VERTEX PHARMACEUTICALS INC / MA

Form 10-Q October 31, 2016 Table of Contents

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm x}$ 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30,2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT $^{\rm 0}{\rm OF}$ 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 04-3039129
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

50 Northern Avenue, Boston, Massachusetts 02210 (Address of principal executive offices) (Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer 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 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 248,033,389

Class Outstanding at October 21, 2016

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016

TABLE OF CONTENTS

		Page
Part I. Fin	nancial Information	
Item 1.	<u>Financial Statements</u>	<u>2</u>
	Condensed Consolidated Financial Statements (unaudited)	<u>2</u> <u>2</u>
	Condensed Consolidated Statements of Operations - Three and Nine Months Ended September 30,	2
	2016 and 2015	<u> </u>
	Condensed Consolidated Statements of Comprehensive Loss - Three and Nine Months Ended	<u>3</u>
	September 30, 2016 and 2015	<u> </u>
	Condensed Consolidated Balance Sheets - September 30, 2016 and December 31, 2015	<u>4</u>
	Condensed Consolidated Statements of Shareholders' Equity and Noncontrolling Interest - Nine	<u>5</u>
	Months Ended September 30, 2016 and 2015	<u> </u>
	Condensed Consolidated Statements of Cash Flows - Nine Months Ended September 30, 2016 and	<u>6</u>
	2015	
	Notes to Condensed Consolidated Financial Statements	<u>7</u>
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>24</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>34</u>
<u>Item 4.</u>	Controls and Procedures	<u>35</u>
Part II. Or	ther Information	
<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>35</u>
Item 1A.	Risk Factors	35 37
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
Item 6.	<u>Exhibits</u>	<u>38</u>
Signature	S	39

"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.

[&]quot;Vertex," "KALYDE@Oand "ORKAMBT are registered trademarks of Vertex. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

Table of Contents

Part I. Financial Information

Item 1. Financial Statements

VERTEX PHARMACEUTICALS INCORPORATED

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended		Nine Months Ended			
	September	-	September 30,			
	2016	2015	2016	2015		
Revenues:						
Product revenues, net	\$409,689	\$302,511	\$1,229,750	\$593,774		
Royalty revenues	3,835	5,759	12,713	17,628		
Collaborative revenues	259	1,546	1,008	2,999		
Total revenues	413,783	309,816	1,243,471	614,401		
Costs and expenses:						
Cost of product revenues	53,222	30,269	147,165	55,059		
Royalty expenses	855	1,691	2,813	6,068		
Research and development expenses	272,370	246,284	799,238	685,741		
Sales, general and administrative expenses	106,055	99,772	322,921	280,026		
Restructuring expenses, net	8	1,826	1,038	682		
Total costs and expenses	432,510	379,842	1,273,175	1,027,576		
Loss from operations	(18,727)	(70,026)	(29,704)	(413,175)		
Interest expense, net	(20,140)	(21,134)	(60,993)	(63,552)		
Other (expenses) income, net	(167)	(1,326)	3,025	(5,025)		
Loss before provision for income taxes	(39,034)	(92,486)	(87,672)	(481,752)		
Provision for income taxes	503	1,330	24,118	31,760		
Net loss	(39,537)	(93,816)	(111,790)	(513,512)		
Loss (Income) attributable to noncontrolling interest	696	(1,333)	(33,207)	30,909		
Net loss attributable to Vertex	\$(38,841)	\$(95,149)	\$(144,997)	\$(482,603)		
Amounts per share attributable to Vertex common shareholders:						
Net loss:						
Basic	\$(0.16)	\$(0.39)	\$(0.59)	\$(2.00)		
Diluted	\$(0.16)	\$(0.39)	\$(0.59)	\$(2.00)		
Shares used in per share calculations:	•	•	•	·		
Basic	244,920	241,969	244,529	240,749		
Diluted	244,920	241,969	244,529	240,749		
The accompanying notes are an integral part of these condensed consolidated financial statements.						

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Condensed Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands)

	Three Mo	onths Ended	Nine Months Ended		
	Septembe	er 30,	September 3	30,	
	2016	2015	2016	2015	
Net loss	\$(39,537	\$(93,816)	\$(111,790)	\$(513,512)	
Changes in other comprehensive loss:					
Unrealized holding gains (losses) on marketable securities	(96) 56	104	186	
Unrealized gains (losses) on foreign currency forward contracts, net of	2,149	4,546	1,936	572	
tax	2,149	4,540	1,930	312	
Foreign currency translation adjustment	(2,508) (1,384)	(7,709)	(164)	
Total changes in other comprehensive loss	(455	3,218	(5,669)	594	
Comprehensive loss	(39,992	(90,598)	(117,459)	(512,918)	
Comprehensive (income) loss attributable to noncontrolling interest	696	(1,333)	(33,207)	30,909	
Comprehensive loss attributable to Vertex	\$(39,296	\$(91,931)	\$(150,666)	\$(482,009)	
The accompanies notes one or internal next of these condensed consol	idated fine	maial statem	anta		

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

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share amounts)

(in thousands, except sna		•		
	September	: 30,	December	31,
	2016		2015	
Assets				
Current assets:				
Cash and cash	¢.	710 (02	Φ	714760
equivalents	\$	719,692	\$	714,768
Marketable securities,				
available for sale	408,749		327,694	
Restricted cash and cash				
equivalents (VIE)	58,420		78,910	
Accounts receivable, net	182 220		173,838	
Inventories	71,799		57,207	
	11,199		37,207	
Prepaid expenses and	61,012		54,736	
other current assets	1 501 001		1 407 152	
Total current assets	1,501,901		1,407,153	
Property and equipment,	687,613		697,715	
net	•		•	
Intangible assets	284,340		284,340	
Goodwill	50,384		50,384	
Cost method investments	\$53,314		_	
Notes receivable			30,000	
Restricted cash	22,087		22,083	
Other assets	10,002		6,912	
Total assets	\$	2,609,641	\$	2,498,587
Liabilities and				
Shareholders' Equity				
Current liabilities:				
Accounts payable	\$	50,914	\$	74,942
Accrued expenses	292,015		305,820	
Deferred revenues,	0.247		16.206	
current portion	9,247		16,296	
Accrued restructuring	2.022		7.004	
expenses, current portion	3,923		7,894	
Capital lease obligations				
current portion	' 17,772		15,545	
Senior secured term				
loan, current portion	297,751		71,296	
Other liabilities, current				
portion	51,219		14,374	
Total current liabilities	722 941		506 167	
	722,841		506,167	
Deferred revenues,	6,559		9,714	
excluding current portion	1			
Accrued restructuring	2 21 4		7.464	
expenses, excluding	3,314		7,464	
current portion				

Capital lease obligations	S, 21 710				42 023		
excluding current portio	n ^{31,/19}				42,923		
Deferred tax liability	133,270				110,439		
Construction financing							
lease obligation,	473,073				472,611		
excluding current portio	n						
Senior secured term							
loan, net of current					223,863		
portion and discount							
Other liabilities,	30,524				31,778		
excluding current portio	n 30,324				31,770		
Total liabilities	1,401,300)			1,404,959	9	
Commitments and							
contingencies							
Shareholders' equity:							
Preferred stock, \$0.01							
par value; 1,000,000							
shares authorized; none							
issued and outstanding a	ıt						
September 30, 2016 and							
December 31, 2015							
Common stock, \$0.01							
par value; 500,000,000							
and 500,000,000 shares							
authorized at September	•						
30, 2016 and December							
31, 2015, respectively;	2,446				2,427		
248,028,962 and	2,440				2,727		
246,306,818 shares							
issued and outstanding a	ıt						
September 30, 2016 and							
December 31, 2015,							
respectively							
Additional paid-in	6,429,726	5			6,197,500	0	
capital	0,125,720	,			0,177,50	O	
Accumulated other							
comprehensive (loss)	(3,845)		1,824		
income							
Accumulated deficit	(5,406,78	1)		(5,261,78	34)
Total Vertex	1,021,546	5			939,967		
shareholders' equity		,					
Noncontrolling interest	186,795				153,661		
Total shareholders' equi	tyl,208,341				1,093,628	8	
Total liabilities and	\$	2,609,641			\$	2,498,587	
shareholders' equity			_				
The accompanying notes are an integral part of these condensed consolidated financial statements.							

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

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

(in thousands)

	Common	1 Stock		Accumulate	d			
	Shares	Amount	Additional Paid-in Capital	Other Comprehens (Loss) Income	Accumulated Deficit	Total Vertex Shareholders Equity	, Noncontrolli Interest	Total ng Shareholders' Equity
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	_	_	_	594	_	594	_	594
Net loss Issuance of	_	_	_	_	(482,603)	(482,603)	(30,909)	(513,512)
common stock under benefit plans	3,882	34	139,419	_	_	139,453	_	139,453
Stock-based compensation expense	_	_	189,697	_	_	189,697	_	189,697
Noncontrolling interest upon consolidation	_	\$—	\$—	\$ <i>—</i>	\$—	\$—	\$ 164,317	\$164,317
Balance at September 30, 2015	₅ 245,646	\$2,419	\$6,106,270	\$ 1,511	\$(5,188,053)	\$922,147	\$ 154,585	\$1,076,732
Balance at December 31, 2015 Other	246,307	\$2,427	\$6,197,500	\$ 1,824	\$(5,261,784)	\$939,967	\$ 153,661	\$1,093,628
comprehensive loss, net of tax	_	_	_	(5,669)	_	(5,669)	_	(5,669)
Net (loss) income Issuance of	_	_	_	_	(144,997)	(144,997)	33,207	(111,790)
common stock under benefit plans	1,722	19	50,875	_	_	50,894	_	50,894
Stock-based compensation expense	_	_	181,351	_	_	181,351	(73)	181,278
Balance at September 30, 2016	5248,029	\$2,446	\$6,429,726	\$ (3,845)	\$(5,406,781)	\$1,021,546	\$ 186,795	\$1,208,341
The accompanying								

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Condensed Consolidated Statements of Cash Flows (unaudited)

(in thousands)

(in thousands)			
	Nine Mon		
	September	: 30,	
	2016	2015	
Cash flows from operating activities:			
Net loss	\$(111,790) \$(513,512	2)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	178,623	186,379	
Depreciation and amortization expense	45,947	46,596	
Deferred income taxes	23,544	7,793	
Other non-cash items, net	(904) (2,876)
Changes in operating assets and liabilities:			
Accounts receivable, net	(9,760) (88,735)
Inventories) (16,127)
Prepaid expenses and other assets)
Accounts payable		6,283	
Accrued expenses and other liabilities	26,121	•	
Accrued restructuring expense)
Deferred revenues	(10,204)
Net cash provided by (used in) operating activities	91,379	(394,575	-
Cash flows from investing activities:	,	,	_
Purchases of marketable securities	(616,625) (292,135)
Maturities of marketable securities	535,379		ĺ
Expenditures for property and equipment	(41,775) (32,775)
Decrease in restricted cash and cash equivalents (VIE)	20,490	14,830	
Investments in other entities	(20,000) —	
Investment in CRISPR Series B preferred stock	(3,075) —	
(Increase) decrease in other assets	(90) (982)
Increase in restricted cash and cash equivalents	(3) (21,980)
Payment for acquisition of variable interest entity		(80,000)
Net cash (used in) provided by investing activities	(125,699	391,546	
Cash flows from financing activities:			
Issuances of common stock under benefit plans	51,165	139,689	
Payments on capital lease obligations	(13,330) (16,515)
Payments on construction financing lease obligation	(356) (281)
Proceeds from capital lease financing	2,030	13,386	
Net cash provided by financing activities	39,509	136,279	
Effect of changes in exchange rates on cash	(265) (2,259)
Net increase in cash and cash equivalents	4,924	130,991	
Cash and cash equivalents—beginning of period	714,768	625,259	
Cash and cash equivalents—end of period	\$719,692	\$756,250)
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$64,662	\$64,231	
Cash received from (paid for) income taxes	\$1,617	\$(1,261)
Capitalization of costs related to construction financing lease obligation	\$824	\$ —	

Issuances of common stock exercises from employee benefit plans receivable \$19 \$(236) The Company has reclassified certain amounts in the period ending September 30, 2015 between operating, investing, and financing to correct improper classifications.

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

<u>Table of Contents</u>
VERTEX PHARMACEUTICALS INCORPORATED
Notes to Condensed Consolidated Financial Statements
(unaudited)

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 September 30, 2016 and 2015.

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, 2015, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 that was filed with the Securities and Exchange Commission (the "SEC") on February 16, 2016 (the "2015 Annual Report on Form 10-K"). The Company has reclassified certain amounts in the condensed consolidated balance sheets for the period ended December 31, 2015 between Accounts receivables, net and Prepaid expenses and other current assets to conform to the current year presentation. Use of Estimates and Summary of Significant Accounting Policies

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

The Company's significant accounting policies are described in Note A, "Nature of Business and Accounting Policies," in the 2015 Annual Report on Form 10-K.

Recent Accounting Pronouncements

In 2014, the Financial Accounting Standards Board ("FASB") issued amended guidance applicable to revenue recognition that will be effective for the year ending December 31, 2018. Early adoption is permitted for the year-ending December 31, 2017. The new guidance applies a more principle based approach to recognizing revenue. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. The Company is in the process of evaluating the new guidance and determining the expected effect on its consolidated financial statements.

In 2016, the FASB issued amended guidance applicable to leases that will be effective for the year ending December 31, 2019. Early adoption is permitted. This update requires an entity to recognize assets and liabilities for leases with lease terms of more than 12 months on the balance sheet. The Company is in the process of evaluating the new guidance and determining the expected effect on its consolidated financial statements.

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

In 2016, the FASB issued amended guidance applicable to share-based compensation to employees that will be effective for the year ending December 31, 2017. Early adoption is permitted. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The Company is in the process of evaluating the new guidance and determining the expected effect on its consolidated financial statements.

In 2016, the FASB issued amended guidance for the classification of certain cash receipts and cash payments on the statement of cash flows to reduce existing diversity in practice. The new accounting guidance is effective for the year ending December 31, 2017. Early adoption is permitted. The Company is in the process of evaluating the new guidance and determining the expected effect on its consolidated financial statements.

For a discussion of other recent accounting pronouncements please refer to Note A, "Nature of Business and Accounting Policies—Recent Accounting Pronouncements," in the 2015 Annual Report on Form 10-K. The Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2016 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 Customers' locations. The Company calculates gross product revenues based on the price that the Company charges its Customers. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and Customer fees, (b) estimated government and private payor rebates, chargebacks and discounts, (c) estimated reserves for expected product returns and (d) estimated costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers.

The Company makes significant estimates and judgments that materially affect the Company's recognition of net product revenues. In certain instances, the Company may be unable to reasonably conclude that the price is fixed or determinable at the time of delivery, in which case it defers the recognition of revenues. Once the Company is able to determine that the price is fixed or determinable, it recognizes the revenues associated with the units in which revenue recognition was deferred.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 30, 2016:

	Rebates,			
Trade	Chargebacks	Product	Other	Total
Allowancersd		Returns	Incentives	Total
	Discounts			
(in thous	ands)			
\$2,089	\$ 44,669	\$1,228	\$ 1,310	\$49,296
14,680	98,242	1,631	5,547	120,100
(82)	(1,081)	(205)	(80)	(1,448)
(14,505)	(70,718)	(345)	(5,607)	(91,175)
()	Allowand in thous \$2,089 14,680	Frade Chargebacks Allowancand Discounts (in thousands) 52,089 \$ 44,669 14,680 98,242	Trade Chargebacks Product Allowancesd Returns Discounts 1 52,089 \$ 44,669 \$ 1,228 14,680 98,242 1,631 82) (1,081) (205	Trade Chargebacks Product Other Allowancersd Returns Incentives Discounts In thousands) \$1,228 \$1,310 \$2,089 \$44,669 \$1,228 \$1,310 \$14,680 98,242 1,631 5,547 \$22 (1,081 (205 (80)

Balance at September 30, 2016 \$2,182 \$71,112 \$2,309 \$1,170 \$76,773

In the three and nine months ended September 30, 2016, the Company sold ORKAMBI in France pursuant to early access programs. The Company has not recognized any product revenues based on these sales because the price is not fixed or determinable due to the ongoing negotiations regarding the reimbursement rate for ORKAMBI in France. If the negotiated reimbursement rate in France is lower than the price currently being paid by Customers in France under these programs, the Company would reimburse the difference between such prices to the Customers. The cash received from sales in France is included as a liability on the Company's condensed consolidated balance sheet, and the increase in "other liabilities, current portion" from December 31, 2015 to September 30, 2016 is primarily due to this liability.

C. Collaborative Arrangements

Cystic Fibrosis Foundation Therapeutics Incorporated

The Company has a research, development and commercialization agreement with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") that was originally entered into in May 2004, and was most recently amended on October 13, 2016 (the "2016 Amendment"). Pursuant to the agreement, as amended, the Company has agreed to pay royalties ranging from low single digits to mid-single digits on potential sales of certain compounds first synthesized and/or tested between March 1, 2014 and August 31, 2016 and tiered royalties ranging from single digits to sub-teens on any approved drugs first synthesized and/or tested during a research term on or before February 28, 2014, including KALYDECO (ivacaftor), ORKAMBI (lumacaftor in combination with ivacaftor), lumacaftor and VX-661 (tezacaftor). For combination products, such as ORKAMBI, sales will be allocated equally to each of the active pharmaceutical ingredients in the combination product consistent with the allocation of net sales for ORKAMBI since the Company began marketing ORKAMBI in mid-2015.

In each of the fourth quarter of 2015 and first quarter of 2016, CFFT earned a commercial milestone payment of \$13.9 million from the Company upon achievement of certain sales levels of lumacaftor. There are no additional commercial milestone payments payable by the Company to CFFT pursuant to the agreement. Pursuant to the 2016 Amendment, the CFFT provided the Company an upfront program award of \$75.0 million and agreed to provide development funding to the Company of up to \$6.0 million annually.

The Company began marketing KALYDECO in the United States and certain countries in the European Union in 2012 and began marketing ORKAMBI in the United States in 2015. The Company received approval for ORKAMBI In the European Union in 2015 and in Canada and Australia in 2016. The Company has royalty obligations to CFFT for ivacaftor, lumacaftor and VX-661 until the expiration of patents covering those compounds. The Company has patents in the United States and European Union covering the composition-of-matter of ivacaftor that expire in 2027 and 2025, respectively, subject to potential patent extensions. The Company has patents in the United States and European Union covering the composition-of-matter of lumacaftor that expire in 2030 and 2026, respectively, subject to potential extension. The Company has patents in the United States and European Union covering the composition-of-matter of VX-661 (tezacaftor) that expire in 2027 and 2028, respectively, subject to potential extension.

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

CRISPR Therapeutics AG

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

The Company will fund all of the discovery activities conducted pursuant to the CRISPR Agreement. For potential hemoglobinapathy treatments, including treatments for sickle cell disease, the Company and CRISPR will share equally all research and development costs and worldwide revenues. For other targets that the Company elects to license, the Company would lead all development and global commercialization activities. For each of up to six targets that the Company elects to license, other than hemoglobinapathy targets, CRISPR has the potential to receive up to \$420.0 million in development, regulatory and commercial milestones and royalties on net product sales. The Company may terminate the CRISPR Agreement upon 90 days' notice to CRISPR prior to any product receiving marketing approval or upon 270 days' notice after a product has received marketing approval. The CRISPR Agreement also may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the CRISPR Agreement will continue in effect until the expiration of the Company's payment obligations under the CRISPR Agreement.

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 timing of achieving the milestones, estimates of future product sales and the appropriate discount rates. The Company bases its estimate of the probability of achieving the relevant milestones on industry data for similar assets and its own experience. The discount rates used in the valuation model represent a measure of credit risk and market risk associated with settling the liabilities. Significant judgment is used in determining the appropriateness of these assumptions at each reporting period. Changes in these assumptions could have a material effect on the fair value of the contingent milestone and royalty payments. The following collaborations are reflected in the Company's financial statements as consolidated VIEs:

Parion Sciences, Inc.

License and Collaboration Agreement

In June 2015, the Company entered into a strategic collaboration and license agreement (the "Parion Agreement") with Parion Sciences, Inc. ("Parion"). Pursuant to the Parion Agreement, the Company is collaborating with Parion to develop investigational epithelial sodium channel ("ENaC") inhibitors, including VX-371 (formerly P-1037) and

VX-551 (formerly P-1055), for the potential treatment of cystic fibrosis, or CF, and other pulmonary diseases. The Company is leading development activities for VX-371 and VX-551 and is responsible for all costs, subject to certain exceptions, related to development and commercialization of the compounds.

Pursuant to the Parion Agreement, the Company has worldwide development and commercial rights to Parion's lead investigational ENaC inhibitors, VX-371 and VX-551, for the potential treatment of CF and all other pulmonary diseases and

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

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

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

The Company determined that 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 affect 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.

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:

> June 4, 2015 (in

thousands) \$80,000

Up-front payment Fair value of contingent milestone and royalty payments 175,340

\$ 255,340

Allocation of Assets and Liabilities

The Company allocated the total consideration to the assets and liabilities of Parion. The following table summarizes the final fair values of the assets and liabilities recorded on the effective date of the agreement:

> June 4, 2015

	(in
	thousands)
Intangible assets	\$255,340
Net assets attributable to noncontrolling interests	(164,317)
Deferred tax liability	(91,023)
Net other assets (liabilities)	(10,468)
Goodwill	\$10,468

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

The Company recorded \$255.3 million of intangible assets on the Company's condensed consolidated balance sheet for Parion's in-process research and development assets. These in-process research and development assets relate to Parion's pulmonary ENaC platform, including the intellectual property related to VX-371 and VX-551, that are licensed by Parion to the Company. The Company recorded Parion's assets and liabilities including (i) the fair value of the intangible assets, (ii) the fair value of the net assets attributable to noncontrolling interest, and (iii) a deferred tax liability resulting from a basis difference in the intangible assets and certain other net liabilities held by Parion. The difference between the fair value of the consideration paid and the fair value of Parion's net assets was recorded as goodwill.

BioAxone Biosciences, Inc.

In October 2014, the Company entered into a license and collaboration agreement (the "BioAxone Agreement") with BioAxone Biosciences, Inc. ("BioAxone"), 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 recorded an in-process research and development intangible asset of \$29.0 million for VX-210 and a corresponding deferred tax liability of \$11.3 million attributable to BioAxone. The Company holds an option to purchase BioAxone at a predetermined price. The option expires on the earliest of (a) the day the FDA accepts the Biologics License Application submission for VX-210, (b) the day the Company elects to continue the license instead of exercising the option to purchase BioAxone and (c) March 15, 2018, subject to the Company's option to extend this date by one year. Aggregate VIE Financial Information

An annual to the second of the

An aggregate summary of net loss attributable to noncontrolling interest related to the Company's VIEs for the three and nine months ended September 30, 2016 and 2015 is as follows:

and mile monais ended september 50, 2010 and 2015 is as follows:	Ended S	Ended September		ths Ended r 30,
	30, 2016	2015	2016	2015
	(in thou	sands)		
Loss attributable to noncontrolling interest before provision for income taxes	\$2,406	\$1,743	\$6,080	\$3,322
(Benefit from) provision for income taxes	(510)	777	20,063	30,367
(Increase) decrease in fair value of contingent milestone and royalty payment	s(1,200)	(3,853)	(59,350)	(2,780)
Net (income) loss attributable to noncontrolling interest	\$696	\$(1,333)	\$(33,207)	\$30,909

The increases in the fair value of the contingent milestone and royalty payments in the nine months ended September 30, 2016 were primarily due to a Phase 2 clinical trial of VX-371, a compound being developed pursuant to the Parion Agreement, achieving its primary safety endpoint in the second quarter of 2016. The fair value of the contingent milestone and royalty payments also reflects changes in market interest rates and the time value of money. During the three and nine months ended September 30, 2016 and 2015, the increase (decrease) in the fair value of the contingent milestone and royalty payments related to the Company's VIEs was as follows:

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

Three Months Nine Months Ended **Ended September** September 30, 30. 2016 2015 2016 2015 (in thousands) \$1,100 \$4,481 \$58,500 \$2,860 Parion BioAxone 100 (80 (628) 850

As of September 30, 2016, the fair value of the contingent milestone and royalty payments related to the Parion Agreement and the BioAxone Agreement was \$232.5 million and \$28.8 million, respectively. As of December 31, 2015, the fair value of the contingent milestone and royalty payments related to the Parion collaboration and the BioAxone collaboration was \$179.0 million and \$28.0 million, respectively.

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

	Septemb 30, 2016	er December 31, 2015
	(in thous	ands)
Restricted cash and cash equivalents (VIE)	\$58,420	\$ 78,910
Prepaid expenses and other current assets	2,360	3,138
Intangible assets	284,340	284,340
Goodwill	19,391	19,391
Other assets	382	455
Accounts payable	1,122	676
Taxes payable	6,263	24,554
Other current liabilities	1,121	7,100
Deferred tax liability, net	133,270	110,438
Other liabilities	300	300
Noncontrolling interest	186,795	153,661

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

Other Collaborations

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

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

Moderna Therapeutics, Inc.

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

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

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

Janssen Pharmaceuticals, Inc.

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

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

Janssen Inc. is responsible for costs related to the development and commercialization of the compounds. During the three and nine months ended September 30, 2016, the Company recorded reimbursement for these development activities of \$2.8 million and \$10.6 million, respectively. During the three and nine months ended September 30, 2015, the Company recorded reimbursement for these development activities of \$4.0 million and \$18.7 million, respectively. The reimbursements are recorded as a reduction to development expense in the Company's condensed consolidated statements of operations primarily due to the fact that Janssen Inc. directs the activities and selects the suppliers associated with these activities.

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 in the following table in the computation of the net loss per share attributable to Vertex common shareholders calculations because the effect would have been anti-dilutive during each period:

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

Three Months Nine Months Ended Ended September 30, September 30, 2016 2015

(in thousands)

Stock options 12,947 12,025 12,947 12,025

Unvested restricted stock and restricted stock units 3,624 3,367 3,624 3,367

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:

Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a Level 1:market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active Level 2: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 September 30, 2016, the Company's investments were primarily in money market funds, short-term government-sponsored enterprise securities, corporate debt securities and commercial paper.

As of September 30, 2016, 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 and short-term government-sponsored enterprise securities. The Company's financial assets valued based on Level 2 inputs consisted of corporate debt securities and commercial paper, which consisted of investments in highly-rated investment-grade corporations.

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

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

	Fair Value Measurements as of September 30, 2016					
	Fair Value Hierarchy					
	Total	Level 1	Level 2	Level	3	
	(in thousan	ids)				
Financial assets carried at fair value:						
Cash equivalents:						
Money market funds	\$101,844	\$101,844	\$ —	\$	_	
Marketable securities:						
Government-sponsored enterprise securities	130,431	130,431	_			
Corporate debt securities	146,942	_	146,942			
Commercial paper	131,376		131,376			
Prepaid and other current assets:						
Foreign currency forward contracts	7,644	_	7,644			
Other assets:						
Foreign currency forward contracts	217	_	217			
Total financial assets	\$518,454	\$232,275	\$286,179	\$		
Financial liabilities carried at fair value:						
Other liabilities, current portion:						
Foreign currency forward contracts	\$(1,459)	\$ —	\$(1,459)	\$		
Other liabilities, excluding current portion:						
Foreign currency forward contracts	(315)		(315)			
Total financial liabilities	\$(1,774)	\$—	\$(1,774)	\$		

Table of Contents

VERTEX PHARMACEUTICALS INCORPORATED

Notes to Condensed Consolidated Financial Statements (unaudited)

	Fair Value Measurements as of December 31, 2015 Fair Value Hierarchy				
	Total	Level 1	Level 2	Level	3
	(in thousands)				
Financial instruments carried at fair value (asset position):					
Cash equivalents:					
Money market funds	\$199,507	\$199,507	\$—	\$	
Government-sponsored enterprise securities	85,994	85,994			
Commercial paper	34,889		34,889		
Corporate debt securities	11,533	_	11,533		
Marketable securities:					
Government-sponsored enterprise securities	87,162	87,162	_		
Commercial paper	99,123		99,123		
Corporate debt securities	141,409	_	141,409		
Prepaid and other current assets:					
Foreign currency forward contracts	5,161	_	5,161		
Other assets:					
Foreign currency forward contracts	605	\$ —	605	\$	
Total financial assets	\$665,383	\$372,663	\$292,720	\$	
Financial instruments carried at fair value (liability position):					
Other liabilities, current portion:					
Foreign currency forward contracts	\$(769)	\$ —	\$(769)	\$	
Other liabilities, excluding current portion:	, , ,		, ,		
Foreign currency forward contracts	(132)		(132)		
Total financial liabilities	. ,	\$	\$(901)	\$	

The Company's VIEs invested in cash equivalents consisting of money market funds of \$57.9 million as of September 30, 2016, 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.