VERTEX PHARMACEUTICALS INC / MA
Form 10-Q
May 05, 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 MARCH 31, 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 (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common Stock, par value $0.01 per share	236,194,337
Class	Outstanding at April 25, 2014

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VERTEX PHARMACEUTICALS INCORPORATED
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 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 March 31, 2014	2013
Revenues:		
Product revenues, net	$103,461	$267,381
Royalty revenues	10,733	43,573
Collaborative revenues	4,257	17,414
Total revenues	118,451	328,368
Costs and expenses:		
Cost of product revenues	8,572	30,955
Royalty expenses	6,904	11,788
Research and development expenses	238,963	218,095
Sales, general and administrative expenses	74,212	92,879
Restructuring expenses	6,188	39
Intangible asset impairment charge	—	412,900
Total costs and expenses	334,839	766,656
Loss from operations	(216,388)	(438,288)
Interest expense, net	(15,717)	(3,465)
Other income (expense), net	451	(1,187)
Loss before provision for (benefit from) income taxes	(231,654)	(442,940)
Provision for (benefit from) income taxes	803	(130,313)
Net loss	(232,457)	(312,627)
Net loss attributable to noncontrolling interest (Alios)	—	4,611
Net loss attributable to Vertex	$(232,457)	$(308,016)
Net loss per share attributable to Vertex common shareholders:		
Basic	$(1.00)	$(1.43)
Diluted	$(1.00)	$(1.43)
Shares used in per share calculations:		
Basic	232,887	215,421
Diluted	232,887	215,421

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 Income (Loss)
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2014	2013
Net loss	$(232,457)	$(312,627)
Changes in other comprehensive loss:		
Unrealized holding gains (losses) on marketable securities	(27)	11
Unrealized losses on foreign currency forward contracts	(36)	—
Foreign currency translation adjustment	72	(610)
Total changes in other comprehensive loss	9	(599)
Comprehensive loss	(232,448)	(313,226)
Comprehensive loss attributable to noncontrolling interest (Alios)	—	4,611
Comprehensive loss attributable to Vertex	$(232,448)	$(308,615)

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)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$424,045	$569,299
Marketable securities, available for sale	900,155	895,777
Accounts receivable, net	59,858	85,517
Inventories	11,261	14,147
Prepaid expenses and other current assets	35,011	23,836
Total current assets	1,430,330	1,588,576
Restricted cash	130	130
Property and equipment, net	726,204	696,911
Goodwill	30,992	30,992
Other assets	9,452	2,432
Total assets	$2,197,108	$2,319,041
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$49,571	$49,327
Accrued expenses	234,386	271,077
Deferred revenues, current portion	28,836	21,510
Accrued restructuring expenses, current portion	9,911	14,286
Capital lease obligations, current portion	18,323	16,893
Other liabilities, current portion	32,473	24,736
Total current liabilities	373,500	397,829
Deferred revenues, excluding current portion	43,889	49,459
Accrued restructuring expenses, excluding current portion	13,956	14,067
Capital lease obligations, excluding current portion	49,495	48,754
Construction financing lease obligation, excluding current portion	473,360	440,937
Other liabilities, excluding current portion	12,030	11,590
Total liabilities	966,230	962,636
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding at March 31, 2014 and December 31, 2013	—	—
Common stock, $0.01 par value; 300,000,000 shares authorized at March 31, 2014 and December 31, 2013; 236,201,333 and 233,788,852 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	2,334	2,320
Additional paid-in capital	5,428,193	5,321,286
Accumulated other comprehensive loss	(297)	(306)
Accumulated deficit	(4,199,352)	(3,966,895)
Total Vertex shareholders' equity	1,230,878	1,356,405
Total liabilities and shareholders' equity	$2,197,108	$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 (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				11		11		11	
Foreign currency translation adjustment				(610)		(610)		(610)	
Net loss					(308,016)	(308,016)	(4,611)	(312,627)	
Issuance of common stock under benefit plans	1,365	11	24,088			24,099	3	24,102	
Stock-based compensation expense			31,451			31,451	123	31,574	
Change in liquidation value of noncontrolling interest							(342)	(342)	342
Balance, March 31, 2013	218,652	$2,160	$4,574,987	$(1,149)	$(3,829,883)	$746,115	$191,845	$937,960	$38,872
Balance, December 31, 2013	233,789	$2,320	$5,321,286	$(306)	$(3,966,895)	$1,356,405	$—	$1,356,405	$—
Unrealized holding losses on marketable securities				(27)		(27)		(27)	
Unrealized losses on foreign currency forward contracts				(36)		(36)		(36)	

Foreign currency translation adjustment				72		72		72	
Net loss					(232,457)	(232,457)		(232,457)	
Issuance of common stock under benefit plans	2,412	14	60,120			60,134		60,134	
Stock-based compensation expense			46,787			46,787		46,787	
Balance, March 31, 2014	236,201	$2,334	$5,428,193	$(297)	$(4,199,352)	$1,230,878	$—	$1,230,878	$—

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)

	Three Months Ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(232,457)	$(312,627)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	15,788	10,691
Stock-based compensation expense	46,580	31,275
Other non-cash based compensation expense	—	2,432
Intangible asset impairment charge	—	412,900
Deferred income taxes	—	(128,703)
Other non-cash items, net	(173)	(975)
Changes in operating assets and liabilities:		
Accounts receivable, net	25,237	(48,834)
Inventories	2,488	9,231
Prepaid expenses and other assets	(17,937)	(24,986)
Accounts payable	978	(40,571)
Accrued expenses and other liabilities	(13,536)	23,236
Accrued restructuring expense	(4,486)	(869)
Deferred revenues	1,756	2,022
Net cash used in operating activities	(175,762)	(65,778)
Cash flows from investing activities:		
Purchases of marketable securities	(380,949)	(458,971)
Sales and maturities of marketable securities	376,544	430,535
Expenditures for property and equipment	(15,526)	(16,607)
Decrease in restricted cash and cash equivalents (Alios)	—	6,975
Decrease (increase) in deposits	(476)	472
Net cash used in investing activities	(20,407)	(37,596)
Cash flows from financing activities:		
Issuances of common stock from employee benefit plans	60,134	21,670
Payments on capital lease obligations	(2,622)	(10,096)
Payments on construction financing lease obligation	(15,146)	(17,709)
Payments returned related to construction financing lease obligation	8,050	—
Net cash provided by (used in) financing activities	50,416	(6,135)
Effect of changes in exchange rates on cash	499	(799)
Net decrease in cash and cash equivalents	(145,254)	(110,308)
Cash and cash equivalents—beginning of period	569,299	489,407
Cash and cash equivalents—end of period	$424,045	$379,099
Supplemental disclosure of cash flow information:		
Cash paid for interest	$15,970	$243
Cash paid for income taxes	$140	$1,541
Capitalization of costs related to construction financing lease obligation	$25,564	$66,052
Assets acquired under capital lease	$3,619	$—

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. In addition, the condensed consolidated financial statements for the period from June 13, 2011 through December 31, 2013, reflect the operations of Alios BioPharma, Inc. (“Alios”), a collaborator that was a variable interest entity (a “VIE”) for which the Company was deemed under applicable accounting guidance to have a variable interest and be the primary beneficiary. As of December 31, 2013, the Company deconsolidated Alios, and the Company's consolidated balance sheets as of March 31, 2014 and December 31, 2013 exclude Alios. All material intercompany balances and transactions have been eliminated. The Company operates in one segment, pharmaceuticals.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the financial position and results of operations for the interim periods ended March 31, 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 and the income tax provision. 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 three months ended March 31, 2014 that had a material effect on the Company's condensed consolidated financial statements.

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

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Notes to Condensed Consolidated Financial Statements (Continued)
(unaudited)

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 three months ended March 31, 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	2,489	16,160	349	600	19,598
Adjustments related to prior period sales	(10)	4,170	2,205	1	6,366
Credits/payments made	(3,128)	(34,006)	(3,311)	(995)	(41,440)
Balance at March 31, 2014	$886	$54,568	$15,042	$1,161	$71,657

C. Collaborative Arrangements

Janssen Pharmaceutica NV

In 2006, the Company entered into a collaboration agreement with Janssen Pharmaceutica NV ("Janssen") for the development, manufacture and commercialization of telaprevir, which Janssen began marketing under the brand name INCIVO in certain of its territories in September 2011. Under the collaboration agreement, Janssen 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) 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 amended the collaboration agreement (the "2013 Janssen Amendment," as amended the "Janssen Agreement").

Janssen 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 Agreement through November 2013. As of November 2013, the effective date of the 2013 Janssen Amendment, there was $32.1 million remaining in deferred revenues related to this up-front license payment.

Janssen paid the Company a tiered royalty averaging in the mid-20% range as a percentage of net sales of INCIVO in Janssen’s territories through 2013. In addition, Janssen is responsible for certain third-party royalties on net sales of INCIVO in its territories.

Pursuant to the 2013 Janssen Amendment, (i) Janssen made a payment of $152.0 million to the Company in the fourth quarter of 2013; (ii) Janssen's obligations to pay the Company royalties on net sales of INCIVO (telaprevir) terminated after

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

the fourth quarter of 2013; and (iii) Janssen 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 and Janssen continue to perform activities related to the telaprevir development program.

The Company determined that the 2013 Janssen Amendment was a material modification to the Janssen 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 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 Agreement in the fourth quarter of 2013. This amount was primarily attributable to (i) the residual consideration received from Janssen, 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 March 31, 2014, the remaining deferred revenue balance related to the Janssen collaboration was $4.3 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 remains responsible for based on INCIVO net sales.

The agreement will continue in effect until the expiration of Janssen’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 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 months ended March 31, 2014 and 2013, the Company recognized the following revenues attributable to the Janssen collaboration:

	Three Months Ended March 31,	
	2014	2013
	(in thousands)	
Royalty revenues (INCIVO)	$4,935	$39,044
Collaborative revenues:		
Up-front and amendment payments revenues	$—	$3,107
Net reimbursement (payment) for telaprevir development costs	1,389	(27)
Reimbursement for manufacturing services	—	10,299
Total collaborative revenues attributable to the Janssen collaboration	$1,389	$13,379
Total revenues attributable to the Janssen collaboration	$6,324	$52,423

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 months ended March 31, 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 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

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

KALYDECO (ivacaftor), lumacaftor (VX-809), VX-661 and any other compounds discovered during the course of the research collaboration with CFFT.

During the three months ended March 31, 2014 and 2013, the Company recognized the following revenues attributable to the CFFT collaboration:

	Three Months Ended March 31,	
	2014	2013
	(in thousands)	
Collaborative revenues attributable to the CFFT collaboration	$2,868	