

Alkermes plc.
Form 10-Q
November 01, 2012
[Table of Contents](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2012

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Edgar Filing: Alkermes plc. - Form 10-Q

Ireland

(State or other jurisdiction of incorporation or organization)

98-1007018

(I.R.S. Employer Identification No.)

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

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 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 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:

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

The number of shares of the issuer's ordinary shares, \$0.01 par value, outstanding as of October 26, 2012, was 131,930,050 shares.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

		Page No.
	<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets – September 30, 2012 and March 31, 2012</u>	3
	<u>Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income</u>	
	<u>For the Three and Six Months Ended September 30, 2012 and 2011</u>	4
	<u>Condensed Consolidated Statements of Cash Flows – For the Six Months Ended</u>	
	<u>September 30, 2012 and 2011</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of</u>	
	<u>Operations</u>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	29
<u>Item 4.</u>	<u>Controls and Procedures</u>	30
	<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	31
<u>Item 1A.</u>	<u>Risk Factors</u>	31
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>Item 5.</u>	<u>Other Information</u>	31
<u>Item 6.</u>	<u>Exhibits</u>	31
<u>Signatures</u>		32
Exhibit Index		
Ex-31.1 Section 302 Certification of Chief Executive Officer		
Ex-31.2 Section 302 Certification of Chief Financial Officer		
Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer		

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements:****ALKERMES PLC AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	September 30, 2012	March 31, 2012
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 132,418	\$ 83,601
Investments short-term	67,033	106,846
Receivables	101,998	96,381
Inventory	40,887	39,759
Prepaid expenses and other current assets	12,583	12,566
Total current assets	354,919	339,153
PROPERTY, PLANT AND EQUIPMENT, NET	295,374	302,995
INTANGIBLE ASSETS, NET	596,864	617,845
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	8,726	55,691
OTHER ASSETS	21,924	26,793
TOTAL ASSETS	\$ 1,370,547	\$ 1,435,217
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 58,406	\$ 79,154
Deferred revenue current	3,582	6,910
Long-term debt current	6,750	3,100
Total current liabilities	68,738	89,164
LONG-TERM DEBT	363,847	441,360
DEFERRED REVENUE LONG-TERM	8,845	7,578
DEFERRED TAX LIABILITIES LONG-TERM	33,568	34,512
OTHER LONG-TERM LIABILITIES	10,541	8,751
Total liabilities	485,539	581,365
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS EQUITY:		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2012 and March 31, 2012, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 131,805,348 and 130,212,530 shares issued; 131,567,817 and 130,177,452 shares outstanding at September 30, 2012 and March 31, 2012, respectively	1,315	1,300
Treasury stock, at cost (237,531 and 35,078 shares at September 30, 2012 and March 31, 2012, respectively)	(3,894)	(571)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,409,562	1,380,742
Accumulated other comprehensive loss	(2,795)	(2,713)
Accumulated deficit	(519,180)	(524,906)
Total shareholders' equity	885,008	853,852
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,370,547	\$ 1,435,217

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

Table of Contents

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 107,327	\$ 54,039	\$ 245,707	\$ 102,979
Product sales, net	15,192	9,887	27,564	19,573
Research and development revenue	1,459	8,052	2,946	11,309
Total revenues	123,978	71,978	276,217	133,861
EXPENSES:				
Cost of goods manufactured and sold	41,491	17,530	83,561	33,749
Research and development	35,088	28,160	72,894	56,210
Selling, general and administrative	31,428	36,234	61,212	67,731
Amortization of acquired intangible assets	10,547	1,817	20,981	1,817
Total expenses	118,554	83,741	238,648	159,507
OPERATING INCOME (LOSS)	5,424	(11,763)	37,569	(25,646)
OTHER (EXPENSE), NET:				
Interest income	216	383	515	885
Interest expense	(22,648)	(7,561)	(32,818)	(7,561)
Other income, net	723	336	1,646	425
Total other (expense), net	(21,709)	(6,842)	(30,657)	(6,251)
(LOSS) INCOME BEFORE INCOME TAXES	(16,285)	(18,605)	6,912	(31,897)
INCOME TAX PROVISION	422	3,650	1,186	3,596
NET (LOSS) INCOME	\$ (16,707)	\$ (22,255)	\$ 5,726	\$ (35,493)
(LOSS) EARNINGS PER ORDINARY SHARE:				
Basic	\$ (0.13)	\$ (0.22)	\$ 0.04	\$ (0.36)
Diluted	\$ (0.13)	\$ (0.22)	\$ 0.04	\$ (0.36)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	131,067	102,474	130,753	99,578
Diluted	131,067	102,474	135,589	99,578
COMPREHENSIVE (LOSS) INCOME:				
Net (loss) income	\$ (16,707)	\$ (22,255)	\$ 5,726	\$ (35,493)
Unrealized gains (losses) on marketable securities, net of tax:				
Holding gains (losses), net of tax of none in the three and six months ended September 30, 2012 and \$111 and \$202 in the three and six months ended September 30, 2011, respectively	567	(188)	426	341
Less: Reclassification adjustment for gains included in net (loss) income	(1,030)		(1,030)	
Unrealized (losses) gains on marketable securities	(463)	(188)	(604)	341
Unrealized gains (losses) on derivative contracts:				
Unrealized losses on derivative contracts		(244)	(72)	(244)
	594		594	

Edgar Filing: Alkermes plc. - Form 10-Q

Less: Reclassification adjustment for losses included in net (loss) income

Unrealized gains (losses) on derivative contracts	594	(244)	522	(244)
COMPREHENSIVE (LOSS) INCOME	\$ (16,576)	\$ (22,687)	\$ 5,644	\$ (35,396)

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

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	2012	Six Months Ended September 30, (In thousands)	2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$	5,726	\$ (35,493)
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization		36,829	6,377
Share-based compensation expense		18,609	12,712
Deferred income taxes		(944)	(9,664)
Excess tax benefit from share-based compensation		(387)	(3,127)
Loss on debt refinancing transaction		12,129	
Prepayment penalty in connection with debt refinancing		(2,800)	
Principal payments on long-term debt attributable to original issue discount		(2,657)	
Other non-cash charges		4,385	719
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables		(5,617)	733
Inventory, prepaid expenses and other assets		(3,111)	(11,921)
Accounts payable and accrued expenses		(17,422)	23,921
Deferred revenue		(2,060)	189
Other long-term liabilities		2,368	
Cash flows provided by (used in) operating activities		45,048	(15,554)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment		(11,206)	(3,654)
Sales of property, plant and equipment		17	3
Acquisition of Elan Drug Technologies, net of cash acquired			(494,962)
Purchases of investments		(99,218)	(134,801)
Sales and maturities of investments		185,392	240,363
Cash flows provided by (used in) investing activities		74,985	(393,051)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements		9,731	15,326
Excess tax benefit from share-based compensation		387	3,127
Proceeds from the issuance of long-term debt		368,557	444,100
Employee taxes paid related to net share settlement of equity awards		(3,323)	(3,105)
Principal payments of long-term debt		(446,568)	
Cash flows (used in) provided by financing activities		(71,216)	459,448
NET INCREASE IN CASH AND CASH EQUIVALENTS		48,817	50,843
CASH AND CASH EQUIVALENTS Beginning of period		83,601	38,394
CASH AND CASH EQUIVALENTS End of period	\$	132,418	\$ 89,237
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$	19,268	\$ 5,877
Cash paid for taxes	\$	2,177	\$ 15
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$	834	\$ 131

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

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Unaudited)

1. THE COMPANY

Alkermes plc (the Company) is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The Company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has a research and development (R&D) center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business (EDT) of Elan Corporation, plc (Elan) were combined under the Company (this combination is referred to as the Business Combination, the acquisition of EDT or the EDT acquisition) in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the historical financial statements of Alkermes, Inc. are included in the comparative periods. Use of the terms such as us, we, our, Alkermes or the Company is meant to refer to Alkermes plc and its consolidated subsidiaries, except where the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. and its consolidated subsidiaries. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market under the symbol ALKS.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and six months ended September 30, 2012 and 2011 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2012. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (U.S.) (commonly referred to as GAAP). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the financial statements and notes thereto of Alkermes, which are contained in the Company's Annual Report on Form 10-K for the year ended March 31, 2012, which has been filed with the U.S. Securities and Exchange Commission (SEC). The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries: Alkermes Ireland Holdings Limited, Alkermes Pharma Ireland Limited, Alkermes U.S. Holdings, Inc., Alkermes, Inc., Eagle Holdings USA, Inc., Alkermes Gainesville LLC, Alkermes Controlled Therapeutics, Inc., Alkermes Europe, Ltd., Alkermes Finance Ireland Limited, Alkermes Finance S.A R.L., Alkermes Finance Ireland (No. 2) Limited and Alkermes Science One Limited. Intercompany accounts and transactions have been eliminated.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments, litigation and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

During the three months ended September 30, 2012, the Company changed the way in which revenue is recognized on VIVITROL® product sales. Prior to August 1, 2012, the Company did not have sufficient history to reasonably estimate returns related to VIVITROL shipments and therefore, the Company deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. During the three months ended September 30, 2012, it was determined there was sufficient history to reliably estimate returns, and revenue on the sales of VIVITROL is now recognized upon delivery to customers, which is the point in time the customer assumes the risks and rewards of ownership. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to Product sales, net, which was recognized during the three months ended September 30, 2012.

Based on this revised revenue recognition policy, a reserve is now estimated for future product returns on VIVITROL gross product sales. This estimate is based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at VIVITROL product sales, net. Once VIVITROL is returned, it is destroyed. At September 30, 2012, the product return reserve is estimated to be 2% of product sales.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious diseases. The Company's chief decision maker, the Chairman and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

Reclassifications

An amount equal to \$3.1 million that was previously classified as Proceeds from the issuance of ordinary shares under share-based compensation arrangements has been reclassified to Employee taxes paid related to net share settlement of equity awards in the accompanying condensed consolidated statements of cash flows to conform to current period presentation.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In June 2011, the FASB issued guidance related to the presentation of comprehensive income. This accounting standard: (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this accounting standard do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income, nor do the amendments affect how earnings per share is calculated or presented. This standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this accounting standard only requires enhanced disclosure, the adoption of this standard did not impact the Company's financial position or results of operations.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

3. ACQUISITIONS

On September 16, 2011, the Company acquired EDT from Elan in a transaction accounted for under the acquisition method of accounting for business combinations, in exchange for \$500.0 million in cash and 31.9 million ordinary shares of Alkermes Inc., valued at \$525.1 million based on a stock price of \$16.46 per share on the acquisition date. EDT developed and manufactured pharmaceutical products that deliver clinical benefits to patients using EDT's experience and proprietary drug technologies, including the oral controlled release platform (OCR) and the bioavailability enhancement platform, including EDT's NanoCrystal® technology. The Company acquired EDT to diversify its commercialized product portfolio and pipeline candidates, enhance its financial resources in order to invest in its proprietary drug candidates, pursue additional growth opportunities and reduce its cost of capital.

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below (in thousands):

Cash	\$	5,225
Receivables		59,398
Inventory		29,669
Prepaid expenses and other current assets		1,806
Property plant and equipment		210,558
Acquired identifiable intangible assets		689,000
Goodwill		92,740
Other assets		4,360
Accounts payable and accrued expenses		(18,650)
Deferred tax liabilities		(48,448)
Other long-term liabilities		(584)
Total	\$	1,025,074

The following unaudited pro forma information presents the combined results of operations for the three and six months ended September 30, 2011 as if the acquisition of EDT had been completed on April 1, 2011. The unaudited pro forma results do not reflect any material adjustments, operating efficiencies or potential cost savings which may result from the consolidation of operations but do reflect certain adjustments expected to have a continuing impact on the combined results.

(In thousands, except per share data)	Three Months Ended September 30, 2011	Six Months Ended September 30, 2011
Revenues	\$ 121,090	\$ 244,049
Net loss	\$ (4,881)	\$ (7,817)
Basic and diluted loss per common share	\$ (0.04)	\$ (0.06)

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

4. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year (In thousands)	Greater than One Year	
September 30, 2012					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 39,494	\$ 5	\$ (3)	\$	\$ 39,496
Corporate debt securities	15,059	54			15,113
International government agency debt securities	11,217	6			11,223
	65,770	65	(3)		65,832
Money market funds	1,201				1,201
Total short-term investments	66,971	65	(3)		67,033
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	8,008			(482)	7,526
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200