

Alkermes plc.
Form 10-Q
July 26, 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 June 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 July 20, 2012, was 130,858,842 shares.

Table of Contents

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

	Page No.
<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u> 3
	<u>Condensed Consolidated Balance Sheets – June 30, 2012 and March 31, 2012</u> 3
	<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) – For the Three Months Ended June 30, 2012 and 2011</u> 4
	<u>Condensed Consolidated Statements of Cash Flows – For the Three Months Ended June 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 Operations</u> 17
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 27
<u>Item 4.</u>	<u>Controls and Procedures</u> 27
<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u> 28
<u>Item 1A.</u>	<u>Risk Factors</u> 28
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 28
<u>Item 5.</u>	<u>Other Information</u> 28
<u>Item 6.</u>	<u>Exhibits</u> 28
<u>Signatures</u>	29
<u>Exhibit Index</u>	
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	
Ex-101 Instance Document	
Ex-101 Schema Document	
Ex-101 Calculation Linkbase Document	
Ex-101 Labels Linkbase Document	
Ex-101 Definition Linkbase Document	
Ex-101 Presentation Linkbase Document	

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

	June 30, 2012	March 31, 2012
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 85,599	\$ 83,601
Investments short-term	78,772	106,846
Receivables	135,656	96,381
Inventory	41,442	39,759
Prepaid expenses and other current assets	10,939	12,566
Total current assets	352,408	339,153
PROPERTY, PLANT AND EQUIPMENT, NET	299,536	302,995
INTANGIBLE ASSETS, NET	607,411	617,845
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	67,559	55,691
OTHER ASSETS	26,013	26,793
TOTAL ASSETS	\$ 1,445,667	\$ 1,435,217
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 58,127	\$ 79,154
Deferred revenue current	10,012	6,910
Long-term debt current	3,100	3,100
Total current liabilities	71,239	89,164
LONG-TERM DEBT	441,083	441,360
DEFERRED REVENUE LONG-TERM	8,146	7,578
DEFERRED TAX LIABILITIES LONG-TERM	34,199	34,512
OTHER LONG-TERM LIABILITIES	8,514	8,751
Total liabilities	563,181	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 June 30, 2012 and March 31, 2012, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 130,967,811 and 130,212,530 shares issued; 130,730,280 and 130,177,452 shares outstanding at June 30, 2012 and March 31, 2012, respectively	1,306	1,300
Treasury stock, at cost (237,531 and 35,078 shares at June 30, 2012 and March 31, 2012, respectively)	(3,894)	(571)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,390,473	1,380,742
Accumulated other comprehensive loss	(2,926)	(2,713)
Accumulated deficit	(502,473)	(524,906)
Total shareholders' equity	882,486	853,852
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,445,667	\$ 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 INCOME (LOSS)****(unaudited)**

	Three Months Ended June 30,	
	2012	2011
	(In thousands, except per share amounts)	
REVENUES:		
Manufacturing and royalty revenues	\$ 138,380	\$ 48,940
Product sales, net	12,372	9,686
Research and development revenue	1,487	3,257
Total revenues	152,239	61,883
EXPENSES:		
Cost of goods manufactured and sold	42,070	16,219
Research and development	37,806	28,050
Selling, general and administrative	29,784	31,497
Amortization of acquired intangible assets	10,434	
Total expenses	120,094	75,766
OPERATING INCOME (LOSS)	32,145	(13,883)
OTHER (EXPENSE) INCOME, NET:		
Interest income	299	502
Interest expense	(10,170)	
Other income, net	923	89
Total other (expense) income, net	(8,948)	591
INCOME (LOSS) BEFORE INCOME TAXES	23,197	(13,292)
INCOME TAX PROVISION (BENEFIT)	764	(54)
NET INCOME (LOSS)	\$ 22,433	\$ (13,238)
EARNINGS (LOSS) PER ORDINARY SHARE:		
Basic and diluted	\$ 0.17	\$ (0.14)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic	130,434	96,649
Diluted	134,945	96,649
COMPREHENSIVE INCOME (LOSS):		
Net income (loss)	\$ 22,433	\$ (13,238)
Unrealized (losses) gains on marketable securities:		
Holding (losses) gains, net of tax of none and \$313, respectively	(141)	529
Unrealized (losses) gains on marketable securities	(141)	529
Unrealized losses on derivative contracts	(72)	
COMPREHENSIVE INCOME (LOSS)	\$ 22,220	\$ (12,709)

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)

	Three Months Ended June 30,	
	2012	2011
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 22,433	\$ (13,238)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Depreciation and amortization	18,018	1,908
Share-based compensation expense	8,162	5,660
Deferred income taxes	(313)	
Other non-cash charges	1,772	(130)
Changes in assets and liabilities, excluding the effect of acquisitions:		
Receivables	(39,275)	(11,615)
Inventory, prepaid expenses and other assets	(242)	1,918
Accounts payable and accrued expenses	(18,931)	(3,234)
Deferred revenue	3,671	474
Other long-term liabilities	6	
Cash flows used in operating activities	(4,699)	(18,257)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(6,733)	(924)
Sales of property, plant and equipment	18	3
Purchases of investments	(40,621)	(67,495)
Sales and maturities of investments	56,686	75,240
Cash flows provided by investing activities	9,350	6,824
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	1,340	11,824
Excess tax benefit from share-based compensation	105	
Employee taxes paid related to net share settlement of equity awards	(3,323)	(2,838)
Principal payments of long-term debt	(775)	
Cash flows (used in) provided by financing activities	(2,653)	8,986
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,998	(2,447)
CASH AND CASH EQUIVALENTS Beginning of period	83,601	38,394
CASH AND CASH EQUIVALENTS End of period	\$ 85,599	\$ 35,947
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Cash paid for interest	\$ 8,642	\$
Cash paid for taxes	\$ 909	\$ 11
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 827	\$ 720

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. Alkermes plc 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 and corporate offices 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 (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. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of the Company, merged with and into Alkermes, Inc. (the Merger), with Alkermes, Inc. surviving as a wholly owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company. At the effective time of the Merger, (i) each share of Alkermes, Inc. common stock then issued and outstanding and all associated rights were canceled and automatically converted into the right to receive one ordinary share of the Company; (ii) all then issued and outstanding options to purchase Alkermes, Inc. common stock granted under any stock option plan were converted into options to purchase, on substantially the same terms and conditions, the same number of ordinary shares of the Company at the same exercise price; and (iii) all then issued and outstanding awards of Alkermes, Inc. common stock were converted into awards of the same number, on substantially the same terms and conditions, of ordinary shares of the Company. As a result, upon consummation of the Merger and the issuance of the ordinary shares of the Company in exchange for the canceled shares of Alkermes, Inc. common stock, the former shareholders of Alkermes, Inc. owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan pursuant to the terms of a shareholder s agreement.

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 months ended June 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

Edgar Filing: Alkermes plc. - Form 10-Q

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.

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

\$2.8 million that was previously classified as Proceeds from the issuance of ordinary shares under share-based compensation arrangements was 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.

Edgar Filing: Alkermes plc. - Form 10-Q

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.

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, 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.

Table of Contents

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

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 months ended June 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 June 30, 2011	
Revenues	\$	124,837
Net loss	\$	(2,643)
Basic and diluted loss per ordinary share	\$	(0.02)

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	
<u>June 30, 2012</u>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 33,367	\$ 11	\$ (7)	\$	\$ 33,371
International government agency debt securities	33,220	12	(11)		33,221
Corporate debt securities	6,298	18			6,316
	72,885	41	(18)		72,908
Held-to-maturity securities:					
Certificates of deposit	4,246				4,246
U.S. government obligations	417				417
	4,663				4,663
Money market funds	1,201				1,201
Total short-term investments	78,749	41	(18)		78,772
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	47,492		(78)		47,414
International government agency debt securities	9,194		(12)		9,182
Corporate debt securities	9,008			(919)	8,089
Strategic investments	644	1,030			1,674
	66,338	1,030	(90)	(919)	66,359
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	67,538	1,030	(90)	(919)	67,559
Total investments	\$ 146,287	\$ 1,071	\$ (108)	\$ (919)	\$ 146,331
<u>March 31, 2012</u>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 62,925	\$ 67	\$ (17)	\$	\$ 62,975
International government agency debt securities	25,646	22	(2)		25,666
Corporate debt securities	12,324	27			12,351
	100,895	116	(19)		100,992
Held-to-maturity securities:					
Certificates of deposit	4,236				4,236
U.S. government obligations	417				417
	4,653				4,653
Money market funds	1,201				1,201

Edgar Filing: Alkermes plc. - Form 10-Q

Total short-term investments	106,749	116	(19)		106,846
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	35,493		(70)		35,423
International government agency debt securities	10,257		(20)		10,237
Corporate debt securities	8,009			(660)	7,349
Strategic investments	644	838			1,482
	54,403	838	(90)	(660)	54,491
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	55,603	838	(90)	(660)	55,691
Total investments	\$ 162,352	\$ 954	\$ (109)	\$ (660)	\$ 162,537

Table of Contents

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

The Company's strategic investments include common stock in public companies with which the Company has or had a collaborative arrangement.

The proceeds from the sales and maturities of marketable securities, excluding strategic equity investments, which were primarily reinvested and resulted in realized gains and losses, were as follows:

(In thousands)	Three Months Ended June 30,	
	2012	2011
Proceeds from the sales and maturities of marketable securities	\$ 56,686	\$ 75,240
Realized gains	\$ 3	\$ 13
Realized losses	\$	\$ 1

The Company's available-for-sale and held-to-maturity securities at June 30, 2012 have contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 58,753	\$ 58,751	\$ 5,863	\$ 5,863
After 1 year through 5 years	79,826	78,842		
Total	\$ 138,579	\$ 137,593	\$ 5,863	\$ 5,863

At June 30, 2012, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments with unrealized losses consist primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's investment in Acceleron Pharma, Inc. (Acceleron) was \$8.7 million at June 30, 2012 and March 31, 2012 which is recorded within Other assets in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company will continue to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

Edgar Filing: Alkermes plc. - Form 10-Q

The Company's investment in Civitas Therapeutics, Inc. (Civitas) was \$1.7 million and \$2.0 million at June 30, 2012 and March 31, 2012, respectively, which is recorded within Other assets in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Civitas under the equity method as the Company has an approximately 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the three months ended June 30, 2012 and 2011, the Company recorded a reduction in its investment in Civitas by \$0.3 million and \$0.1 million, respectively, which represented the Company's proportionate share of Civitas' net losses for these periods.

Table of Contents

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

5. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

(In thousands)	June 30, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	80,785	80,785		
International government agency debt securities	42,403	34,307	8,096	
Corporate debt securities	14,405	4,019	8,807	1,579
Strategic equity investments	1,674	1,674		
Interest rate cap contracts	4		4	
Total	\$ 140,472	\$ 121,986	\$ 16,907	\$ 1,579
Liabilities:				
Interest rate swap contract	\$ (594)		(594)	
Total	\$ (594)	\$	\$ (594)	\$

(In thousands)	March 31, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	98,398	98,398		
International government agency debt securities	35,903	30,902		5,001
Corporate debt securities	19,700		14,045	5,655
Strategic equity investments	1,482	1,482		
Interest rate cap contracts	20		20	
Total	\$ 156,704	\$ 131,983	\$ 14,065	\$ 10,656
Liabilities:				
Interest rate swap contract	\$ (522)		(522)	
Total	\$ (522)	\$	\$ (522)	\$

The Company transfers its financial assets and liabilities measured at fair value on a recurring basis between the fair value hierarchies at the end of each reporting period. The following table illustrates the rollforward of the fair value of the Company's investments whose fair value is determined using Level 3 inputs:

(In thousands)	Fair Value
Balance, April 1, 2012	\$ 10,656

Edgar Filing: Alkermes plc. - Form 10-Q

Investments transferred into Level 3		1,579
Investments transferred out of Level 3		(10,510)
Total unrealized losses included in comprehensive loss		(146)
Balance, June 30, 2012	\$	1,579

During the three months ended June 30, 2012, there was one investment in corporate debt securities transferred from Level 2 to Level 1 as trading in this security increased to a level such that the fair value for the security could be derived from a quoted price in an active market. There were no transfers of any securities from Level 1 to Level 2 during the three months ended June 30, 2012.

Table of Contents

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

During the three months ended June 30, 2012, there was one investment in corporate debt securities and one investment in international government agency debt securities that were transferred from Level 3 to Level 2 as trading in these securities resumed during the period. Also during the three months ended June 30, 2012, there were two investments in corporate debt securities that were transferred from Level 2 to Level 3 as trading in these securities ceased during the period.

The Company's international government agency debt securities and corporate debt securities classified as Level 2 are initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market observable data. The market observable data includes reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company's Level 3 securities consist of two corporate debt securities that are not currently trading and a third party pricing service was used to determine the estimated fair value of these securities. The third party pricing service develops its estimate of fair value through a proprietary model using variables including reportable trades and last trade date, bids and offers, trading frequency, benchmark yields, credit spreads and other industry and economic events. The Company validates the prices provided by its third party pricing service by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming the activity in the relevant markets. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its pricing services at June 30, 2012.

In September and December 2011, the Company entered into interest rate cap agreements, and in September 2011, the Company entered into an interest rate swap agreement. These agreements are described in greater detail in Note 11, *Derivative Instruments*. The fair value of the Company's interest rate cap and interest rate swap agreements were based on an income approach, which excludes accrued interest, and takes into consideration then-current interest rates and then-current creditworthiness of the Company or the counterparty, as applicable.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's condensed consolidated balance sheets consist of the \$310.0 million first lien term loan facility (the First Lien Term Loan) and the \$140.0 million second lien term loan facility (the Second Lien Term Loan) and, together with the First Lien Term Loan, the Term Loans). The estimated fair value of the Term Loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future, at June 30, 2012 is as follows:

(In thousands)	Carrying Value	Estimated Fair Value
First Lien Term Loan	\$ 306,351	\$ 308,836
Second Lien Term Loan	\$ 137,832	\$ 141,750

6. INVENTORY

Edgar Filing: Alkermes plc. - Form 10-Q

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventory consists of the following:

(In thousands)	June 30,		March 31,	
	2012		2012	
Raw materials	\$	13,935	\$	12,841
Work in process		7,777		9,569
Finished goods (1)		19,173		16,968
Consigned-out inventory (2)		557		381
Total inventory	\$	41,442	\$	39,759

-
- (1) At June 30, 2012 and March 31, 2012, the Company had \$1.6 million and \$1.3 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.
- (2) At June 30, 2012 and March 31, 2012, consigned-out inventory relates to VIVITROL® inventory in the distribution channel for which the Company has not recognized revenue.

Table of Contents

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

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	June 30, 2012	March 31, 2012
Land	\$ 8,189	\$ 8,189
Building and improvements	140,187	139,820
Furniture, fixture and equipment	188,398	177,729
Leasehold improvements	24,050	45,798
Construction in progress	37,304	44,766
Subtotal	398,128	416,302
Less: accumulated depreciation	(98,592)	(113,307)
Total property, plant and equipment, net	\$ 299,536	\$ 302,995

The Company reclassified \$11.5 million of Furniture, fixture, and equipment and \$0.7 million of Land at March 31, 2012 as Buildings and improvements to revise prior period presentation.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consist of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	June 30, 2012 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (25,814)	\$ 473,886
NanoCrystal technology	13	74,600	(2,720)	71,880
OCR technology	12	66,300	(4,655)	61,645
Total		\$ 640,600	\$ (33,189)	\$ 607,411

The Company recorded \$10.4 million of amortization expense related to its intangible assets during the three months ended June 30, 2012. Based upon the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet as of June 30, 2012 is expected to be in the range of approximately \$42.0 million to \$70.0 million annually through fiscal year 2018.

As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit, which is the Company, was less than its carrying amount, and an impairment of goodwill was not recorded.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	June 30, 2012	March 31, 2012
Accounts payable	\$ 12,766	\$ 18,400
Accrued compensation	13,331	25,023
Accrued interest	2,464	2,472
Accrued other	29,566	33,259
Total accounts payable and accrued expenses	\$ 58,127	\$ 79,154

Table of Contents

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

10. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	June 30, 2012	March 31, 2012
First Lien Term Loan, due September 16, 2017	\$ 306,351	\$ 306,822
Second Lien Term Loan, due September 16, 2018	137,832	137,638
Total	444,183	444,460
Less: current portion	(3,100)	(3,100)
Long-term debt	\$ 441,083	\$ 441,360

11. DERIVATIVE INSTRUMENTS

In December 2011, the Company entered into an interest rate cap agreement with Morgan Stanley Capital Services LLC (MSCS) at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate cap agreement expires in December 2013, has a notional value of \$160.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of gain as other income in the accompanying condensed consolidated statements of operations and comprehensive income (loss) due to the increase in value of this contract during the three months ended June 30, 2012.

In September 2011, the Company entered into an interest rate cap agreement with HSBC Bank USA at a cost of less than \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate cap agreement became effective upon the issuance of the Term Loans, expires in December 2012, has a notional value of \$65.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss as other expense in the accompanying condensed consolidated statements of operations and comprehensive income (loss) due to the decline in value of this contract during the three months ended June 30, 2012.

In September 2011, the Company entered into an interest rate swap agreement with MSCS to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate swap agreement becomes effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. This contract has been designated as a cash flow hedge and accordingly, to the extent effective, any unrealized gains or losses on this interest rate swap contract is reported in accumulated other comprehensive loss. To the extent the hedge is ineffective, hedge transaction gains and losses are reported in other (expense) income, net when the interest payment on the related debt is recognized.

Edgar Filing: Alkermes plc. - Form 10-Q

The following table summarizes the fair value and presentation in the condensed consolidated balance sheets for derivatives designated and not designated as hedging instruments:

(In thousands)	Balance Sheet Location	Fair Value at June 30, 2012
<i>Interest rate swap</i>		
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$ (594)
<i>Interest rate caps</i>		
Asset derivatives not designated as a hedging instruments	Other long-term assets	\$ 4

The following table summarizes the effect of derivatives designated as hedging instruments on the condensed consolidated statements of operations and comprehensive income (loss):

(In thousands)	Amount Recognized in Accumulated Other Comprehensive Loss (Effective Portion)	Amount Reclassified from Accumulated Other Comprehensive Loss into Earnings (Effective Portion)	Amount of Loss Recorded (Ineffective Portion)
June 30, 2012	\$ (594)	\$	\$

Table of Contents

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

The cash flow hedge was deemed to be effective at June 30, 2012. Accordingly, the Company included the \$0.1 million loss incurred during the three months ended June 30, 2012 within accumulated other comprehensive loss. The Company expects that when this contract matures, any amounts in accumulated other comprehensive loss is to be reported as an adjustment to interest expense. The Company considers the impact of its and MSCS credit risk on the fair value of the contract as well as the ability of each party to execute its obligations under the contract. As of June 30, 2012, credit risk did not materially change the fair value of the Company's interest rate swap contract.

12. SHARE-BASED COMPENSATION

Share-based compensation expense consists of the following:

(In thousands)	Three Months Ended June 30,	
	2012	2011
Cost of goods manufactured and sold	\$ 1,081	\$ 556
Research and development	2,310	1,935
Selling, general and administrative	4,771	3,169
Total share-based compensation expense	\$ 8,162	\$ 5,660

At June 30, 2012 and March 31, 2012, \$0.5 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

13. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per ordinary share is calculated based upon net income (loss) available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the calculation of diluted earnings (loss) per ordinary share, the Company uses the weighted average number of ordinary shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options and restricted stock units.

(In thousands)	Three Months Ended June 30,	
	2012	2011
Numerator:		
Net income (loss)	\$ 22,433	\$ (13,238)
Denominator:		
Weighted average number of ordinary shares outstanding	130,434	96,649

Edgar Filing: Alkermes plc. - Form 10-Q

Effect of dilutive securities:		
Stock options	3,276	
Restricted stock units	1,235	
Dilutive ordinary share equivalents	4,511	
Shares used in calculating diluted earnings (loss) per share	134,945	96,649

The following potential ordinary equivalent shares have not been included in the net income (loss) per ordinary share calculations because the effect would have been anti-dilutive.

(In thousands)	Three Months Ended	
	2012	June 30, 2011
Stock options	6,165	7,877
Restricted stock units		1,554
Total	6,165	9,431

Table of Contents

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

14. INCOME TAXES

The Company recorded an income tax provision of \$0.8 million and an income tax benefit of \$0.1 million for the three months ended June 30, 2012 and 2011, respectively. The tax provision of \$0.8 million in the three months ended June 30, 2012 primarily relates to foreign taxes on income.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. As of June 30, 2012, the Company has determined, based on the weight of all available evidence, that it is not more likely than not that the Company's remaining U.S. and Irish deferred tax assets will be realized and a valuation allowance has been recorded.

15. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 3 of this Quarterly Report on Form 10-Q (Form 10-Q), and Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended March 31, 2012 (the Annual Report), which has been filed with the Securities and Exchange Commission (SEC).

On September 16, 2011, the business of Alkermes, Inc. and its consolidated subsidiaries (Old Alkermes) and the drug technologies business (EDT) of Elan Corporation, plc (Elan) were combined (this combination is referred to as the Business Combination, the acquisition of EDT, or the EDT acquisition) under Alkermes plc. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of Alkermes plc, merged with and into Old Alkermes (the Merger), with Old Alkermes surviving as an indirect, wholly-owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company.

Use of the terms such as us, we, our, Alkermes, or the Company in this Form 10-Q is meant to refer to Alkermes plc and its consolidated subsidiaries, except when the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Old Alkermes. Prior to September 16, 2011, Old Alkermes was an independent biotechnology company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market (the NASDAQ) under the symbol ALKS.

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

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products.

Forward-Looking Statements

This document contains and incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, would, expect, anticipate, continue or other similar words. These statements discuss expectations, contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Form 10-Q include, without limitation, statements regarding:

Edgar Filing: Alkermes plc. - Form 10-Q

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding the commercialization of our products, including the sales and marketing efforts of our partners and, for VIVITROL® (naltrexone for extended-release injectable suspension), our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the successful manufacture of our products, by us or our partners, for clinical use and commercial sale;
- our expectations regarding the competitive landscape, and changes therein, related to our products;
- our expectations regarding our collaborations and other significant agreements relating to our products and our ability to establish and maintain successful development collaborations;

Table of Contents

- our expectations regarding the impact of new accounting pronouncements;
- our expectations regarding our intellectual property rights, ability to protect our intellectual property rights and not infringe upon third-party intellectual property rights;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with respect to managing such exposures; and
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including the risks and uncertainties described or discussed in this Form 10-Q and in our Annual Report (including, without limitation, in Item 1A *Risk Factors* thereof).

The forward-looking statements contained and incorporated herein represent our judgment as of the date of this Form 10-Q, and we caution readers not to place undue reliance on such statements. The information contained in this Form 10-Q is provided by us as of the date of this Form 10-Q and, except as required by law, we do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

Executive Summary

On September 16, 2011, the business of Old Alkermes and EDT were combined under Alkermes. We paid Elan \$500.0 million in cash and issued Elan 31.9 million ordinary shares, which had a fair value of \$525.1 million on the closing date of the Merger, for the EDT business. Upon consummation of the Merger, the former shareholders of Old Alkermes owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan pursuant to the terms of a shareholder's agreement.

The Business Combination was accounted for using the acquisition method of accounting for business combinations with Old Alkermes being treated as the accounting acquirer under accounting principles generally accepted in the United States (U.S.) (GAAP), which means that the operating results of Old Alkermes are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition. Accordingly, the financial results presented for the three months ended June 30, 2011 reflect only the operations of Old Alkermes.

Net income for the three months ended June 30, 2012, was \$22.4 million or earnings of \$0.17 per ordinary share basic and diluted, as compared to a net loss of \$13.2 million, or a loss of \$0.14 per ordinary share basic and diluted, for the three months ended June 30, 2011. Total revenues increased by 146% during the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, which was primarily due to the expansion of our product portfolio as a result of the Business Combination and a \$20.0 million sale of certain of our intellectual property unrelated to our key clinical development programs. Operating expenses increased by 59% during the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, which was primarily due the inclusion of expenses associated with the former EDT business and increased clinical study costs due to the advancement of pipeline candidates into later stages of development, partially offset by the elimination of one-time merger related costs related to the Business Combination.

Table of Contents**ESTABLISHED LICENSED-PRODUCT PORTFOLIO**

Our commercial products are described in the table below, including, among other things, the territory in which the marketer has the right to sell the product, once approved, and the source of revenues for us:

Product	Indication	Technology	Territory	Revenue Source	Marketer
<i>RISPERDAL</i> ® <i>CONSTA</i> ®	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
<i>INVEGA</i> ® <i>SUSTENNA</i> ® <i>XEPLION</i> ®	Schizophrenia	NanoCrystal®	Worldwide	Royalty	Janssen
<i>AMPYRA</i> ® <i>FAMPYRA</i> ®	Treatment to improve walking in patients with multiple sclerosis (MS)	Oral Controlled Release (OCR) (MXDAS®)	U.S. Worldwide	Manufacturing and Royalty	Acorda Therapeutics, Inc. in U.S. Biogen Idec (ex-U.S. under sublicense from Acorda)
<i>BYDUREONTM</i>	Type 2 diabetes	Extended-release microsphere	U.S. Worldwide	Royalty	Amylin
<i>VIVITROL</i>	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States (CIS)	Product sales Manufacturing and Royalty	Alkermes plc Janssen
<i>TRICOR</i> ® <i>LIPANTHYL</i> ® <i>LIPIDIL</i> ® <i>SUPRALIP</i> ®	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	Abbott
<i>ZANAFLEX</i> ® <i>CAPSULES</i> ® <i>ZANAFLEX</i> ® <i>TABLETS</i>	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing and Royalty	Acorda
<i>AVINZA</i> ®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer
<i>EMEND</i> ®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Royalty	Merck
<i>FOCALIN</i> ® XR <i>RITALIN LA</i> ®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis
<i>MEGACE</i> ® ES	Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)
<i>LUVOX CR</i> ®	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Manufacturing and Royalty	Jazz Pharmaceuticals plc
<i>RAPAMUNE</i> ®	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
<i>NAPRELAN</i> ®	Various mild to moderate pain indications	OCR (IPDAS®)	U.S. Canada	Manufacturing	Shionogi Sunovion Pharmaceuticals Canada, Inc.

Table of Contents

<i>VERAPAMIL SR</i> <i>VERELAN®</i> <i>VERELAN® PM</i> <i>VERAPAMIL PM</i> <i>VERECAPS®</i> <i>UNIVER®</i>	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing	UCB Kremers-Urban Watson; Cephalon; Aspen; Orient Europharma
<i>DILZEM SR</i> <i>DILZEM XL</i> <i>DILTELAN</i> <i>ACALIX CD</i> <i>DINISOR</i> <i>TILAZEM CR</i> <i>CARDIZEM CD</i>	Hypertension and/or Angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon; Pfizer; Roemmers; Kun Wha; Orient Europharma; Sanofi-Aventis
<i>AFE Datab® CR</i> <i>(AB Rated to Adalat CC®)</i> <i>(Nifedipine) (A)</i>	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Watson Pharmaceutical

KEY COMMERCIAL PRODUCTS

We have five principal commercial products which either currently, or in the future, are expected to contribute meaningfully to our revenues.

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, which are two long-acting atypical antipsychotics, incorporate our extended-release injectable technology. They are products of Janssen. RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia and for the treatment of bipolar I disorder. INVEGA SUSTENNA/XEPLION is a once-monthly, long-acting injectable atypical antipsychotic approved by the FDA for the acute and maintenance treatment of schizophrenia in adults.

In June 2012, we announced that Janssen initiated a phase 3 clinical research program for a three-month formulation of INVEGA SUSTENNA for the treatment of schizophrenia. Two phase 3 studies are expected to enroll approximately 1,800 patients with schizophrenia and will assess the efficacy, safety and tolerability of the three-month injectable formulation. The clinical studies are expected to be completed in the second half of calendar year 2014.

AMPYRA/FAMPYRA

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. AMPYRA was approved by the FDA in January 2010 as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). It

Edgar Filing: Alkermes plc. - Form 10-Q

is the first and, currently, only product to be approved for this indication. A product of Acorda, it incorporates our OCR technology. FAMPYRA received conditional marketing approval in the European Union (EU) in July 2011 and is currently being sold by Biogen Idec in select countries outside of the U.S. AMPYRA and FAMPYRA are manufactured by us.

BYDUREON

We collaborated with Amylin on the development of a once-weekly formulation of exenatide, BYDUREON, for the treatment of type 2 diabetes. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in Amylin s BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology. Amylin is responsible for commercializing exenatide products, including BYDUREON, in the U.S. Eli Lilly and Company (Lilly) has exclusive rights to commercialize exenatide products outside of the U.S. until December 31, 2013 or such earlier date as agreed upon between Lilly and Amylin pursuant to the terms of their transition agreement, following which Amylin will have such exclusive rights.

In June 2012, Bristol-Myers Squibb Company (Bristol-Myers) and Amylin announced that Bristol-Myers will acquire Amylin, subject to the successful completion of a cash tender offer and second step merger and satisfaction of other customary closing conditions. Bristol-Myers and AstraZeneca PLC also announced that, following the completion of Bristol-Myers proposed acquisition of Amylin, the

Table of Contents

companies intend to enter into collaboration arrangements, based on the framework of their existing diabetes alliance, regarding the development and commercialization of Amylin's portfolio of products, including BYDUREON.

In June 2012, Amylin and we announced results from a long-term extension of the DURATION-1 study, which showed that BYDUREON was associated with clinically significant and sustained improvements in glycemic control during four years of treatment in adults with type 2 diabetes. Patients completing four years of BYDUREON treatment experienced clinically significant improvements in A1C (1.7 percentage points) and fasting plasma glucose (-37 mg/dL) from baseline. A1C is a measure of average blood sugar over three months. Although BYDUREON is not indicated for weight loss, patients treated with BYDUREON also lost an average of 5.5 pounds from baseline. Along with Amylin, we also announced the results from an analysis of seven randomized clinical studies demonstrating that patients treated with BYDUREON experienced improvements in A1C, fasting glucose, weight and pulse pressure, regardless of baseline body weight. Results from an additional study were announced in June that showed that a significantly greater proportion of patients treated with BYDUREON achieved target glucose levels and weight loss compared to those treated with LEVEMIR® (insulin detemir).

VIVITROL

VIVITROL is the first and only once-monthly injectable medication for the treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification. The medication uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently market and sell, VIVITROL in the U.S. and Cilag GmbH International (Cilag) sells VIVITROL in Russia and other countries in the Commonwealth of Independent States (CIS).

Other Commercial Products

We expect revenues from our other commercial products will decrease in the future due to existing and expected competition from generic manufacturers. For a more detailed discussion of current and expected future revenue contribution of such products, please see Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report which has been filed with the SEC.

KEY DEVELOPMENT PROGRAMS

We also have several proprietary and partnered product candidates in various stages of development.

We are studying ALKS 9070 for the treatment of schizophrenia. ALKS 9070 is designed to provide once-monthly dosing of a medication that converts *in vivo* into aripiprazole, a molecule that is commercially available under the name ABILIFY®. ALKS 9070 is our first product candidate to leverage our proprietary LinkeRx product platform. A phase 3 trial to assess the efficacy, safety and tolerability of ALKS 9070 in approximately 690 patients experiencing acute exacerbation of schizophrenia is currently on-going and the clinical data from this study, expected mid-calendar 2013, will form the basis of a New Drug Application (NDA) to the FDA for ALKS 9070 for the treatment of schizophrenia.

ALKS 5461 is a combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for the treatment of major depressive disorder (MDD) in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 has also been evaluated for the treatment of cocaine dependence. A phase 2 study is currently on-going to evaluate the efficacy and safety of ALKS 5461 when administered once daily for four weeks in approximately 130 patients with MDD who have inadequate response to antidepressant therapy. Data from this study are expected in the first half of calendar year 2013. Also, a phase 1b study of ALKS 5461 for cocaine dependence funded through a \$2.4 million grant from the National Institute on Drug Abuse (NIDA) has completed. The single-center, placebo-controlled trial was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of ALKS 5461 in opioid-experienced cocaine abusers. Results from the study showed that ALKS 5461 was generally well tolerated and once-daily sublingual administration of ALKS 5461 blocked subjective effects of co-administered cocaine. No further studies of ALKS 5461 for cocaine dependence are planned at this time.

ALKS 33 is an oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 is being evaluated as a potential treatment for alcohol dependence; there are currently no ongoing clinical trials of ALKS 33 for the treatment of alcohol dependence.

ALKS 37 is an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced constipation, (OIC). In May, 2012, we announced results from our phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study for ALKS 37 in approximately 150 patients. The study was designed to assess the safety, tolerability, pharmacokinetic profile and efficacy of ALKS 37. Although ALKS 37 was generally well tolerated at all dose levels and subjects taking ALKS 37 demonstrated an increase in bowel movements compared to baseline, the product profile did not satisfy our pre-specified criteria for advancing into phase 3 clinical trials. Based

Table of Contents

on this evaluation, Alkermes has decided not to advance ALKS 37. A second phase 2b study of ALKS 37 for the treatment of OIC is concluding, and no additional clinical studies for ALKS 37 are planned.

ZOHYDRO ER (hydrocodone bitartrate extended-release capsules) is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. (Zogenix) for the U.S. market. ZOHYDRO ER utilizes our oral controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. In May 2012, Zogenix announced that it submitted an NDA to the FDA for ZOHYDRO ER, and in July 2012, Zogenix announced that the FDA accepted for review the NDA for ZOHYDRO ER. The FDA has assigned a target action date of March 1, 2013 for the ZOHYDRO ER NDA. We will earn manufacturing revenues in the U.S. for ZOHYDRO ER and are entitled to receive a royalty on U.S. sales of ZOHYDRO ER, if approved. We have maintained all rights to the product in territories outside the U.S. and will seek to develop and license the product through commercial partnerships in those territories.

Results of Operations*Manufacturing and Royalty Revenues*

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)
	2012	June 30, 2011	
Manufacturing and royalty revenues:			
RISPERDAL CONSTA	\$ 36.8	\$ 48.5	\$ (11.7)
AMPYRA/FAMPYRA	17.1		17.1
TRICOR 145	12.0		12.0
INVEGA SUSTENNA/XEPLION	11.1		11.1
RITALIN LA/FOCALIN XR	10.9		10.9
VERELAN	6.0		6.0
Other	44.5	0.4	44.1
Manufacturing and royalty revenues	\$ 138.4	\$ 48.9	\$ 89.5

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators.

Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earned manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen's net sales of RISPERDAL CONSTA. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to a 33% decrease in the quantity shipped to Janssen and a 12% decrease in royalty revenues; partially offset by a 15% increase in the net unit sales price. Janssen's end-market sales of RISPERDAL CONSTA were \$354.8 million and \$403.6 million during the three months ended June 30, 2012 and 2011.

Edgar Filing: Alkermes plc. - Form 10-Q

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, our long-acting atypical antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalties on end-market sales of INVEGA SUSTENNA/XEPLION of 5% up to the first \$250 million in calendar-year sales; 7% on calendar-year sales of between \$250 million and \$500 million; and 9% on calendar-year sales exceeding \$500 million. The royalty rate resets at the beginning of each calendar-year. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION. Increased competition may lead to reduced unit sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, as well as increasing pricing pressure. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S., and INVEGA SUSTENNA/XEPLION is covered by a patent until 2018 in the EU and 2019 in the U.S., and as such, we do not anticipate any generic versions in the near-term for either of these products.

Included in other manufacturing and royalty revenues for the three months ended June 30, 2012 is \$20.0 million of license revenue related to the sale of certain of our intellectual property unrelated to our key clinical development programs.

The increase in royalty revenues from TRICOR 145, AMPYRA/FAMPYRA, RITALIN LA/FOCALIN XR, INVEGA SUSTENNA/XEPLION, VERELAN and the other manufacturing and royalty revenues were due to the addition of the portfolio of commercialized products from the former EDT business. Our financial expectations for the TRICOR 145 and RITALIN LA/FOCALIN XR franchise for fiscal year 2013 anticipates revenue erosion from generic competition assuming generic entry in mid-calendar 2012, with revenues declining by roughly one-half each quarter, starting in the second quarter of fiscal 2013.

Table of Contents

We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen Idec continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the U.S. and FAMPYRA is covered by a patent until 2025 in the EU, and as such, we do not anticipate any generic versions of these products in the near-term. A number of companies are working to develop products to treat multiple sclerosis that may compete with AMPYRA/FAMPYRA, which may negatively impact future sales of the products.

Product Sales, net

Our product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three months ended June 30, 2012 and 2011:

(In millions)	Three Months Ended			
	June 30,		June 30,	
	2012	% of Sales	2011	% of Sales
Product sales, gross	\$ 17.7	100.0%	\$ 14.1	100.0%
Adjustments to product sales, gross:				
Medicaid rebates	(1.3)	(7.3)%	(1.2)	(8.5)%
Chargebacks	(1.3)	(7.3)%	(1.2)	(8.5)%
Reserve for inventory in the channel				
(1)	(0.7)	(4.0)%	(0.7)	(5.0)%
Other	(2.0)	(11.3)%	(1.3)	(9.2)%
Total adjustments	(5.3)	(29.9)%	(4.4)	(31.2)%
Product sales, net	\$ 12.4	70.1%	\$ 9.7	68.8%

(1) Our reserve for inventory in the channel is an estimate that reflects the deferral of the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel as we do not yet have the history to reasonably estimate returns related to these shipments. We estimate the product shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by our customers as well as prescription information.

The increase in product sales, gross for the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was due to a 21% increase in the number of units sold. We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S. As previously noted, we defer the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel. During the three months ended September 30, 2012, we will have sufficient history to estimate returns upon shipment of VIVITROL into the distribution channel, and we will no longer defer the recognition of revenue until the product has left the distribution channel. We expect that this change will result in a decrease to our provision for product returns and result in an increase in product sales, net to be recognized during the three months ended September 30, 2012.

In addition, we anticipate that Janssen-Cilag will increase sales of VIVITROL in Russia and the CIS, which are recorded as manufacturing and royalty revenues. In addition, there exists the potential to launch the product in other countries around the world. A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence that may compete with VIVITROL, which may negatively impact future sales of VIVITROL. Increased competition may lead to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021 and, as such, we do not

anticipate any generic versions of this product in the near-term.

Research and Development Revenue

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)
	2012	June 30, 2011	
Research and development revenue	\$ 1.5	\$ 3.3	\$ (1.8)

Research and development (R&D) revenue is generally earned for services performed and milestones achieved under arrangements with our collaborators. The decrease in R&D revenue for the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to the \$3.0 million milestone payment we earned upon the receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication during the three months ended June 30, 2011.

Table of Contents**Costs and Expenses***Cost of Goods Manufactured and Sold*

Cost of goods manufactured and sold	\$	42.1	\$	16.2	\$	(25.9)
-------------------------------------	----	------	----	------	----	--------

The increase in cost of goods manufactured and sold in the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to the \$29.8 million increase in cost of goods manufactured from the addition of EDT's portfolio of commercialized products, partially offset by a \$4.7 million decrease in cost of goods manufactured from RISPERDAL CONSTA due to a decrease in the quantity of RISPERDAL CONSTA shipped to Janssen.

Research and Development Expense

Research and development expense	\$	37.8	\$	28.1	\$	(9.7)
----------------------------------	----	------	----	------	----	-------

The increase in R&D expense in the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to a \$5.1 million increase related to clinical study activity and the addition of \$4.7 million of R&D expense from the former EDT business. The increase in clinical study expense was primarily due to the ALKS 9070 development program, which has both phase 3 and phase 1 studies underway partially offset by a decrease in activities related to the ALKS 37 program as we decided not to advance ALKS 37 after the results from the phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study were announced in May 2012.

A significant portion of our R&D expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative R&D activities are tracked by project and may be reimbursed to us by our partners. We account for our R&D expenses on a departmental and functional basis in accordance with our budget and management practices.

Selling, General and Administrative Expense

Selling, general and administrative expense	\$	29.8	\$	31.5	\$	1.7
---	----	------	----	------	----	-----

The decrease in selling, general and administrative (SG&A) expense for the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to an \$8.3 million decrease in professional services expense primarily due to costs incurred in connection with the Business Combination during the three months ended June 30, 2011, partially offset by the addition of \$5.4 million of SG&A costs from the former EDT business.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets	\$	10.4	\$		\$	(10.4)
--	----	------	----	--	----	--------

In connection with the Business Combination, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which are expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based upon our most recent analysis, amortization of intangible assets included within our consolidated balance sheet as of June 30, 2012, is expected to be in the range of approximately \$42.0 million to \$70.0 million annually through fiscal year 2018.

Table of Contents*Other (Expense) Income, Net*

Interest income	\$	0.3	\$	0.5	\$	(0.2)
Interest expense		(10.2)				(10.2)
Other income, net		0.9		0.1		0.8
Total other (expense) income, net	\$	(9.0)	\$	0.6	\$	(9.6)

The increase in interest expense for the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was due to our entry into \$450.0 million of term loan financing in September 2011. The first lien term loan facility (the First Lien Term Loan) has a principal amount of \$308.5 million outstanding at June 30, 2012, and an interest rate of three-month LIBOR plus 5.25%. The second lien term loan facility (the Second Lien Term Loan and together the Term Loans) has a principal amount of \$140.0 million outstanding at June 30, 2012 and an interest rate of three-month LIBOR plus 8.00%. Under both loan agreements, three-month LIBOR is subject to an interest rate floor of 1.50%.

We expect interest expense to increase in fiscal year 2013, as fiscal year 2013 will include a full year of interest expense on the Term Loans. Beyond fiscal year 2013, we anticipate that interest expense will decrease as the Term Loans are paid down.

Income Tax Provision (Benefit)

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)
	2012	June 30, 2011	
Income tax provision (benefit)	\$	0.8	\$ (0.1) \$ (0.9)

We recorded an income tax provision of \$0.8 million and an income tax benefit of \$0.1 million for the three months ended June 30, 2012 and 2011, respectively. The tax provision of \$0.8 million in the three months ended June 30, 2012 primarily relates to foreign taxes on income.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of our assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. As of June 30, 2012, we determined, based on the weight of all available evidence, that it is not more likely than not that our remaining U.S. and Irish deferred tax assets will be realized and a valuation allowance has been recorded.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)	June 30,		March 31,	
	2012		2012	
Cash and cash equivalents	\$	85.6	\$	83.6
Investments short-term		78.8		106.8
Investments long-term		67.6		55.7
Total cash, cash equivalents and investments	\$	232.0	\$	246.1
Working capital	\$	281.2	\$	250.0
Outstanding borrowings current and long-term	\$	444.2	\$	444.5

Table of Contents

Our cash flows for the three months ended June 30, 2012 and 2011 were as follows:

(In millions)	Three Months Ended			
	2012		June 30, 2011	
Cash and cash equivalents, beginning of period	\$	83.6	\$	38.4
Cash (used in) operating activities		(4.7)		(18.3)
Cash provided by investing activities		9.4		6.8
Cash (used in) provided by financing activities		(2.7)		9.0
Cash and cash equivalents, end of period	\$	85.6	\$	35.9

Our primary sources of liquidity are cash provided by past operating activities, payments we have received under R&D arrangements and other arrangements with collaborators, term loan financing and private placements of debt securities. The decrease in cash used in operating activities during the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to an increase in cash provided by our customers partially offset by an increase in cash used to pay our suppliers, our employees and payments made for interest on the Term Loans. Both the increase in cash provided by our customers and the increase in cash used to pay our suppliers and employees are primarily due to the Business Combination. The increase in cash provided from investing activities during the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to an increase in the net sales of investments, partially offset by an increase in purchases of property, plant and equipment. The decrease in cash provided by financing activities during the three months ended June 30, 2012, as compared to the three months ended June 30, 2011, was primarily due to a decrease in cash received from the issuance of ordinary shares related to share-based compensation arrangements partially offset by principal payments on our Term Loans.

Our investments at June 30, 2012 consist of the following:

(In millions)		Amortized		Gross Unrealized		Estimated
		Cost		Gains	Losses	
Investments	short-term	\$	78.8	\$		\$ 78.8
Investments	long-term available-for-sale		66.3		1.0	(1.0) 66.3
Investments	long-term held-to-maturity		1.2			1.2
Total		\$	146.3	\$	1.0	(1.0) \$ 146.3

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At June 30, 2012, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

Edgar Filing: Alkermes plc. - Form 10-Q

At June 30, 2012 and March 31, 2012, 1% and 7%, respectively, of our investments are valued using unobservable, or Level 3 inputs, to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. During the three months ended June 30, 2012, the two securities that were included in Level 3 at March 31, 2012 were transferred out of Level 3 as trading in these securities resumed during the period. Also during the three months ended June 30, 2012, there were two investments in corporate debt securities that were transferred from Level 2 to Level 3 as trading in these securities ceased during the period.

We believe that our current cash and cash equivalents and short and long-term investments, combined with anticipated revenues will generate sufficient cash flows to meet our current anticipated liquidity and capital requirements for the next twelve months.

Borrowings

At June 30, 2012, our borrowings consisted of the Term Loans, with an outstanding principal balance of \$448.5 million. Please refer to Note 10 *Long-Term Debt* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of our outstanding Term Loans.

Table of Contents

Contractual Obligations

Refer to Part II, Item 7 of our Annual Report for the year ended March 31, 2012 in the *Contractual Obligations* section for a discussion of our contractual obligations. Our contractual obligations as of June 30, 2012 were not materially changed from the date of that report.

Off-Balance Sheet Arrangements

At June 30, 2012, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different assumptions or conditions. Refer to *Critical Accounting Estimates* within Part II, Item 7 of our Annual Report for a discussion of our critical accounting estimates.

New Accounting Standards

Refer to New Accounting Pronouncements included in Note 2, *Summary of Significant Accounting Policies* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of new accounting standards.

Item 3. *Quantitative and Qualitative Disclosures about Market Risk*

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks during the first three months of fiscal year 2013, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products as well as certain operating costs arising from expenses and payables at our Irish operations that are settled in Euro. These foreign currency exchange rate risks are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report for the year ended March 31, 2012. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk during the first three months of fiscal year 2013.

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, (the Exchange Act) at June 30, 2012. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2012 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control over Financial Reporting

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of certain of our products. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations, cash flows or financial position.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in Part I, Item 1A *Risk Factors*, of our Annual Report for the fiscal year ended March 31, 2012.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc., program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the quarter ended June 30, 2012. As of June 30, 2012, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million under this program.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2012, Mr. Robert A. Breyer and Paul J. Mitchell, each a director of the Company, entered into trading plans in accordance with Rule 10b5-1, and in a manner consistent with the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

Item 6. Exhibits

(a) List of Exhibits:

Edgar Filing: Alkermes plc. - Form 10-Q

Exhibit**No.**

- 31.1 Rule 13a-14(a)/15d-14(a) Certification (filed herewith).
- 31.2 Rule 13a-14(a)/15d-14(a) Certification (filed herewith).
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
- 101 The following materials from Alkermes PLC's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements (furnished herewith).

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALKERMES plc

(Registrant)

By: /s/ Richard F. Pops
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ James M. Frates
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: July 26, 2012