

ALEXION PHARMACEUTICALS INC

Form 10-Q

April 25, 2014

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 1934
For the quarterly period ended March 31, 2014

or
 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: 0-27756

ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

13-3648318

(State or Other Jurisdiction of Incorporation or Organization)(I.R.S. Employer Identification No.)

352 Knotter Drive, Cheshire Connecticut 06410

(Address of Principal Executive Offices) (Zip Code)

203-272-2596

(Registrant's telephone number, including area code)

N/A

(Former name, former address, and former fiscal year, if changed since last report)

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 No

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Check One:

Large accelerated filer Accelerated filer Non-accelerated filer (Do not check if a smaller reporting company)
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 No

Common Stock, \$0.0001 par value

197,796,456

Class

Outstanding as of April 23, 2014

Alexion Pharmaceuticals, Inc.
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Alexion Pharmaceuticals, Inc.
 Condensed Consolidated Balance Sheets
 (unaudited)
 (amounts in thousands, except per share amounts)

	March 31, 2014	December 31, 2013
Assets		
Current Assets:		
Cash and cash equivalents	\$528,285	\$529,857
Marketable securities	1,029,193	984,994
Trade accounts receivable, net	429,021	421,752
Inventories	126,154	102,602
Deferred tax assets	45,871	41,432
Prepaid expenses and other current assets	87,356	106,220
Total current assets	2,245,880	2,186,857
Property, plant and equipment, net	218,086	201,109
Intangible assets, net	603,021	609,719
Goodwill	254,073	254,073
Deferred tax assets	3,366	3,394
Other assets	55,240	62,544
Total assets	\$3,379,666	\$3,317,696
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$35,339	\$21,596
Accrued expenses	196,369	402,344
Deferred revenue	58,859	53,801
Current portion of long-term debt	48,000	48,000
Other current liabilities	58,255	56,688
Total current liabilities	396,822	582,429
Long-term debt, less current portion	45,500	65,000
Contingent consideration	106,241	106,744
Facility lease obligation	38,417	32,230
Deferred tax liabilities	45,986	101,241
Other liabilities	45,722	47,973
Total liabilities	678,688	935,617
Commitments and contingencies (Note 16)		
Stockholders' Equity:		
Preferred stock, \$.0001 par value; 5,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$.0001 par value; 290,000 shares authorized; 199,319 and 197,941 shares issued at March 31, 2014 and December 31, 2013, respectively	20	20
Additional paid-in capital	2,291,363	2,106,183
Treasury stock, at cost, 1,122 and 985 shares at March 31, 2014 and December 31, 2013, respectively	(102,422) (80,365
Accumulated other comprehensive loss	(26,435) (22,857
Retained earnings	538,452	379,098
Total stockholders' equity	2,700,978	2,382,079
Total liabilities and stockholders' equity	\$3,379,666	\$3,317,696

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

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Alexion Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(amounts in thousands, except per share amounts)

	Three months ended March 31,	
	2014	2013
Net product sales	\$566,616	\$338,941
Cost of sales	32,939	35,269
Operating expenses:		
Research and development	191,457	74,536
Selling, general and administrative	129,291	108,826
Impairment of intangible asset	3,464	—
Acquisition-related costs	(38) 3,234
Amortization of purchased intangible assets	—	104
Total operating expenses	324,174	186,700
Operating income	209,503	116,972
Other income and expense:		
Investment income	2,213	437
Interest expense	(1,063) (1,171
Foreign currency gain	1,258	503
Income before income taxes	211,911	116,741
Income tax provision	52,557	34,524
Net income	\$159,354	\$82,217
Earnings per common share		
Basic	\$0.81	\$0.42
Diluted	\$0.79	\$0.41
Shares used in computing earnings per common share		
Basic	197,797	194,771
Diluted	201,804	199,057

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

Alexion Pharmaceuticals, Inc.
 Condensed Consolidated Statements of Comprehensive Income
 (unaudited)
 (amounts in thousands)

	Three months ended March 31,	
	2014	2013
Net income	\$ 159,354	\$ 82,217
Other comprehensive income (loss), net of tax:		
Foreign currency translation	506	(1,449)
Unrealized gains on marketable securities	811	—
Unrealized losses on pension obligation	—	(1)
Unrealized (losses) gains on hedging activities, net of tax of \$(1,245), and \$2,510, respectively	(4,895)	25,777
Other comprehensive (loss) income, net of tax	(3,578)	24,327
Comprehensive income	\$ 155,776	\$ 106,544

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

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Alexion Pharmaceuticals, Inc.
 Condensed Consolidated Statements of Cash Flows
 (unaudited)
 (amounts in thousands)

	Three months ended March 31,		
	2014	2013	
Cash flows from operating activities:			
Net income	\$ 159,354	\$ 82,217	
Adjustments to reconcile net income to net cash flows from operating activities:			
Depreciation and amortization	9,268	6,266	
Impairment of intangible asset	3,464	—	
Change in fair value of contingent consideration	(38) 2,211	
Share-based compensation expense	23,840	16,855	
Premium amortization of available-for-sale securities	4,175	—	
Deferred taxes	(58,311) 25,820	
Unrealized foreign currency loss	263	2,721	
Unrealized loss (gain) on forward contracts	161	(7,718)
Excess tax benefit from stock options	(130,407) (21,332)
Other	173	25	
Changes in operating assets and liabilities:			
Accounts receivable	63	(26,232)
Inventories	(20,900) (5,469)
Prepaid expenses and other assets	33,633	13,522	
Accounts payable, accrued expenses and other liabilities	(60,680) (40,989)
Deferred revenue	4,887	(1,400)
Net cash (used in) provided by operating activities	(31,055) 46,497	
Cash flows from investing activities:			
Purchases of available-for-sale securities	(145,565) —	
Proceeds from maturity or sale of available-for-sale securities	99,250	—	
Purchases of trading securities	(1,219) —	
Purchases of other investments	(25,000) —	
Purchases of property, plant and equipment	(17,733) (5,493)
Other	70	(76)
Net cash used in investing activities	(90,197) (5,569)
Cash flows from financing activities:			
Payments on term loan	(19,500) —	
Excess tax benefit from stock options	130,407	21,332	
Repurchase of common stock	(22,057) (35,107)
Net proceeds from the exercise of stock options	30,404	9,527	
Other	(42) (60)
Net cash provided by (used in) financing activities	119,212	(4,308)
Effect of exchange rate changes on cash	468	(3,161)
Net change in cash and cash equivalents	(1,572) 33,459	
Cash and cash equivalents at beginning of period	529,857	989,501	
Cash and cash equivalents at end of period	\$ 528,285	\$ 1,022,960	

Supplemental cash flow disclosures from investing and financing activities:

Construction in process related to facility lease obligation \$ 6,187 \$ —

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

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in thousands except per share amounts)

1. Business

Alexion Pharmaceuticals, Inc. ("Alexion", the "Company", "we", "our" or "us") is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Our marketed product Soliris is the first and only therapeutic approved for patients with either of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system: paroxysmal nocturnal hemoglobinuria (PNH), a life-threatening and ultra-rare genetic blood disorder, and atypical hemolytic uremic syndrome (aHUS), a life-threatening and ultra-rare genetic disease. We are also evaluating additional potential indications for Soliris in other severe and ultra-rare diseases in which uncontrolled complement activation is the underlying mechanism, and we are progressing in various stages of development with additional product candidates as potential treatments for patients with severe and life-threatening ultra-rare disorders. We were incorporated in 1992 and began commercial sale of Soliris in 2007.

2. Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013. In our opinion, the accompanying unaudited consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of our financial statements for interim periods in accordance with accounting principles generally accepted in the United States. The condensed consolidated balance sheet data as of December 31, 2013 was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2013 included in our Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2014 are not necessarily indicative of the results to be expected for the full year.

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss), net of tax, in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

The accompanying unaudited condensed consolidated financial statements include the accounts of Alexion Pharmaceuticals, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Our significant accounting policies are described in Note 1 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2013.

3. Inventories

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the weighted-average cost method.

The components of inventory are as follows:

	March 31, 2014	December 31, 2013
Raw materials	\$12,192	\$12,170
Work-in-process	68,662	62,192
Finished goods	45,300	28,240
	\$126,154	\$102,602

Alexion Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

(amounts in thousands except per share amounts)

4. Intangible Assets and Goodwill

The following table summarizes the carrying amount of our intangible assets and goodwill, net of accumulated amortization:

	March 31, 2014	December 31, 2013
Licenses, patents and purchased technology, net	\$7,971	\$ 11,205
Acquired in-process research and development	595,050	598,514
Intangible assets	\$603,021	\$ 609,719
Goodwill	\$254,073	\$ 254,073

During the three months ended March 31, 2014, we reviewed for impairment the value of an early stage, Phase I indefinite-lived intangible asset related to the Taligen acquisition. We initiated such review based on a reassessment of scientific findings associated with this acquired asset. As a result, in the first quarter of 2014, we recognized an impairment charge of \$3,464 to adjust this asset to fair value, which was determined to be de minimis.

5. Debt

On February 7, 2012, we entered into a Credit Agreement (Credit Agreement) with a syndicate of banks that provides for a \$240,000 senior secured term loan facility payable in equal quarterly installments of \$12,000 starting June 30, 2012 and a \$200,000 senior secured revolving credit facility through February 7, 2017. In addition to borrowings upon prior notice, the revolving credit facility includes borrowing capacity in the form of letters of credit up to \$60,000 and borrowings on same-day notice, referred to as swingline loans, of up to \$10,000. Borrowings can be used for working capital requirements, acquisitions and other general corporate purposes. With the consent of the lenders and the administrative agent and subject to satisfaction of certain conditions, we may increase the term loan facility and/or the revolving credit facility by an aggregate amount not to exceed \$150,000.

As of March 31, 2014, we had \$93,500 outstanding on the term loan. As of March 31, 2014, we had open letters of credit of \$9,773, and our borrowing availability under the revolving facility was \$190,227.

The fair value of our long term debt, which is measured using Level 2 inputs, approximates book value.

6. Earnings Per Common Share

Basic earnings per common share (EPS) are computed by dividing net income by the weighted-average number of shares of common stock outstanding. For purposes of calculating diluted EPS, the denominator reflects the potential dilution that could occur if stock options, unvested restricted stock, unvested restricted stock units or other contracts to issue common stock were exercised or converted into common stock, using the treasury stock method.

The following table summarizes the calculation of basic and diluted EPS for the three months ended March 31, 2014 and 2013:

	Three months ended March 31,	
	2014	2013
Net income used for basic and diluted calculation	\$ 159,354	\$ 82,217
Shares used in computing earnings per common share—basic	197,797	194,771
Weighted-average effect of dilutive securities:		
Stock awards	4,007	4,286
Dilutive potential common shares	4,007	4,286

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Shares used in computing earnings per common share—diluted	201,804	199,057
Earnings per common share:		
Basic	\$0.81	\$0.42
Diluted	\$0.79	\$0.41

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Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
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The following table represents the potentially dilutive shares excluded from the calculation of EPS for the three months ended March 31, 2014, and 2013 because their effect is anti-dilutive:

	Three months ended	
	March 31, 2014	2013
Potentially dilutive securities:		
Options to purchase common stock	1,136	2,998
Unvested restricted stock and restricted stock units	505	9
	1,641	3,007

7. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale investments by type of security at March 31, 2014 and December 31, 2013 were as follows:

	March 31, 2014			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	\$78,941	\$—	\$—	\$78,941
Corporate bonds	512,935	831	(218)	513,548
Municipal bonds	219,404	112	(40)	219,476
Other government-related obligations:				
U.S.	41,975	19	(17)	41,977
Foreign	159,065	94	(192)	158,967
Bank certificates of deposit	18,019	1	—	18,020
	\$1,030,339	\$1,057	\$(467)	\$1,030,929
	December 31, 2013			
	Amortized Cost Basis	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Commercial paper	\$112,679	\$—	\$—	\$112,679
Corporate bonds	476,459	487	(588)	476,358
Municipal bonds	202,396	47	(40)	202,403
Other government-related obligations:				
U.S.	46,466	30	(7)	46,489
Foreign	156,974	54	(204)	156,824
Bank certificates of deposit	33,004	—	—	33,004
	\$1,027,978	\$618	\$(839)	\$1,027,757

The aggregate fair value of available-for-sale securities in an unrealized loss position as of March 31, 2014 and December 31, 2013 was \$346,410 and \$461,634, respectively. These investments have been in a continuous unrealized loss position for less than 12 months. As of March 31, 2014, we believe that the cost basis of our available-for-sale investments is recoverable.

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in thousands except per share amounts)

The fair values of available-for-sale securities by classification in the condensed consolidated balance sheet were as follows:

	March 31, 2014	December 31, 2013
Cash and cash equivalents	\$4,000	\$43,780
Marketable securities	1,026,929	983,977
	\$1,030,929	\$1,027,757

The fair values of available-for-sale debt securities at March 31, 2014, by contractual maturity, are summarized as follows:

	March 31, 2014
Due in one year or less	\$447,201
Due after one year through three years	578,731
Due after three years through five years	4,997
	\$1,030,929

As of March 31, 2014 and December 31, 2013, the fair value of our trading securities was \$2,264 and \$1,017, respectively.

We utilize the specific identification method in computing realized gains and losses. Realized gains and losses on our trading securities and available-for-sale investments were not material for the three months ended March 31, 2014.

8. Derivative Instruments and Hedging Activities

We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, and expenses that are denominated in currencies other than the U.S. dollar, primarily the Euro, Japanese Yen, British Pound and Swiss Franc. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

We enter into foreign exchange forward contracts, with durations of up to 36 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. These hedges are designated as cash flow hedges upon contract inception. At March 31, 2014, we have open contracts with notional amounts totaling \$1,342,742 that qualified for hedge accounting.

The impact on accumulated other comprehensive income (AOCI) and earnings from foreign exchange contracts that qualified as cash flow hedges, for the three months ended March 31, 2014 and 2013 were as follows:

	Three months ended March 31,	
	2014	2013
Gain (loss) recognized in AOCI, net of tax	\$(3,944)	\$30,924
Gain reclassified from AOCI to net product sales (effective portion), net of tax	\$1,108	\$4,715
Gain (loss) reclassified from AOCI to other income and expense (ineffective portion), net of tax	\$(157)	\$432

Assuming no change in foreign exchange rates from market rates at March 31, 2014, \$3,209 of losses recognized in AOCI will be reclassified to revenue over the next 12 months.

We enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge

Alexion Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(amounts in thousands except per share amounts)

transactions are designed to offset gains and losses on underlying balance sheet exposures. As of March 31, 2014, the notional amount of foreign exchange contracts where hedge accounting is not applied was \$310,846.

We recognized a gain of \$2,289 and \$6,950, in other income and expense, for the three months ended March 31, 2014 and 2013, respectively, associated with the foreign exchange contracts not designated as hedging instruments. These amounts were largely offset by gains or losses in monetary assets and liabilities.

The following tables summarize the fair value of outstanding derivatives at March 31, 2014 and December 31, 2013:

	March 31, 2014		Liability Derivatives	
	Asset Derivatives	Fair	Balance Sheet	Fair
	Balance Sheet	Value	Balance Sheet	Value
	Location		Location	
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	\$18,263	Other current liabilities	\$21,017
Foreign exchange forward contracts	Other non-current assets	6,362	Other non-current liabilities	13,121
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	143	Other current liabilities	327
Total fair value of derivative instruments		\$24,768		\$34,465

	December 31, 2013		Liability Derivatives	
	Asset Derivatives	Fair	Balance Sheet	Fair
	Balance Sheet	Value	Balance Sheet	Value
	Location		Location	
Derivatives designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	\$21,815	Other current liabilities	\$20,228
Foreign exchange forward contracts	Other non-current assets	9,839	Other non-current liabilities	14,864
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	—	Other current liabilities	—
Total fair value of derivative instruments		\$31,654		\$35,092

Alexion Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

(amounts in thousands except per share amounts)