the extent practicable, Parion shall use Commercially Reasonable Efforts to transfer relationships to Vertex by (i) assignment of any relevant agreements with such vendor or contractor, if permitted by such agreement or (ii) assisting Vertex to establish a business relationship with such vendors and/or contractors.
 - **3.5** Adverse Event Reports. Subject to Section 4.5, to the extent required under Applicable Law relevant to a Party's own activities in a country, such Party shall, and shall cause its respective Affiliates and sublicensees to, furnish timely notice to any competent Regulatory Authority of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Licensed Products.

3.6 Governance/Coordination.

3.6.1 Establishment of JSC; Membership. Within 10 Business Days following the Effective Date, or as soon as practicable thereafter, Vertex and Parion shall establish the Joint Steering Committee (the "JSC"). The JSC shall have and perform the responsibilities set forth in Section 3.6.2. Each

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of Vertex and Parion shall designate in writing an equal number (not less than three) of representatives to the JSC. The chair of the JSC shall be a representative of Vertex. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JSC by giving written notice to the other Party's Alliance Manager. Each Party may also, in its reasonable discretion and with reasonable advanced notice to the other Party's Alliance Manager, invite non-member representatives of such Party to attend JSC meetings, as appropriate, to provide input with respect to matters on the agenda, provided that such non-member representatives are subject to appropriate confidentiality obligations substantially equivalent to those of Section 8.1.

- **3.6.2 Responsibilities.** The JSC shall be responsible for overseeing the Parties' activities under this Agreement and shall be responsible for:
- **(a)** ensuring the exchange of, and reviewing, data, reports or other information submitted to the JSC by each of the Parties and subcommittees, if any, of the JSC;
 - **(b)** reviewing and approving changes to the Development Plan and associated budgets;
 - **(c)** reviewing protocols for Clinical Trials;
 - (d) allocating Development and commercialization responsibilities among the Parties;
- **(e)** reviewing and approving the progress of any Licensed Compounds selected as a Lead Compound or a Back-Up Compound to any Lead Compound for any Indication in preclinical and research;
 - **(f)** providing strategic oversight with respect to the conduct of the research and Development programs;
 - **(g)** reviewing all data and updates with respect to the conduct of the research and Development programs;
 - **(h)** attempting to resolve all matters between the Parties that are in dispute;
 - (i) making such other decisions as may be delegated to the JSC pursuant to this Agreement; and
 - (j) establishing subcommittees as it deems appropriate to manage specific activities.
- **3.6.3 Schedule of Meetings; Agenda.** During the Term, the JSC shall meet at least once per Calendar Quarter for a regular meeting. Special meetings of the JSC may be convened by either Party upon not less than [***] written notice to the other Party; provided, that, (i) notice of any special meeting may be waived at any time and (ii) attendance of a representative of a Party at a special meeting shall constitute a valid waiver of notice of such Party. Regular and special meetings of the JSC may be held in person, by teleconference or videoconference or as agreed by both Parties in person; provided (i) that any member shall be entitled to participate by teleconference and (ii) at least one regular meeting per Calendar Year shall be held in person, alternating between the primary location of Parion and Vertex, unless otherwise agreed by

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the Parties. Once scheduled, meetings may only be cancelled with notice at least [***] in advance of such scheduled meeting date, and must be rescheduled within [***] thereafter. The Vertex Alliance Manager shall consult with the Parion Alliance Manager to include topics Parion wishes to discuss and shall prepare and circulate to each JSC member an agenda for each JSC meeting not later than one week before a quarterly meeting and a reasonable time prior to any special meeting. Representatives of each Party or of its Affiliates who are not members of the JSC (including the Alliance Managers, the Patent Coordinators or external advisers), may attend JSC meetings as non-voting observers.

- **3.6.4 Quorum; Voting; Decisions.** At each JSC meeting, (i) the presence in person of at least one member designated by each Party shall constitute a quorum and (ii) the representatives of a Party shall have one collective vote on all matters before the JSC at such meeting. Subject to Section 3.6.6, all decisions of the JSC shall be agreed by both Parties. The JSC may also act by written consent signed by at least one member of the JSC designated by each Party. Whenever any action by the JSC is called for hereunder during a time period in which the JSC is not scheduled to meet, the chair of the JSC shall cause the JSC to take the action in the requested time period by calling a special meeting or by circulating a written consent.
- **3.6.5 Minutes.** Vertex's Alliance Manager shall have the initial responsibility for keeping minutes of JSC meetings that record all decisions and all actions recommended or taken in reasonable detail, provided that, if requested by Parion's Alliance Manager, such responsibility shall alternate between Vertex's Alliance Manager and Parion's Alliance Manager on an annual basis. Drafts of the minutes shall be prepared and circulated to the members of the JSC by the responsible Alliance Manager within [***] after the meeting. Each member of the JSC shall have [***] following distribution of the draft minutes to provide comments on the draft minutes. Draft minutes shall be approved, or disapproved and revised, as soon as practicable (and in any event at the next regularly scheduled JSC meeting). Upon approval, final minutes of each meeting shall be circulated to the members of the JSC by the responsible Alliance Manager.
- **3.6.6 Decision Making.** The JSC members shall use reasonable efforts to reach agreement on any and all JSC matters. If the JSC is unable to reach consensus with respect to a particular matter within [***], the matter shall be referred to the Executive Officers, who shall use reasonable efforts to reach agreement on such matters. If such Executive Officers are unable to reach consensus with respect to a particular matter with [***] of it being referred to such Executive Officer, [***] will have the right to make the final decision with respect to such matters, including Clinical Trial designs [***], the right to select clinical research organizations, manufacturers and other Third Party vendors, the selection of Lead Compounds and Back-Up Compounds for any Indications, and the decision to cease or progress Development of a Licensed Compound or Licensed Product; provided that such Executive Officer (a) shall take into reasonable consideration the recommendations and concerns raised by [***], (b) shall make such decisions in good faith using reasonable business judgment, which shall not be unreasonably delayed, and (c) shall not have the right to unilaterally: (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 [***] reasonably believes would constitute a violation of Applicable Laws; or (v) make a determination that a Party is in material breach of any obligation under this Agreement.

3.6.7 Expenses. Vertex and Parion shall each bear all expenses of their respective JSC representatives, Alliance Managers and non-voting observers related to their participation on the JSC and attendance at JSC meetings.

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- **3.6.8 Alliance Managers.** Promptly after the Effective Date, if the Parties mutually agree, each Party shall appoint an individual to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be permitted to attend meetings of the JSC. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party.
- **3.6.9 Subcommittees.** From time to time, the JSC may establish subcommittees to oversee particular projects or activities within the scope of authority of the JSC, as it deems necessary or advisable (each, a "**Subcommittee**"). Each Subcommittee shall meet with such frequency as the JSC shall determine; provided that each Subcommittee shall meet at least [***]. All decisions of each Subcommittee shall be made by unanimous vote or written consent, with Vertex and Parion each having one vote in all decisions. If, with respect to a matter that is subject to a Subcommittee's decision-making authority, the Subcommittee cannot reach unanimity, the matter shall be referred to the JSC, which shall resolve such matter in accordance with Section 3.6.6.
- **3.6.10 Alliance Governance Board.** Vertex and Parion shall establish an Alliance Governance Board with three members designated by Vertex and three members designated by Parion that will meet by teleconference on a [***] basis to discuss the progress of the activities being conducted pursuant to this Agreement. Meetings may be held in person, by teleconference or videoconference or as agreed by both Parties in person; provided (i) that any member shall be entitled to participate by teleconference and (ii) at least one regular meeting per Calendar Year shall be held in person, alternating between the primary location of Parion and Vertex, unless otherwise agreed by the Parties. Vertex's [***] representatives shall initially be its [***]. Parion's representatives shall initially be [***], one of which members Parion will designate to chair the Alliance Governance Board. The Alliance Governance Board shall have no authority to make decisions with respect to the activities contemplated by this Agreement.

ARTICLE 4 COMMERCIALIZATION, MANUFACTURING, SUPPLY & REGULATORY MATTERS

4.1 Commercialization by Vertex. Subject to Section 5.1 and the terms of the Joint Commercialization Agreement, Vertex shall use Commercially Reasonable Efforts to commercialize each Licensed Product in each Major Market for which it obtains Marketing Approval (and, where applicable, Pricing Approval) in the Field in the Territory, and shall use Commercially Reasonable Efforts to launch each Licensed Product [***]. Where permissible pursuant to Applicable Law, Vertex shall include Parion's logo on Licensed Products in proximity to Vertex's logo on such Licensed Product. For purposes of clarity, Parion shall retain ownership of all right, title and interest in and to any Parion company-specific names or company-specific logos, including all associated goodwill.

4.2 Clinical Supply.

- **4.2.1** Parion shall manufacture, or have manufactured, clinical quantities of P-1037 for use in the Northern Trial, the Southern Trial and Phase IIa Clinical Trials to evaluate P-1037 in PCD, NCFB and COPD.
- **4.2.2** Vertex shall use Commercially Reasonable Efforts to manufacture, or have manufactured, clinical quantities of Licensed Compounds and Licensed Products for use in Clinical Trials to be conducted other than those set forth in Section 4.2.1, including (a) to support the Phase I Clinical Trial

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of P-1055 in healthy volunteers as provided in Section 3.2.3(a)(iii). After such supply for clinical quantities is established and validated, Vertex shall use Commercially Reasonable Efforts to manufacture, or have manufactured clinical quantities of Licensed Products for use in the Development Plan.

- **4.2.3** Until Vertex assumes responsibility for manufacturing P-1037 pursuant to Section 4.2.2, Parion shall, to the extent requested by Vertex, use Commercially Reasonable Efforts to supply clinical quantities of the Licensed Products comprising P-1037 for use by Vertex in the Development of such Licensed Products in accordance with the Development Plan; provided that Vertex shall reimburse Parion for Collaboration Expenses incurred after the Effective Date related to such supply. Vertex shall have the right (i) at reasonable times, upon reasonable notice and subject to Parion's policies and procedures in effect at such time for visitors to its facilities, to have a reasonable number of its representatives observe Parion's manufacturing activities, including access to all technical documentation associated with manufacturing activities, along with Third Party documentation, and (ii) to review and reasonably comment on any manufacturing agreements with Third Parties related to Licensed Compounds and Licensed Products prior to Parion entering into such agreements. At Vertex's option, Parion and Vertex shall enter into a supply agreement setting forth any additional terms and conditions of such supply and a reasonable and/or a customary quality agreement that shall set forth the terms and conditions upon which Parion and any of its Affiliates will conduct their quality activities in connection with such supply, including (x) a right of Vertex to audit Parion and Parion's Third Party contract manufacturing organization, (y) coordination regarding inspections by Regulatory Authorities and (z) the exchange of information between the Parties regarding the foregoing and quality issues in general. Such agreements shall be negotiated and agreed by the Parties in good faith.
 - **4.3 Manufacture of Licensed Products; Commercial Supply.** Vertex shall be responsible for securing commercial supply of Licensed Compounds and Licensed Products within the Field.

4.4 Regulatory Matters.

- **4.4.1** Each Party shall adhere to Applicable Laws governing the use of investigational drugs, including procedures and requirements for the submission to and review by Regulatory Authorities of said investigational applications.
- **4.4.2** As between the Parties, following the Effective Date, Vertex shall be responsible for, at its expense, filing, obtaining and maintaining approvals for Development and commercialization of Licensed Compounds and Licensed Products in the Field in the Territory, including any Regulatory Filing, Marketing Approval or Pricing Approval therefor, consistent with Applicable Law. Except as may be required by Applicable Law with respect to Clinical Trials being conducted by Parion, Vertex shall be the sole point of contact with all Regulatory Authorities for all Licensed Compounds and Licensed Products. Vertex shall provide Parion with copies of all material correspondence from Vertex to Regulatory Authorities and from Regulatory Authorities to Vertex. To the extent practicable and permitted by Applicable Law, Vertex shall allow one representative of Parion to attend material meetings and listen to material teleconferences with Regulatory Authorities regarding the Development of Licensed Compounds and Licensed Products. Notwithstanding the foregoing, upon Vertex's reasonable request and at Vertex's expense, Parion will support the Development of Licensed Compounds and Licensed Products by providing governmental regulatory authorities (e.g., the FDA) with access to and the right to audit any Data and associated documents that are in the control of Parion as of the Effective Date and are relied on by Vertex in its Regulatory Filings for Licensed Compounds and Licensed Products. For sake of clarity, Parion shall not make any submission to any Regulatory Authority without first obtaining Vertex's prior written consent.

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- **4.4.3** Parion hereby assigns to Vertex all Regulatory Filings filed by Parion that relate to Licensed Compounds and Licensed Products and all associated supporting documents and Data. As soon as practicable after the Effective Date, Parion and Vertex shall file with the FDA and applicable Regulatory Authorities in non-U.S. jurisdictions, customary (i) notices of transfer of IND ownership, (ii) notices of acceptances of transfer of IND ownership and (iii) any similar documentation to properly affect the transfer of such Regulatory Filings from Parion to Vertex.
 - **4.5 Pharmacovigilance; Adverse Event Reports.** Within [***] of the Effective Date, the Parties will create more specific guidelines for the respective obligations of the Parties relative to the foregoing provisions (a "**Safety Data Exchange Agreement**"). The Safety Data Exchange Agreement will set forth guidelines and procedures for the receipt, investigation, recording, review, communication, reporting and exchange between the Parties of adverse event reports (which, for purposes of information exchange between the Parties, shall include adverse events and serious adverse events, and any other information concerning the safety of any Licensed Product or Licensed Compound). Without limiting the foregoing, the Parties shall meet to establish a safety oversight working group comprised of members of both Parties, which, except as otherwise provided in the Safety Data Exchange Agreement, shall discuss processes and procedures for sharing information needed to support Vertex's regulatory responsibilities and to comply with applicable regulatory pharmacovigilance requirements. Any such procedures shall not be construed to restrict either Party's ability to take any action that it deems to be appropriate or required of it under the applicable regulatory requirements, if permitted by Applicable Laws. It is contemplated that Vertex (i) shall maintain a unified worldwide adverse event database for Licensed Products, and be responsible for reporting adverse events and serious adverse events to the applicable Regulatory Authorities and (ii) shall be responsible for all signal detection and risk management activities and will develop and approve the contents of all safety communications to Regulatory Authorities, including but not limited to expedited non-clinical and clinical safety reports and aggregate reports to health authorities, institutional review boards and ethics committees.

[***] if Vertex commercializes the P-1055 Lead Compound Licensed Product for COPD in the Territory, subject to JSC oversight and [***] to support such P-1055 Lead Compound Licensed Product for COPD.

ARTICLE 5 PARION PROFIT/LOSS-SHARING OPTION; JOINT COMMERCIALIZATION AGREEMENT

5.1 Parion Profit/Loss-Sharing Option.

5.1.1 Profit/Loss-Sharing Option. [***] following Completion of Phase III Clinical Trial(s) of a P-1055 Lead Compound Licensed Product that provide (in Vertex's reasonable opinion) the basis to file an NDA in an Indication with respect to which Parion has made a Parion Co-Development Election, Vertex shall deliver to Parion (a) a Key Results Memorandum with data from such Phase III Clinical Trials for such P-1055 Lead Compound Licensed Product, (b) [***], (c) [***]. If Parion has fully satisfied its obligations with respect to funding of Shared Development Costs pursuant to such Parion Co-Development Election, Parion shall have the option, exercisable by written notice (the "**Exercise Notice**") from Parion to Vertex on or before the [***] following Parion's receipt of the foregoing materials to opt-in (the "**Profit/Loss-Sharing Option**") to jointly (with Vertex and/or Affiliate(s) designated by Vertex) commercialize such P-1055 Lead Compound Licensed Product for such Indication in the Territory. The Parties shall meet within [***] after receipt of such information to discuss [***].

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- **5.1.2 Expiration of Profit/Loss-Sharing Option.** Failure by Parion to provide its Exercise Notice within the applicable time as set forth in Section 5.1.1 shall result in the expiration of the applicable Profit/Loss-Sharing Option with respect to such P-1055 Lead Compound Licensed Product, in which event Parion shall have no right to jointly commercialize such P-1055 Lead Compound Licensed Product.
 - **5.2** Effects of Exercising Profit/Loss-Sharing Option. If Parion exercises the Profit/Loss-Sharing Option with respect to the P-1055 Lead Compound Licensed Product for the applicable Indication as permitted hereunder, then, commencing upon such date of exercise by Parion and during the remainder of the applicable Profit-Share Term:
- **5.2.1** The P-1055 Lead Compound Licensed Product for commercialization in NCFB and/or COPD, as applicable, shall be deemed a "**Shared Product**."
- **5.2.2** Within [***] after the exercise of the Profit/Loss-Sharing Option by Parion, Parion and Vertex (and/or any Affiliates designated by Vertex) shall enter into an Agreement (such agreement, the "**Joint Commercialization Agreement**"), which agreement the Parties shall negotiate in good faith and which shall include appropriate plans and budgets, for such joint commercialization activities (including manufacturing plans and supply forecasts) with respect to such Shared Product (or provisions for establishing such plans) and shall be based on (a) terms and conditions that are substantially the same as those set forth in Section 5.2, Article 8 and <u>Exhibit G</u> and (b) such other reasonable and customary provisions for transactions of this type as the Parties may agree.
- **5.2.3** Each Party shall use Commercially Reasonable Efforts to commercialize such Shared Product(s) for the Territory during the Profit-Share Term in accordance with the applicable Joint Commercialization Agreement.

5.2.4 [***]; and

5.2.5 [***].

ARTICLE 6 FINANCIAL TERMS

- **6.1 <u>Upfront Payment.</u>** In partial consideration of the rights granted by Parion to Vertex hereunder and subject to the terms and conditions of this Agreement, no later than the fifth Business Day after the Effective Date, Vertex shall pay Parion a non-creditable, non-refundable upfront payment of eighty million Dollars (\$80,000,000).
- **6.2 Option Fees**. In partial consideration of the rights granted by Parion to Vertex under this Agreement with respect to any Option Compound pursuant to Section 2.8, upon the date of exercise by Vertex of any Option with respect to an Option Compound pursuant to Section 2.8, Vertex shall pay Parion a non-creditable, non-refundable payment of [***] (each, an "**Option Fee**").
- **6.3 Development Costs.** Vertex shall pay Development costs as set forth in Section 3.1.1, provided that if Parion elects to jointly Develop a Licensed Product through any Co-Development Election in accordance with Section 3.2.6, the Parties will share Development costs for the applicable Licensed Product for the applicable Indication as set forth in Section 3.2.6(g).

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6.4 Milestones.

6.4.4 Vertex shall pay to Parion the following non-creditable, non-refundable amounts for achievement by the Licensed Compound or the Licensed Product of the following event milestones:

(a) Development Milestones for the first Licensed Product (excluding Licensed Products comprising [***]) Developed by Vertex for CF:

Develop	oment and Regulatory Milestone Event	Dollars (in Millions)
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***]	[***]
(v)	[***]	[***]
(vi)	[***]	[***]
(vii)	[***]	[***]
(viii)	[***]	[***]
	TOTAL	\$490.0

(b) Development Milestones for the first Licensed Product (excluding Licensed Products comprising [***]) Developed by Vertex for CF, in Indications other than CF are as follows:

Development and Regulatory Milestone Event		Dollars (in Millions)
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***] <u>1</u>	[***]
(v)	[***] <u>1</u>	[***]
	TOTAL	[***]

⁽¹⁾ For the avoidance of doubt, Vertex shall have no obligation to pursue the achievement of any of the relevant milestones set forth in clauses (b)(iii), (b)(iv) or (b)(v) above.

(c) Development Milestones for a Licensed Product (excluding Licensed Products comprising [***]) containing a different Licensed Compound than the Licensed Compound contained in the first Licensed Product Developed by Vertex for CF, including a P-1055 Lead Compound Licensed Product, in pulmonary Indications other than CF (a "Second Compound Licensed Product") are as follows, subject to Section 3.2.6(h)(iii) ([***]):

Develop	Dollars (in Millions)	
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***] <u>2</u>	[***]
(iv)	[***] <u>2</u>	[***]
(v)	[***] <u>2</u>	[***]
(vi)	[***] <u>2</u>	[***]
(vii)	[***]2	[***]
	TOTAL	[***]

⁽²⁾ For the avoidance of doubt, Vertex shall have no obligation to pursue achievement of any of the Development Milestones set forth in this Section 6.4.1(c)(ii) - 6.4.1(c)(vii) for a Second Compound Licensed Product.

(d) Development Milestones for a Licensed Product comprising a Licensed Compound that is an Option Compound in any Indication in the Field (an "**Option Compound Licensed Product**"), are as follows: ³

Development and Regulatory Milestone Event		Dollars (in Millions)
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]
(iv)	[***]	[***]
(v)	[***]	[***]
(vi)	[***]	[***]
(vii)	[***]	[***]
	TOTAL	\$230.0

- (3) For the avoidance of doubt, Vertex shall have no obligation to pursue achievement of any of the Development Milestones set forth in this Section 6.4.1(d)(i) 6.4.1(d)(vii) for an Option Compound Licensed Product.
- **6.4.2** Each milestone payment set forth in Section 6.4.1 shall be payable by Vertex upon the first achievement of the related milestone event by Vertex or any of its Affiliates or sublicensees, and Vertex shall provide notice to Parion promptly upon achievement of such milestone event and no later than [***] from such achievement. Upon receipt of Vertex's notice that a milestone event has been achieved or the achievement by Parion or its Affiliates of a milestone event, Parion shall prepare and provide Vertex with the corresponding invoice and Vertex shall pay Parion each such milestone payment within [***] after receipt of such invoice.
- **6.4.3** The obligation to pay each milestone set forth in Section 6.4.1 is imposed only once regardless of how many Licensed Compounds and Licensed Products are developed by Vertex or how many times each such milestone is achieved. For the avoidance of doubt, even if a Licensed Compound or Licensed Product is Developed for more than one Indication or more than one Licensed Compounds or Licensed Products are Developed, each Development Milestone is payable only once.

6.5 Royalties.

6.5.3 Royalty Rates for Territory.

(a) Standard Royalty. Subject to Section 6.5.1(b) and Section 6.6, as to each Licensed Product sold in the Territory, subject to adjustment under Sections 6.5.3, 6.5.4 and 6.5.5, Vertex shall pay Parion royalties on aggregate annual (Calendar Year) Net Sales of such Licensed Product in the Territory, at the incremental royalty rates set forth below, on a Licensed Product-by-Licensed Product basis:

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Calendar Year Net Sales (in Dollars) for such Licensed Product ⁴ in the Territory	Royalty Rates as a Percentage (%) of Net Sales
[***]	[***]
[***]	[***]
[***]	[***]

(4) For the avoidance of doubt, a Licensed Product is comprised of all formulations, dosage strengths and package sizes of such pharmaceutical product, for all Indications, comprised of the same Licensed Compound.

(b) Supplemental Royalty. Subject to Section 6.6, if Parion jointly Develops a P-1055 Lead Compound Licensed Product for NCFB or COPD, as applicable, pursuant to Section 3.2.6, but does not jointly commercialize such P-1055 Lead Compound Licensed Product for NCFB or COPD, as applicable, pursuant to Section 5.1.1, as to such P-1055 Lead Compound Licensed Product sold in the Territory for such Indication, subject to adjustment under Sections 6.5.3, 6.5.4 and 6.5.5, Vertex shall in addition to the royalties payable pursuant to Section 6.5.1(a), pay Parion supplemental royalties (the "**Supplemental Royalty Rate**") on aggregate annual (Calendar Year) Net Sales of such P-1055 Lead Compound Licensed Product for such Indication in the Territory, [***] as such rate may be adjusted in accordance with Section 3.2.6(h)(iv). If the Supplemental Royalty Rate applies to such P-1055 Lead Compound Licensed Product for one Indication but not other Indications for which such P-1055 Lead Compound Licensed Product is being sold, then the Royalty Rate to be applied to Net Sales of such P-1055 Lead Compound Licensed Product for the Indication to which the Supplemental Royalty Rate applies [***]. If the P-1055 Lead Compound Licensed Product is being commercialized by Vertex for such Indication and one or more other Indication(s), Vertex shall [***]. If Parion exercises its right under the NCFB Co-Development Election or the COPD Co-Development Election in accordance with Section 3.2.6, [***].

(c) Royalty Stacking. Notwithstanding the foregoing, the maximum reduction that can be made to any of the royalty rates set forth in this Section 6.5.1 (including the Supplemental Royalty Rate) subject to adjustment under Sections 6.5.3, 6.5.4 and 6.5.5 shall [***] during the Royalty Term, unless Section 6.5.4(b) applies, in which case the maximum reduction [***]. For the purposes of allocating any of the foregoing royalty reductions to the relevant Net Sales to which such reduction applies, [***].

6.5.2 Royalty Term. The applicable royalties payable to Parion under Section 6.5.1 (as the royalty rates applicable under each of the foregoing may be reduced as set forth in Sections 6.5.3, 6.5.4 and 6.5.5) above shall be paid by Vertex on each Licensed Product, on a Licensed Product-by-Licensed Product and a country-by-country basis for the Royalty Term.

6.5.3 [***] **Lack of Patent Coverage.** Notwithstanding anything in Section 6.5 to the contrary, if during any period within the applicable Royalty Term no Valid Claim of a Parion Patent which would be infringed by a Licensed Product except for the licenses granted herein (or the only Valid Claim of a Parion Patent as to a Licensed Product is a claim pursuant to a Joint Patent) in a country, the royalty rate for such Licensed Product in such country shall be [***] of the royalty rate set forth in Section 6.5.1 (including the Supplemental Royalty Rate) for the Royalty Term.

6.5.4 [***] Generic Competition.

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- (a) If one or more Generic Products with respect to a Licensed Product is marketed and sold in a given country by one or more Third Parties during any Calendar Quarter during the Royalty Term and Net Sales of such Licensed Product during such Calendar Quarter have [***], relative to average quarterly Net Sales of such Licensed Product in such country during the [***] Calendar Quarters immediately prior to the Calendar Quarter during which such Generic Product(s) was first marketed and sold in such country (as such, the "Baseline Net Sales"), then the royalty rate for such Licensed Product in such country, on a Licensed Product-by-Licensed Product and country-by-country basis, shall thereafter be [***] of the applicable royalty rate set forth in 6.5.1 or 6.4.3.
- **(b)** If one or more Generic Products with respect to a Licensed Product is marketed and sold in a given country by one or more Third Parties during any Calendar Quarter during the Royalty Term, and Net Sales of such Licensed Product during such Calendar Quarter have [***] relative to the Baseline Net Sales of such Licensed Product, then the royalty rate for such Licensed Product in such country, on a Licensed Product-by-Licensed Product and country-by-country basis, shall thereafter be [***] of the applicable royalty rate set forth in Section 6.5.1 and 6.5.3.
- **6.5.5 Third Party Licenses.** If, during the Term, Vertex determines, in its reasoned business judgment, that it is necessary to obtain a license from any Third Party for intellectual property with respect to a Licensed Product or Licensed Compound (but excluding any Third Party intellectual property relating to the manufacture, use or sale of a delivery device for such Licensed Product or Licensed Compound), Vertex shall notify Parion to such effect. Upon execution of a final agreement with such Third Party, Vertex shall provide an executed copy to Parion. In such event, [***] under this Agreement with respect to Net Sales of such Licensed Product or Licensed Compound in any such country, such [***]; provided that, following the Effective Date, at Vertex's direction, [***].
- **6.5.6 Royalties Payable Only Once.** The obligation to pay royalties is imposed only once with respect to the same unit of a Licensed Product.
 - **6.6 Profit Sharing.** Upon Parion's exercise of the Profit/Loss-Sharing Option for a Shared Product for an applicable Indication pursuant to Section 5.1, during the Profit-Share Term for such Shared Product, the Parties shall share in Net Profit/Losses (as defined in Exhibit G) for such Shared Product for such Indication in accordance with the applicable Joint Commercialization Agreement as follows; [***].
 - **6.7** Payment/Reports. During the Term, following the First Commercial Sale of a Licensed Product, within [***] after the end of each Calendar Quarter, Vertex shall deliver a report specifying on a Licensed Product-by-Licensed Product and country-by-country basis: (i) gross sales in the relevant Calendar Quarter, (ii) Net Sales in the relevant Calendar Quarter, including a summary of deductions applied to determine Net Sales, (iii) a summary of any allocations made with respect to compulsory payments and Combination Products; (iv) a summary of the then-current exchange rate methodology then in use by Vertex, and (v) royalties payable on such Net Sales. All royalty payments due under Section 6.5 for each Calendar Quarter shall be due and payable within [***] after the end of the Calendar Quarter. Parion may disclose a copy of this Agreement and information related to the milestone payments and royalties payable by Parion to Vertex under Article 6, including the quarterly royalty reports due under Section 6.7, to Third Parties in connection with the proposed or actual sale by Parion of all or a portion of its interests in such payments, provided that any such Third Party is not a competitor of Vertex and agrees to be bound by confidentiality and non-use obligations that are no less stringent than those contained in this Agreement. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars using Vertex's then-current

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standard exchange rate methodology, fairly applied, for the translation of foreign currency into Dollars as employed on a consistent basis throughout Vertex's operations and consistent with GAAP.

- **6.8** Payment Method. All payments due under this Agreement to Parion shall be made by wire transfer in immediately available funds to an account designated by Parion. All payments hereunder shall be made in the legal currency of the United States of America, and all references to "\$" or "Dollars" shall refer to U.S. dollars (i.e., the legal currency of the United States).
- 6.9 Withholding Tax. Where any sum due to be paid to Parion hereunder is subject to any withholding or similar tax, Vertex shall pay such withholding or similar tax to the appropriate government authority and deduct the amount paid from the amount then due Parion, in a timely manner and promptly transmit to Parion an official tax certificate or other evidence of such withholding sufficient to enable Parion to claim such payment of taxes. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Vertex to Parion under this Agreement. Parion shall provide Vertex any tax forms that may be reasonably necessary in order for Vertex not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added 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 or value added tax.
- **6.10 Records.** Each Party shall keep, and shall require its Affiliates and any permitted sublicensee to keep, proper books of records and accounts in which full, true and correct entries (in conformity with GAAP), which shall be made for the purpose of calculating all payments under this Agreement, and compliance with the other terms and conditions of this Agreement, and related background information. Such books, records and information shall be maintained for a period of [***] following the end of the Calendar Year to which they pertain and kept reasonably accessible, and shall be made available for inspection pursuant to Section 6.11.
- 6.11 Inspection of Records. Vertex shall permit, and shall require any permitted sublicensee to permit, an independent registered public accounting firm designated by Parion to visit and inspect, during regular business hours and under the guidance of officers of the entity being inspected, and to examine the books or records and accounts of Vertex (and any other Selling Party) to the extent relating to this Agreement and to discuss the affairs, finances and accounts of Vertex (and any other Selling Party) to the extent relating to this Agreement. Vertex shall permit the employees of the independent registered public accounting firm (subject to reasonable obligations of confidentiality to Vertex) appointed by Parion to inspect the books and records described in Section 6.10; provided that such inspection shall not occur more often than once per Calendar Year and shall be limited to books and records for the three Calendar Year period referred to in Section 6.10. The costs and fees of any such independent registered public accounting firm shall be at the expense of Parion, unless such inspection reveals any underpayment of the aggregate amounts due to Parion hereunder in any Calendar Year by [***] for such period, in which case the full costs of such inspection shall be borne by Vertex. Any underpayment and, if applicable, the costs of such inspection, shall be paid by Vertex to Parion within [***] with interest on the underpayment at the rate specified in Section 6.12 from the date such payment was originally due.
- **6.12 Late Payment.** Any payments or portions thereof due hereunder that are not paid when due shall accrue interest from the date due until paid at an annual rate equal to [***] (or the maximum allowed by Applicable Law, if less).

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6.13 Reimbursement of Development Expenses.

- (a) As soon as practicable, but in any event within five Business Days after the end of each Calendar Quarter, Parion shall provide to Vertex a flash report estimating reimbursable Collaboration Expenses and/or Shared Development Costs, if any, incurred by it and its Affiliates.
- **(b)** Within [***] after the end of each [***], Parion shall submit to Vertex an itemized report of Collaboration Expenses and/or Shared Development Costs (the "**Development Report**") if any, incurred by Parion and its Affiliates during such [***], including reasonable supporting documentation.
- **(c)** With respect to any Collaboration Expenses to the extent Parion has not made a Co-Development Election with respect to such Collaboration Expenses, [***].
- (d) If Parion has made a Co-Development Election, within [***] after receipt of the report described in Section 6.13(b), Vertex shall, using the Development Report, prepare a reconciliation report with respect to the Development of the P-1055 Lead Compound in the applicable Indication during such [***], which shall include an itemized report of Vertex's Shared Development Costs for such [***], including reasonable supporting documentation (the "Development Reconciliation Report"). The Development Reconciliation Report shall set forth, in reasonable detail a statement of any amount owed by one Party to the other Party ("Development Reconciliation Payment") to achieve the allocation of the Shared Development Costs for such [***] set forth in Section 3.2.6(g). Within [***] after delivery by Vertex of a Development Reconciliation Report to Parion, Vertex or Parion, as the case may be, shall pay the Development Reconciliation Payment to the other Party.
- (e) Each Party (the "Audited Party") shall permit, and shall require any permitted sublicensee to permit, an independent registered public accounting firm designated by the other Party (the "Auditing Party") to visit and inspect, during regular business hours and under the guidance of officers of the entity being inspected, and to examine the books or records and accounts of the Audited Party to the extent relating to this Agreement and to discuss the affairs, finances and accounts of the Audited Party to the extent relating to this Agreement. The Audited Party shall permit the employees of the independent registered public accounting firm (subject to reasonable obligations of confidentiality to Audited Party) appointed by the Auditing Party to inspect the books and records in order to verify the Collaboration Expenses and Shared Development Costs, as applicable of the Audited Party; provided that such inspection shall not occur more often than once per Calendar Year. The costs and fees of any such independent registered public accounting firm shall be at the expense of the Auditing Party, unless such inspection reveals any overstatement of the aggregate amounts of such Collaboration Expenses or Shared Development Costs, as applicable reported by the Audited Party hereunder in any Calendar Year by [***] for such period, in which case the full costs of such inspection shall be borne by the Audited Party. Any amount necessary to correct an overstatement of Collaboration Expenses or Shared Development Costs and, if applicable, the costs of such inspection, shall be paid by the Audited Party to the Auditing Party within [***] with interest on the overpayment at the rate specified in Section 6.12 from the date such payment was originally due.

ARTICLE 7
INTELLECTUAL PROPERTY

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- **7.1 Intellectual Property.** The ownership of inventions made subsequent to the Effective Date, as a result of activities conducted by either Party pursuant to this Agreement, shall be governed by the provisions set forth in Sections 7.1.1 through 7.1.4 below.
- **7.1.1 Parion Inventions.** Inventions, patentable or not, that: (i) are made solely by employees of Parion, its Affiliates or Third Parties under obligation to assign their inventions to Parion or its Affiliates; and (ii) result from activities pursuant to this Agreement, shall be the exclusive property of Parion or its designated Affiliates ("**Parion Inventions**"). Parion shall provide Vertex with a quarterly report summarizing all such Parion Inventions.
- **7.1.2 Joint Inventions.** Inventions, patentable or not, that: (i) are made jointly by employees of Parion or its Affiliates and employees of Vertex or its Affiliates, or Third Parties under obligation to assign their inventions to Parion or Vertex (or Affiliates of Parion or Vertex, as the case may be), and (ii) result from activities pursuant to this Agreement, shall be the joint property of Parion and Vertex or its designated Affiliate ("**Joint Inventions**"). The Parties agree to keep each other informed of such inventions. The JSC will compile a quarterly report summarizing all such Joint Inventions.
- **7.1.3 Vertex Inventions.** Inventions, patentable or not, that: (i) are made solely by employees of Vertex, its Affiliates or Third Parties under obligation to assign their inventions to Vertex or its Affiliates; and (ii) result from activities pursuant to this Agreement, shall be the exclusive property of Vertex or its designated Affiliate ("**Vertex Inventions**"). Vertex shall provide Parion with a [***] report summarizing all such Vertex Inventions.
- **7.1.4 Cooperation.** Vertex and Parion each agree to obtain the cooperation of their respective employees or obligated Third Parties that are inventors in the preparation, filing, and prosecution of patent applications directed to any inventions that may arise hereunder.

7.2 Patent Prosecution.

- **7.2.1 Parion Patents.** As between the Parties, Vertex shall have the first right to control at Vertex's expense the Prosecution and Maintenance of the Parion Patents (including Joint Patents) in Parion's name (or with respect to Joint Patents, in the names of both Parties) using counsel reasonably acceptable to Parion. Vertex agrees to: (i) keep Parion reasonably informed with respect to such activities; (ii) consult in good faith with Parion regarding such matters, including the Vertex's patent strategy with respect to such Patents, and any plans for the amendment and/or abandonment of any claims thereof covering the Licensed Products or Licensed Compounds; (iii) provide Parion with copies of all material communications from any patent authority regarding such Patents, and provi de Parion, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses; (iv) consider in good faith any reasonable comments to such filings and responses provided by Parion timely delivered to Vertex; and (v) provide Parion with final copies of such documents.
- **7.2.2 Abandoned Patents.** Vertex shall Prosecute and Maintain all Parion Patents (including Joint Patents) diligently and in good faith in each country in the Territory where Vertex [***]. If Vertex determines in its sole discretion that it is not [***] to Prosecute or Maintain a Parion Patent (including any Joint Patent) related to the Licensed Products or Licensed Compounds in the Field in a country in the Territory, then Vertex may abandon such Parion Patent (or any such Joint Patent) in such country. Vertex shall provide Parion with notice at least [***] prior to the date such abandonment would become effective. In such event, Parion shall have the right, at its option, to control the Prosecution and Maintenance of such Parion Patents (including Joint Patents) at its own expense, and convert Vertex's exclusive license under

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Section 2.1 to a non-exclusive license under such Parion Patent (or Joint Patent) in such country in the Territory.

- 7.2.3 Outside Scope Patents. In the instance that a Parion Patent claims Licensed Compounds and/or Licensed Products and also claims ENaC Inhibitors (including any [***]) being developed or commercialized by Parion outside the scope of this Agreement ("Outside Scope Claims"), Vertex will control the Prosecution and Maintenance for these Outside Scope Claims in accordance with Parion's instructions; provided that, if, in Vertex's reasonable judgment, such Prosecution and Maintenance will not adversely affect the Prosecution and Maintenance of such Parion Patents for purposes within the scope of this Agreement, then Vertex shall provide notice thereof to Parion together with the basis for its judgment, and the Parties shall discuss and try to resolve such concern. If the Parties cannot agree on how to conduct the Prosecution and Maintenance of the Outside Scope Claims and claims relating to Licensed Products and Licensed Compounds in the Field, then Vertex may abandon such Parion Patent pursuant to Section 7.2.2. For the Prosecution and Maintenance of any Parion Patents that include Outside Scope Claims, Parion shall reimburse Vertex for [***] of such expenses with respect to such Prosecution and Maintenance in the [***], and for [***] of all expenses with respect to such Prosecution and Maintenance in the Territory within [***] after receipt from Vertex of an invoice for such amount together with documentation substantiating such expenses.
- **7.2.4** "**Prosecution and Maintenance**" shall mean, with respect to an application for a Patent, the preparing, filing, prosecuting and maintenance of such application for Patent up to and including grant through the expiration of such Patent. For clarity, it shall include all administrative patent actions before the United States Patent and Trademark Office or similar agencies in other jurisdictions, such as re-examinations, reissues, or the conduct of post-grant proceedings, inter-partes review and interferences, the defense of oppositions and other similar proceedings with respect to the particular Patent .
- 7.2.5 **Patent Rights Term Extensions.** Vertex shall control patent term extensions, adjustments or restorations, or supplementary protection certificates (together with patent term extensions, adjustments and restorations, collectively "**Patent Term Extensions**") of Parion Patents and Joint Patents as they apply to the Licensed Products or Licensed Compounds as Vertex determines in its discretion. Parion will cooperate as reasonably requested by Vertex in applying for Patent Term Extensions. Vertex will select which, if any, Parion Patent(s) or Joint Patent(s) as they apply to the Licensed Products or Licensed Compounds is to be extended or restored.

7.3 <u>Defense of Third Party Infringement Claims</u>.

7.3.1 Notification. If any Licensed Product or Licensed Compound manufactured, used or sold by Vertex, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent or of misappropriation of Know-How relating to the manufacture, use, sale, offer for sale or importation of Licensed Product or Licensed Compound in the Field in the Territory (each, a "Third-Party Infringement Claim"), the Party first having notice of the claim or assertion shall promptly notify the other Party. Subject to the indemnification obligations of Parion pursuant to Article 10 and to [***], regardless of whether such an action for infringement is commenced solely against a Party or both Parties jointly and/or any of their respective Affiliates or sublicensees of Vertex, as the case may be, with respect to any Licensed Product or Licensed Compound Developed and commercialized by Vertex, its Affiliates and/or its sublicensees under this Agreement, Vertex shall undertake and control any defense or settlement of any Third-Party Infringement Claim using counsel of its choice, and shall do so at its sole cost and expense. If Parion is named as a defendant in such suit, Parion shall have the right to participate in such defense and settlement with its or their own counsel, at its or their sole cost. Vertex shall not enter into any

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settlement of any Third-Party Infringement Claim that is instituted or threatened to be instituted against Parion without Parion's prior written consent, which shall not be unreasonably withheld, delayed or conditioned, unless such settlement includes a release of all liability in favor of Parion and/or an assumption of any unreleased liability by Vertex. As requested by Vertex, Parion shall provide reasonable cooperation and assistance to Vertex in connection with Vertex's control of the defense or settlement of a Third-Party Infringement Claim. Such cooperation and assistance shall include executing all necessary and proper documents and taking such actions as shall be appropriate to allow Vertex control to defense and settlement of such Third-Party Infringement Claim. Vertex shall reimburse Parion for the reasonable, documented, out-of-pocket costs incurred by Parion in providing such assistance and cooperation. For the avoidance of doubt, Vertex shall have no obligation to reimburse Parion for any costs or expenses incurred as a result of exercising their right to participate in the defense and settlement of a Third-Party Infringement Claim with its or their own counsel. In any event, Vertex shall keep Parion reasonably informed of the progress of such suit. To the extent reasonable, both Parties shall cooperate in good faith to (a) ensure that Vertex has the ability to continue to commercialize Licensed Products, (b) avoid or minimize any additional royalties on Licensed Products, and (c) avoid any action that may have a material adverse effect on the other Party.

- **7.4 Enforcement.** Subject to the provisions of this Section 7.4, if either Party reasonably believes that any Parion Patent or Joint Patent is being infringed by a Third Party or is subject to a declaratory judgment or nullity action (including as a result any filing of an ANDA under Section 5.5(j) of the FFDCA), or that any Parion Know-How or Joint Know-How is being misappropriated by a Third Party, in each case as applicable with respect to the keeping, manufacture, use, sale, offer for sale or importation in the Territory of a product that is or could be competitive with a Licensed Product for any application within the Field (an "Infringing Product"), such Party shall promptly notify the other Party. If such event occurs, Vertex shall have the initial right (but not the obligation) to enforce such Parion Patent or Joint Patent infringement, or to defend any declaratory judgment or nullity action with respect thereto or Parion Know-How or Joint Know-How with respect to such misappropriation thereto (an "Enforcement Action"). For clarity, Vertex shall have the initial right, but not the obligation to prosecute any patent infringement, litigation action, or defend any declaratory judgment or nullity action, including those filed under the America Invents Act, as it may be amended. If Vertex is unable to initiate or prosecute any Enforcement Action solely in its own name, Parion, at Vertex's cost, shall join such action voluntarily and shall execute and cause its Affiliates to execute all documents necessary for Vertex to initiate litigation to prosecute and maintain such action. If Vertex fails to initiate an Enforcement Action relating to an Infringing Product in a country in the Territory, within [***] of notice of such infringement or misappropriation (or within [***], with respect to an ANDA filing or its equivalent in any country), Parion shall have the right, but not the obligation, to initiate an Enforcement Action against such infringement or misappropriation at its own expense. In such case, Vertex shall cooperate with Parion in such Enforcement Action, at Parion's expense.
- **7.5 Cooperation.** The Party initiating or defending any such Third-Party Infringement Claim or Enforcement Action shall keep the other Party reasonably informed of the progress of any such Third-Party Infringement Claim or Enforcement Action, and such other Party shall have the right to participate with counsel of its own choice.
- **7.6 Recoveries.** With respect to any Third-Party Infringement Claim or any Enforcement Action, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:
 - (a) [***]:
 - **(b)** [***]; and

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- **(c)** with respect to any Enforcement Actions, the Party that initiated and prosecuted the action shall receive [***] of such remaining amount and [***] of such remaining amount shall be allocated to the other Party:
- **(d)** with respect to any Third-Party Infringement Claims, the amount of any recovery remaining shall be allocated as follows:
 - (i) if the recovery is based upon Vertex's lost profits (as demonstrated in the final award or settlement), [***]; and
 - (ii) if the recovery is based upon the allocation of a reasonable royalty or is otherwise not determinable to be based on Vertex's lost profits as provided in clause [***].
- 7.7 <u>Litigation with Respect to Vertex Patents</u>. If a Third Party infringes a Vertex Patent, any Enforcement Action relating to such Vertex Patent shall be initiated at Vertex's sole discretion, and amounts recovered by Vertex for the infringement of such rights shall belong solely to Vertex. Vertex shall have the sole and exclusive right to initiate an Enforcement Action to enforce Vertex Patents.
- **7.8** Orange Book Listing. Upon a Party's receipt of a notice of allowance (or equivalent) of an applicable Parion Patent (including Joint Patent), Parion shall promptly provide Vertex with all information reasonably required by Vertex to list such Parion Patent or Joint Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory (collectively, "Orange Book and Equivalents"). Vertex shall have the sole right to determine which such Parion Patents (including Joint Patents) or other Patent shall be included in the Orange Book and Equivalents for Licensed Products, and to file supplementary protection certificates with respect thereto.
- **7.9 Trademarks.** As between the Parties, all trademarks and trade dress rights in Licensed Products for use in the Field in the Territory shall be owned exclusively by Vertex ("**Product Trademarks**").

ARTICLE 8 CONFIDENTIALITY

- **8.1** Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, the Parties agree that the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as expressly provided for in this Agreement any confidential or proprietary information or materials furnished to it by the other Party pursuant to this Agreement or any confidentiality agreement previously entered into by and between the Parties (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information shall not be deemed to include information or materials to the extent that it can be established by written documentation by the receiving Party that such information or material:
- **(a)** was already known to or possessed by the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;
- **(b)** was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

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- **(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 this Agreement;
- **(d)** was independently developed by the receiving Party without the use of any of the other Party's Confidential Information, as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- **(e)** 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 others.

For the purposes of this Agreement, all information and Data regarding Licensed Products or Licensed Compounds (but for the avoidance of doubt, subject to Section 2.9, does not include any information and Data regarding ENaC Inhibitors (including any [***]) that are not Licensed Products or Licensed Compounds) generated after the Effective Date pursuant to activities contemplated by this Agreement shall be deemed to be Confidential Information of Vertex and the exceptions set forth in the immediately preceding sentence shall not apply to such information and Data.

8.2 Authorized Use and Disclosure.

8.2.1 Each Party may use and disclose Confidential Information of the other Party solely as follows: (i) in connection with the performance of its obligations or exercise of rights granted to such Party in this Agreement under appropriate confidentiality provisions; (ii) to the extent such disclosure is reasonably necessary in filing for, prosecuting or maintenance of Patents, copyrights and trademarks (including applications therefor) by Vertex or by Parion or its licensors in accordance with this Agreement, the Prosecution and Maintenance of Patents, or defending Litigation, complying with applicable governmental regulations, conducting preclinical or clinical trials, filing for, obtaining and maintaining regulatory approvals (including all Regulatory Filings and Marketing Approvals); (iii) to the extent required by Applicable Law, provided, however, that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency or if prohibited by Applicable Law), give reasonable advance notice to the other Party of such disclosure requirement and will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iv) in communication with existing and potential consultants, investors, lenders, other financial institutions and advisors (including financial advisors, lawyers and accountants) and others on a need to know basis in order to comply with such Party's obligations under this Agreement, in each case under appropriate confidentiality and non-use provisions substantially equivalent to those of this Agreement with a reasonable duration based on the disclosee; (v) with respect to Parion, as required pursuant to the Parion Agreements, or (vi) to the extent mutually agreed to by the Parties, provided that one Party shall not unreasonably withhold, delay or condition its consent to disclosure if requested by the other Party with respect to a potential acquirer, merger partner or commercial partner. For the avoidance of doubt, in no event shall Parion or any Parion Affiliate be entitled to use or disclose the Confidential Information of Vertex and/or its Affiliates, directly or indirectly, in connection with the Development of (x) products, or (y) Licensed Products, other than strictly under the terms of this Agreement. Each of the Parties shall ensure that each of its directors, executive officers, employees and other representatives are bound by confidentiality and non-use obligations sufficient to enable such Party to cause such individuals to comply with the terms of this Article 8 and shall be responsible for any breach by such individuals of the terms of this Agreement.

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8.2.2 If either Party concludes that a copy of this Agreement must be filed with a securities exchange or regulatory or governmental body to which that Party is subject wherever situated, such Party shall provide the other Party with a copy of this Agreement showing any sections as to which the filing Party proposes to request confidential treatment, shall provide the other Party with an opportunity and a reasonable time period to comment on any such proposal and to suggest additional portions of the Agreement for confidential treatment and shall take such Party's reasonable comments into consideration before filing the Agreement. If the filing Party disagrees with the other Party's additional confidential treatment request, the Parties shall have an opportunity to discuss the matter in good faith before the Agreement is filed.

8.3 Publications.

- **8.3.1** Each Party shall submit to the other Party any proposed publication or public disclosure containing clinical or scientific results or plans related to the Licensed Compounds or Licensed Products in the Field at least [***] in advance (or [***] in advance in the case of an abstract) of the proposed date of submission for publication or of disclosure, so as to allow that Party to review such proposed publication or disclosure. The reviewing Party will promptly review such proposed publication or disclosure and make any objections or comments that it may have thereto. The submitting Party shall give good faith consideration to any such objections and comments and, if the reviewing Party informs the submitting Party that its proposed publication or disclosure contains Confidential Information of the reviewing Party, then the submitting Party shall delete such Confidential Information from the proposed publication or disclosure. In addition, if the reviewing Party informs the submitting Party that the proposed publication or disclosure discloses any patentable invention made wholly or in part by the reviewing Party that has not yet been protected through the filing of a patent application, then the submitting Party shall either (a) delay such proposed publication or disclosure, for up to [***] from the date the reviewing Party informed the submitting Party of its objection, to permit the timely preparation and first filing of patent application(s) on the invention involved, or (b) remove the identified disclosures before publication or disclosure. If the submitting Party does not receive any written comments from the reviewing Party within the [***] review period, the reviewing Party will be deemed to have no objection to the submitting Party's planned publication or public disclosure. Notwithstanding the foregoing, neither Parion nor any of its Affiliates shall disclose through a publication or other public disclosure, or facilitate a publication or other public disclosure by a Third Party of, clinical or scientific results, data or analyses relating to the Licensed Compounds, the Licensed Products or any other proprietary Vertex compound without the prior written consent of Vertex.
- **8.3.2** Section 8.3.1 shall not apply to publications or public disclosures that are permitted or granted to a Third Party pursuant to the sponsored research or clinical trial agreements set forth on Exhibit I, provided that Parion shall extend to Vertex any rights of review, comment and approval that Parion has pursuant to any such agreements and to the extent Parion has any right of review, comment or approval under any such agreements, Parion agrees to exercise such right at Vertex's direction and for Vertex's benefit. With respect to any agreement listed on Exhibit I not executed prior to the Effective Date, if Parion executes such agreement in substantially the form provided to Vertex prior to the Effective Date (or in a form approved by Vertex after the Effective Date, such approval not to be unreasonably withheld), then the publications and public disclosures permitted or granted to a Third Party pursuant to such agreement shall not be subject to Section 8.3.1.
 - **8.4** Confidential Terms. Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, such approval not to be unreasonably withheld, conditioned or delayed, except as permitted under Section 8.2.1(iv) or 8.2.1(v), or to the extent required by Applicable Law, including securities laws. Notwithstanding the foregoing, (a) the terms and conditions of this Agreement may be disclosed and used by a Party to the extent Confidential

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Information may be disclosed and used by a receiving Party under Sections 8.1 and 8.2, and (b) the Parties have agreed to issue the press release attached hereto as Exhibit H promptly following Effective Date. In the event the Parties agree to any other public disclosure of any of the terms and conditions of this Agreement, the Parties shall cooperate in good faith to coordinate such disclosure and work diligently and reasonably to agree on the text of any such proposed disclosure in an expeditious manner. The principles to be observed in such public disclosures shall include accuracy, compliance with Applicable Law and regulatory guidance documents and the need to keep investors and others informed regarding the Parties' business and other activities.

- **8.5** <u>Vertex Information Rights</u>. If Vertex determines in good faith that Parion is an entity that is subject to financial consolidation with Vertex for the purposes of its quarterly and annual financial statements (or otherwise requires such information in order to comply with GAAP), Parion shall make available to Vertex:
- (a) as soon as practicable, but in any event within [***] after the end of each Calendar Quarter (i) an unaudited balance sheet as of the end of such Calendar Quarter, (ii) unaudited statements of income and cash flows for such Calendar Quarter, (iii) an unaudited statement of stockholders' equity for such period, and (iv) a detailed trial balance as of the end of such Calendar Quarter, all prepared in accordance with GAAP (except that such financial statements may (x) be subject to year-end audit adjustments and (y) not contain all notes thereto that may be required in accordance with GAAP) and thereafter will promptly provide such other information as Vertex may reasonably request; and
- **(b)** as soon as practicable, but in any event within [***] after the end of each Calendar Year (a) an audited balance sheet as of the end of such Calendar Year, (b) audited statements of income and cash flows for such Calendar Year, (c) an audited statement of stockholders' equity for such Calendar Year and (d) a detailed trial balance as of the end of such Calendar Year, together with related footnotes all prepared in accordance with GAAP and audited and certified by a nationally recognized independent public accounting firm; and
- **(c)** on or prior to December 31 of each Calendar Year, Parion shall preform a 409A analysis of the fair value of Parion's stock as of December 1 of such year as prepared by an independent valuation expert.

ARTICLE 9 REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Mutual Representations and Warranties.

- **9.1.1** Vertex Parent and Vertex UK each represents and warrants to Parion, as of the Effective Date, that:
- **(a)** It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

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[***].

- **(b)** The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (i) such Party's charter documents, bylaws or other organizational documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which such entity is bound; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such entity;
- **(c)** This Agreement is a legal, valid and binding obligation of such entity enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and
- **(d)** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.
 - **9.1.2** Parion represents and warrants to Vertex, as of the Effective Date, that:
- **(a)** It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement. Parion was duly organized in the State of Delaware under the name CyFi, Inc. on June 23, 1999, and has maintained its corporate existence in the State of Delaware on an uninterrupted basis since the date of its incorporation;
- **(b)** The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (i) its charter documents, bylaws or other organizational documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which it is bound; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to it;
- **(c)** This Agreement is a legal, valid and binding obligation of such entity enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and
- **(d)** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.
- **9.2** Additional Representations and Warranties of Parion. Parion further represents, warrants to Vertex, as of the Effective Date, and where specifically referenced, covenants to Vertex, as follows:
- **9.2.1** Parion (i) is entitled to grant the licenses specified herein and (ii) [***], has the right to use all Regulatory Filings, Know-How and Patents necessary for the Parties to make, have made, use,

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sell, offer for sale, and import Licensed Products and Licensed Compounds identified as of the Effective Date in the Field in the Territory as contemplated under this Agreement;

- **9.2.2** All Parion Patents existing as of the Effective Date (the "**Existing Patents**") are listed on <u>Exhibit A</u> [***] all Existing Patents are (i) to the extent issued (unless otherwise indicated on <u>Exhibit A</u>), subsisting and not invalid or unenforceable, in whole or in part, (ii) solely and exclusively owned by Parion, free of any encumbrance, lien or claim of ownership by any Third Party, (iii) to the extent pending, being diligently prosecuted in the respective patent offices in which such applications have been filed in accordance with Applicable Law and Parion and its Affiliates have presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office and (iv) filed and maintained properly and correctly and all applicable fees applicable thereto have been paid on or before the due date for payment;
- **9.2.3** As of the Effective Date, other than Parion Agreements, there are no license or other agreements with Third Parties regarding the Existing Patents or the Parion Know-How in existence as of the Effective Date to which Parion or any of its Affiliates is a party covering or relating to the Development or commercialization of any Licensed Compound or Licensed Product identified as of the Effective Date;
- **9.2.4** The Existing Patents represent all Patents that Parion or its Affiliates own relating to the Licensed Compounds or the Licensed Products identified as of the Effective Date or the keeping, manufacture, use, sale, offer for sale, and import thereof as contemplated as of the Effective Date[***]. All intellectual property rights relating to the Licensed Compounds or Licensed Products identified as of the Effective Date, if any, or the making, having made, using, selling, keeping, offering for sale, and importing thereof licensed to Parion or its Affiliates pursuant to the Parion Agreements are Controlled by Parion and the rights and obligations of the Parties hereunder are fully consistent with and are not limited by the Parion Agreements, including such that the rights granted to Vertex hereunder to intellectual property licensed pursuant to a Parion Agreements are no more restricted than the analogous rights granted to Vertex hereunder with respect to intellectual property rights wholly owned by Parion or its Affiliates. [***] no rights or licenses are required for Vertex to keep, make, have made, use, sell, offer for sale, and import Licensed Compounds and Licensed Products identified as of the Effective Date in the Field in the Territory as contemplated herein as of the Effective Date other than those granted under Section 2.1, provided that Parion is making no representation regarding any nebulizer device that may be used to administer the Licensed Products;
- **9.2.5** [***] any right or license to any Licensed Compound or Licensed Product identified as of the Effective Date that (but for any such right or license) would be Controlled by Parion or to any Patents or Know-How of Parion relating thereto. [***];
- **9.2.6** Neither Parion nor any of its Affiliates (i) has previously entered into any agreement, whether written or oral, assigning, transferring, licensing, conveying or otherwise encumbering its right, title or interest in or to the Existing Patents, Parion Know-How, Regulatory Filings, the Licensed Compound or the Licensed Products identified as of the Effective Date (including by granting any covenant not to sue with respect thereto) or any Patent or other intellectual property or proprietary right or Know-How that would be Existing Patents, Parion Know-How or Regulatory Filings but for such assignment, transfer, license, conveyance or encumbrance and has not entered into any agreement agreeing to do any of the foregoing or (ii) will enter into any such agreements, grant any such right, title or interest to any Person that is inconsistent with or otherwise diminish the rights and licenses granted to Vertex under this Agreement, in each case other than non-exclusive licenses granted to Third Party services providers to enable such services providers to perform the services for which they were contracted by Parion or its Affiliates;

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- **9.2.7** No pending claim or litigation has been brought by any Person alleging that (i) the Existing Patents are invalid or unenforceable or (ii) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of the Existing Regulatory Filings, the Existing Patents or the Parion Know-How existing as of the Effective Date or the manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds or Licensed Products identified as of the Effective Date as contemplated herein as of the Effective Date, violates, infringes, constitutes misappropriation or otherwise conflicts or interferes with or would violate, infringe or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person;
- **9.2.8** Parion has obtained from its Affiliates the licenses and other rights necessary for Parion to grant to Vertex the rights and licenses provided herein and for Vertex to perform its obligations hereunder;
- **9.2.9** [***] no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Existing Patents, the Parion Know-How or the Regulatory Filings in existence as of the Effective Date;
- **9.2.10** [***] each of the Existing Patents properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Existing Patent is issued or such application is pending;
- 9.2.11 Each Person who has or has had any rights in or to any Existing Patents or any Parion Know-How, has assigned and has executed an agreement assigning its entire right, title and interest in and to such Existing Patents and Parion Know-How to Parion. All officers, employees, agents and consultants of Parion or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Existing Patent or Parion Know-How or who are or will be performing Parion's Development activities hereunder or who otherwise have access to any Confidential Information of Vertex (the "Inventor Personnel"), (i) in the case of current or former Inventor Personnel, have executed and delivered and (ii) in the case of future Inventor Personnel, will execute and deliver, to Parion or such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Parion or such Affiliate of any Parion Patents, Parion Know-How and any and all other Know-How that relate to the Licensed Compounds or Licensed Products, the current form of which has been made available for review by Vertex. [***] no current officer, employee, agent or consultant of Parion or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Parion or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Parion;
- **9.2.12** All material works of authorship and all other materials subject to copyright protection included in Parion Know-How are original and were either created by employees of Parion or its Affiliates within the scope of their employment or are otherwise works made for hire and all right, title and interest in and to such materials have been legally and fully assigned and transferred to Parion or such Affiliate;
- **9.2.13** [***] Parion has obtained the right (including under any Patents and other intellectual property rights) to use all Know-How and all other materials (including any formulations and manufacturing processes and procedures) developed or delivered by any Third Party under any agreements between Parion and any such Third Party with respect to the Licensed Compound and the Licensed Product identified as of the Effective Date and Parion has the rights under each such agreement to transfer such rights,

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Know-How or other materials to Vertex and its designees and to grant Vertex the right to use such rights, Know-How or other materials in the manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds or the Licensed Products identified as of the Effective Date as contemplated hereunder as of the Effective Date without restriction;

- **9.2.14** The inventions claimed or covered by the Existing Patents (i) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401;
- **9.2.15** Parion has made (and will make) available to Vertex all Regulatory Filings, material Parion Know-How and other material Know-How in its possession or Control related to the Licensed Compound or the Licensed Products and all such Regulatory Filings, Parion Know-How and other Know-How are (and, if made available after the Effective Date, will be), [***] true, complete and correct in all material respects;
- **9.2.16** The Parion Know-How that Parion has determined, in the exercise of reasonable business discretion, to maintain as confidential, has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality. [***] no material breach of such confidentiality has been committed by any Third Party;
- **9.2.17** Parion and its Affiliates have generated, prepared, maintained and retained all Regulatory Filings that are required to be maintained or retained pursuant to and in accordance with, to the extent applicable, good laboratory and clinical practice and Applicable Law and all such information is true, complete and correct and what it purports to be;
- **9.2.18** Neither Parion nor any of its Affiliates, nor any of its or their respective officers, employees or agents has (i) committed (or after the Effective Date, will commit) an act, (ii) made (or after the Effective Date, will make) a statement or (iii) failed (or after the Effective Date, will fail) to act or make a statement that, in any case ((i), (ii) (iii)), that (x) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds or the Licensed Products or (y) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory, with respect the manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds or the Licensed Products;
- **9.2.19** Parion and its Affiliates have conducted, and [***], their respective contractors and consultants have conducted, (and, with respect to Development occurring after the Effective Date, will conduct) all Development of the Licensed Compound and the Licensed Products in accordance with, to the extent applicable, good laboratory, pharmacovigilance and clinical practice and Applicable Law. Parion and its Affiliates have, [***] employed (and, with respect to such tests and studies that Parion will perform, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the preclinical and clinical studies with respect to the Licensed Compound and Licensed Products;
- **9.2.20** True, complete and correct copies (as of the Effective Date) of all material adverse information and any other information with respect to the safety and efficacy of Licensed Compounds and Licensed Products identified as of the Effective Date [***] have been provided to Vertex prior to the Effective

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Date. Neither Parion nor any of its Affiliates has Knowledge of anything that could materially adversely affect the acceptance or the subsequent approval, by any Regulatory Authority of any filing, application or request for Marketing Approval (or the scope of such approval);

- **9.2.21** With respect to any Licensed Compound or Licensed Product manufactured and supplied by or on behalf of Parion, (i) all such Licensed Compounds and Licensed Products shall be in conformity with the applicable specifications for such Licensed Compounds and Licensed Products, (ii) such Licensed Compounds and Licensed Products shall have been manufactured in conformance with cGMP, all other Applicable Law, this Agreement and any supply agreement (including the related quality agreement), if applicable, (iii) such Licensed Compounds and Licensed Products shall have been manufactured in facilities that are in compliance with Applicable Law at the time of such manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities), and (iv) such Licensed Compounds and Licensed Products shall not be adulterated or misbranded under the FFDCA and similar provisions of the laws of the other major markets;
- **9.2.22** Neither Parion nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section;
 - **9.2.23** Parion has complied with, and as of the Effective Date is in compliance with, each of the Parion Agreements;
 - **9.2.24** Parion had less than \$15,300,000 in total assets as of its most recent regularly prepared balance sheet;
- **9.2.25** The representations and warranties of Parion in this Agreement and the information, documents and materials furnished to Vertex in connection with its due diligence prior to the Effective Date, do not, taken as a whole, (i) contain any untrue statement of a material fact or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading; and
- **9.2.26** Parion and its Affiliates do not control and have not conducted research on or developed any compound that (a) is or has been, as of the Effective Date, [***] and (b) is not [***].
 - **9.3** Additional Representations, Warranties and Covenants of Vertex. Vertex further represents, warrants to Parion, as of the Effective Date, and where specifically referenced, covenants to Parion, as follows:
- **9.3.1** Vertex covenant and agree that Vertex and its Affiliates will conduct, and their respective contractors and consultants will conduct all Development, manufacture and commercialization of the Licensed Compounds and the Licensed Products in accordance with, to the extent applicable, good laboratory, pharmacovigilance, and clinical practice and Applicable Laws;
- **9.3.2** With respect to any Licensed Compound or Licensed Product manufactured and supplied by or on behalf of Vertex under this Agreement, (i) all such Licensed Compounds and Licensed Products shall be in conformity with the applicable specifications for such Licensed Compounds and Licensed Products, (ii) such Licensed Compounds and Licensed Products shall have been manufactured in conformance with cGMP, all other Applicable Law and under this Agreement, (iii) such Licensed Compounds and Licensed Products shall have been manufactured in facilities that are in compliance with Applicable

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Law at the time of such manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities), and (iv) such Licensed Compounds and Licensed Products shall not be adulterated or misbranded under the FFDCA and similar provisions of the laws of the other major markets; and

9.3.3 Vertex shall inform Parion in writing promptly if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

9.4 Additional Covenants of Parion. Parion hereby covenants for the Term as follows:

- **9.4.1** Parion shall obtain from each of its Affiliates, sublicensees, employees and agents, and from the employees and agents of its Affiliates, sublicensees and agents, who are or will be involved in the manufacture of Licensed Compounds or Licensed Products or are otherwise participating in the manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds or Licensed Products or who otherwise have access to any Confidential Information of Vertex, rights to any and all Know-How that relate to the Licensed Compounds or Licensed Products and are generated pursuant to and during the time of such Person's relationship with Parion or its Affiliate, such that Vertex shall, by virtue of this Agreement, receive from Parion, without payments beyond those required by this Agreement, the licenses and other rights granted to Vertex hereunder (and such that the scope of such licenses and other rights are not limited in scope or exclusivity by a failure to so obtain such rights from such Persons);
- **9.4.2** [***], but without limiting [***], Parion shall not and shall cause its Affiliates not to (i) incur, create, assume or permit the incurrence, creation or assumption of any encumbrance, lien or claim of ownership by any Third Party with respect to Parion Patents or Parion Know-How, (ii) dispose of any Parion Patents or Parion Know-How, or (iii) waive, release, grant, license or transfer any right, title or interest in or to any Parion Patents or Parion Know-How, in any manner that would limit the scope, or the exclusivity, of the license rights granted in Section 2.1;
- **9.4.3** Parion shall comply with, including by taking all actions necessary to comply with and not taking any action that would result in any noncompliance with, the Parion Agreements;
- **9.4.4** No transfer of property is being made and no obligation is being incurred in connection with the transactions contemplated by this Agreement with the intent to hinder, delay or defraud any of Parion's current or future creditors. Parion agrees that it shall not take or cause to be taken or omit to take any action that could reasonably be expected to result in a determination pursuant to Applicable Law that any aspect of this transaction may be deemed a "fraudulent conveyance" or otherwise subject to claims of certain creditors of Parion or any of its Affiliates, or their respective trustees in any bankruptcy proceedings; and
- **9.4.5** Parion shall inform Vertex in writing promptly if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.
 - **9.5** <u>Disclaimer.</u> EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR

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IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 10

INDEMNIFICATION

- 10.1 Indemnification by Parion. Parion hereby agrees to defend, hold harmless and indemnify (collectively "Indemnify") Vertex and its Affiliates, and its and their agents, contractors, directors, officers and employees (the "Vertex Indemnitees") from and against any liability or expense (including reasonable legal expenses and reasonable attorneys' fees) (collectively "Losses") to the extent resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a "Third-Party Claim") arising out of (i) a breach of any of Parion's representations and warranties and covenants under Sections 9.1, 9.2 or 9.4; (ii) Parion's acceptance, use, handling, storage or disposal of Licensed Compounds; or (iii) the Development, manufacture, commercialization, storage, handling, use, sale, offer for sale or importation of any Licensed Compounds or Licensed Products by or under authority of Parion, or other exercise of any rights or licenses granted to Parion hereunder. Parion's obligation to Indemnify the Vertex Indemnitees pursuant to this Section 10.1 shall not apply to the extent that any such Losses (A) arise from the gross negligence or willful misconduct of any Vertex Indemnitee; or (B) arise from any breach by Vertex of this Agreement.
- Indemnification by Vertex. Vertex hereby agrees to Indemnify Parion, its Affiliates, its and their agents, contractors, directors, officers and employees, and its, agents, contractors, directors, officers and employees (all of the foregoing, the "Parion Indemnitees") from and against any and all Losses to the extent resulting from Third-Party Claims arising out of: (i) a breach of any of Vertex's representations and warranties and covenants under Sections 9.1 or 9.3; (ii) Vertex's, or its sublicensee's, acceptance, use, handling, storage or disposal of Licensed Compounds; or (iii) the Development, manufacture, commercialization, storage, handling, use, sale, offer for sale or importation of any Licensed Compounds or Licensed Products by or under authority of Vertex or any sublicensee, or other exercise of the rights and licenses granted to Vertex hereunder. Vertex's obligation to Indemnify the Parion Indemnitees pursuant to the foregoing sentence shall not apply to the extent that any such Losses (A) arise from the gross negligence or willful misconduct of any Parion Indemnitee; or (B) arise from any breach by Parion of this Agreement.
- **10.3 Shared Product Indemnification.** Notwithstanding the foregoing provisions of Sections 10.1 and 10.2, the Parties shall separately address indemnification with respect to the Shared Product, if any, in the Joint Commercialization Agreement therefor.
- **10.4 Procedure.** To be eligible to be Indemnified hereunder, the indemnified Party shall provide the indemnifying Party with prompt notice of the Third-Party Claim giving rise to the indemnification obligation pursuant to this Section 10.4 and, subject to the rights of the applicable licensor under the Parion Agreements, the exclusive ability to defend (with the reasonable cooperation of the indemnified Party) or settle any such claim; provided, however, that the indemnifying Party shall not enter into any settlement that admits fault or wrongdoing by the indemnified Party or creates any obligation on the part of the indemnified Party without the indemnified Party's written consent, such consent not to be unreasonably

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withheld or delayed. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party.

10.5 Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION ARISING IN ANY WAY OUT OF THIS AGREEMENT; PROVIDED THAT THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO BREACHES OF ARTICLE 8 AND ARTICLE 9.

ARTICLE 11

INSURANCE

11.1 <u>Insurance</u>. Each Party shall have and maintain such types and amounts of insurance covering its manufacture, use, sale, offer for sale, and import thereof of the Licensed Compounds and Licensed Products as is (i) normal and customary in the pharmaceutical industry generally for parties similarly situated and (ii) otherwise required by Applicable Law. Upon request by the other Party, each Party shall provide to the other Party evidence of its insurance coverage. The insurance policies shall be under an occurrence form, but if only a claimsmade form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement in its entirety for a period of five years. Notwithstanding the foregoing, Vertex may self-insure in whole or in part the insurance requirements described above.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. This Agreement shall become effective as of the Effective Date and, unless earlier terminated by either Party pursuant to the provisions of this Article 12, shall continue in full force and effect until the date on which Vertex has no remaining royalty payment obligations for any Licensed Products in any country in the Territory (the "**Term**").

12.2 <u>Termination by Vertex</u>.

- 12.2.1 Vertex shall have the right to (a) terminate this Agreement in its entirety or (b) terminate this Agreement with respect to one or more Licensed Products throughout the Territory, on a Licensed Product-by-Licensed Product basis, in either case ((a) or (b)) prior to any Licensed Product that would be affected by such termination receiving Marketing Approval in any country in the Territory for any or no reason upon 90 calendar days' prior written notice to Parion. After any Licensed Product that would be affected by such termination has received Marketing Approval in any country in the Territory, Vertex shall have the right, at its sole discretion, to (i) terminate this Agreement in its entirety or (ii) terminate this Agreement with respect to such Licensed Product, in either case ((i) or (ii)) for any or no reason on 180 calendar days' prior written notice to Parion.
- **12.2.2** Vertex shall have the right to (a) terminate this Agreement in its entirety or (b) terminate this Agreement with respect to one or more Licensed Products throughout the Territory, on a Licensed Product-by-Licensed Product basis, in either case ((a) or (b)) immediately at any time and in its sole discretion upon written notice to Parion, if Vertex determines that such Licensed Product is unsafe for administration to humans.

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- **12.2.3** Without limiting Section 12.2.1 or 12.2.2, on a Licensed Product-by-Licensed Product basis, if Vertex determines the Development or commercialization of a Licensed Product in a country in the Territory is not commercially viable or feasible, Vertex shall have the right to terminate this Agreement as to such Licensed Product at any time on a country-by-country basis and in its sole discretion upon [***] prior written notice to Parion.
- **12.2.4** After giving notice of termination pursuant to this Section 12.2 and until the effective date of termination, Vertex shall have no obligations under this Agreement: (i) to initiate any new clinical or non-clinical studies of any terminated Licensed Product, (ii) to make any further filings for Marketing Approval of any terminated Licensed Product in any terminated country, or (iii) initiate sales of any terminated Licensed Product in any terminated country. During such period, Vertex shall commence the activities set forth in Section 12.5.2(g).
 - **12.3 Termination for Material Breach.** On a Licensed Product-by-Licensed Product basis, upon any material breach of this Agreement as to any Licensed Product by either Party (in such capacity, the "**Breaching Party**"), the other Party (in such capacity, the "**Non-Breaching Party**") may terminate this Agreement as to such Licensed Product by providing [***] prior written notice to the Breaching Party (unless such breach is a failure to make any payment as and when due, in which case such required prior written notice shall be [***]), specifying the material breach. The termination shall become effective at the end of the [***] period unless (a) the Breaching Party cures such breach during such [***] period (unless the breach is a payment breach and the Party owing payment believes in good faith that such payment is not due and has notified the other Party thereof and paid any undisputed amount to the other Party, in which case the dispute shall be settled, and this Agreement as to such Licensed Product shall not be terminated as long as the dispute is pending or thereafter if the Breaching Party pays all amounts due within [***] following a final judgment determining the portion of the disputed amount due, if any), or (b) solely with respect to a breach that is not a payment breach, if such breach is not susceptible to cure within [***] of the receipt of written notice of the breach, the Breaching Party is diligently pursuing a cure and effects such cure within an additional [***] after the end of the initial [***] cure period.
 - **12.4** Termination Upon Specified Events. If Vertex experiences a Change of Control, Vertex (or the appropriate successor entity) shall provide written notice to Parion of the transaction that resulted in the Change of Control (the "Event Notice"), on the date of consummation of such transaction, together with a progress report with respect to the status of Licensed Compounds and Licensed Products in Development, including the status of any Regulatory Filings through the date of the Event Notice. Parion shall have the option, exercisable by written notice from Parion to Vertex (or the appropriate successor entity) on or before the 30th calendar day following Parion's receipt of the Event Notice, to terminate this Agreement in its entirety effective upon 30 calendar days' written notice. Parion's option set forth in this Section 12.4, shall terminate on the earlier to occur of (i) the date on which Vertex Initiates the first Phase III Clinical Trial of a Licensed Product pursuant to this Agreement or (ii) the date Parion experiences a Change of Control.

12.5 Effects of Expiration or Termination.

12.5.1 Expiry of Royalty Obligations. On a Licensed Product-by-Licensed Product and country-by-country basis, following expiry of the applicable Royalty Term (but not earlier termination of this Agreement) with respect to such Licensed Product in such country, Vertex shall retain a fully paid-up, non-royalty-bearing, perpetual, irrevocable, exclusive license to the Parion Patents and the Parion Know-How and Parion's interest in Joint Know-How and Joint Patents to make, have made, use, sell, keep, offer for sale, and import the applicable Licensed Product in the Field in such country.

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- 12.5.2 Termination by Vertex without Cause or Termination by Parion with Cause. Upon any termination of this Agreement (i) in its entirety or any termination of this Agreement with respect to one or more Licensed Products throughout the Territory or in a country (as applicable) (it being understood that, if this Agreement is terminated in its entirety, then all references below to "terminated Licensed Product" shall instead be references to all Licensed Products, and "the terminated countries" shall instead be references to "the Territory"), in either case pursuant to Section 12.2.1, 12.2.2 or 12.2.3, or (ii) any termination of this Agreement with respect to one or more Licensed Products by Parion pursuant to Section 12.3, or (iii) any termination of this Agreement in its entirety by Parion pursuant to Section 12.4:
- (a) with respect to Parion's Co-Development Option pursuant to Section 3.2.6 with respect to such terminated Licensed Product, if applicable, (i) if such Co-Development Option is unexercised at such time, such Co-Development Option shall terminate as of the effective date of termination and be of no force and effect, or (ii) if previously exercised, all rights and obligations of the Parties arising from such exercise with respect to such terminated Licensed Product that was the subject of such exercise shall terminate as of the effective date of termination and be of no force and effect;
- **(b)** if this Agreement is terminated in its entirety, Vertex's Option pursuant to Section 2.8 with respect to any Option Compound, if unexercised at such time, shall terminate as of the effective date of termination and be of no force and effect;
- **(c)** all licenses granted by Parion to Vertex pursuant to Section 2.1 with respect to such terminated Licensed Product (including any sublicenses granted thereunder or any other sublicenses granted pursuant to Section 2.2) shall be of no force and effect;
 - (d) [***];
- **(e)** with respect to Parion's Profit/Loss-Sharing Option pursuant to Section 5.1.1 with respect to such terminated Licensed Product, if applicable, (i) if such Profit/Loss Option is unexercised at such time, such Profit/Loss Option shall terminate as of the effective date of termination and be of no force and effect, or (ii) if previously exercised, all rights and obligations of the Parties arising from such exercise with respect to such terminated Licensed Product that was the subject of such exercise shall terminate as of the effective date of termination and be of no force and effect;
 - **(f)** if this Agreement is terminated in its entirety, the provisions of Section 2.9 shall terminate;
- **(g)** promptly after the notice date of any such termination pursuant to Section 12.2 or otherwise after effective date of such termination, Vertex shall commence winding down its Development, manufacturing and commercialization activities for the terminated Licensed Products in the terminated countries under the oversight of the JSC, and shall use good faith efforts to complete any and all such wind-down Development and commercialization activities within [***] after the notice date or effective date of such termination, as applicable;
- **(h)** Vertex shall and hereby does grant to Parion a non-exclusive, royalty-bearing license with the right to grant sublicenses, under the Vertex Inventions (including any Patents covering such Vertex Inventions) Controlled by Vertex to develop, make, have made, use, market, sell, have sold, offer to sell, import distribute and otherwise exploit any terminated Licensed Product in a terminated country;

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- (i) if requested by Parion, Vertex shall, at Vertex's cost, and hereby does assign and shall cause its Affiliates (as applicable) to assign, to Parion, effective as of the effective date of such termination, all of Vertex's (or its Affiliate's) right, title and interest in and to the Product Trademark and all relevant trademark applications and registrations with respect to the terminated Licensed Product in the terminated country. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this Section 12.5.2(i);
- (j) if this Agreement is terminated in its entirety or as to a terminated Licensed Product on a worldwide basis, Vertex shall assign to Parion or Parion's designee its entire right in all clinical and related study data and other Data and information based on use or research on the terminated Licensed Product, all safety data and annual safety reports filed with any Regulatory Authority with respect to such terminated Licensed Product, and all Regulatory Filings and Marketing Approvals relating to such terminated Licensed Product;
- **(k)** if there is any termination of this Agreement with respect to one or more Licensed Products other than on a worldwide basis, Vertex shall provide to Parion or Parion's designee a right of reference and right to use in the terminated country all clinical and related study data and other Data and information based on use or research on the terminated Licensed Product, all safety data and annual safety reports filed with any Regulatory Authority with respect to such terminated Licensed Product in the terminated country, and all Regulatory Filings and Marketing Approvals relating to the terminated Licensed Product in the terminated country;
- (l) within [***] after any such notice of termination, Vertex shall notify Parion of any and all agreements between Vertex (and/or its Affiliates) and Third Parties with respect to the conduct of Development, manufacturing and/or commercialization activities for the terminated Licensed Product in the terminated country. At Parion's request, which request shall be made within [***] after receipt of the foregoing information, Vertex shall use Commercially Reasonable Efforts to transfer relationships to Parion by assignment of any relevant agreements with Third Parties, if permitted by such agreement; and
- **(m)** if such termination is a termination of this Agreement in its entirety, each Party shall promptly return all Confidential Information and proprietary materials of the other Party that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of determining such Party's obligations hereunder.
- **12.5.3 Termination Under Section 12.2.1 or 12.2.3.** In addition to the provisions of Section 12.5.2, upon any termination of this Agreement in its entirety by Vertex pursuant to Section 12.2.1 or 12.2.3 [***].
- **12.5.4 Termination Under Section 12.4.** In addition to the provisions of Section 12.5.2, upon any termination of this Agreement by Parion pursuant to Section 12.4, if any Licensed Product that was being Developed by Vertex pursuant to this Agreement is subsequently commercialized by Parion, Parion shall pay Vertex a royalties on such terminated Licensed Product based on where each such Licensed Product was in Development at the effective date of termination, as follows:
- **(a)** If the effective date of termination is [***] with respect to such Licensed Product, the royalty rates set forth in Column A;

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(b) If the effective date of termination is [***] with respect to such Licensed Product, the royalty rates set forth in

Column B; and

(c) If the effective date of termination is [***] with respect to such Licensed Product, the royalty rates set forth in

Column C:

Calendar Year Net Sales (in Dollars) for such Licensed Product* in the Territory	Royalty Rates as a Percentage (%) of Net Sales		
	Column A	Column B	Column C
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

^{*} For the avoidance of doubt, a Licensed Product is comprised of all formulations, dosage strengths and package sizes of such pharmaceutical product, for all Indications, comprised of the same Licensed Compound.

- **12.5.5 Termination by Vertex with Cause.** Upon any termination of this Agreement in its entirety or with respect to one or more Licensed Products by Vertex pursuant to Section 12.3:
- (a) with respect to Parion's Co-Development Option pursuant to Section 3.2.6 with respect to such terminated Licensed Product, if applicable, (i) if such Co-Development Option is unexercised at such time, such Co-Development Option shall terminate as of the effective date of termination and be of no force and effect, or (ii) if previously exercised, all rights and obligations of the Parties arising from such exercise with respect to such terminated Licensed Product that was the subject of such exercise shall terminate as of the effective date of termination and be of no force and effect;
- **(b)** with respect to Parion's Profit/Loss-Sharing Option pursuant to Section 5.1.1 with respect to such terminated Licensed Product, if applicable, (i) if such Profit/Loss Option is unexercised at such time, such Profit/Loss Option shall terminate as of the effective date of termination and be of no force and effect, or (ii) if previously exercised, all rights and obligations of the Parties arising from such exercise with respect to such terminated Licensed Product that was the subject of such exercise shall terminate as of the effective date of termination and be of no force and effect;
- **(c)** If this Agreement is terminated in its entirety, Vertex's Option pursuant to Section 2.8 with respect to any Option Product, if unexercised at such time, shall terminate as of the effective date of termination and be of no force and effect;
- (d) all licenses granted by Parion to Vertex pursuant to Section 2.1 (including all sublicenses granted thereunder or any other sublicenses granted pursuant to Section 2.2) with respect to such terminated Licensed Products shall survive the termination on the following terms:

(i)[***]; or

(ii)[***].

- **(e)** any licenses granted by Vertex to Parion pursuant to this Agreement with respect to such terminated Licensed Product shall terminate; and
- **(f)** if such termination is a termination of this Agreement in its entirety, each Party shall promptly return all Confidential Information and proprietary materials of the other Party with respect to such Licensed Product that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of determining such Party's obligations hereunder.
- **12.5.6 Accrued Obligations.** Expiration or termination of this Agreement in its entirety or with respect to one or more Licensed Products for any reason shall not release either Party from any obligation or liability that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination.
- **12.5.7 General Survival.** The following provisions shall survive expiration or termination of this Agreement for any reason: ARTICLE 1 (Definitions); Sections 3.5 (Adverse Event Reports), 6.9 (Withholding Tax), 6.10 (Records), 6.11 (Inspection of Records), 6.12 (Late Payment), 7.1 (Intellectual Property) (except for the last sentence of 7.1.2), 7.3 (Defense of Third Party Infringement Claims), 7.4 (Enforcement), 7.5 (Cooperation) and 7.6 (Recoveries) (but with respect to 7.3, 7.4, 7.5 and 7.6, solely with respect to actions that are ongoing at the time of such termination) and 7.9 (Trademarks), ARTICLE 8 (Confidentiality) (except Section 8.5 (Vertex Information Rights)), ARTICLE 10 (Indemnification), Section 12.5 (Effects of Expiration or Termination); and ARTICLE 13 (Miscellaneous) (except for Section 13.3 (Assignment)).

ARTICLE 13 MISCELLANEOUS

- **13.1** Governing Law. Except for matters of intellectual property law, which shall be determined in accordance with the national intellectual property laws relevant to the intellectual property in question, this Agreement, and any disputes between the Parties relating to the subject matter of this Agreement, shall be construed and the respective rights of the Parties hereto determined according to the substantive laws of the State of New York, USA, excluding (a) its conflicts of laws principles; (b) the United Nations Conventions on Contracts for the International Sale of Goods; (c) the 1974 Convention on the Limitation Period in the International Sale of Goods; and (d) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.
- 13.2 <u>Venue</u>. Each Party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts located in New York City, New York for the purpose of any claim, controversy, action, cause of action, suit or litigation between the Parties arising in whole or in part under or in connection with this Agreement and agrees that such courts are a proper venue for such action. Each Party agrees that effective process may be served to a Party pursuant to Section 13.1. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy such as temporary restraining order, preliminary injunction or other interim equitable relief) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, know-how or any other proprietary right or otherwise to avoid irreparable harm.
- **13.3 Assignment.** This Agreement shall not be assignable by any Party to any Third Party without the written consent of the non-assigning Party and any such attempted assignment shall be void.

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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 pertains (whether by merger, reorganization, acquisition, sale or otherwise), and agrees in writing to be bound by the terms and conditions of this Agreement. No assignment or transfer of this Agreement shall be valid and effective unless and until the assignee/transferee agrees in writing to be bound by the provisions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties. Except as expressly provided in this Section 13.3, any attempted assignment or transfer of this Agreement to any Third Party shall be null and void.

13.4 Notices. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile or by express courier service (signature required) or five calendar days after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within two calendar days after such mailing, to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party will have last given by notice to the other Party in accordance with this Section 13.4. Any notice or other document served by facsimile shall be promptly confirmed by personal delivery, express courier service or registered post.

If to Parion, to: Parion Sciences, Inc.

2800 Meridian Parkway

Suite 195

Durham, North Carolina 27713

Attn: Paul Boucher Facsimile No.:

Telephone No.: (919) 313-1195

with a copy to: Reed Smith LLP

136 Main Street

Suite 250

Princeton, New Jersey 08540 **Attn:** Diane M. Frenier

Facsimile No.: (609) 951-0824 **Telephone No.:** (609) 514-5999

If to Vertex, to: Vertex Pharmaceuticals Incorporated

50 Northern Avenue

Boston, Massachusetts 02210

Attn: Office of Business Development

Facsimile No.: 857-263-4527 **Telephone No.:** 617-341-6100

with copies to: Vertex Pharmaceuticals Incorporated

50 Northern Avenue

Boston, Massachusetts 02210 **Attn:** Corporate Legal

Facsimile No.: 857-263-4527 **Telephone No.:** 617-341-6100

Wilmer Cutler Pickering Hale and Dorr LLP

60 State Street

Boston, Massachusetts 02109 Attn: Steven D. Barrett Facsimile No.: 617-526-5000 Telephone No.: 617-526-6000

- **13.5 Waiver.** Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.
- 13.6 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

13.7 Entire Agreement/Modification.

- **13.7.1** This Agreement, including its Exhibits, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties relative to the subject matter hereof and thereof and supersedes and terminates all prior agreements and understandings between the Parties with respect thereto.
- **13.7.2** Each of the Parties acknowledges that in agreeing to enter into this Agreement, it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of the other Party before the signature of this Agreement. Except in the case of fraud, each of the Parties waives all rights and remedies which, but for this sub-section, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- **13.7.3** No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.
 - **13.8 Relationship of the Parties.** The Parties agree that the relationship of Parion and Vertex established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.
 - **13.9 Force Majeure.** Except with respect to payment of money, neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, strike, flood, or governmental acts or restriction, or other like cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any such obligation under this Agreement is delayed owing to such a

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force majeure for any continuous period of more than [***], this Agreement may be terminated by the Party whose performance has not been affected by such force majeure event.

- **13.10** Compliance with Laws. Notwithstanding anything to the contrary contained herein, all rights and obligations of Parion and Vertex are subject to prior compliance with, and each Party shall comply with, all United States and foreign export and import laws, regulations, and orders, and such other United States and foreign laws, regulations, and orders as may be applicable, including obtaining all necessary approvals required by the applicable agencies of the governments of the United States and foreign jurisdictions.
- 13.11 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "day" means a calendar day unless otherwise specified; (iii) the word "notice" shall mean notice in writing (whether or not specifically stated); (iv) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (v) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;" (vi) provisions that require that a Party, the Parties or a committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (vii) words of any gender include the other gender; (viii) words using the singular or plural number also include the plural or singular number, respectively; and (ix) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.
- **13.12** Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and both of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile or digital transmission, each of which shall be binding when received by the applicable Party.

"SIGNATURE PAGE FOLLOWS"

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IN WITNESS WHEREOF, the Parties have executed this Strategic Collaboration and License Agreement in duplicate originals by their duly authorized representatives as of the date and year first above written.

PARION SCIENCES, INC.	VERTEX PHARMACEUTICALS INCORPORATED	
By: <u>/s/ Paul Bucher</u>	By: /s/ Ian Smith	
Name: Paul Boucher	Name: Ian Smith	
Title: President	Title: Chief Financial Officer	
Date: <u>June 4, 2015</u>	Date: <u>June 4, 2015</u>	
	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	
	By: <u>/s/ Ian Smith</u>	
	Name: Ian Smith	
	Title: Director	
	Date: <u>June 4, 2015</u>	

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EXHIBIT A

Parion Patents

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 35 pages were omitted. [***]

A-1

EXHIBIT B

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

EXHIBIT C

Identifier Cover Page of Northern Trial Protocol

Protocol No. PS-G201 P-1037 Solution for Inhalation CONFIDENTIAL



P-1037 SOLUTION FOR INHALATION

Protocol # PS-G201

CLEAN-CF

(CLEARING LUNGS WITH ENAC INHIBITION IN CYSTIC FIBROSIS)

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF P-1037 SOLUTION FOR INHALATION IN PATIENTS WITH CYSTIC FIBROSIS (CF)

> Original Protocol Release Date: 17 Dec 2014 Protocol Amendment # 1 Release Date: 12 Feb 2015

> > US IND No. 115168

Sponsor: Parion Sciences, Inc. 2800 Meridian Parkway, Suite 195 Durham, NC 27713

For Parion Sciences:

Vice President, Drug Development

Karl H Donn, Ph.D.

Signature

Date

STATEMENT OF CONFIDENTIALITY

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by federal or state law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you which is indicated as privileged or confidential.

EXHIBIT D

Description of Southern Trial

The "Southern" Phase IIa trial is planned to be [***]. They will be required to have [***].

The planned treatment duration [***].

The primary end-point [***]. The intent is that trial [***].

[***]. In order to optimise the ability [***].

EXHIBIT E

[***] From the Northern Trial and Southern Trial data [***]

EXHIBIT E-1

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

EXHIBIT F

Third Party Vendors and Contractors of Parion

Research

Chemistry

[***]	Medicinal Chemistry	
[[]	Medicinal Chemistry	
Pharmacology		
[***]	Sheep MCC Studies	
[***]	Renal pharmacology	
[***]	Receptor selectivity	
[***]	Ion shannel off towart activity	
	Ion channel off target activity	
[***]	Cytotoxicity assays	
Toxicology		
[***]	Non-GLP safety studies	
[***]	Non-GLP Ames test	
Drug Metabolism/PK/TK		
[***]	Rat and Dog PK studies	
[***]	Bioanalysis	

Preclinical Development

CMC

[***]	Manufacture Drug Substance
	Frantitute Brug Substance
[***]	Manufacture Drug Substance
	Release Testing for Drug Substance
	Stability Studies on Drug Substance
[***]	Release Testing for Drug Substance – Microbial Limits
[***]	Release Testing for Drug Substance – Bacterial Endotoxins
[***]	Synthesis of starting materials
[***]	Synthesis of starting materials
[***]	Micronization of API for formulation development
[***]	Polymorph and salt screening
[***]	MDI feasibility and prototype BFS formulation
[***]	[***] nebulizer and MDI characterization
Drug Metabolism	
[***]	QWBA and drug disposition studies
Toxicology	
I	

Clinical Development

CMC

[***]	Store Drug Substance
[***]	Compound CTS for Phase I study
	Bulk drug product manufacturing Blow, fill seal packaging
	Quality control Endotoxin and Sterility testing (release)
	Release testing Stability testing
[***]	Clinical packaging
[***]	Return receipt and processing of drug product
[***]	Manufacturing, packaging, testing and release of [***] nebulizer
[***]	Assembly of [***] nebulizer

Clinical

[***]	Central Laboratory Facility
	Clinical Trial Supply Compounding
[***]	Spirometry training
[***]	Data Management and EDC
[***]	PK validation and bioanalysis
[***]	Back up Central Laboratory
[***]	Central Laboratory Facility
[***]	Biostatistics
[***]	Medical Reviewer for CSRs 101, 103 and 117
[***]	Unblinded Pharmacy Monitor
[***]	Medical Writers (CSRs 101, 103 and 117)
[***]	PK Medical Writer (study 101)
[***]	Clinical Trial Supply Compounding (study 103 and 117)
[***]	Randomization code (study 117)
[***]	Project Management, Monitoring (study 117)
[***]	Medical monitoring, Project Management, Clinical Monitoring, Monitoring, Data Management, Statistics, Randomization code generation, site qualification, maintain trial master file (PS-G201
[***]	Pharmacovigilence, serious adverse event processing and tracking (PS-G201)
[***]	Centralized Spirometry with data base and over-read (PS-G201)
[***]	Centralized laboratory with database (PS-G201)

Regulatory

[***]	Regulatory contact and submissions, consultants, publishing

EXHIBIT G

Joint Commercialization Agreement Term Sheet

All capitalized terms used but not otherwise defined in this <u>Exhibit G</u> will have the meanings ascribed to them in the Strategic Collaboration and License Agreement (the "SCLA").

- 1. Parties. Parion Sciences, Inc. ("Parion") and Vertex Pharmaceuticals Incorporated ("Vertex Parent") and Vertex Pharmaceuticals (Europe) Limited ("Vertex UK" and, together with, Vertex Parent "Vertex").
- 2. **Product and Indications**: Shared Product for NCFB or COPD, as applicable, commercialized in the Territory. The Parties will focus their commercialization efforts with respect to the Shared Product on particular Indication(s) as set forth in the Joint Commercialization Plan (as defined below).
- 3. **Territory**: Worldwide.
- 4. **Term**: [***], unless earlier terminated in accordance with the SCLA or the terms of an applicable Joint Commercialization Agreement (the "JCA").
- 5. **Conduct of Joint Commercialization**: The Parties shall jointly commercialize the Shared Product for the applicable Indication in the Territory in accordance with a Joint Commercialization Plan approved by the JSC, as such Joint Commercialization Plan may be amended by the JSC from time to time.
- 6. **Governance**: The JSC shall oversee the Parties' commercialization of Shared Products for the Territory.
- 7. **Joint Commercialization Plans**: At an appropriate time to be determined by the JSC (but in any event at least [***] prior to commercial launch of the applicable Shared Product for the applicable Indication in the Territory), the JSC shall formulate and approve an initial joint plan for commercialization of such Shared Product for the Territory (the "**Joint Commercialization Plan**"). The Joint Commercialization Plan may be amended or updated from time to time by the JSC, including any amendments or updates to any anticipated timelines or to the then-current budget. The Joint Commercialization Plan shall encompass the planned commercialization strategy in the Territory for the applicable Shared Product and shall set forth the corresponding budget of Shared Commercialization Costs, anticipated timelines, commercialization activities to be performed by each Party, commercial supply forecasts, and the other matters described below. The initial Joint Commercialization Plan shall include the budgeted Shared Commercialization Costs for pre-launch commercialization activities in the Territory and for commercialization activities through at least two Calendar Years after the First Commercial Sale of the Shared Product in the Territory. The Joint Commercialization Plan shall be updated by the JSC on an annual or more frequent basis. The responsibilities allocated to each of the Parties shall be based on their respective capabilities and geographic scope. Initially, the Parties anticipate that [***], which will be reflected in the Joint Commercialization Plans.
- 8. **Responsibilities of the Parties Generally**: Each Party shall use Commercially Reasonable Efforts to fulfill all responsibilities assigned to it under the Joint Commercialization Plan and shall comply with the JCA and all Applicable Laws. Neither Party shall be required to undertake specific activities with respect to the commercialization of the Shared Product for the Territory unless such assigned activities are set forth in the Joint Commercialization Plan.
 - a) Parion Responsibilities:

- i) Parion shall undertake the responsibilities allocated to Parion in the Joint Commercialization Plan under the direction and oversight of the JSC; and
- ii) Parion shall, if Parion determines to be operationally involved, use (A) an appropriate management infrastructure to supervise the Sales Representatives, MSLs, medical affairs personnel and other appropriate functional groups (collectively, "Commercialization Personnel") employed by Parion and required to oversee performance of Parion's Commercialization obligations under the Joint Commercialization Plan and (B) Commercialization Personnel of sufficient number and adequate experience to implement its responsibilities under the Joint Commercialization Plan.

b) Vertex Responsibilities:

- i) Vertex shall undertake the responsibilities allocated to Vertex in the Joint Commercialization Plan under the direction and oversight of the JSC;
- ii) Vertex shall use (A) an appropriate management infrastructure to supervise the Commercialization Personnel employed by Vertex and required to oversee performance of Vertex's Commercialization obligations under the Joint Commercialization Plan and (B) Commercialization Personnel of sufficient number and adequate experience to implement its responsibilities under the Joint Commercialization Plan;
- iii) Vertex shall have the sole right and responsibility to (A) [***] and (B) [***]. Vertex shall be responsible for distribution, invoicing and collection with respect to sales of the Shared Product in the Territory and shall book such sales (it being understood that Vertex shall be solely and exclusively responsible for its own revenue recognition with respect to the Shared Product, and Parion shall have no responsibility therefor);
- iv) Vertex shall have the sole right to manufacture the Shared Product or contract a Third Party to manufacture the Shared Product, in either case, in a commercially reasonable manner, including managing raw material supply for manufacturing the Shared Product, warehousing and distributing the Shared Product; and
- v) Vertex will update the JSC at least once a Calendar Quarter with respect to material manufacturing matters for the Shared Product.

9. Allocation and Reconciliation of Net Profits/Losses; Patent Enforcement Recoveries:

- a) <u>Allocation</u>: Vertex and Parion shall each receive (in the case of profits) or pay (in the case of losses), as applicable, their respective allocations of Net Profit/Losses with respect to the Shared Product for the applicable Indication in the Territory, as set forth in Section 6.6, to be calculated and paid in accordance with the reporting, reconciliation and payment provisions of this Section 9.
- b) <u>Reconciliation of Net Profits/Losses; Reporting Gross Revenues and Shared Expenses</u>: Every [***] during the Profit-Share Term, in accordance with the applicable Joint Commercialization Agreement, Parion and Vertex shall perform a reconciliation of the applicable elements of Net Profits/Losses realized or incurred by each Party under such Joint Commercialization Agreement during the prior [***].

- c) <u>Allocation</u>. If any Product comprising a particular Vertex Selected Compound is being commercialized by Vertex as both a Shared Product for an applicable Indication and as a Licensed Product for one or more other Indication(s), [***].
- d) <u>Payment</u>. Within [***] after each [***] reconciliation of Net Profits/Losses, Vertex or Parion, as the case may be, shall pay the applicable amount due to the other Party.
- e) <u>Reporting</u>. Reports of actual expenditure compared to budget shall be made to the JSC on a [***] basis. Significant variances from the total overall budgets and significant variances in budget line items shall only be included in calculating Net Profits/Losses when approved by the JSC.
- f) Audits and Interim Review. Either Party shall have the right to request that the other Party's independent, certified accounting firm perform an audit or interim review of the other Party's books in order to express an opinion regarding such Party's calculations hereunder. Such audits or review will be conducted at the expense of the requesting Party and no more than once each Calendar Year. In accordance with Section 6.11, at the request and expense of an auditing Party, the audited Party shall permit an independent, certified public accountant appointed by the auditing Party, at reasonable times and upon reasonable written notice, to examine such records as may be necessary to: (i) determine the correctness of any report or payment made under a Joint Commercialization Agreement; (ii) determine the correctness of any Cost of Goods and Shared Commercialization Costs reported under a Joint Commercialization Agreement; provided, however, that such examination shall not be permitted more than once in any 12-month period.

10. Adverse Events; Recall; Product Liability Claims.

- a) Subject to Sections 3.5 and 4.5 of the SCLA, the Parties shall establish procedures for reporting adverse events and other Shared Product related safety issues. Unless otherwise agreed by the Parties, Vertex shall have the right and primary responsibility to make decisions and to take immediate action with respect to Shared Product safety issues, including recalls, in all cases, after reasonable consultation with Parion; provided, however, that Vertex may make such decision without consultation with Parion to the extent necessary for Vertex to comply with its regulatory obligations.
- b) Any Losses arising out of any Third Party Claim arising out of or resulting from the Development, manufacture or commercialization of any Shared Product for use or sale in the Field in the Territory ("**Product Liability Costs**"), [***], except to the extent such Losses arise out of any Third Party Claim based on (a) a Party's breach of any of its representations, warranties, covenants or obligations pursuant to the SCLA or the JCA, or (b) the negligence or willful misconduct of a Party, its Affiliates, its or its Affiliates' sublicensees, or any of the respective officers, directors, employees and agents of each of the foregoing entities, in the performance of obligations or exercise of rights under the SCLA or the JCA.
- 11. **Joint Marketing and Sales Meetings:** The Parties shall plan and implement periodic joint sales and marketing meetings to be determined by the JSC.
- 12. **Miscellaneous**. Subject to Section 5.1.1 of the SCLA, the JCA shall be based on this <u>Exhibit G</u> and contain provisions regarding representations and warranties, indemnifications, termination rights, and other reasonable and customary provisions to be agreed by the Parties.

13. **Definitions**:

"Allocable Overhead" means costs incurred by a Party or for its account which are attributable to a Party's supervisory services, occupancy costs, corporate bonus (to the extent not charged directly to department), and its payroll, information systems, human relations or purchasing functions and which are allocated to company departments based on space occupied or headcount or other activity-based method consistently applied by a Party, or a standard rate if agreed to by the Parties. Allocable Overhead shall not include any costs attributable to [***].

"Cost of Goods" shall mean Vertex's (or its Affiliates') [***] of manufacturing (or acquiring from a Third Party) Shared Product for commercialization in the Territory, [***], determined in accordance with GAAP, consistently applied; which shall be comprised of:

"Net Profits/Losses" shall mean [***].

"Recoveries" shall mean all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party solely in connection with the judgment, award or settlement of any enforcement of intellectual property Controlled by Vertex, Parion or the Parties jointly, in each case covering the Shared Product, which is an Infringing Product.

"Sales Representative" shall mean a professional pharmaceutical sales representative employed by either Party to conduct primarily detailing and other promotional efforts with respect to a Shared Product and who has been trained by either Party in accordance with a training protocol to be agreed upon by the Parties as set forth in the Joint Commercialization Plan.

"Shared Commercialization Costs" shall mean all bona fide, reasonable [***] incurred by a Party with respect to commercialization of the Shared Product in accordance with the Joint Commercialization Plan, including:

- a) [***]<u>.</u>
- b) [***];
- c) [***]
- d) [***]
- e) [***]
- f) [***]; and
- g) Such other costs as the Parties may agree.

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Press Release

[See Attached]

Vertex and Parion Sciences Establish Collaboration to Develop Epithelial Sodium Channel (ENaC) Inhibitors in Cystic Fibrosis and Other Pulmonary Diseases

-ENaC inhibition aims to restore or improve hydration of cell surfaces in the lungs to improve lung function-

-Parion to receive \$80 million up-front payment with potential for additional development and regulatory milestones and royalty payments-

BOSTON and DURHAM, NC -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Parion Sciences today announced that the companies will collaborate to develop investigational epithelial sodium channel (ENaC) inhibitors for the potential treatment of cystic fibrosis (CF) and other pulmonary diseases. Under the agreement, Vertex gains worldwide development and commercial rights to Parion's investigational ENaC inhibitors, including P-1037 and P-1055, for CF and other pulmonary diseases. P-1037 is currently being evaluated in an exploratory Phase 2a study in people with CF, regardless of genotype, and Vertex and Parion plan to begin an additional Phase 2a study that adds P-1037 to treatment with the investigational combination of lumacaftor and ivacaftor for people with CF who have two copies of the F508del mutation. Parion will receive an \$80 million up-front payment from Vertex with the potential to receive additional development and regulatory milestone payments and tiered royalties related to P-1037 and P-1055 in CF and other pulmonary diseases.

"This collaboration with Parion complements our ongoing work in CF and supports our two key goals in this disease – to increase the number of people eligible for new CF medicines and to enhance the benefit of treatment," said Jeffrey Chodakewitz, M.D., Executive Vice President and Chief Medical Officer at Vertex. "The goal of these planned studies of P-1037 is to determine whether ENaC inhibition can improve lung function in people with CF, including those with mutations unlikely to respond to treatment with the investigational combination of lumacaftor and ivacaftor.

Beyond CF, this agreement helps to diversify our pipeline by providing opportunities to evaluate P-1037 as part of Phase 2a studies in multiple other diseases that impact the lungs."

"ENaC inhibition represents a promising opportunity to potentially enhance the benefit of existing treatments for people with CF, and we have worked diligently to bring P-1037 from our research labs and into Phase 2 development," said Paul Boucher, President and Chief Executive Officer of Parion. "Vertex is the leader in developing new medicines that treat the underlying cause of CF. We are pleased to enter into this collaboration to unify the scientific expertise of both companies to advance P-1037 in CF and other pulmonary diseases."

Cystic fibrosis is a rare genetic disease that is caused by defective or missing cystic fibrosis transmembrane conductance regulatory (CFTR) proteins resulting from mutations in the CFTR gene. The defective or missing CFTR proteins result in poor flow of salt and water into and out of the cell in a number of organs, including the lungs. The defective CFTR protein that causes CF is also believed to increase the function of ENaC, which may contribute to dehydration of the cell surface of lungs in people with CF. In CF, the poor flow of salt and water in cells prevents cilia on the surface of the cell from beating properly, which leads to a buildup of abnormally thick, sticky mucus that can cause chronic lung infections and progressive lung damage, eventually leading to death.

About the Collaboration

Under the terms of the collaboration, Vertex obtained worldwide development and commercial rights to Parion's lead investigational ENaC inhibitors, including P-1037 and P-1055, for the potential treatment of CF and all other pulmonary diseases. Parion received an \$80 million up-front payment and has the potential to receive up to an additional \$490 million in development and regulatory milestone payments for development of ENaC inhibitors in CF, including \$360 million related to global filing and approval milestones. Parion has the potential to receive up to \$370 million in additional development and regulatory milestones for P-1037 and P-1055 in non-CF pulmonary indications. Parion may also receive an additional \$230 million in development and regulatory milestones should Vertex elect to develop an additional ENaC inhibitor from Parion's research program. Parion will receive tiered royalties on potential sales of P-1037 and P-1055 in CF and other pulmonary diseases that range from the low double digits to mid-teens as a percentage

of sales. Vertex will lead future development activities for P-1037 and P-1055 in CF and other pulmonary diseases.

Parion recently initiated an exploratory Phase 2a study of inhaled P-1037 in approximately 120 people with CF. The study is enrolling people with a confirmed diagnosis of CF and any CFTR mutation, including those who have mutations not expected to respond to ivacaftor alone. The study is evaluating the use of P-1037, with and without hypertonic saline, compared to placebo. Patients in the study will continue to receive standard CF medicines.

Preclinical evaluation in human bronchial epithelial cells from people with CF who have two copies of the F508del mutation showed that the addition of investigational P-1037 to the investigational combination of lumacaftor and ivacaftor resulted in an additional increase in both airway surface liquid and cilia beat frequency compared to baseline and to the use of P-1037 or lumacaftor/ivacaftor alone. Improvements in airway surface liquid height and cilia beat frequency are direct measures of increased hydration of the cell surface. This *in vitro* observation suggests that the addition of P-1037 to the investigational combination of lumacaftor and ivacaftor could enable enhanced function of the cell's cilia to clear mucus from the cell surface, potentially resulting in improved lung function. Based on these preclinical results, Vertex is preparing to conduct a Phase 2a study to evaluate whether the addition of P-1037 to the combination of lumacaftor and ivacaftor in people with CF who have two copies of the F508del mutation provides additional benefit as compared to the combination of lumacaftor and ivacaftor alone. This Phase 2a study is expected to begin in early 2016.

Beyond CF, Vertex and Parion plan to conduct additional Phase 2a studies of P-1037 across multiple other pulmonary diseases where the disease results in defective hydration of the cell surfaces in the lung. These diseases include Chronic Obstructive Pulmonary Disease (COPD), Non-CF Bronchiectasis (NCFB) and Primary Ciliary Dyskinesia (PCD). Parion will conduct Phase 2a development in these diseases and retains an option to participate in co-development and co-commercialization activities related to one of these non-CF pulmonary diseases.

Vertex continues to expect 2015 non-GAAP Research and Development and Sales, General and Administrative expenses to be in the range of \$1.05 to \$1.10 billion.

About Cystic Fibrosis

CF is a rare, life-threatening genetic disease affecting approximately 75,000 people in North America, Europe and Australia. Children must inherit two defective *CFTR* genes — one from each parent — to have CF. There are more than 1,900 known mutations in the *CFTR* gene. Some of these mutations, which can be determined by a genetic, or genotyping, test, lead to CF by creating non-working or too few CFTR proteins at the cell surface. The defective or missing CFTR protein results in poor flow of salt and water into and out of the cell in a number of organs, including the lungs. This leads to the buildup of abnormally thick, sticky mucus that can cause chronic lung infections and progressive lung damage. The defective CFTR protein that causes CF is also believed to increase the function of ENaC, which may contribute to dehydration of the cell surface of lungs in people with CF. Today, the median predicted age of survival for a person with CF is between 34 and 47 years, but the median age of death remains in the mid-20s.

About Parion Sciences

Parion Sciences is a development stage biopharmaceutical company dedicated to research, development and commercialization of treatments to improve and extend the lives of patients with innate mucosal surface defense deficiencies of the lung or eye. Parion has a diverse pipeline of pre- clinical and clinical candidates for the treatment of these diseases via distinctive mechanisms of action and approaches. Parion is at the forefront of ENaC development and leverages its scientific expertise in epithelial biology to expand the company's platforms and novel chemical compounds into new potential indications to treat mucosal defects. Parion has received grant funding from the National Institutes of Health and continues to have a long-standing and valued relationship with Cystic Fibrosis Foundation Therapeutics, Inc. For more information, please see our website at www.Parion.com.

About Vertex

Vertex is a global biotechnology company that aims to discover, develop and commercialize innovative medicines so people with serious diseases can lead better lives. In addition to our clinical development programs focused on cystic fibrosis, Vertex has more than a dozen ongoing research programs aimed at other serious and life-threatening diseases.

Founded in 1989 in Cambridge, Mass., Vertex today has research and development sites and commercial offices in the United States, Europe, Canada and Australia. For five years in a row, *Science* magazine has named Vertex one of its Top Employers in the life sciences. For additional information and the latest updates from the company, please visit www.vrtx.com.

Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, Dr. Chodakewitz's statements in the second paragraph of the press release, Mr. Boucher's statements in the third paragraph of the press release, information regarding Vertex's 2015 non-GAAP operating expenses and the information provided regarding the development timeframe of P-1037. While Vertex believes the forward-looking statements contained in this press release are accurate, these forward-looking statements represent the company's beliefs only as of the date of this press release and there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that the company's expectations regarding its 2015 non-GAAP operating expenses may be incorrect (including because one or more of the company's assumptions underlying its expense expectations may not be realized) or that data may not support further development of the compounds subject to the collaboration due to safety, efficacy or other reasons, and other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the company's website at www.vrtx.com. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

(VRTX-GEN)

Vertex Pharmaceuticals Incorporated

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or

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Parion Sciences

Paul Boucher, President & CEO 919-313-1195

EXHIBIT I

Existing SRAs and CTAs

<u>CTAs</u>

[***]

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: August 4, 2015 /s/ Jeffrey M. Leiden

Jeffrey M. Leiden Chief Executive Officer and President

CERTIFICATION

I, Ian F. Smith, 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
- The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2015 /s/ Ian F. Smith

Ian F Smith

Executive Vice President 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 June 30, 2015 (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: August 4, 2015

/s/ Jeffrey M. Leiden

Jeffrey M. Leiden

Chief Executive Officer and President

Date: August 4, 2015

/s/ Ian F. Smith

Ian F. Smith

Executive Vice President 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.