

Alkermes plc.
Form 10-Q
October 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 September 30, 2013

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Edgar Filing: Alkermes plc. - Form 10-Q

Ireland

(State or other jurisdiction of incorporation or organization)

98-1007018

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

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer Accelerated filer Non-accelerated filer 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 October 28, 2013, was 136,762,382 shares.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2013**

Page No.

PART I - FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements (unaudited); Condensed Consolidated Balance Sheets – September 30, 2013 and March 31, 2013</u>	4
	<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) – For the Three and Six Months Ended September 30, 2013 and 2012</u>	5
	<u>Condensed Consolidated Statements of Cash Flows – For the Six Months Ended September 30, 2013 and 2012</u>	6
	<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	25
<u>Item 4.</u>	<u>Controls and Procedures</u>	25

PART II - OTHER INFORMATION

<u>Item 1.</u>	<u>Legal Proceedings</u>	26
<u>Item 1A.</u>	<u>Risk Factors</u>	26
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
<u>Item 5.</u>	<u>Other Information</u>	26
<u>Item 6.</u>	<u>Exhibits</u>	26
<u>Signatures</u>		27
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		
Ex-101 Instance Document		
Ex-101 Schema Document		
Ex-101 Calculation Linkbase Document		
Ex-101 Labels Linkbase Document		
Ex-101 Definition Linkbase Document		
Ex-101 Presentation Linkbase Document		

Table of Contents

Forward-Looking Statements

This report contains and incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, would, expect, anticipate, continue or other similar words. These statements discuss expectations, contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q (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;

- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial scope and 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 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.

Edgar Filing: Alkermes plc. - Form 10-Q

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 on Form 10-K for the year ended March 31, 2013, as amended (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.

Note Regarding Company

Alkermes plc (as used in this report, together with our subsidiaries, Alkermes , the Company , us , we , or our) 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 substantial 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.

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

(unaudited)

	September 30, 2013	March 31, 2013
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 173,505	\$ 96,961
Investments short-term	165,921	124,391
Receivables	120,448	124,620
Inventory	40,708	43,483
Prepaid expenses and other current assets	22,998	19,133
Total current assets	523,580	408,588
PROPERTY, PLANT AND EQUIPMENT, NET	274,377	288,435
INTANGIBLE ASSETS NET	550,421	575,993
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	55,815	82,827
OTHER ASSETS	15,504	21,708
TOTAL ASSETS	\$ 1,512,437	\$ 1,470,291
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 64,282	\$ 76,910
Long-term debt current	6,750	6,750
Deferred revenue current	2,685	2,270
Total current liabilities	73,717	85,930
LONG-TERM DEBT	359,122	362,258
OTHER LONG-TERM LIABILITIES	17,486	23,260
DEFERRED TAX LIABILITIES, NET LONG-TERM	36,014	37,603
DEFERRED REVENUE LONG-TERM	9,121	8,866
Total liabilities	495,460	517,917
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS EQUITY:		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2013 and March 31, 2013, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 137,242,939 and 134,065,107 shares issued; 136,646,516 and 133,751,610 shares outstanding at September 30, 2013 and March 31, 2013, respectively	1,369	1,338
Treasury stock, at cost (596,423 and 313,497 shares at September 30, 2013 and March 31, 2013, respectively)	(14,404)	(5,380)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,524,783	1,458,857
Accumulated other comprehensive income (loss)	5,580	(2,518)
Accumulated deficit	(500,351)	(499,923)
Total shareholders' equity	1,016,977	952,374
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,512,437	\$ 1,470,291

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 September 30,		Six Months Ended September 30,	
	2013	2012	2013	2012
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 118,571	\$ 107,327	\$ 238,359	\$ 245,707
Product sales, net	19,227	15,192	36,606	27,564
Research and development revenue	2,004	1,459	3,468	2,946
Total revenues	139,802	123,978	278,433	276,217
EXPENSES:				
Cost of goods manufactured and sold	45,423	41,491	91,414	83,561
Research and development	45,947	35,088	79,409	72,894
Selling, general and administrative	39,454	31,428	72,387	61,212
Amortization of acquired intangible assets	12,856	10,547	25,572	20,981
Total expenses	143,680	118,554	268,782	238,648
OPERATING (LOSS) INCOME	(3,878)	5,424	9,651	37,569
OTHER (EXPENSE), NET:				
Interest income	295	216	456	515
Interest expense	(3,477)	(22,648)	(6,945)	(32,818)
Other (expense) income, net	(469)	723	(639)	1,646
Total other (expense), net	(3,651)	(21,709)	(7,128)	(30,657)
(LOSS) INCOME BEFORE INCOME TAXES	(7,529)	(16,285)	2,523	6,912
INCOME TAX PROVISION	233	422	2,951	1,186
NET (LOSS) INCOME	\$ (7,762)	\$ (16,707)	\$ (428)	\$ 5,726
(LOSS) EARNINGS PER ORDINARY SHARE:				
Basic	\$ (0.06)	\$ (0.13)	\$ (0.00)	\$ 0.04
Diluted	\$ (0.06)	\$ (0.13)	\$ (0.00)	\$ 0.04
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	136,106	131,067	135,358	130,753
Diluted	136,106	131,067	135,358	135,589
COMPREHENSIVE INCOME (LOSS):				
Net (loss) income	\$ (7,762)	\$ (16,707)	\$ (428)	\$ 5,726
Unrealized gains (losses) on marketable securities	8,506	(463)	8,099	(604)
Unrealized (losses) gains on derivative contracts		594		522
COMPREHENSIVE INCOME (LOSS)	\$ 744	\$ (16,576)	\$ 7,671	\$ 5,644

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)

	2013	Six Months Ended September 30, (In thousands)	2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	\$	(428)	\$ 5,726
Adjustments to reconcile net (loss) income to cash flows from operating activities:			
Depreciation and amortization		47,401	36,829
Share-based compensation expense		23,018	18,609
Excess tax benefit from share-based compensation		(8,456)	(387)
Deferred income taxes		(1,516)	(944)
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		1,773	4,385
Changes in assets and liabilities:			
Receivables		4,172	(5,617)
Inventory, prepaid expenses and other assets		(3,706)	(3,111)
Accounts payable and accrued expenses		(7,727)	(17,422)
Deferred revenue		670	(2,060)
Other long-term liabilities		(1,086)	2,368
Cash flows provided by operating activities		54,115	45,048
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment		(9,198)	(11,206)
Proceeds from the sale of equipment		6	17
Investment in Civitas		(1,191)	
Purchases of investments		(54,088)	(99,218)
Sales and maturities of investments		56,400	185,392
Cash flows (used in) provided by investing activities		(8,071)	74,985
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements		33,943	9,731
Excess tax benefit from share-based compensation		8,456	387
Proceeds from the issuance of long-term debt			368,557
Employee taxes paid related to net share settlement of equity awards		(8,524)	(3,323)
Principal payments of long-term debt		(3,375)	(446,568)
Cash flows provided by (used in) financing activities		30,500	(71,216)
NET INCREASE IN CASH AND CASH EQUIVALENTS		76,544	48,817
CASH AND CASH EQUIVALENTS Beginning of period		96,961	83,601
CASH AND CASH EQUIVALENTS End of period	\$	173,505	\$ 132,418
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$	1,184	\$ 834

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

Table of Contents

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

1. THE COMPANY

Alkermes plc 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 CNS disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes has an R&D center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and six months ended September 30, 2013 and 2012 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2013. 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, 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.

In May 2013, the Company announced that it was changing its fiscal year-end from March 31 to December 31, effective within the year-ended December 31, 2013. The Company will file the report for the transition period ending December 31, 2013 in its Annual Report on Form 10-K.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly owned subsidiaries as disclosed in Note 2: *Summary of Significant Accounting Policies* within Part II Items of our annual report. 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 ongoing basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments, litigation and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Segment Information

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

Table of Contents

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

New Accounting Pronouncements

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

3. INVESTMENTS

Investments consisted of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year	Greater than One Year	
			(In thousands)		
September 30, 2013					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 132,502	\$ 84	\$ (15)	\$	\$ 132,571
Corporate debt securities	18,641	44			18,685
International government agency debt securities	13,455	11	(2)		13,464
	164,598	139	(17)		164,720
Money market funds	1,201				1,201
Total short-term investments	165,799	139	(17)		165,921
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	17,207		(31)	(145)	17,031
U.S. government and agency debt securities	14,799		(26)	(11)	14,762
Equity securities	8,732	8,051			16,783
International government agency debt securities	6,043		(4)		6,039
	46,781	8,051	(61)	(156)	54,615
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	47,981	8,051	(61)	(156)	55,815
Total investments	\$ 213,780	\$ 8,190	\$ (78)	\$ (156)	\$ 221,736
March 31, 2013					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 102,093	\$ 29	\$ (1)	\$	\$ 102,121
Corporate debt securities	10,946	27			10,973
International government agency debt securities	10,089	8	(1)		10,096

Edgar Filing: Alkermes plc. - Form 10-Q

	123,128	64	(2)		123,190
Money market funds	1,201				1,201
Total short-term investments	124,329	64	(2)		124,391
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	60,047		(17)		60,030
Corporate debt securities	18,725		(26)	(162)	18,537
International government agency debt securities	3,060				3,060
	81,832		(43)	(162)	81,627
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	83,032		(43)	(162)	82,827
Total investments	\$ 207,361	\$ 64	\$ (45)	\$ (162)	\$ 207,218

Table of Contents

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

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

(In thousands)	Six Months Ended September 30,	
	2013	2012
Proceeds from the sales and maturities of marketable securities	\$ 56,400	\$ 185,392
Realized gains	\$ 15	\$ 273
Realized losses	\$	\$

The Company's available-for-sale and held-to-maturity securities at September 30, 2013 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	\$ 86,899	\$ 86,938	\$ 1,200	\$ 1,200
After 1 year through 5 years	115,748	115,613		
Total	\$ 202,647	\$ 202,551	\$ 1,200	\$ 1,200

At September 30, 2013, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of U.S. government and agency debt securities and 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 equity securities at September 30, 2013 include common stock and warrants in Acceleron Pharma, Inc. (Acceleron), which the Company accounts for as an available-for-sale marketable security. During the three months ended September 30, 2013, Acceleron announced their closing of their initial public offering (IPO) and their registration statement was declared effective by the SEC on September 18, 2013. Prior to the IPO, the Company's investment in Acceleron, consisting of preferred stock and warrants, was accounted for under the cost method as Acceleron, until September 2013, was a privately-held company over which the Company did not exercise significant influence. In connection with the IPO, the Company's investment in preferred stock was converted to common stock.

The Company's investment in Civitas Therapeutics, Inc. (Civitas) was \$2.6 million and \$0.8 million at September 30, 2013 and March 31, 2013, respectively, which was recorded within Other assets in the accompanying condensed consolidated balance sheets. In September 2013, the Company invested an additional \$1.2 million and converted a promissory note in the amount of \$1.2 million into 844,415 shares of Civitas Series B preferred stock. The Company is accounting for its investment in Civitas Series B preferred stock under the cost method of accounting as the Series B preferred stock is not considered to be in-substance common stock. The Company is accounting for its investment in Civitas Series A preferred stock under the equity method as the Series A preferred stock is considered to be in-substance common stock, the Company

Edgar Filing: Alkermes plc. - Form 10-Q

had approximate 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the six months ended September 30, 2013 and 2012, 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. The Company will continue to record its proportionate share of Civitas' net income or loss in future periods.

Table of Contents

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

4. 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)	September 30, 2013		Level 1		Level 2		Level 3	
Assets:								
Cash equivalents	\$	1,201	\$	1,201	\$		\$	
U.S. government and agency debt securities		147,332		63,420		83,912		
Corporate debt securities		35,716				35,716		
International government agency debt securities		19,503				19,503		
Equity securities		16,783		15,976				807
Total	\$	220,535	\$	80,597	\$	139,131	\$	807
Liabilities:								
Interest rate swap contract	\$	(366)	\$		\$	(366)	\$	
Total	\$	(366)	\$		\$	(366)	\$	

(In thousands)	March 31, 2013		Level 1		Level 2		Level 3	
Assets:								
Cash equivalents	\$	1,201	\$	1,201	\$		\$	
U.S. government and agency debt securities		162,151		75,025		87,126		
Corporate debt securities		29,510				29,510		
International government agency debt securities		13,156				13,156		
Total	\$	206,018	\$	76,226	\$	129,792	\$	
Liabilities:								
Interest rate swap contract	\$	(541)	\$		\$	(541)	\$	
Total	\$	(541)	\$		\$	(541)	\$	

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.

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the six months ended September 30, 2013. The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at September 30, 2013:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)		Fair Value
Balance, April 1, 2013	\$	
Conversion of investment from cost method to available-for-sale		807
Balance, September 30, 2013	\$	807

During the six months ended September 30, 2013, our Level 3 investments consisted of warrants to purchase the common stock of Acceleron. The Company used a Black-Scholes model to determine the fair value of these warrants. The assumptions used in the Black-Scholes model included estimates for expected life, interest rates and for the volatility of Acceleron's common stock.

Table of Contents

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

A third-party pricing service was used to determine the estimated fair value of the Company's debt securities. The third-party pricing service develops its estimates 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 service at September 30, 2013.

The Company's investments in U.S. government and agency debt securities, 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 include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market-observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company entered into an interest rate swap agreement in September 2011 and interest rate cap agreement in December 2011. 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 the 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 consolidated balance sheets consists of the \$300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% (Term Loan B-1) and the \$75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor (Term Loan B-2). 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 September 30, 2013, was as follows:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 294,743	\$ 296,629
Term Loan B-2	\$ 71,129	\$ 71,606

5. 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:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	September 30, 2013		March 31, 2013	
Raw materials	\$	14,771	\$	13,506
Work in process		13,059		13,842
Finished goods(1)		12,878		16,135
Total inventory	\$	40,708	\$	43,483

(1) At September 30, 2013 and March 31, 2013, the Company had \$1.8 million and \$0.6 million, respectively, of VIVITROL finished goods inventory located at its third-party warehouse and shipping service provider.

Table of Contents

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

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2013	March 31, 2013
Land	\$ 8,457	\$ 8,357
Building and improvements	147,836	141,092
Furniture, fixture and equipment	216,025	197,743
Leasehold improvements	23,960	24,137
Construction in progress	21,713	39,399
Subtotal	417,991	410,728
Less: accumulated depreciation	(143,614)	(122,293)
Total property, plant and equipment, net	\$ 274,377	\$ 288,435

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	September 30, 2013 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (70,447)	\$ 429,253
NanoCrystal technology	13	74,600	(7,458)	67,142
OCR technology	12	66,300	(12,274)	54,026
Total		\$ 640,600	\$ (90,179)	\$ 550,421

The Company recorded \$25.6 million of amortization expense related to its finite-lived intangible assets during the six months ended September 30, 2013. Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at September 30, 2013 is expected to be approximately \$40.0 million for the nine months ending December 31, 2013, and \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the years ending December 31, 2014 through 2017, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30,		March 31,	
	2013		2013	
Accounts payable	\$	12,124	\$	18,282
Accrued compensation		17,727		30,432
Accrued interest		934		970
Accrued other		33,497		27,226
Total accounts payable and accrued expenses	\$	64,282	\$	76,910

Table of Contents

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

During the three months ended June 30, 2013, the Company recorded a \$1.0 million out-of-period adjustment to correct an over-accrued liability from the prior year. The Company believes the impact of this out-of-period adjustment is immaterial to both the previously issued and current period financial statements.

9. RESTRUCTURING

On April 4, 2013, the Company approved a restructuring plan at its Athlone, Ireland manufacturing facility consistent with the evolution of the Company's product portfolio and designed to improve operational performance for the future. The restructuring plan calls for the Company to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from its customers resulting from generic competition. The Company expects to continue to generate revenues from the manufacturing of these products during the nine months ending December 31, 2013 and, for certain of these products, into the year ending December 31, 2015.

As a result of the termination of these services, it was contemplated that the Company will also implement a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the year ended March 31, 2013, the Company recorded restructuring charges of \$12.3 million, which consisted of severance and outplacement services. At September 30, 2013, the Company had paid in cash \$1.2 million in connection with this restructuring plan and recorded an adjustment to the restructuring accrual due to changes in foreign currency of \$0.3 million. Restructuring activity during the six months ended September 30, 2013 was as follows:

(In thousands)	Severance and Outplacement Services	
Balance, April 1, 2013	\$	12,300
Payments		(1,239)
Adjustments		335
Balance, September 30, 2013	\$	11,396

At September 30, 2013 and March 31, 2013, \$3.1 million and none, respectively, of the restructuring accrual was included within Accounts payable and accrued expenses, and \$8.3 million and \$12.3 million, respectively, was included within Other long-term liabilities in the accompanying condensed consolidated balance sheets.

10. LONG-TERM DEBT

Long-term debt consisted of the following:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	September 30, 2013	March 31, 2013
Term Loan B-1, due September 25, 2019	\$ 294,743	\$ 296,029
Term Loan B-2, due September 25, 2016	71,129	72,979
Total	365,872	369,008
Less: current portion	(6,750)	(6,750)
Long-term debt	\$ 359,122	\$ 362,258

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 bears 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 (expense) income, net in the accompanying condensed consolidated statements of operations and comprehensive income (loss) due to the decrease in value of this contract during the six months ended September 30, 2013. At September 30, 2013 and March 31, 2013, this contract had an immaterial balance included within Other assets in the accompanying condensed consolidated balance sheets.

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

Table of Contents

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

December 2012, expires in December 2014, has a notional value of \$65.0 million and is not designated as a hedging instrument. Included within Interest expense in the accompanying condensed consolidated statements of operations and comprehensive income (loss) is \$0.2 million related to income for the increase in value of this contract during the six months ended September 30, 2013. At September 30, 2013 and March 31, 2013, this contract had a fair value of \$0.4 million and \$0.5 million, respectively, and is included within Other long-term liabilities in the accompanying condensed consolidated balance sheets.

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2013	2012	2013	2012
Cost of goods manufactured and sold	\$ 1,149	\$ 1,223	\$ 2,152	\$ 2,304
Research and development	2,825	2,348	4,990	4,658
Selling, general and administrative	10,235	6,876	15,876	11,647
Total share-based compensation expense	\$ 14,209	\$ 10,447	\$ 23,018	\$ 18,609

At September 30, 2013 and March 31, 2013, \$0.6 million of share-based compensation cost was capitalized and recorded as Inventory in the accompanying condensed consolidated balance sheets.

13. (LOSS) EARNINGS PER SHARE

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

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net (loss) income	\$ (7,762)	\$ (16,707)	\$ (428)	\$ 5,726
Denominator:				
Weighted average number of ordinary shares outstanding	136,106	131,067	135,358	130,753

Edgar Filing: Alkermes plc. - Form 10-Q

Effect of dilutive securities:				
Stock options				3,604
Restricted stock units				1,232
Dilutive ordinary share equivalents				4,836
Shares used in calculating diluted (loss) earnings per share	136,106	131,067	135,358	135,589

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

(In thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2013	2012	2013	2012
Stock options	9,241	9,986	8,883	6,472
Restricted stock units	1,229	1,238	1,338	
Total	10,470	11,224	10,221	6,472

Table of Contents

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

14. INCOME TAXES

The Company recorded an income tax provision of \$0.2 million and \$3.0 million for the three and six months ended September 30, 2013, respectively, and an income tax provision of \$0.4 million and \$1.2 million for the three and six months ended September 30, 2012, respectively. The income tax provision in the three and six months ended September 30, 2013 primarily relates to U.S. Federal and state taxes on income offset by a discrete benefit of \$3.0 million from the settlement of uncertain tax benefits. The tax provision in the three and six months ended September 30, 2012 primarily related to foreign taxes on income and was prepared on a discrete quarterly and year-to-date basis, respectively, as the yearly effective tax rate was not considered a reliable estimate for the current quarter and year-to-date provision.

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. At September 30, 2013, the Company determined, based on the weight of all available positive and negative evidence, on a jurisdiction-by-jurisdiction basis, that it is more likely than not that a significant portion of the net deferred tax assets will not be realized, and a valuation allowance has been recorded. However, if the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of the deferred tax asset could change and the valuation allowance could be released in part or in whole.

The Company resolved substantially all of its uncertain tax positions during the three months ended June 30, 2013, resulting in the discrete benefit of \$3.0 million.

15. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. For example, the Company is currently involved in various Paragraph IV litigation in the U.S. 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 4 of this 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 our Annual Report, which has been filed with the SEC.

Executive Summary

Net loss for the three months ended September 30, 2013 was \$7.8 million, or \$0.06 per ordinary share basic and diluted, as compared to a net loss of \$16.7 million, or \$0.13 per ordinary share basic and diluted, for the three months ended September 30, 2012. Net loss for the six months ended September 30, 2013 was \$0.4 million, or \$0.00 per ordinary share basic and diluted, as compared to net income of \$5.7 million, or \$0.04 per ordinary share basic and diluted, for the six months ended September 30, 2012.

During the three and six months ended September 30, 2013, we recorded total revenues of \$139.8 million and \$278.4 million, respectively. During the three and six months ended September 30, 2012, we recorded total revenues of \$124.0 million and \$276.2 million, respectively. Revenues from our five key commercial products, as summarized below, accounted for 73% and 72% of our total revenues in the three and six months ended September 30, 2013, respectively, as compared to 59% and 56% in the three and six months ended September 30, 2012, respectively. Included in the three and six months ended September 30, 2012 was \$20.0 million of intellectual property license revenue unrelated to key development programs.

COMMERCIAL PRODUCT PORTFOLIO

Our primary 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</i> ®	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (Janssen)
<i>CONSTA</i> ®					
<i>INVEGA</i> ®	Schizophrenia	NanoCrystal®	United States (U.S.)	Royalty	Janssen
<i>SUSTENNA</i> ®/					
<i>XEPLION</i> ®			ROW		

Edgar Filing: Alkermes plc. - Form 10-Q

<i>AMPYRA®/</i>	Treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed	Oral Controlled Release (OCR) Matrix Drug Absorption System (MXDAS®)	U.S.	Manufacturing and Royalty	Acorda Therapeutics, Inc. (Acorda)
<i>FAMPYRA®</i>			ROW		Biogen Idec International GmbH (Biogen Idec), under sublicense from Acorda
<i>BYDUREON®</i>	Type 2 diabetes	Extended-release microsphere	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.	Product sales	Alkermes plc
<i>TRICOR®</i>	Cholesterol lowering	NanoCrystal	Russia and Commonwealth of Independent States (CIS) Worldwide	Manufacturing and Royalty	Janssen (Cilag)
<i>LIPANTHYL®</i>					AbbVie Inc.
<i>LIPANTHYL®</i>					Abbott Laboratories
<i>LIPIDIL</i>					
<i>SUPRALIP</i> (and other trade names under which <i>fenofibrate</i> 145 mg is sold)					
<i>ZANAFLEX®</i>	Muscle spasticity	OCR	U.S.	Manufacturing (capsules only) and Royalty	Acorda; Actavis, Inc. (formerly Watson Pharmaceutical)
<i>CAPSULES®</i>		Spheroidal Oral Drug Absorption System (SODAS®)			
<i>ZANAFLEX®</i>					
<i>TABLETS</i>					
<i>TIZANIDINE HYDROCHLORIDE</i> (AB Rated to <i>ZANAFLEX</i>)					

Table of Contents

<i>CAPSULES</i>)					
<i>AVINZA</i> ®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer, Inc. (Pfizer)
<i>EMEND</i> ®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck & Co. Inc. (Merck)
<i>FOCALIN</i> ® XR	Attention Deficit Hyperactivity Disorder	OCR	Worldwide	Manufacturing and Royalty	Novartis AG (Novartis)
<i>RITALIN LA</i> ®		(SODAS)			
<i>MEGACE</i> ® ES	Anorexia, 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 (Jazz)
<i>RAPAMUNE</i> ®	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
<i>NAPRELAN</i> ®	Various mild to moderate pain indications	OCR Intestinal Protective Drug Absorption System (IPDAS®)	U.S. Canada	Manufacturing	Shionogi Sunovion Pharmaceuticals Canada, Inc.
<i>VERAPAMIL SR</i>	Hypertension	OCR	Licensed on country/region basis throughout the world	Manufacturing and Royalty (on select formulations)	UCB
<i>VERELAN</i> ®		(SODAS)			Kremers-Urban;
<i>VERELAN</i> ® PM					Cephalon;
<i>VERAPAMIL PM</i>					Aspen Pharma;
<i>VERECAPS</i> ®					Orient Europharma;
<i>UNIVER</i>					Actavis, Inc.
<i>DILZEM</i>	Hypertension and/or Angina	OCR	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon;
<i>DILZEM SR</i>		(SODAS)			Pfizer;
<i>DILZEM XL</i>					Kun Wha;
<i>DILTELAN</i>					Orient Europharma;
<i>ACALIX CD</i>					Sanofi;
<i>DINISOR</i>					Valeant Pharmaceuticals International Inc.
<i>TILAZEM CR</i>					

CARDIZEM® CD

AFEDitab® CR Hypertension OCR U.S. Manufacturing Actavis, Inc.

(AB Rated to Adalat
CC®) (MXDAS)

KEY COMMERCIAL PRODUCTS

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

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION

RISPERDAL CONSTA (risperidone long-acting injection) and INVEGA SUSTENNA/XEPLION (paliperidone palmitate extended-release injectable suspension) are long-acting atypical antipsychotics that incorporate our proprietary technologies. They are products of Janssen.

RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is exclusively manufactured by us and is marketed and sold by Janssen worldwide. It was first approved for the treatment of schizophrenia in the U.S. in 2003 and in countries in Europe in 2002. The U.S. Food and Drug Administration (FDA) approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder in May 2009. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in many countries outside of the U.S.

INVEGA SUSTENNA uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA was approved by the FDA for

Table of Contents

the acute and maintenance treatment of schizophrenia in adults in the U.S. in 2009. Paliperidone palmitate extended-release for injectable suspension is also approved in the EU and other countries worldwide, and is marketed and sold in the EU under the trade name XEPLION. INVEGA SUSTENNA/XEPLION is manufactured and commercialized worldwide by Janssen.

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 in January 2010 and received conditional approval in the EU in July 2011. 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 in January 2012 and received marketing authorization in the EU in June 2011 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. BYDUREON is manufactured by Bristol-Myers.

VIVITROL

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 FDA approved VIVITROL for the treatment of alcohol dependence in April 2006 and for the prevention of relapse to opioid dependence, following opioid detoxification, in October 2010. 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 the CIS, where it was approved for the treatment of alcohol dependence in 2008 and for opioid dependence in 2011. VIVITROL is manufactured by us.

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 and within Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report, which has been filed with the SEC.

KEY DEVELOPMENT PROGRAMS

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

We are studying aripiprazole lauroxil 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. In October 2013, we announced completion of patient enrollment in our phase 3 study designed to assess the efficacy, safety and tolerability of aripiprazole lauroxil in patients experiencing acute exacerbation of schizophrenia. The clinical data from this study, expected in the first half of calendar-year 2014, may form the basis of a New Drug Application (NDA) to the FDA for aripiprazole lauroxil for the treatment of schizophrenia.

ALKS 33 is an oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 has completed a phase 2 study in alcohol dependence and is currently being evaluated as a component of both ALKS 5461 and ALKS 3831.

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. In April 2013, we announced positive results from a phase 2 study conducted in patients with MDD and inadequate response to standard therapies. In the phase 2 study, ALKS 5461 met its primary endpoint, met key secondary endpoints and demonstrated significant reduction in depressive symptoms versus placebo. In October 2013, we announced that we have successfully completed our end-of-phase 2 interactions with the FDA, and the FDA granted ALKS 5461 Fast Track status, which is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions with the potential to address an unmet medical need. We plan to advance ALKS 5461 into phase 3 development in early calendar-year 2014. We expect to conduct three core efficacy studies that will include approximately 400 patients each and that will feature elements similar to those utilized in our phase 2 study, including sequential parallel comparison design.

Table of Contents

ZOXYDRO ER (hydrocodone bitartrate extended-release capsule), which utilizes our OCR technology, is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. (Zogenix) for the U.S. market. In October 2013, Zogenix announced that ZOXYDRO ER was approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are ineffective. We have also entered into a license and distribution agreement with Paladin Labs Inc. in respect of ZOXYDRO ER in Canada. We maintain all rights to the product in territories outside the U.S. and Canada and intend to explore commercial partnerships to develop and license the product in those territories.

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is composed of ALKS 33, a novel potent mu-opioid antagonist, in combination with the established antipsychotic drug olanzapine, generally available under the name ZYPREXA®. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in patients suffering from schizophrenia with alcohol use. In July 2013, we announced the initiation of a double-blind, active-controlled, dose-ranging phase 2 study of ALKS 3831 in approximately 400 patients with schizophrenia. In addition to safety and tolerability, the phase 2 study is designed to evaluate the impact of ALKS 3831 on weight and other metabolic factors in patients and to confirm the attenuation of olanzapine-induced weight gain observed in the phase 1 study of ALKS 3831. We expect to provide topline results from the study in the first half of calendar-year 2015. A second, planned phase 2 study will investigate the potential utility of ALKS 3831 for the large number of patients suffering from schizophrenia with alcohol use, a group representing as many as 50% of patients with schizophrenia. This study is planned to start in calendar-year 2014 following a planned meeting with the FDA.

We have an MMF program that has resulted in novel, small-molecule prodrugs of monomethyl fumarate (MMF) for the treatment of multiple sclerosis. Our MMF prodrugs are designed to rapidly and efficiently convert to MMF in the body and to offer advantages over the currently marketed dimethyl fumarate prodrug, TECFIDERA®. We expect to file an Investigational New Drug (IND) application and initiate a phase 1 study in mid calendar-year 2014.

ALKS 7106 is our novel, small-molecule drug candidate derived from our opioid modulator platform. ALKS 7106 is a potent oral opioid analgesic designed for the treatment of pain with intrinsically low potential for abuse and overdose death, two liabilities associated with other opioid medicines. In July 2013, we presented preclinical data showing that ALKS 7106 had more potent analgesic properties than morphine and was well tolerated at doses far in excess of those required for analgesic action. Additional preclinical data for ALKS 7106 demonstrated a ceiling effect on neurotransmitter release over a broad concentration range, suggesting low potential for abuse and overdose death. We expect to file an IND and initiate a phase 1 study in mid calendar-year 2014.

In July 2013, we presented preclinical data showing that RDB 1419, a novel biologic cancer immunotherapy candidate based on interleukin-2 and its receptors, preferentially expanded the number of tumor-killing cells involved in immunotherapeutic effects on cancer. Additional preclinical data demonstrated that RDB 1419 inhibited lung metastases in a model of lung cancer. RDB 1419 was engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic and to provide safety and tolerability advantages over existing therapies. We expect to conduct IND-enabling activities for RDB 1419 in calendar-year 2014.

A three-month formulation of INVEGA SUSTENNA is in development by Janssen Research & Development, LLC. Two phase 3 studies are underway with approximately 1,800 patients with schizophrenia to assess the efficacy, safety and tolerability of the three-month injectable formulation. Janssen is expected to submit a NDA to the FDA in calendar-year 2014 and an application with the European Medicines Agency in calendar-year 2015. The investigational product is being developed by Janssen Pharmaceutica, NV, licensee to our proprietary technology for nanoparticles.

Edgar Filing: Alkermes plc. - Form 10-Q

Line extensions for BYDUREON are in development by Bristol-Myers. These line extensions include a dual-chamber pen device, which Bristol-Myers expects to be on the market by mid calendar-year 2014, and weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres.

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 and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012:

Edgar Filing: Alkermes plc. - Form 10-Q

Table of Contents

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
Manufacturing and royalty revenues:						
RISPERDAL CONSTA	\$ 33.4	\$ 34.0	\$ (0.6)	\$ 67.9	\$ 70.8	\$ (2.9)
INVEGA SUSTENNA/XEPLION	29.2	16.3	12.9	51.0	28.1	22.9
AMPYRA/FAMPYRA	12.6	5.0	7.6	32.5	22.2	10.3
RITALIN LA/FOCALIN XR	9.2	9.1	0.1	20.4	20.0	0.4
BYDUREON	7.0	3.3	3.7	12.4	6.3	6.1
TRICOR 145	3.5	12.5	(9.0)	7.6	24.5	(16.9)
Other	23.7	27.1	(3.4)	46.5	73.8	(27.3)
Manufacturing and royalty revenues	\$ 118.6	\$ 107.3	\$ 11.3	\$ 238.3	\$ 245.7	\$ (7.4)

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three and six months ended September 30, 2013, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$326.0 million and \$616.0 million, respectively, as compared to \$212.0 million and \$408.0 million in the three and six months ended September 30, 2012, respectively. The increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION also resulted in our achieving a higher royalty rate earlier in the six months ended September 30, 2013, as compared to the six months ended September 30, 2012. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION of 5% up to the first \$250 million in calendar-year net sales; 7% on calendar-year net sales of between \$250 million and \$500 million; and 9% on calendar-year net sales exceeding \$500 million. The royalty rate resets at the beginning of each calendar-year to 5%.

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was primarily due to a 96% and 55% increase in the number of units shipped in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012 and an increase in royalties earned on end-market sales. During the three and six months ended September 30, 2013, our estimate of Acorda's and Biogen's end-market sales of AMPYRA/FAMPYRA were \$99.8 million and \$194.4 million, as compared to \$82.0 million and \$168.0 million in the three and six months ended September 30, 2012.

The increase in BYDUREON royalty revenues in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was primarily due to an increase in end-market sales of BYDUREON by Bristol-Myers. During the three and six months ended September 30, 2013, our estimate of Bristol-Myers end-market sales of BYDUREON were \$87.5 million and \$154.4 million, respectively, as compared to \$46.1 million and \$80.8 million in the three and six months ended September 30, 2012, respectively.

The decrease in TRICOR 145 royalty revenue in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was due to a decrease in end-market net sales of TRICOR 145 by Abbott due to the introduction of a generic version of this product in November 2012.

The decrease in our other manufacturing and royalty revenues in the six months ended September 30, 2013, as compared to the six months ended September 30, 2012, was primarily due to the sale of intellectual property license revenue, unrelated to our key development programs, of \$20.0 million in the three months ended June 30, 2012.

Edgar Filing: Alkermes plc. - Form 10-Q

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, our long acting antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen Idec continues to launch FAMPYRA in the rest of the world. We 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 November 2012 and the potential entry of a generic version of certain doses of FOCALIN XR, which could occur at any time.

Product Sales, net

Our product sales, net 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 six months ended September 30, 2013 and 2012:

Table of Contents

(In millions)	Three Months Ended September 30,				Six Months Ended September 30,			
	2013	% of Sales	2012	% of Sales	2013	% of Sales	2012	% of Sales
Product sales, gross	\$ 26.3	100.0%	\$ 18.9	100.0%	\$ 50.6	100.0%	\$ 36.6	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(2.0)	(7.6)%	(1.4)	(7.4)%	(3.7)	(7.3)%	(2.6)	(7.1)%
Chargebacks	(1.7)	(6.5)%	(1.4)	(7.4)%	(3.4)	(6.7)%	(2.7)	(7.4)%
Co-pay assistance	(1.2)	(4.6)%	(0.7)	(3.7)%	(2.5)	(4.9)%	(1.4)	(3.8)%
Other	(2.2)	(8.4)%	(0.2)	(1.1)%	(4.4)	(8.7)%	(2.3)	(6.3)%
Total adjustments	(7.1)	(27.1)%	(3.7)	(19.6)%	(14.0)	(27.7)%	(9.0)	(24.6)%
Product sales, net	\$ 19.2	72.9%	\$ 15.2	80.4%	\$ 36.6	72.3%	\$ 27.6	75.4%

The increase in product sales, gross for the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was due to a 41% and 39% increase in the number of units sold, respectively. The increase in Medicaid rebates, chargebacks and co-pay assistance are all primarily due to the increase in VIVITROL gross product sales. We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S.

Costs and Expenses*Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
Cost of goods manufactured and sold	\$ 45.4	\$ 41.5	\$ (3.9)	\$ 91.4	\$ 83.6	\$ (7.8)

The increase in cost of goods manufactured and sold in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was primarily due to a charge of \$1.8 million and \$3.7 million, respectively, for depreciation expense, and an increase in the cost of goods manufactured for RISPERDAL CONSTA of \$1.8 million and \$3.2 million, respectively, primarily due to an increase in standard costs, as compared to the prior periods. The charge for depreciation expense is due to the acceleration of depreciation of certain of our manufacturing assets at our Athlone manufacturing facility that will have no future use at the completion of our restructuring plan in the year ending December 31, 2015.

Research and Development Expense

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include costs related to clinical and non-clinical activities performed by contract research organizations, consulting fees, laboratory services, purchases of drug product materials and third-party manufacturing development costs. Internal R&D expenses include employee-related expenses, occupancy costs, depreciation and general overhead. We track external R&D expenses for each of our development programs, however, internal R&D expenses are not tracked by individual program as they benefit multiple programs or our technologies in general.

The following table sets forth our external R&D expenses relating to our individual key development programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

Table of Contents

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
External R&D Expenses:						
Key development programs:						
Aripiprazole lauroxil	\$ 17.6	\$ 9.5	\$ (8.1)	\$ 22.3	\$ 21.2	\$ (1.1)
ALKS 3831	2.3		(2.3)	4.6		(4.6)
ALKS 5461	1.2	2.4	1.2	3.0	4.0	1.0
ALKS 37		0.7	0.7		3.1	3.1
Other development programs	4.2	3.8	(0.4)	9.4	7.5	(1.9)
Total external R&D expenses	25.3	16.4	(8.9)	39.3	35.8	(3.5)
Internal R&D expenses:						
Employee-related	14.4	12.5	(1.9)	27.8	25.3	(2.5)
Occupancy	2.2	1.3	(0.9)	4.5	2.5	(2.0)
Depreciation	2.1	1.5	(0.6)	4.3	2.9	(1.4)
Other	1.9	3.4	1.5	3.5	6.4	2.9
Total internal R&D expenses	20.6	18.7	(1.9)	40.1	37.1	(3.0)
Research and development expenses	\$ 45.9	\$ 35.1	\$ (10.8)	\$ 79.4	\$ 72.9	\$ (6.5)

These amounts are not necessarily predictive of future R&D expenditures. In an effort to allocate our spending most effectively, we continually evaluate the products under development, based on the performance of such products in preclinical and/or clinical trials, our expectations regarding the likelihood of their regulatory approval and our view of their commercial viability, among other factors.

The increase in expense related to the aripiprazole lauroxil program in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was primarily due to the timing of patient enrollments in our phase 3 study, which began in December 2011 and the start of an extension study in the three months ended September 30, 2013, to assess the long-term safety and durability of effect of aripiprazole lauroxil in subjects with stable schizophrenia.

The increase in expense related to the ALKS 3831 program in the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was due to the timing of studies related to the program. We announced positive topline results from a phase 1 study in January 2013 and, in July 2013, we announced the initiation of a phase 2 study of ALKS 3831 to assess the safety, tolerability and impact of ALKS 3831 on weight and other metabolic factors in patients with schizophrenia. We did not incur material external R&D expenses related to our MMF, ALKS 7106 or RDB 1419 programs during the three and six months ended September 30, 2013 or 2012.

We expect R&D expenses to increase in calendar-year 2014 as more late-stage clinical trials get underway for our products.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
Selling, general and administrative expense	\$ 39.5	\$ 31.4	\$ (8.1)	\$ 72.4	\$ 61.2	\$ (11.2)

Edgar Filing: Alkermes plc. - Form 10-Q

The increase in selling, general and administrative (SG&A) expense for the three and six months ended September 30, 2013 as compared to the three and six months ended September 30, 2012, was primarily due to a \$5.9 million and \$8.0 million increase in employee-related expenses, respectively. The increase in employee-related expenses was primarily due to an increase in share-based compensation of \$3.4 million and \$4.2 million in the three and six months ended September 30, 2013, respectively, resulting from an increase in our stock price and an increase in headcount. Additionally, during the three and six months ended September 30, 2013, there was a \$3.2 million and \$3.4 million increase in professional service fees and marketing expenses, which are primarily due to an increase in activity related to the anticipated launch of the aripiprazole lauroxil program and activities related to the VIVITROL label update. We expect SG&A expenses to increase in calendar-year 2014 as launch planning activities accelerate for aripiprazole lauroxil.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
Amortization of acquired intangible assets	\$ 12.9	\$ 10.5	\$ (2.4)	\$ 25.6	\$ 21.0	\$ (4.6)

Table of Contents

The intangible assets being amortized in the three and six months ended September 30, 2013 and 2012 were acquired as part of the acquisition of Elan Drug Technologies (EDT) in September 2011. In connection with the acquisition of EDT, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which were 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 on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at September 30, 2013 is expected to be approximately \$40.0 million for the nine months ending December 31, 2013, and \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the years ending December 31, 2014 through 2017, respectively.

Restructuring

On April 4, 2013, we approved a restructuring plan at our Athlone, Ireland manufacturing facility consistent with the evolution of our product portfolio and designed to improve operational performance in the future. The restructuring plan calls for the Company to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from its customers resulting from generic competition. We expect to continue to generate revenues from the manufacturing of these products during the nine months ending December 31, 2013 and, for certain of these products, into the year ending December 31, 2015.

As a result of the termination of these services, we expect a corresponding reduction in headcount of up to 130 employees. The restructuring plan commenced on March 31, 2013 and will be implemented over a period of approximately two years. During the year ended March 31, 2013, we recorded a one-time restructuring charge, expected to be settled in cash payments, consisting solely of severance and other employee-related expenses of \$12.3 million. During the six months ended September 30, 2013, we reduced the restructuring accrual by \$0.9 million, primarily due to payments to our former employees. We expect the restructuring plan will result in annual cost savings of between \$15.0 million and \$20.0 million by the year ending December 31, 2016 and beyond. As part of the restructuring plan, we expect to incur non-cash charges resulting from the acceleration of depreciation of certain of our manufacturing assets of \$7.5 million in the nine months ending December 31, 2013 and \$7.8 million in the year ending December 31, 2014.

Other (Expense), Net

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2013	2012		2013	2012	
Interest income	\$ 0.3	\$ 0.2	\$ 0.1	\$ 0.5	\$ 0.5	\$
Interest expense	(3.5)	(22.6)	19.1	(6.9)	(32.8)	25.9
Other income, net	(0.5)	0.7	(1.2)	(0.7)	1.6	(2.3)
Total other (expense), net	\$ (3.7)	\$ (21.7)	\$ 18.0	\$ (7.1)	\$ (30.7)	\$ 23.6

The decrease in interest expense for the three and six months ended September 30, 2013, as compared to the three and six months ended September 30, 2012, was primarily due to a decrease in the principal amount and interest rates associated with our long-term debt. As a result of two refinancing transactions we completed during the year ended March 31, 2013, we reduced our outstanding principal balance from \$450.0 million to \$375.0 million, and we were able to reduce our blended interest rate from 7.6% to 3.4%.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	September 30, 2013		March 31, 2013	
Cash and cash equivalents	\$	173.5	\$	97.0
Investments short-term		166.0		124.4
Investments long-term		55.8		82.8
Total cash, cash equivalents and investments	\$	395.3	\$	304.2
Working capital	\$	449.9	\$	322.7
Outstanding borrowings current and long-term	\$	365.9	\$	369.0

Table of Contents*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 our term loan facility, which has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as we meet certain conditions, including a specified leverage ratio.

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 six months ended September 30, 2013 and 2012:

(In millions)	Six Months Ended September 30,			
	2013		2012	
Cash and cash equivalents, beginning of period	\$	97.0	\$	83.6
Cash provided by operating activities		54.1		45.0
Cash (used in) provided by investing activities		(8.1)		75.0
Cash provided by (used in) financing activities		30.5		(71.2)
Cash and cash equivalents, end of period	\$	173.5	\$	132.4

The increase in cash flows provided by operating activities in the six months ended September 30, 2013, as compared to the six months ended September 30, 2012, was primarily due to a decrease in cash used for working capital of \$18.2 million, partially offset by a decrease in cash provided from net (loss) income of \$9.1 million. The decrease in cash provided from working capital was primarily due to a decrease in cash used for accounts payable and accrued expenses of \$9.7 million and an increase in cash provided by accounts receivable of \$9.8 million. The decrease in cash provided from net (loss) income was partially due to a \$0.4 million net loss in the six months ended September 30, 2013, as compared to \$5.7 million of net income in the prior period.

The increase in cash flows used in investing activities in the six months ended September 30, 2013, as compared to the six months ended September 30, 2012, was primarily due to a decrease in the net sales of investments of \$83.9 million. During the three months ended September 30, 2012, we used \$78.0 million of cash in connection with the refinancing of our long-term debt, which was primarily provided by the sale of investments.

The increase in cash flows provided by financing activities in the six months ended September 30, 2013, as compared to the six months ended September 30, 2012, was due to the \$78.0 million of net cash used in connection with the refinancing of our long-term debt during the prior period, a \$24.2 million increase in cash received from our employees upon the exercise of stock awards and a \$8.1 million increase in the excess tax-benefit from share-based compensation, partially offset by a \$5.2 million increase in employee taxes paid related to the net share settlement of equity awards.

Our investments at September 30, 2013 consist of the following:

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)		Amortized		Gross Unrealized			Estimated	
		Cost		Gains	Losses	Fair Value		
Investments	short-term	\$	165.8	\$	0.1	\$	165.9	
Investments	long-term available-for-sale		46.8		8.0	(0.2)	54.6	
Investments	long-term held-to-maturity		1.2				1.2	
Total		\$	213.8	\$	8.1	\$ (0.2)	\$ 221.7	

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, corporate debt securities and equity securities. The equity securities consist of common stock and warrants of Acceleron, which the Company reclassified from a cost method investment to an available-for-sale investment, following Acceleron's IPO in September 2013. 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

Table of Contents

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 September 30, 2013, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At September 30, 2013 and March 31, 2013, \$0.8 million and none of our investments were valued using Level 3 inputs, respectively. Level 3 inputs are unobservable and are significant to the overall fair value measurement and require a significant degree of judgment.

Borrowings

At September 30, 2013, our borrowings consisted of a term loan facility with an outstanding principal balance of \$368.3 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.

Contractual Obligations

Refer to Part II, Item 7 of our Annual Report in the *Contractual Obligations* section for a discussion of our contractual obligations. Our contractual obligations as of September 30, 2013 were not materially changed from the date of that report.

Off-Balance Sheet Arrangements

At September 30, 2013, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

Critical Accounting Estimates

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

New Accounting Standards

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

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

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks since March 31, 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 since March 31, 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*)), on September 30, 2013. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2013 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

Table of Contents

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.

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. 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 our Annual Report. For a further discussion of our Risk Factors, refer to 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 September 30, 2013. As of September 30, 2013, 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 September 30, 2013, Ms. Geraldine A. Henwood, a director of the Company, Mr. Richard F. Pops, both a director and executive officer of the Company, Dr. Elliot W. Ehrich and Messrs. James L. Botkin, James M. Frates, Michael J. Landine and Gordon G. Pugh, all executive officers 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:

Exhibit

No.	
10.1 +*	Alkermes plc Stock Option and Incentive Plan, as amended (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on August 1, 2013).
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 September 30, 2013, 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).

* Previously filed.

+ Indicates a management contract or any compensatory plan, contract, or arrangement.

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: October 31, 2013