

Alkermes plc.
Form 10-Q
January 31, 2013
[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 December 31, 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)

Ireland

(State or other jurisdiction of incorporation or organization)

98-1007018

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

Edgar Filing: Alkermes plc. - Form 10-Q

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 ☒

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The number of shares of the issuer's ordinary shares, \$0.01 par value, outstanding as of January 28, 2013, was 133,167,011 shares.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2012**

		Page No.
	<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets December 31, 2012 and March 31, 2012</u>	3
	<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) For the Three and Nine Months Ended December 31, 2012 and 2011</u>	4
	<u>Condensed Consolidated Statements of Cash Flows For the Nine Months Ended December 31, 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>	19
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	32
<u>Item 4.</u>	<u>Controls and Procedures</u>	32
	<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	33
<u>Item 1A.</u>	<u>Risk Factors</u>	33
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 5.</u>	<u>Other Information</u>	33
<u>Item 6.</u>	<u>Exhibits</u>	33
<u>Signatures</u>		34
Exhibit Index		
Ex-31.1 Section 302 Certification of Chief Executive Officer		
Ex-31.2 Section 302 Certification of Chief Financial Officer		
Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer		

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

	December 31, 2012 (In thousands, except share and per share amounts)	March 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 135,892	\$ 83,601
Investments short-term	73,412	106,846
Receivables	119,835	96,381
Inventory	45,686	39,759
Prepaid expenses and other current assets	12,697	12,566
Total current assets	387,522	339,153
PROPERTY, PLANT AND EQUIPMENT, NET	292,186	302,995
INTANGIBLE ASSETS, NET	586,315	617,845
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	29,976	55,691
OTHER ASSETS	23,024	26,793
TOTAL ASSETS	\$ 1,411,763	\$ 1,435,217
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 67,655	\$ 79,154
Deferred revenue current	2,874	6,910
Long-term debt current	6,750	3,100
Total current liabilities	77,279	89,164
LONG-TERM DEBT	362,349	441,360
DEFERRED REVENUE LONG-TERM	9,140	7,578
DEFERRED TAX LIABILITIES LONG-TERM	32,932	34,512
OTHER LONG-TERM LIABILITIES	10,124	8,751
Total liabilities	491,824	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 December 31, 2012 and March 31, 2012, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 132,733,001 and 130,212,530 shares issued; 132,419,749 and 130,177,452 shares outstanding at December 31, 2012 and March 31, 2012, respectively	1,324	1,300
Treasury stock, at cost (313,252 and 35,078 shares at December 31, 2012 and March 31, 2012, respectively)	(5,375)	(571)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,429,573	1,380,742
Accumulated other comprehensive loss	(2,661)	(2,713)
Accumulated deficit	(502,922)	(524,906)
Total shareholders' equity	919,939	853,852
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,411,763	\$ 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 December 31,		Nine Months Ended December 31,	
	2012	2011	2012	2011
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 118,274	\$ 112,780	\$ 363,981	\$ 215,759
Product sales, net	15,917	10,597	43,481	30,170
Research and development revenue	1,718	2,266	4,664	13,575
Total revenues	135,909	125,643	412,126	259,504
EXPENSES:				
Cost of goods manufactured and sold	38,914	42,752	122,475	76,501
Research and development	31,319	40,493	104,213	96,703
Selling, general and administrative	29,867	35,469	91,079	103,200
Amortization of acquired intangible assets	10,549	11,896	31,530	13,713
Total expenses	110,649	130,610	349,297	290,117
OPERATING INCOME (LOSS)	25,260	(4,967)	62,829	(30,613)
OTHER (EXPENSE), NET:				
Interest income	155	350	670	1,235
Interest expense	(4,703)	(10,458)	(37,521)	(18,019)
Other (expense) income, net	(49)	345	1,597	770
Total other (expense), net	(4,597)	(9,763)	(35,254)	(16,014)
INCOME (LOSS) BEFORE INCOME TAXES	20,663	(14,730)	27,575	(46,627)
INCOME TAX PROVISION	4,405	98	5,591	3,694
NET INCOME (LOSS)	\$ 16,258	\$ (14,828)	\$ 21,984	\$ (50,321)
EARNINGS (LOSS) PER ORDINARY SHARE:				
Basic	\$ 0.12	\$ (0.11)	\$ 0.17	\$ (0.46)
Diluted	\$ 0.12	\$ (0.11)	\$ 0.16	\$ (0.46)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	132,097	129,670	131,202	109,645
Diluted	137,497	129,670	136,216	109,645
COMPREHENSIVE INCOME (LOSS):				
Net income (loss)	\$ 16,258	\$ (14,828)	\$ 21,984	\$ (50,321)
Unrealized gains (losses) on marketable securities, net of tax:				
Holding gains (losses), net of tax	134	27	561	368
Less: Reclassification adjustment for gains included in net income (loss)			(1,030)	
Unrealized gains (losses) on marketable securities	134	27	(469)	368
Unrealized gains (losses) on derivative contracts:				
Unrealized losses on derivative contracts		(33)	(72)	(276)
			594	

594

Edgar Filing: Alkermes plc. - Form 10-Q

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

Unrealized losses on derivative contracts			(33)		522		(276)
COMPREHENSIVE INCOME (LOSS)	\$	16,392	\$	(14,834)	\$	22,037	\$ (50,229)

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)**

	Nine Months Ended December 31,		
	2012		2011
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$	21,984	\$ (50,321)
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization		55,430	27,251
Share-based compensation expense		26,835	21,743
Deferred income taxes		(1,580)	(11,239)
Excess tax benefit from share-based compensation		(4,354)	(3,127)
Loss on debt refinancing transaction		12,129	
Prepayment penalty in connection with debt refinancing		(2,800)	
Principal payments on long-term debt attributable to original issue discount		(2,657)	
Other non-cash charges		4,903	2,664
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables		(23,454)	(22,050)
Inventory, prepaid expenses and other assets		(7,753)	(8,052)
Accounts payable and accrued expenses		(7,190)	23,971
Deferred revenue		(2,473)	1,398
Other long-term liabilities		2,227	
Cash flows provided by (used in) operating activities		71,247	(17,762)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment		(13,958)	(8,859)
Sales of property, plant and equipment		74	3
Promissory note issued to Civitas Therapeutics, Inc.		(1,116)	
Acquisition of Elan Drug Technologies, net of cash acquired			(494,774)
Investment in Acceleron Pharmaceuticals, Inc.			(231)
Purchases of investments		(161,508)	(159,322)
Sales and maturities of investments		220,188	267,604
Cash flows provided by (used in) investing activities		43,680	(395,579)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements		17,513	16,573
Excess tax benefit from share-based compensation		4,354	3,127
Proceeds from the issuance of long-term debt		368,557	444,100
Employee taxes paid related to net share settlement of equity awards		(4,804)	(3,522)
Principal payments of long-term debt		(448,256)	
Cash flows (used in) provided by financing activities		(62,636)	460,278
NET INCREASE IN CASH AND CASH EQUIVALENTS		52,291	46,937
CASH AND CASH EQUIVALENTS Beginning of period		83,601	38,394
CASH AND CASH EQUIVALENTS End of period	\$	135,892	\$ 85,331
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$	22,431	\$ 13,482
Cash paid for taxes	\$	3,135	\$ 10,070
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$	1,674	\$ 2,139

Edgar Filing: Alkermes plc. - Form 10-Q

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 (Continued)

1. THE COMPANY

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

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

Principles of Consolidation

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

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.

Table of Contents

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

Revenue Recognition

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

Based on this revised revenue recognition policy, a reserve is now estimated for future product returns on VIVITROL gross product sales. This estimate is based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at VIVITROL product sales, net. Once VIVITROL is returned, it is destroyed. At December 31, 2012, the product return reserve is estimated to be 2% of product sales and amounts to \$3.0 million.

Segment Information

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

Reclassifications

An amount equal to \$3.5 million that was previously classified as Proceeds from the issuance of ordinary shares under share-based compensation arrangements has been reclassified to Employee taxes paid related to net share settlement of equity awards in the accompanying condensed consolidated statements of cash flows to conform to current period presentation.

New Accounting Pronouncements

Edgar Filing: Alkermes plc. - Form 10-Q

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

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

3. ACQUISITIONS

On September 16, 2011, the Company acquired EDT from Elan in a transaction accounted for under the acquisition method of accounting for business combinations, in exchange for \$500.0 million in cash and 31.9 million ordinary shares of Alkermes Inc., valued at \$525.1 million based on a stock price of \$16.46 per share on the acquisition date. EDT developed and manufactured pharmaceutical products that deliver clinical benefits to patients using EDT's experience and proprietary drug technologies, including the oral controlled release platform (OCR) and the bioavailability enhancement platform, including EDT's NanoCrystal® technology.

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 nine months ended December 31, 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)	Nine Months Ended December 31, 2011
Revenues	\$ 368,570
Net loss	\$ (21,705)
Basic and diluted loss per common share	\$ (0.17)

Table of Contents

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

4. INVESTMENTS

Investments consist of the following:

December 31, 2012	Amortized Cost	Gains	Gross Unrealized Losses Less than One Year (In thousands)	Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 50,202	\$ 20	\$ (3)	\$	\$ 50,219
Corporate debt securities	12,939	48			12,987
International government agency debt securities	8,999	6			9,005
	72,140	74	(3)		72,211
Money market funds	1,201				1,201
Total short-term investments	73,341	74	(3)		73,412
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	16,005		(44)		15,961
Corporate debt securities	10,022		(2)	(310)	9,710
International government agency debt securities	3,105				3,105
	29,132		(46)	(310)	28,776
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	30,332		(46)	(310)	29,976
Total investments	\$ 103,673	\$ 74	\$ (49)	\$ (310)	\$ 103,388
March 31, 2012					
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
Total short-term investments	106,749	116	(19)		106,846

Edgar Filing: Alkermes plc. - Form 10-Q

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

The Company's strategic investments at March 31, 2012 include common stock in a public company with which the Company had a collaborative arrangement. The Company sold this investment during the three months ended September 30, 2012 and recorded a gain of \$1.2 million within Other income, net in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

Table of Contents

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

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)	Nine Months Ended December 31,	
	2012	2011
Proceeds from the sales and maturities of marketable securities	\$ 220,188	\$ 267,604
Realized gains	\$ 10	\$ 37
Realized losses	\$ (1)	\$ (11)

The Company's available-for-sale and held-to-maturity securities at December 31, 2012 had 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	\$ 30,993	\$ 30,994	\$ 1,200	\$ 1,200
After 1 year through 5 years	70,279	69,993		
Total	\$ 101,272	\$ 100,987	\$ 1,200	\$ 1,200

At December 31, 2012, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted 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 December 31, 2012 and March 31, 2012, which was 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.

The Company's investment in Civitas Therapeutics, Inc. (Civitas) was \$1.2 million and \$2.0 million at December 31, 2012 and March 31, 2012, respectively, which was 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

Edgar Filing: Alkermes plc. - Form 10-Q

board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the nine months ended December 31, 2012 and 2011, the Company recorded a reduction in its investment in Civitas of \$0.8 million and \$0.6 million, respectively, which represented the Company's proportionate share of Civitas' net losses for these periods.

In December 2012, the Company and four other existing investors agreed to provide Civitas with a promissory note in the amount of \$9.0 million. The promissory note will pay 6% interest per year, is payable on demand at any time on or after December 18, 2013 and is convertible into either common or preferred shares of Civitas upon a majority vote of the promissory note holders on or after December 18, 2013, or in the event of a qualified financing as defined in the Note Purchase Agreement. The Company's share of the promissory note, \$1.1 million, was recorded within Prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets.

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)	December 31, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201		\$
U.S. government and agency debt securities	66,180	66,180		
Corporate debt securities	22,697	2,033	20,664	
International government agency debt securities	12,110	3,105	9,005	
Total	\$ 102,188	\$ 72,519	\$ 29,669	\$
Liabilities:				
Interest rate swap contract	\$ (631)		\$ (631)	\$
Total	\$ (631)		\$ (631)	\$

(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 was determined using Level 3 inputs:

(In thousands)	Fair Value
Balance, April 1, 2012	\$ 10,656
Investments transferred into Level 3	1,579
Investments transferred out of Level 3	(12,247)
Total unrealized gains included in comprehensive loss	12

Edgar Filing: Alkermes plc. - Form 10-Q

Balance, December 31, 2012

\$

Table of Contents

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

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the nine months ended December 31, 2012. During the nine months ended December 31, 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. Later in the nine months ended December 31, 2012, these investments were transferred from Level 3 to Level 2 as trading in these securities resumed during the period.

The Company's international government agency debt securities and corporate debt securities classified as Level 2 were 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.

A third-party pricing service was used to determine the estimated fair value of 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 December 31, 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 \$300.0 million, seven-year term loan bearing interest at three-Month LIBOR plus 3.5% (Term Loan B-1) and the \$75.0 million, four-year term loan bearing interest at three-Month LIBOR plus 3.0% (Term Loan B-2 and together with Term Loan B-1, the New Term Loan Facility). The estimated fair value of these 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 December 31, 2012, was as follows:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 295,382	\$ 302,431
Term Loan B-2	\$ 73,717	\$ 74,804

6. INVENTORY

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

(In thousands)	December 31, 2012		March 31, 2012	
Raw materials	\$	13,813	\$	12,841
Work in process		10,555		9,569
Finished goods (1)		21,318		16,968
Consigned-out inventory (2)				381
Total inventory	\$	45,686	\$	39,759

(1) At December 31, 2012 and March 31, 2012, the Company had \$0.5 million and \$1.3 million, respectively, of VIVITROL finished goods inventory located at its third-party warehouse and shipping service provider.

(2) At March 31, 2012, consigned-out inventory related to VIVITROL inventory in the distribution channel for which the Company had not recognized revenue. As previously disclosed, in August 2012, the Company changed the way in which revenue is recognized on

Table of Contents

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

VIVITROL product sales and it no longer expects to have consigned-out inventory.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	December 31, 2012	March 31, 2012
Land	\$ 8,189	\$ 8,189
Building and improvements	141,276	139,820
Furniture, fixture and equipment	193,118	177,729
Leasehold improvements	24,049	45,798
Construction in progress	39,916	44,766
Subtotal	406,548	416,302
Less: accumulated depreciation	(114,362)	(113,307)
Total property, plant and equipment, net	\$ 292,186	\$ 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 consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	December 31, 2012 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (42,150)	\$ 457,550
NanoCrystal technology	13	74,600	(4,501)	70,099
OCR technology	12	66,300	(7,634)	58,666
Total		\$ 640,600	\$ (54,285)	\$ 586,315

The Company recorded \$31.5 million of amortization expense related to its intangible assets during the nine months ended December 31, 2012. Based upon the Company's most recent analysis, the Company expects the amortization of intangible assets included within its condensed

Edgar Filing: Alkermes plc. - Form 10-Q

consolidated balance sheet as of December 31, 2012 to be in the range of approximately \$42.0 million to \$70.0 million annually over the next five fiscal years.

During the three months ended December 31, 2012, the Company performed its annual goodwill impairment test. The Company's goodwill, which solely relates to the EDT acquisition in the fiscal year ended March 31, 2012, has been assigned to a reporting unit which consists of the former EDT business. Goodwill is reviewed for impairment utilizing a two-step process. The first step requires the Company to compare the fair value of the reporting unit to its respective carrying value, which includes goodwill. If the fair value of the reporting unit exceeds its carrying value, the goodwill is not considered impaired. If the carrying value is higher than the fair value, there is an indication that an impairment may exist and the second step is required. In step two, the implied fair value of goodwill is calculated as the excess of the fair value of a reporting unit over the fair values assigned to its assets and liabilities. If the implied fair value of goodwill is less than the carrying value of the reporting unit's goodwill, the difference is recognized as an impairment loss.

The Company worked with a valuation firm and established fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account (1)

Table of Contents

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

assumptions that market participants would use in their estimates of fair value, (2) current period actual results, and (3) budgeted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration the Company's estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies.

The Company determined that the fair value of its reporting unit was substantially in excess of its respective carrying value and there was no impairment in the value of this asset as of December 31, 2012.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	December 31, 2012	March 31, 2012
Accounts payable	\$ 14,401	\$ 18,400
Accrued compensation	23,003	25,023
Accrued interest	1,312	2,472
Accrued other	28,939	33,259
Total accounts payable and accrued expenses	\$ 67,655	\$ 79,154

10. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	December 31, 2012	March 31, 2012
Term Loan B-1, due September 25, 2019	\$ 295,382	\$
Term Loan B-2, due September 25, 2016	73,717	
First Lien Term Loan, due September 16, 2017		306,822
Second Lien Term Loan, due September 16, 2018		137,638
Total	369,099	444,460
Less: current portion	(6,750)	(3,100)

Edgar Filing: Alkermes plc. - Form 10-Q

Long-term debt	\$	362,349	\$	441,360
----------------	----	---------	----	---------

In September 2012, the Company entered into the New Term Loan Facility to refinance its \$310.0 million first lien term loan facility (the First Lien Term Loan) and \$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 First Lien Term Loan was amended and restated to, among other things, provide for new term loans under the New Term Loan Facility, including Term Loan B-1 and Term Loan B-2, the proceeds of which, together with cash on hand, were used to repay the balance of the Term Loans (the Debt Refinancing). Term Loan B-1 has a principal balance of \$300.0 million, matures on September 25, 2019, bears interest at three-month LIBOR plus 3.5% and was issued with an original issue discount of \$3.0 million. Term Loan B-2 has a principal balance of \$75.0 million, matures on September 25, 2016, bears interest at three-month LIBOR plus 3.0% and was issued with an original issue discount of \$0.4 million. Under the New Term Loan Facility, LIBOR for both tranches is subject to an interest rate floor of 1.0%. Term Loan B-1 amortizes in equal quarterly amounts of 0.25% of the original principal amount of the loan, with the balance payable at maturity. Term Loan B-2 amortizes in equal quarterly amounts of 1.25% of the original principal amount of the loan for the first three years after funding, with the balance payable at maturity. The New Term Loan Facility is guaranteed by certain subsidiaries of the Company (the Guarantors) and is secured by a first priority lien on substantially all of the assets and properties of the Company and the Guarantors (subject to certain exceptions and limitations).

Table of Contents

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

Scheduled maturity with respect to the New Term Loan Facility is as follows (in thousands):

Fiscal Year:

2013	\$	1,688
2014		6,750
2015		6,750
2016		6,750
2017		64,875
Thereafter		286,499
Total	\$	373,312

Required quarterly principal payments of \$0.8 million on Term Loan B-1 and \$0.9 million on Term Loan B-2 began on December 31, 2012. Commencing with the completion of the Company's fiscal year ended March 31, 2014, the Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the New Term Loan Facility, are met. The Company may make prepayments of principal without premium or penalty, however, in the event that, prior to September 25, 2013, the Company prepays any of Term Loan B-1 or Term Loan B-2 pursuant to repricing transaction or an amendment of the New Term Loan Facility that results in a repricing transaction, the Company will be subject to a prepayment premium of 1% of the amount of the term loan being repaid or the aggregate amount of the applicable term loan outstanding immediately prior to such amendment.

The New Term Loan Facility has incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The New Term Loan Facility includes a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The New Term Loan Facility also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2012.

The Debt Refinancing was a restructuring of the Term Loans and involved multiple lenders who were considered members of a loan syndicate. In determining whether the Debt Refinancing was to be accounted for as a debt extinguishment or modification, the Company considered whether creditors remained the same or changed and whether the change in debt terms was substantial. The terms of the New Term Loan Facility were considered substantially different from the original Term Loans if the present value of the cash flows under the New Term Loan Facility was at least 10% different from the present value of the remaining cash flows under the Term Loans (commonly referred to as the 10% Test). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of creditors who did not participate in the New Term Loan Facility were accounted for as a debt extinguishment.

As the New Term Loan Facility has a prepayment option exercisable at any time, the Company assumed the prepayment option was exercised immediately on the date of the refinancing for purposes of applying the 10% Test. When there was a change in principal balance for individual creditors in the Debt Refinancing, in applying the 10% Test, the Company used the cash flows related to the lowest common principal balance between the Term Loans and the New Term Loan Facility (commonly referred to as the Net Method). Under the Net Method, any principal in excess of a creditor's rollover money was treated as a new, separate debt issuance, and any decrease in principal was treated as a partial extinguishment of debt.

New costs paid to creditors and third parties in connection with the Debt Refinancing were allocated to the New Term Loan Facility and then further allocated to each creditor. Once these costs were allocated to the individual creditors, an analysis of each creditor was performed and a determination made as to whether the refinancing was accounted for as a debt extinguishment or modification under the 10% Test. For debt considered to be extinguished, the unamortized deferred financing costs and unamortized original issue discount associated with the extinguished debt were expensed. For debt considered to be modified, the unamortized deferred financing costs and unamortized original issue discount associated with the modified debt continue to be amortized, new financing costs were expensed and new third-party fees were capitalized. For new creditors in the Debt Refinancing, new financing costs and original issue discount fees were capitalized and will be amortized over the estimated repayment period of the new debt.

Table of Contents

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

The Debt Refinancing resulted in a \$12.1 million charge in the three months ended September 30, 2012, which was included in Interest expense in the accompanying condensed consolidated statement of operations and comprehensive income (loss) and was comprised of the following (in thousands):

Extinguished debt:		
Unamortized deferred financing costs	\$	4,600
Unamortized original issue discount		2,657
Modified debt:		
Debt financing costs		1,967
Original issue discount		105
Prepayment penalty		2,800
Total	\$	12,129

At December 31, 2012, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were \$4.5 million and \$4.2 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the new debt using the effective interest method. During the nine months ended December 31, 2012, and 2011, the Company had amortization expense of \$5.5 million and \$2.1 million, respectively, related to deferred financing costs and original issue discount.

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 long-term debt 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 loss as Other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income due to the increase in value of this contract during the nine months ended December 31, 2012. At December 31, 2012, this contract has an immaterial balance included within Other assets in the accompanying condensed consolidated balance sheet.

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 long-term debt bear interest. The interest rate cap agreement became effective on September 16, 2011 and expired in December 2012, had a notional value of \$65.0 million and was not designated as a hedging instrument. The Company recorded an immaterial amount of loss within Other income, net in the accompanying condensed consolidated statements of operations and comprehensive (loss) income due to the decline in value of this contract during the nine months ended December 31, 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 long-term debt bear interest. The interest rate swap agreement became effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. This contract was designated as a cash flow hedge, however, in connection with the Debt Refinancing, the cash flow hedge was deemed to no longer be effective for accounting purposes and

Edgar Filing: Alkermes plc. - Form 10-Q

accordingly, the Company reclassified its unrealized losses of \$0.6 million to Interest expense in the accompanying condensed consolidated statement of operations and comprehensive (loss) income. The following table summarizes the beginning and ending accumulated derivative loss for the interest rate swap:

Unrealized losses included in accumulated other comprehensive income at March 31, 2012	\$	(522)
Unrealized losses incurred during the nine months ended December 31, 2012		(72)
Reclassification of unrealized losses to realized losses during the nine months ended December 31, 2012		594
Unrealized losses included in accumulated other comprehensive income at December 31, 2012	\$	

Table of Contents

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

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

(In thousands)	Balance Sheet Location	Fair Value December 31, 2012	March 31, 2012
<i>Interest rate swap</i>			
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$ (631)	
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$	(522)

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2012	2011	2012	2011
Cost of goods manufactured and sold	\$ 1,000	\$ 801	\$ 3,304	\$ 1,886
Research and development	2,281	2,470	6,939	6,714
Selling, general and administrative	4,945	5,760	16,592	13,143
Total share-based compensation expense	\$ 8,226	\$ 9,031	\$ 26,835	\$ 21,743

At December 31, 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.

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2012	2011	2012	2011
Numerator:				
Net income (loss)	\$ 16,258	\$ (14,828)	\$ 21,984	\$ (50,321)
Denominator:				
Weighted average number of ordinary shares outstanding	132,097	129,670	131,202	109,645
Effect of dilutive securities:				
Stock options	4,015		3,727	
Restricted stock units	1,385		1,287	
Dilutive ordinary share equivalents	5,400		5,014	
Shares used in calculating diluted earnings (loss) per share	137,497	129,670	136,216	109,645

Table of Contents

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

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 December 31,		Nine Months Ended December 31,	
	2012	2011	2012	2011
Stock options	4,566	9,033	5,786	8,323
Restricted stock units		1,164		1,477
Total	4,566	10,197	5,786	9,800

14. INCOME TAXES

The Company recorded an income tax provision of \$4.4 million and \$5.6 million for the three and nine months ended December 31, 2012, respectively, and an income tax provision of \$0.1 million and \$3.7 million for the three and nine months ended December 31, 2011, respectively. The income tax provision of \$4.4 million and \$5.6 million in the three and nine months ended December 31, 2012, respectively, primarily relates to U.S. Federal and state taxes on income. The income tax provision in the nine months ended December 31, 2011 primarily related to a \$13.2 million current tax expense on the taxable transfer of the BYDUREON® intellectual property from the U.S. to Ireland and a deferred tax benefit of \$10.2 million in connection with the Business Combination, as the Company recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

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 December 31, 2012, the Company determined, based on the weight of all available evidence, that it is not more likely than not that its remaining U.S. and Irish deferred tax assets will be realized and hence a valuation allowance was recorded on the net deferred tax asset.

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 current 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 the drug technologies business ("EDT") of Elan Corporation, plc ("Elan") were combined under Alkermes plc (this combination is referred to as the "Business Combination," the "acquisition of EDT" or the "EDT acquisition"). 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 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 (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 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 our 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:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

Edgar Filing: Alkermes plc. - Form 10-Q

- our expectations regarding the commercialization of our products;
- 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 competitive landscape, and changes therein, related to our products;
- our expectations regarding our collaborations and other significant agreements relating to our products;
- 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.

Table of Contents

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, in connection with the Business Combination, 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. The Business Combination was accounted for using the acquisition method of accounting for business combinations with Alkermes, Inc. being treated as the accounting acquirer under accounting principles generally accepted in the United States (U.S.) (GAAP). As a result, the operating results of Alkermes, Inc. are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition.

Net income for the three months ended December 31, 2012, was \$16.3 million or \$0.12 per ordinary share basic and diluted, as compared to a net loss of \$14.8 million, or \$0.11 per ordinary share basic and diluted for the three months ended December 31, 2011. Net income for the nine months ended December 31, 2012, was \$22.0 million or \$0.17 per ordinary share basic and \$0.16 per ordinary share diluted, as compared to a net loss of \$50.3 million, or \$0.46 per ordinary share basic and diluted for the nine months ended December 31, 2011.

Total revenues increased by 8% and 59% during the three and nine months ended December 31, 2012, respectively, as compared to the three and nine months ended December 31, 2011. The increase in the revenues for the three months ended December 31, 2012, as compared to the three months ended December 31, 2011 is primarily due to the growth in our key commercial products. Expenses in the three months ended December 31, 2012 decreased as compared to the three months ended December 31, 2011 primarily due to the timing of clinical trial expenses and the inclusion of merger-related expenses during the three months ended December 31, 2011. The increases in revenues and expenses in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, is primarily due to the revenues and expenses from the former EDT business.

In September 2012, we entered into a new term loan facility, which includes a \$300.0 million, seven-year term loan bearing interest at three-month LIBOR plus 3.5% (Term Loan B-1) and a \$75.0 million, four-year term loan bearing interest at three-month LIBOR plus 3.0% (Term Loan B-2) and together with Term Loan B-1, the New Term Loan Facility). The New Term Loan Facility refinanced our \$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) and reduced our overall outstanding debt in the process to \$375.0 million (the Debt Refinancing). Under the New Term Loan Facility, LIBOR for both tranches is subject to an interest rate floor of 1.0%. We expect that the refinancing transaction will result in savings of approximately \$18.0 million in cash interest annually. The Debt Refinancing resulted in a charge of \$12.1 million in the three months ended September 30, 2012, which was recorded within Interest expense in the accompanying condensed consolidated statement of operations and comprehensive income (loss).

COMMERCIAL 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 and the source of revenues for us:

Product	Indication	Technology	Territory	Revenue Source	Marketer
<i>RISPERDAL® CONSTA®</i>	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
<i>INVEGA® SUSTENNA®/XEPLION®</i>	Schizophrenia	NanoCrystal	Worldwide	Royalty	Janssen
<i>AMPYRA® FAMPYRA®</i>	Treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in	Oral Controlled Release (OCR)	U.S. Worldwide	Manufacturing and Royalty	Acorda Therapeutics, Inc. (Acorda) in U.S. Biogen Idec (ex-

Table of Contents

	walking speed	(MXDAS®)			U.S. under sublicense from Acorda)
<i>BYDUREON®</i>	Type 2 diabetes	Extended-release microsphere	U.S. Worldwide	Royalty	Bristol-Myers Squibb Company (Bristol-Myers) and AstraZeneca PLC (Astra Zeneca)
<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; Cilag GmbH International (Cilag)
<i>TRICOR®/ LIPANTHYL® LIPIDIL®/ SUPRALIP®</i>	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	Abbott
<i>ZANAFLEX® CAPSULES®/ ZANAFLEX® 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® XR/ RITALIN LA®</i>	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis
<i>MEGACE® ES</i>	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.
<i>VERELAN®/ VERELAN® PM/ VERAPAMIL PM/ VERAPAMIL SR/ UNIVER® VERECAPS®/ DILZEM SR/ DILZEM XL/ DILTELAN/ ACALIX CD/ DINISOR/ TILAZEM CR/ CARDIZEM CD</i>	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing	UCB Kremers-Urban Watson; Cephalon; Aspen; Orient Europharma
	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>AFEDitab® CR (AB Rated to Adalat CC®) (Nifedipine)</i>	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Watson Pharmaceutical

Table of Contents

KEY COMMERCIAL PRODUCTS

The following five principal commercial products in our commercial product portfolio are expected to contribute meaningfully to our revenues.

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION (paliperidone palmitate), which are two long-acting atypical antipsychotics, incorporate our injectable extended-release microsphere and NanoCrystal technology, respectively. They are products of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (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.

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 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 is the first and, currently, only product to be approved for this indication. The product incorporates our OCR technology. AMPYRA and FAMPYRA are manufactured by us.

BYDUREON

We collaborated with Amylin Pharmaceuticals, Inc., now a wholly-owned subsidiary of Bristol-Myers, on the development of a once-weekly formulation of exenatide, BYDUREON, which was approved by the FDA for the treatment of type 2 diabetes. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology. Through their diabetes collaboration, Bristol-Myers and AstraZeneca co-develop and market

Amylin's portfolio of products, including BYDUREON.

VIVITROL

Edgar Filing: Alkermes plc. - Form 10-Q

VIVITROL is the first and only once-monthly injectable medication approved by the FDA 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 sells VIVITROL in Russia and other countries in the Commonwealth of Independent States (CIS).

Other Commercial Products

We expect that revenues from our other commercial products will decrease in the future due to existing and expected competition from generic manufacturers, as discussed in greater detail herein.

KEY DEVELOPMENT PROGRAMS

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

We are studying aripiprazole lauroxil, which we formerly referred to as ALKS 9070, for the treatment of schizophrenia. Aripiprazole lauroxil 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®. Aripiprazole lauroxil is our first product candidate to leverage our proprietary LinkeRx® product platform. A phase 3 trial to assess the efficacy, safety and tolerability of aripiprazole lauroxil in approximately 690 patients experiencing acute exacerbation of schizophrenia is currently on-going, and the clinical data from this study, expected in late calendar-year 2013, will form the basis of a New Drug Application (NDA) to the FDA for aripiprazole

Table of Contents

lauroxil for the treatment of schizophrenia.

In January 2013, we announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for U.S. Patent Application 12/823,007, titled Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders. The allowed claims will cover a class of compounds that includes aripiprazole lauroxil. We expect the patent to issue within the next month and provide a patent term that would expire no earlier than 2030.

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. 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 standard antidepressant therapies. Data from this study are expected in the second quarter of calendar-year 2013.

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 and we announced positive topline results from a phase 2 study in December 2010; there are currently no ongoing clinical trials of ALKS 33 for the treatment of alcohol dependence.

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 December 2012, the FDA Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) voted 2-11 [with 1 abstention] against the approval of ZOHYDRO ER. The FDA has assigned a target action date of March 1, 2013 for the ZOHYDRO ER NDA. We have also entered into a license and distribution agreement with Paladin Labs Inc. in respect of ZOHYDRO ER in Canada. We will earn manufacturing revenues and a royalty on U.S. and Canadian sales of ZOHYDRO ER, if approved and when commercialized. We have maintained all rights to the product in territories outside the U.S. and Canada and will seek to develop and license the product through commercial partnerships in those territories.

A three-month formulation of INVEGA SUSTENNA is in development by Janssen Research & Development, LLC. 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. These clinical studies are expected to be completed in the second half of calendar 2014. The investigational product is being developed by Janssen Pharmaceutica, NV, licensee to our proprietary technology for nanoparticles.

Line extensions for BYDUREON are in development by Bristol-Myers. These line extensions include a dual-chamber pen device, weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. Bristol-Myers is expected to submit data for the dual-chamber pen device for FDA review in mid calendar 2013.

In January 2013, we announced positive topline results from a phase 1 study of a new antipsychotic candidate, ALKS 3831, a combination of ALKS 33, and olanzapine, a molecule that is commercially available under the name ZYPREXA®. ALKS 3831 is in development for the treatment of schizophrenia and is designed to attenuate the antipsychotic-related metabolic side effect of weight gain. The multicenter,

randomized, double-blind, placebo- and active-controlled study was designed to compare the mean change from baseline in body weight in 106 healthy volunteers following three weeks of once-daily, oral administration of ALKS 3831, compared to olanzapine alone or placebo. Data from the study showed that patients administered ALKS 3831 demonstrated significantly less weight gain compared to patients taking olanzapine. Weight gain is a common and clinically relevant side effect of atypical antipsychotic medications, and olanzapine has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs. Based on the positive results of the phase 1 study, we plan to meet with the FDA and initiate a phase 2 study of ALKS 3831 in mid calendar-year 2013.

Results of Operations

Manufacturing and Royalty Revenues

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. The following table compares manufacturing and royalty revenues earned in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011:

Table of Contents

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011	
Manufacturing and royalty revenues:			
RISPERDAL CONSTA	\$ 32.0	\$ 38.3	\$ (6.3)
INVEGA SUSTENNA/XEPLION	20.5	9.3	11.2
AMPYRA/FAMPYRA	18.4	10.2	8.2
RITALIN LA/FOCALIN XR	9.8	11.6	(1.8)
TRICOR 145	6.8	15.7	(8.9)
Other	30.8	27.7	3.1
Manufacturing and royalty revenues	\$ 118.3	\$ 112.8	\$ 5.5

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was primarily due to a 25% decrease in the number of units shipped to Janssen and a 7% decrease in royalty revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$385.4 million in the three months ended December 31, 2011 to \$358.2 million in the three months ended December 31, 2012.

The increase in INVEGA SUSTENNA/XEPLION royalty revenue in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION from \$135.0 million in the three months ended December 31, 2011 to \$228.0 million in the three months ended December 31, 2012.

We expect revenues from our long-acting atypical antipsychotic franchise, which consists of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn 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. 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 to 5%. 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. Given that RISPERDAL CONSTA is covered by patents that will expire in the U.S. in 2023 and in the E.U. in 2021 and INVEGA SUSTENNA/XEPLION is covered by patents that will expire in the U.S. in 2019 and in the EU in 2022, we do not anticipate any generic versions in the near-term for either of these products.

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was primarily due to an increase in AMPYRA shipments from a second-source manufacturer of AMPYRA to Acorda. We recognize both manufacturing and royalty revenues on AMPYRA upon our and the second-source manufacturer's shipment of AMPYRA to Acorda at a percentage of Acorda's net selling price. Our estimate of end-market sales of AMPYRA/FAMPYRA increased from \$68.5 million in the three months ended December 31, 2011 to \$83.2 million in the three months ended December 31, 2012.

The decrease in RITALIN LA/FOCALIN XR manufacturing revenue in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was due to a decrease in the number of units shipped to Novartis in the three months ended December 31, 2012 as compared to the three months ended December 31, 2011.

Edgar Filing: Alkermes plc. - Form 10-Q

The decrease in TRICOR 145 royalty revenue in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was due to a decrease in end-market sales of TRICOR 145 by Abbott from \$314.3 million in the three months ended December 31, 2011 to \$130.0 million in the three months ended December 31, 2012 due primarily to the introduction of a generic version of this product in November 2012.

We continue to anticipate manufacturing and royalty revenue erosion in the RITALIN LA/FOCALIN XR and TRICOR 145 franchises for the foreseeable future due to the entry of a generic version of TRICOR 145 in late-calendar 2012 and the potential entry of a generic version of certain doses of FOCALIN XR, which could occur at any time.

The following table compares manufacturing and royalty revenues earned in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011:

Table of Contents

	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
(In millions)	2012	2011	
Manufacturing and royalty revenues:			
RISPERDAL CONSTA	\$ 102.9	\$ 131.1	\$ (28.2)
INVEGA SUSTENNA/XEPLION	48.6	10.0	38.6
AMPYRA/FAMPYRA	40.5	10.8	29.7
TRICOR 145	31.3	17.5	13.8
RITALIN LA/FOCALIN XR	29.7	13.1	16.6
Other	111.0	33.3	77.7
Manufacturing and royalty revenues	\$ 364.0	\$ 215.8	\$ 148.2

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to a 27% decrease in the number of units shipped to Janssen, and a 10% decrease in royalty revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$1,179.0 million during the nine months ended December 31, 2011 to \$1,064.0 million during the nine months ended December 31, 2012. The increase in revenues from INVEGA SUSTENNA/XEPLION, AMPYRA/FAMPYRA, TRICOR 145, RITALIN LA/FOCALIN XR and other manufacturing and royalty revenues was primarily due to the addition of these products from the former EDT business on September 16, 2011.

Included in other manufacturing and royalty revenues for the nine months ended December 31, 2012 is \$20.0 million of revenue related to the exercise of an option to license certain of our intellectual property that is not used in our key clinical development programs or commercial 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 and nine months ended December 31, 2012 and 2011:

(In millions)	Three Months Ended December 31,				Nine Months Ended December 31,			
	2012	% of Sales	2011	% of Sales	2012	% of Sales	2011	% of Sales
Product sales, gross	\$ 21.6	100.0%	\$ 15.2	100.0%	\$ 58.2	100.0%	\$ 42.6	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(1.7)	(7.9)%	(1.3)	(8.6)%	(4.3)	(7.4)%	(3.6)	(8.5)%
Chargebacks	(1.4)	(6.5)%	(0.9)	(5.9)%	(4.1)	(7.0)%	(3.0)	(7.0)%
Product returns (1)	(0.1)	(0.5)%	(0.8)	(5.3)%	0.4	0.7%	(1.5)	(3.5)%
Other	(2.5)	(11.6)%	(1.6)	(10.6)%	(6.7)	(11.5)%	(4.3)	(10.1)%
Total adjustments	(5.7)	(26.4)%	(4.6)	(30.3)%	(14.7)	(25.3)%	(12.4)	(29.1)%
Product sales, net	\$ 15.9	73.6%	\$ 10.6	69.7%	\$ 43.5	74.7%	\$ 30.2	70.9%

Edgar Filing: Alkermes plc. - Form 10-Q

(1) During the three months ended September 30, 2012, we changed the method by which we recognized revenue on VIVITROL product sales. Prior to August 1, 2012, we did not have sufficient history to reasonably estimate returns related to VIVITROL shipments, and therefore we deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. As we now have sufficient history to reliably estimate returns, we recognize revenue on the sales of VIVITROL upon delivery to our customers and provide a reserve for future returns. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to product sales, net, which was recognized during the three months ended September 30, 2012.

The increase in product sales, gross for the three and nine months ended December 31, 2012, as compared to the three and nine months ended December 31, 2011, was due to a 42% and 37% increase in the number of units sold, respectively. We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S.

We anticipate that Cilag will increase sales of VIVITROL in Russia and the CIS, which are recorded as manufacturing and royalty revenues. In addition, the potential exists 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,

Table of Contents

as well as increasing pricing pressure. VIVITROL is covered by patents 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 December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Research and development revenue	\$ 1.7	\$ 2.3	\$ (0.6)	\$ 4.7	\$ 13.6	\$ (8.9)

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 nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to milestone payments we received during the nine months ended December 31, 2011. In July 2011, we recognized a \$7.0 million milestone payment earned upon the first sale of BYDUREON in the E.U. and, in April 2011, we recognized a \$3.0 million milestone payment earned upon the receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication.

Costs and Expenses*Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Cost of goods manufactured and sold	\$ 38.9	\$ 42.8	\$ 3.9	\$ 122.5	\$ 76.5	\$ (46.0)

The decrease in cost of goods manufactured and sold in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was primarily due to a \$4.0 million decrease in cost of goods manufactured related to the EDT product portfolio and a \$2.2 million decrease in cost of goods manufactured from RISPERDAL CONSTA, partially offset by a \$2.5 million increase in cost of goods manufactured and sold from VIVITROL. As a result of the Business Combination, inventory manufactured by EDT prior to September 16, 2011 was acquired by Alkermes at its fair value or stepped-up value. Therefore, this inventory carried a higher cost than our cost to manufacture the products. When this inventory was sold during the three months ended December 31, 2011, the stepped-up inventory was charged to cost of goods manufactured, which resulted in a higher cost of goods manufactured during the three months ended December 31, 2011, as compared to the three months ended December 31, 2012. The decrease in cost of goods manufactured from RISPERDAL CONSTA was primarily due to a decrease in the number of units shipped to Janssen, and the increase in cost of goods manufactured and sold from VIVITROL was primarily due to a higher number of units sold in the U.S. and Russia.

The increase in cost of goods manufactured and sold in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to a \$49.2 million increase in cost of goods manufactured related to EDT's portfolio of commercialized

Edgar Filing: Alkermes plc. - Form 10-Q

products and a \$4.6 million increase in cost of goods manufactured and sold from VIVITROL, partially offset by a \$8.1 million decrease in cost of goods manufactured from RISPERDAL CONSTA. The increase in cost of goods manufactured related to EDT's portfolio of commercialized products is primarily due to only having approximately four and a half months of EDT sales activity included in the nine months ended December 31, 2011. The increase in cost of goods manufactured and sold from VIVITROL is primarily due to a higher number of units sold in the U.S. and Russia, and the decrease in cost of goods manufactured from RISPERDAL CONSTA is primarily due to a decrease in the number of units shipped to Janssen.

Research and Development Expense

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)		Nine Months Ended December 31,		Change Favorable/ (Unfavorable)	
	2012	2011			2012	2011		
Research and development expense	\$ 31.3	\$ 40.5	\$ 9.2	\$	104.2	\$ 96.7	\$ (7.5)	

The decrease in R&D expense in the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was primarily due to a \$2.6 million decrease in costs related to the Meloxicam program, a \$2.6 million R&D tax credit due in Ireland, and a \$3.5 million decrease in costs related to the ALKS 37 program, partially offset by a \$2.3 million increase in costs related to the aripiprazole lauroxil program. During the three months ended March 31, 2012, we decided not to continue to develop the Meloxicam program ourselves. The R&D tax credit is available in Ireland and is based on qualified R&D activities performed in our Athlone, Ireland facility. Costs related to the ALKS 37 program decreased as in May 2012, we decided not to advance ALKS 37 program after the results from

Table of Contents

the phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study did not satisfy our pre-specified criteria for advancing into phase 3 clinical trials.

The increase in R&D expenses in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to a \$16.9 million increase in costs related to the aripiprazole lauroxil program, partially offset by an \$11.6 million decrease in costs related to the termination of the ALKS 37 program.

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.

Table of Contents*Selling, General and Administrative Expense*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Selling, general and administrative expense	\$ 29.9	\$ 35.5	\$ 5.6	\$ 91.1	\$ 103.2	\$ 12.1

The decrease in selling, general and administrative (SG&A) expense for the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was primarily due to a \$5.6 million decrease in professional services expense. The decrease in SG&A expense for the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to a \$26.1 million decrease in professional services expense, partially offset by \$8.8 million of SG&A expense from the former EDT business. The decrease in professional services expense is primarily due to costs incurred in connection with the Business Combination during the three and nine months ended December 31, 2011.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Amortization of acquired intangible assets	\$ 10.5	\$ 11.9	\$ 1.4	\$ 31.5	\$ 13.7	\$ (17.8)

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, over the next five fiscal years we expect the amortization of intangible assets included within our consolidated balance sheet as of December 31, 2012 to be in the range of approximately \$42.0 million to \$70.0 million annually.

Other (Expense), Net

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2012	2011		2012	2011	
Interest income	\$ 0.2	\$ 0.4	\$ (0.2)	\$ 0.6	\$ 1.2	\$ (0.6)
Interest expense	(4.7)	(10.5)	5.8	(37.5)	(18.0)	(19.5)
Other income, net	(0.1)	0.3	(0.4)	1.6	0.8	0.8
Total other (expense), net	\$ (4.6)	\$ (9.8)	\$ 5.2	\$ (35.3)	\$ (16.0)	\$ (19.3)

The decrease in interest expense for the three months ended December 31, 2012, as compared to the three months ended December 31, 2011, was due to the Debt Refinancing. The increase in interest expense for the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011 was primarily due to the Debt Refinancing as well as an additional quarter of interest expense in the nine

Edgar Filing: Alkermes plc. - Form 10-Q

months ended December 31, 2012 as we didn't enter into the Term Loans until the three months ended September 30, 2011. Included in interest expense in the three and nine months ended December 31, 2012 is a less than \$0.1 million and \$0.6 million charge, respectively, related to the loss on an interest rate swap. Prior to the Debt Refinancing, our interest rate swap was deemed to be an effective cash flow hedge against the three-month LIBOR rate at which our Term Loans bore interest. In connection with the Debt Refinancing, this cash flow hedge was no longer considered to be effective and we reclassified all previously unrealized losses on the hedge from accumulated other comprehensive (loss) income to interest expense.

We expect interest expense to decrease beyond fiscal year 2013 due to the Debt Refinancing and as the New Term Loan Facility is paid down.

Table of Contents*Income Tax Provision*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)		Nine Months Ended December 31,		Change Favorable/ (Unfavorable)	
	2012	2011			2012	2011		
Income tax provision	\$ 4.4	\$ 0.1	\$ (4.3)	\$ 5.6	\$ 3.7	\$ (1.9)		

The tax provision in the three and nine months ended December 31, 2012 primarily relates to U.S. Federal and state taxes on income. The income tax provision in the nine months ended December 31, 2011 primarily related to a \$13.2 million current tax expense on the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland and a deferred tax benefit of \$10.2 million in connection with the Business Combination, as we recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

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 December 31, 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 hence a valuation allowance was recorded on the net deferred tax asset.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	December 31, 2012	March 31, 2012
Cash and cash equivalents	\$ 135.9	\$ 83.6
Investments short-term	73.4	106.8
Investments long-term	30.0	55.7
Total cash, cash equivalents and investments	\$ 239.3	\$ 246.1
Working capital	\$ 310.2	\$ 250.0
Outstanding borrowings current and long-term	\$ 369.1	\$ 444.5

Sources and Uses of Cash

We expect that funds generated from results of operations will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments for the foreseeable future. In the event business conditions were to deteriorate, we could rely on borrowings under the New Term Loan Facility, which has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long we meet certain conditions, including a specified leverage ratio.

Edgar Filing: Alkermes plc. - Form 10-Q

Information about our cash flows, by category, is presented in the condensed consolidated statements of cash flows. The following table summarizes our cash flows for the nine months ended December 31, 2012 and 2011:

(In millions)	Nine Months Ended December 31,			
	2012		2011	
Cash and cash equivalents, beginning of period	\$	83.6	\$	38.4
Cash provided by (used in) operating activities		71.2		(17.8)
Cash provided by (used in) investing activities		43.7		(395.6)
Cash (used in) provided by financing activities		(62.6)		460.3
Cash and cash equivalents, end of period	\$	135.9	\$	85.3

Cash provided by operating activities increased in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, which was primarily due to an increase in cash provided from net income of \$124.7 million. This was partially offset by changes in working capital, most notably from an increase in cash used for accounts payable and accrued expenses of \$31.2 million, as well as \$5.5 million of payments made in connection with the Debt Refinancing. In connection with the Debt Refinancing, we incurred a \$2.8

Table of Contents

million prepayment penalty, and, as the Term Loans were originally issued at a discount, we allocated \$2.7 million of the total principal repayment to the original issue discount, both of which were classified as operating activities.

The increase in cash flows provided by investing activities in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to \$494.8 million of cash used in the purchase of the former EDT business in September 2011, partially offset by a decrease in the net sales of investments of \$49.6 million and an increase in cash used to purchase property, plant and equipment of \$5.1 million. During the nine months ended December 31, 2012, we sold investments which were used as part of the \$83.5 million of total cash paid in connection with the Debt Refinancing. The increase in cash used for property, plant and equipment is due to an increase in cash spent on technology infrastructure and our physical plant in Athlone, Ireland and Gainesville, GA.

The increase in cash flows used in financing activities in the nine months ended December 31, 2012, as compared to the nine months ended December 31, 2011, was primarily due to the \$444.1 million of cash received upon the issuance of the Term Loans in September 2011, partially offset by the \$78.0 million of net cash used in the Debt Refinancing that was attributable to financing activities.

Our investments at December 31, 2012 consist of the following:

(In millions)		Amortized Cost		Gains	Gross Unrealized Losses		Estimated Fair Value
Investments	short-term	\$	73.3	\$	0.1	\$	73.4
Investments	long-term available-for-sale		29.2			(0.4)	28.8
Investments	long-term held-to-maturity		1.2				1.2
Total		\$	103.7	\$	0.1	(0.4)	\$ 103.4

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 December 31, 2012, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At December 31, 2012 and March 31, 2012, none 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 nine months ended December 31, 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.

Borrowings

At December 31, 2012, our borrowings consisted of the New Term Loan Facility, with an outstanding principal balance of \$373.3 million. Please refer to Note 10 *Long-Term Debt* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of our outstanding long-term debt.

Table of Contents*Contractual Obligations*

Refer to Part II, Item 7 of our Annual Report in the *Contractual Obligations* section for a discussion of our contractual obligations. With the exception of the information in such disclosure related to the Term Loans, which were refinanced as part of the Debt Refinancing, our contractual obligations as of December 31, 2012 were not materially changed from the date of that report.

The New Term Loan Facility has contractual cash obligations as follows:

Contractual Cash Obligations	Total	Less Than One Year (Fiscal 2013)	Three Years (Fiscal 2014- 2015)	Five Years (Fiscal 2016- 2017)	Five Years (After Fiscal 2018)
Term Loan B-1 - Principal	\$ 299,250	\$ 750	\$ 6,000	\$ 6,000	\$ 286,500
Term Loan B-1 - Interest	87,797	3,367	26,629	26,089	31,712
Term Loan B-2 - Principal	74,063	938	7,500	65,625	
Term Loan B-2 - Interest	10,099	741	5,588	3,770	

Off-Balance Sheet Arrangements

At December 31, 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.

During the three months ended September 30, 2012, we changed the way in which we recognize revenue on VIVITROL product sales. Prior to the three months ended September 30, 2012, we did not have sufficient history to reasonably estimate returns related to VIVITROL shipments and, therefore, we deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. During the three months ended September 30, 2012, we determined that we have sufficient history to reliably estimate returns and we now recognize revenue on the sales of VIVITROL upon delivery to our customers, which is the point in time the buyer assumes the risks and rewards of ownership.

During the period in which we record VIVITROL product sales, we estimate a reserve for future product returns related to those sales. This estimate is based on our historical return rates as well as specifically identified anticipated returns due to known business conditions and product expiry dates. We record the return amounts as a deduction to arrive at our net VIVITROL product sales. Once VIVITROL is returned, it is destroyed. At December 31, 2012, our product return reserve rate is estimated to be 2% of our product sales.

During the three months ended December 31, 2012, we performed our annual goodwill impairment test. The goodwill for each reporting unit is tested using a two-step process. A reporting unit is an operating segment, as defined by the segment reporting accounting standards, or a component of an operating segment. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and is reviewed by management. Two or more components of an operating segment may be aggregated and deemed a single reporting unit for goodwill impairment testing purposes if the components have similar economic characteristics. As of December 31, 2012, we have one operating segment and two reporting units. Our goodwill, which solely relates to the EDT acquisition in the fiscal year ended March 31, 2012, has been assigned to one reporting unit which consists of the former EDT business.

The first step of the goodwill impairment test requires us to compare the fair value of the reporting unit to its respective carrying value, which includes goodwill. If the fair value of the reporting unit exceeds its carrying value, the goodwill is not considered impaired. If the carrying value is higher than the fair value, there is an indication that an impairment may exist and the second step is required. In step two, the implied fair value of goodwill is calculated as the excess of the fair value of a reporting unit over the fair values assigned to its assets and liabilities. If the implied fair value of goodwill is less than the carrying value of the reporting unit's goodwill, the difference is recognized as an impairment loss.

Table of Contents

We worked with a valuation firm and established fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account (1) assumptions that market participants would use in their estimates of fair value, (2) current period actual results, and (3) budgeted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration our estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies.

We determined that the fair value of the former EDT business reporting unit was in excess of its respective carrying value and there was no impairment in the value of this asset as of December 31, 2012. A decline in the estimated fair value of a reporting unit could result in goodwill impairment, and a related non-cash impairment charge against earnings, if the estimated fair value for the reporting unit is less than the carrying value of the net assets of the reporting unit, including its goodwill. A large decline in estimated fair value of a reporting unit could result in an adverse effect on our financial condition and results of operations. In order to evaluate the sensitivity of the fair value calculations relating to our goodwill impairment assessment, we applied a hypothetical decrease to the estimated fair value of the former EDT business reporting unit and we determined that a decrease in fair value of at least 47% would be required before this reporting unit would have a carrying value in excess of its fair value.

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 nine 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. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk during the first nine 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 December 31, 2012. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 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 Paragraph IV litigation in the U.S. and a similar suit in 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.

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 December 31, 2012. As of December 31, 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 December 31, 2012, Mr. Paul J. Mitchell, a director of the Company; Mr. Richard F. Pops, a director and executive officer of the Company; and Ms. Kathryn L. Biberstein, Mr. Elliott W. Ehrich, Mr. James M. Frates and Mr. Michael J. Landine, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and 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.
- 31.2 Rule 13a-14(a)/15d-14(a) Certification.
- 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 December 31, 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: January 31, 2013