VERTEX PHARMACEUTICALS INC / MA
Form 10-Q
November 06, 2014
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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 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

or

o 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	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	240,521,809
Class	Outstanding at October 31, 2014

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FOR THE QUARTER ENDED SEPTEMBER 30, 2014

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

“Vertex,” “INCIVEK®” and “KALYDECO™” are registered trademarks of Vertex. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q, including “INCIVO™” and “TELAVIC™,” are the property of their respective owners.

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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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product revenues, net	$137,099	$186,653	$362,879	$708,823
Royalty revenues	8,386	27,012	32,134	119,705
Collaborative revenues	33,502	8,035	40,846	32,290
Total revenues	178,987	221,700	435,859	860,818
Costs and expenses:				
Cost of product revenues	10,208	20,048	28,435	75,698
Royalty expenses	3,976	7,291	18,525	32,315
Research and development expenses	190,939	219,442	654,043	643,636
Sales, general and administrative expenses	75,224	86,427	226,882	283,133
Restructuring expenses	40,843	12,048	46,761	12,863
Intangible asset impairment charge	—	—	—	412,900
Total costs and expenses	321,190	345,256	974,646	1,460,545
Loss from operations	(142,203)	(123,556)	(538,787)	(599,727)
Interest expense, net	(20,384)	(95)	(51,686)	(10,109)
Other income (expense), net	(3,990)	4,751	34,192	3,360
Loss from continuing operations before provision for (benefit from) income taxes	(166,577)	(118,900)	(556,281)	(606,476)
Provision for (benefit from) income taxes	3,419	2,555	4,915	(123,774)
Loss from continuing operations	(169,996)	(121,455)	(561,196)	(482,702)
Loss from discontinued operations, net of tax benefit of $0, $3,306, $0 and $9,089, respectively	(64)	(7,207)	(703)	(20,299)
Loss from discontinued operations attributable to noncontrolling interest (Alios)	—	4,530	—	13,688
Net loss from discontinued operations attributable to Vertex	(64)	(2,677)	(703)	(6,611)
Net loss attributable to Vertex	$(170,060)	$(124,132)	$(561,899)	$(489,313)
Net loss per share from continuing operations:				
Basic	$(0.72)	$(0.53)	$(2.40)	$(2.17)
Diluted	$(0.72)	$(0.53)	$(2.40)	$(2.17)
Net loss from discontinued operations per share attributable to Vertex common shareholders:				
Basic	$—	$(0.01)	$—	$(0.03)
Diluted	$—	$(0.01)	$—	$(0.03)
Net loss per share attributable to Vertex common shareholders:				
Basic	$(0.72)	$(0.54)	$(2.40)	$(2.20)
Diluted	$(0.72)	$(0.54)	$(2.40)	$(2.20)
Shares used in per share calculations:				
Basic	236,137	230,505	234,207	222,764
Diluted	236,137	230,505	234,207	222,764

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Loss from continuing operations	$(169,996)	$(121,455)	$(561,196)	$(482,702)
Loss from discontinued operations	(64)	(7,207)	(703)	(20,299)
Net loss	(170,060)	(128,662)	(561,899)	(503,001)
Changes in other comprehensive loss:				
Unrealized holding gains (losses) on marketable securities	(30)	166	25	7
Unrealized gains on foreign currency forward contracts	1,838	—	1,713	—
Foreign currency translation adjustment	(624)	514	(271)	(7)
Total changes in other comprehensive loss	1,184	680	1,467	—
Comprehensive loss	(168,876)	(127,982)	(560,432)	(503,001)
Comprehensive loss attributable to noncontrolling interest (Alios)	—	4,530	—	13,688
Comprehensive loss attributable to Vertex	$(168,876)	$(123,452)	$(560,432)	$(489,313)

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

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VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$718,563	$569,299
Marketable securities, available for sale	759,174	895,777
Accounts receivable, net	114,308	85,517
Inventories	16,753	14,147
Prepaid expenses and other current assets	41,298	23,836
Total current assets	1,650,096	1,588,576
Restricted cash	121	130
Property and equipment, net	720,878	696,911
Goodwill	30,992	30,992
Other assets	3,999	2,432
Total assets	$2,406,086	$2,319,041
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$38,472	$49,327
Accrued expenses	244,279	271,077
Deferred revenues, current portion	21,210	21,510
Accrued restructuring expenses, current portion	38,384	14,286
Capital lease obligations, current portion	18,124	16,893
Other liabilities, current portion	11,709	24,736
Total current liabilities	372,178	397,829
Deferred revenues, excluding current portion	34,723	49,459
Accrued restructuring expenses, excluding current portion	17,218	14,067
Capital lease obligations, excluding current portion	42,200	48,754
Construction financing lease obligation, excluding current portion	473,172	440,937
Senior secured term loan	294,740	—
Other liabilities, excluding current portion	15,950	11,590
Total liabilities	1,250,181	962,636
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding at September 30, 2014 and December 31, 2013	—	—
Common stock, $0.01 par value; 300,000,000 shares authorized at September 30, 2014 and December 31, 2013; 240,238,090 and 233,788,852 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	2,375	2,320
Additional paid-in capital	5,681,163	5,321,286
Accumulated other comprehensive gain (loss)	1,161	(306)
Accumulated deficit	(4,528,794)	(3,966,895)
Total shareholders' equity	1,155,905	1,356,405
Total liabilities and shareholders' equity	$2,406,086	$2,319,041

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Vertex Shareholders' Equity	Noncontrolling Interest in Discontinued Operations (Alios)	Total Shareholders' Equity	Redeemable Noncontrolling Interest (Alios)
	Shares	Amount							
Balance, December 31, 2012	217,287	$2,149	$4,519,448	$(550)	$(3,521,867)	$999,180	$196,672	$1,195,852	$38,530
Unrealized holding gains on marketable securities				7		7		7	
Foreign currency translation adjustment				(7)		(7)		(7)	
Net loss					(489,313)	(489,313)	(13,688)	(503,001)	
Issuance of common stock under benefit plans	8,029	79	248,207			248,286	(70)	248,216	
Convertible senior subordinated notes (due 2015) conversion	8,276	83	402,182			402,265		402,265	
Stock-based compensation expense			104,470			104,470	348	104,818	
Change in liquidation value of noncontrolling interest							(1,094)	(1,094)	1,094
Balance, September 30, 2013	233,592	$2,311	$5,274,307	$(550)	$(4,011,180)	$1,264,888	$182,168	$1,447,056	$39,624
Balance, December 31, 2013	233,789	$2,320	$5,321,286	$(306)	$(3,966,895)	$1,356,405	$—	$1,356,405	$—
Unrealized holding gains on marketable				25		25		25	

securities									
Unrealized gains on foreign currency forward contracts				1,713		1,713		1,713	
Foreign currency translation adjustment				(271)		(271)		(271)	
Net loss attributable to Vertex					(561,899)	(561,899)		(561,899)	
Issuance of common stock under benefit plans	6,449	55	223,812			223,867		223,867	
Stock-based compensation expense			136,065			136,065		136,065	
Balance, September 30, 2014	240,238	$2,375	$5,681,163	$1,161	$(4,528,794)	$1,155,905	$—	$1,155,905	$—

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

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

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Loss from continuing operations	$(561,196)	$(482,702)
Loss from discontinued operations	(703)	(20,299)
Net loss	(561,899)	(503,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	46,921	30,734
Stock-based compensation expense	135,160	103,933
Other non-cash based compensation expense	—	5,856
Intangible asset impairment charge	—	412,900
Deferred income taxes	—	(130,164)
Impairment of property and equipment	978	6,650
Write-down of inventories to net realizable value	—	10,358
Other non-cash items, net	7	5,307
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,315)	20,737
Inventories	(4,901)	5,212
Prepaid expenses and other assets	(19,110)	(16,477)
Accounts payable	(5,544)	(46,005)
Accrued expenses and other liabilities	12,210	26,172
Accrued restructuring expense	27,249	2,810
Deferred revenues	(15,085)	(15,447)
Net cash used in operating activities	(391,329)	(80,425)
Cash flows from investing activities:		
Purchases of marketable securities	(1,066,772)	(1,850,015)
Sales and maturities of marketable securities	1,203,400	1,842,361
Expenditures for property and equipment	(36,525)	(36,922)
Decrease in restricted cash and cash equivalents	9	31,807
Decrease in restricted cash and cash equivalents (Alios)	—	18,924
Decrease (increase) in deposits	(92)	1,094
Net cash provided by investing activities	100,020	7,249
Cash flows from financing activities:		
Issuances of common stock from employee benefit plans	201,274	242,360
Payments to redeem secured notes (due 2015)	—	(158)
Payments on capital lease obligations	(17,215)	(14,601)
Payments on construction financing lease obligation	(45,438)	(63,242)
Proceeds from senior secured term loan	294,383	—
Payments returned related to construction financing lease obligation	8,050	—
Net cash provided by financing activities	441,054	164,359
Effect of changes in exchange rates on cash	(481)	2,591
Net increase in cash and cash equivalents	149,264	93,774
Cash and cash equivalents—beginning of period	569,299	489,407
Cash and cash equivalents—end of period	$718,563	$583,181
Supplemental disclosure of cash flow information:		

Cash paid for interest	$2,817	$7,637
Cash paid for income taxes	$798	$—
Conversion of convertible senior subordinated notes (due 2015) for common stock	$—	$399,842
Unamortized deferred debt issuance costs exchanged	$—	$4,230
Capitalization of costs related to construction financing lease obligation	$25,564	$176,484
Assets acquired under capital lease	$8,985	$38,520
Issuances of common stock exercises from employee benefit plans receivable	$23,035	$—

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

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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 and (ii) its wholly-owned subsidiaries. The condensed consolidated statements of operations in this Quarterly Report on Form 10-Q reflect the operations of Alios BioPharma, Inc. (“Alios”), as well as direct expenses Vertex incurred as a result of the Alios Agreement, as discontinued operations. 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, 2014 and 2013.

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, 2013, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 that was filed with the Securities and Exchange Commission (the “SEC”) on February 11, 2014 (the "2013 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, noncontrolling interest (Alios), the consolidation and deconsolidation of a VIE, leases, discontinued operations presentation 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 2013 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 2013 Annual Report on Form 10-K. The Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2014 that had a material effect on the Company's condensed consolidated financial statements.

In the second quarter of 2014, the Financial Accounting Standards Board issued amended guidance applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2017. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption is not permitted. The new guidance applies a more principles-based approach to recognizing revenue. The Company is evaluating the new guidance and the expected effect on the Company’s condensed consolidated financial statements.

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B. Product Revenues, Net

The Company sells its products principally to a limited number of major and selected regional wholesalers and specialty pharmacy providers in North America as well as government-owned and supported customers in Europe (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 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 nine months ended September 30, 2014:

	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
	(in thousands)				
Balance at December 31, 2013	$1,535	$68,244	$15,799	$1,555	$87,133
Provision related to current period sales	6,772	30,720	1,691	1,210	40,393
Adjustments related to prior period sales	(8)	5,052	(2,778)	(72)	2,194
Credits/payments made	(7,255)	(67,557)	(6,052)	(1,808)	(82,672)
Balance at September 30, 2014	$1,044	$36,459	$8,660	$885	$47,048

C. Collaborative Arrangements

Janssen Pharmaceutica NV

In 2006, the Company entered into 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. Under the Janssen HCV Agreement, Janssen NV agreed to be responsible for 50% of the drug development costs incurred under the development program for the parties’ territories (North America for the Company, and the rest of the world, other than specified countries in Asia, for Janssen NV) and has exclusive rights to commercialize telaprevir in its territories including Europe, South America, the Middle East, Africa and Australia. In November 2013, the Company and Janssen NV amended the collaboration agreement (the "2013 Janssen HCV Amendment").

Janssen NV made a $165.0 million up-front license payment to the Company in 2006. The Company amortized the up-front license payment over the Company’s estimated period of performance under the Janssen HCV Agreement through November 2013. As of November 2013, the effective date of the 2013 Janssen HCV Amendment, there was $32.1 million remaining in deferred revenues related to this up-front license payment.

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Janssen NV paid the Company a tiered royalty averaging in the mid-20% range as a percentage of net sales of INCIVO in Janssen NV’s territories through 2013. Janssen NV was, and continues to be, responsible for certain third-party royalties on net sales of INCIVO in its territories.

Pursuant to the 2013 Janssen HCV Amendment, (i) Janssen NV made a payment of $152.0 million to the Company in the fourth quarter of 2013; (ii) Janssen NV's obligations to pay the Company royalties on net sales of INCIVO (telaprevir) terminated after the fourth quarter of 2013; and (iii) Janssen NV received a fully-paid license to commercialize INCIVO in its territories, subject to the continued payment of certain third-party royalties on its net sales of INCIVO.

The Company determined that the 2013 Janssen HCV Amendment was a material modification to the Janssen HCV Agreement because there was a material change to the consideration and deliverables under the agreement and determined that there is one undelivered element under the Janssen HCV Agreement, as amended, which is the continuation of certain telaprevir development activities. The Company recognized $182.4 million of collaborative revenues pursuant to the Janssen HCV Agreement in the fourth quarter of 2013. This amount was primarily attributable to (i) the residual consideration received from Janssen NV, including the $152.0 million fourth quarter 2013 payment and the remaining deferred revenues related to the 2006 up-front payment, less (ii) the best estimate of selling price for the remaining telaprevir development activities. As of September 30, 2014, the remaining deferred revenue balance related to the Janssen NV collaboration was $3.3 million and will be recognized as collaborative revenues as telaprevir development program activities are completed. In addition to the collaborative revenues, the Company will continue to record royalty revenues and corresponding royalty expenses related to third-party royalties that Janssen NV remains responsible for based on INCIVO net sales.

The Janssen HCV Agreement will continue in effect until the expiration of Janssen NV’s third-party royalty obligations, which expire on a country-by-country basis on the later of (a) the last-to-expire patent covering INCIVO or (b) the last required payment by Janssen NV to the Company pursuant to the agreement. In the European Union, the Company has a patent covering the composition-of-matter of INCIVO that expires in 2026.

During the three and nine months ended September 30, 2014 and 2013, the Company recognized the following revenues attributable to the Janssen HCV collaboration:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Royalty revenues (INCIVO)	$2,284	$20,994	$12,917	$104,108
Collaborative revenues:				
Up-front and amendment payments revenues	$—	$3,107	$—	$9,321
Net reimbursement for telaprevir development costs	1,390	1,413	4,262	1,422
Reimbursement for manufacturing services	—	—	—	10,299
Total collaborative revenues attributable to the Janssen HCV collaboration	$1,390	$4,520	$4,262	$21,042
Total revenues attributable to the Janssen HCV collaboration	$3,674	$25,514	$17,179	$125,150

Mitsubishi Tanabe Pharma Corporation

The Company has a collaboration agreement (the “MTPC Agreement”) with Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe") pursuant to which Mitsubishi Tanabe has a fully-paid license to manufacture and commercialize TELAVIC (the brand name under which Mitsubishi Tanabe is marketing telaprevir) in Japan and other specified countries in Asia. The Company recognized no collaborative revenues attributable to the Mitsubishi Tanabe collaboration in the three and nine months ended September 30, 2014 and 2013.

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

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VERTEX PHARMACEUTICALS INCORPORATED
Notes to Condensed Consolidated Financial Statements
(unaudited)

financial support for (i) development activities for VX-661, a corrector compound discovered under the collaboration, and (ii) additional research and development activities directed at discovering new corrector compounds. Under the April 2011 Amendment, CFFT agreed to provide the Company with up to $75.0 million in funding over approximately five years for corrector-compound research and development activities. The Company retains the right to develop and commercialize KALYDECO (ivacaftor), lumacaftor (VX-809), VX-661 and any other compounds discovered during the course of the research collaboration with CFFT.

During the three and nine months ended September 30, 2014 and 2013, the Company recognized the following revenues attributable to the CFFT collaboration:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Collaborative revenues attributable to the CFFT collaboration	$1,983	$3,515	$6,455	$11,318

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, lumacaftor and VX-661. The April 2011 Amendment provides for a tiered royalty in the same range on net sales of corrector compounds 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 corrector compounds such as lumacaftor or VX-661. The Company began marketing KALYDECO in the United States and certain countries in the European Union in 2012. 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. 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 corrector compounds. The collaboration also may be terminated by either party for a material breach by the other, subject to notice and cure provisions.

Alios BioPharma, Inc.

In June 2011, the Company entered into a license and collaboration agreement (the “Alios Agreement”) with Alios, a privately-held biotechnology company. 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 April 2014, Vertex and Alios amended the Alios Agreement to eliminate the Company's obligations to conduct further development activities with respect to VX-135. In October 2014, the Company provided notice to Alios that the Alios Agreement would terminate in accordance with its terms in December 2014.

Under applicable accounting guidance, the Company consolidated Alios as a variable interest entity for the period from June 13, 2011 through December 31, 2013. The Company deconsolidated Alios as of December 31, 2013 and recorded a full impairment charge related to the Alios HCV nucleotide analogue program because the Company no longer had a variable interest in Alios as a whole and did not possess the power to direct the activities that most significantly affect the economic performance of Alios based on, among other factors, the decline in significance to Alios of the licensed HCV nucleotide analogue program.

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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.

Noncontrolling Interest (Alios)

Prior to the deconsolidation, the Company recorded net loss (income) attributable to noncontrolling interest (Alios) on its condensed consolidated statements of operations, reflecting Alios' net loss (income) for the reporting period, adjusted for changes in the fair value of contingent milestone payments and royalties payable by the Company to Alios, which was evaluated each reporting period. As noted above, as of September 30, 2014 the operations of Alios are presented as discontinued operations in these condensed consolidated financial statements. A summary of net loss from discontinued operations attributable to noncontrolling interest (Alios) for the three and nine months ended September 30, 2013 is as follows:

	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013
	(in thousands)	
Loss before benefit from income taxes	$9,056	$21,177
Decrease (increase) in fair value of contingent milestone and royalty payments	(1,220)	1,600
Benefit from income taxes	(3,306)	(9,089)
Loss from discontinued operations attributable to noncontrolling interest (Alios)	$4,530	$13,688

The Company used present-value models to determine the estimated fair value of the contingent milestone and royalty payments until it deconsolidated Alios, based on assumptions regarding the probability of achieving the relevant milestones, estimates regarding the time to develop drug candidates, estimates of future product sales and the appropriate discount and tax rates. The Company based 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 represented a measure of credit risk associated with settling the liability. Significant judgment was used in determining the appropriateness of these assumptions at each reporting period.

The Company's net loss from discontinued operations attributable to noncontrolling interest (Alios) for the three and nine months ended September 30, 2014 was insignificant due to the deconsolidation of Alios effective December 31, 2013.

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 become 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. The collaboration was subject to the expiration of the waiting period under the Hart–Scott–Rodino Antitrust Improvements Act of 1976. The waiting period expired in July 2014; therefore, there was no accounting impact relating to this agreement during the six months ended June 30, 2014.

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 a non-refundable up-front payment of $30.0 million from Janssen Inc. in the third quarter of 2014 upon expiration of the waiting period under the Hart–Scott–Rodino Antitrust Improvements Act of 1976. Pursuant to the Janssen Influenza Agreement, the

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Company will receive an additional non-refundable payment of $5.0 million in the fourth quarter of 2014 and 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. Janssen Inc. may terminate the Janssen Influenza Agreement, subject to certain exceptions, upon six months' notice.

The Company evaluated the deliverables, consisting of licenses to intellectual property and the obligation to complete certain fully-reimbursable research and development activities as directed by Janssen Inc., pursuant to the Janssen Influenza Agreement under multiple element arrangement guidance for collaborative arrangements. The Company concluded that the license has stand-alone value from the research and development activities and determined the relative selling price of these deliverables based on the Company's best estimate of selling price. The Company utilized a discounted cash flow model to determine its best estimate of selling price for the licenses to intellectual property and determined the best estimate of selling price for the research and development activities to be the estimated cost to complete the activities plus a commercially reasonable margin. The Company determined the license had stand-alone value based on the resources and know-how possessed by Janssen Inc. The Company concluded that the Janssen Influenza Agreement and the amendment to the Janssen Influenza Agreement should be accounted for as separate contracts due to the fact that the amendment did not impact the Company's obligations under the original agreement. Based on this analysis, the Company recognized $30.0 million in collaborative revenues related to the up-front payment in the three and nine months ended September 30, 2014. The Company is recording the reimbursement for the research and development activities 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. Net Loss Per Share Attributable to Vertex Common Shareholders

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 per share attributable to Vertex common shareholder calculations because the effect would have been anti-dilutive during each period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Stock options	13,097	16,807	13,097	16,807
Unvested restricted stock and restricted stock units	2,672	2,838	2,672	2,838

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 September 30, 2014, the Company's investments were in money market funds, government-sponsored enterprise securities, corporate debt securities and commercial paper.

As of September 30, 2014, 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 government-sponsored enterprise securities. 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. During the three and nine months ended September 30, 2014 and 2013, the Company did not record an other-than-temporary impairment charge related to its financial assets.

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

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	Fair Value Measurements as of September 30, 2014			
		Fair Value Hierarchy		
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Financial assets carried at fair value:				
Cash equivalents:				
Money market funds	$343,129	$343,129	$—	$—
Marketable securities:				
Government-sponsored enterprise securities	467,868	467,868	—	—
Commercial paper	46,496	—	46,496	—
Corporate debt securities	244,810	—	244,810	—
Total	$1,102,303	$810,997	$291,306	$—

The fair value of the Company’s foreign currency forward contracts, which were not material as of September 30, 2014, were based on Level 2 inputs and were determined using third party pricing services. Please refer to Note H, "Hedging," for further information regarding the Company’s foreign currency forward contracts.

As of September 30, 2014, the carrying value of the Company's Term Loan was $294.7 million, which was recorded on its condensed consolidated balance sheet. The fair value of the Term Loan was $294.7 million and is 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 and the discount on the Term Loan. The Level 3 inputs related to the Term Loan are the amounts of the estimated future interest payments. Please refer to Note L, "Long-term Obligations" for further information regarding the Company's Term Loan.

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F. Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
As of September 30, 2014				
Cash and cash equivalents:				
Cash and money market funds	$718,562	$1	$—	$718,563
Total cash and cash equivalents	$718,562	$1	$—	$718,563
Marketable securities:				
Government-sponsored enterprise securities (due within 1 year)	$467,857	$27	$(16)	$467,868
Commercial paper (due within 1 year)	46,402	94	—	46,496
Corporate debt securities (due within 1 year)	213,352	2	—	213,354
Corporate debt securities (due after 1 year through 5 years)	31,497	—	(41)	31,456
Total marketable securities	$759,108	$123	$(57)	$759,174
Total cash, cash equivalents and marketable securities	$1,477,670	$124	$(57)	$1,477,737
As of December 31, 2013				
Cash and cash equivalents:				
Cash and money market funds	$569,299	$—	$—	$569,299
Total cash and cash equivalents	$569,299	$—	$—	$569,299
Marketable securities:				
Government-sponsored enterprise securities (due within 1 year)	$600,496	$7	$(53)	$600,450
Commercial paper (due within 1 year)	83,384	109	—	83,493
Corporate debt securities (due within 1 year)	189,674	14	(34)	189,654
Corporate debt securities (due after 1 year through 5 years)	22,181	6	(7)	22,180