

Alkermes plc.
Form 10-Q
April 30, 2014
[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 March 31, 2014

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Edgar Filing: Alkermes plc. - Form 10-Q

Ireland

(State or other jurisdiction of incorporation or organization)

98-1007018

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

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐
(Do not check if a smaller reporting company)

Smaller reporting company ☐

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

The number of the registrant's ordinary shares, \$0.01 par value, outstanding as of April 24, 2014 was 144,515,176 shares.

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2014

		Page No.
	<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements (unaudited):</u>	
	<u>Condensed Consolidated Balance Sheets March 31, 2014 and December 31, 2013</u>	5
	<u>Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income For the Three Months Ended March 31, 2014 and 2013</u>	6
	<u>Condensed Consolidated Statements of Cash Flows For the Three Months Ended March 31, 2014 and 2013</u>	7
	<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	28
<u>Item 4.</u>	<u>Controls and Procedures</u>	29
	<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	30
<u>Item 1A.</u>	<u>Risk Factors</u>	30
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 5.</u>	<u>Other Information</u>	30
<u>Item 6.</u>	<u>Exhibits</u>	30
<u>Signatures</u>		31
<u>Exhibit Index</u>		
	Ex-31.1 Section 302 Certification of Chief Executive Officer	
	Ex-31.2 Section 302 Certification of Chief Financial Officer	
	Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer	
	Ex-101 Instance Document	
	Ex-101 Schema Document	
	Ex-101 Calculation Linkbase Document	
	Ex-101 Labels Linkbase Document	
	Ex-101 Definition Linkbase Document	
	Ex-101 Presentation Linkbase Document	

Table of Contents

Cautionary Note Concerning 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, believe, plan, other similar words. These statements discuss future expectations, and 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 and development programs;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding our collaborations and other significant agreements relating to our products and development programs;
- 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;
- our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations; and
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

Actual results might differ materially from those expressed or implied by the forward-looking statements contained in this Form 10-Q because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Form 10-Q might not occur. For more information regarding the risk and uncertainties of our business, see Item 1A Risk Factors of our Transition Report on Form 10-K for the nine-month period ended December 31, 2013 (the Transition Report) and any subsequent reports filed with the Securities and Exchange Commission.

Edgar Filing: Alkermes plc. - Form 10-Q

Unless otherwise indicated, information contained in this Form 10-Q concerning the disorders targeted by our products and the markets in which we operate is based on information from various third-party sources (including, without limitation, industry publications, medical and clinical journals and studies, surveys and forecasts) as well as our internal research. Our internal research involves assumptions that we have made, which we believe are reasonable, based on data from those and other similar sources and on our knowledge of the markets for our marketed and development products. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. These projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Item 1A Risk Factors of our Transition Report. These and other factors could cause results to differ materially from those expressed in the estimates included in this Form 10-Q.

Note Regarding Company

Alkermes plc (as used in this report, together with our subsidiaries, Alkermes, the Company, us, we, and our) is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. 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.

Table of Contents

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations (®) and registration applications (TM), including IPDAS®, LinkeRx®, MXDAS®, NanoCrystal®, SODAS®, VERELAN® and VIVITROL®. The following are trademarks of the respective companies listed: ABILIFY® Otsuka Pharmaceutical Co., Ltd.; ADALAT® Bayer AG Corporation; AFEDITAB® Actavis, Inc.; AMPYRA®, FAMPYRA®, ZANAFLEX® and ZANAFLEX CAPSULES® Acorda Therapeutics, Inc.; AVINZA® King Pharmaceuticals Research and Development, Inc.; BYDUREON® and BYETTA® Amylin Pharmaceuticals, LLC; DILZEM® Cephalon (UK) Limited or Warner-Lambert Company LLC (depending on the jurisdiction); DILTELAN® Elan Corporation plc or Cephalon Limited (depending on the jurisdiction); EMEND® Merck Sharp & Dohme Corp.; FOCALIN XR® and RITALIN LA® Novartis AG; INVEGA® SUSTENNA®, RISPERDAL® CONSTA® and XEPLION® Johnson & Johnson Corp. (or its affiliate); LUVOX CR® Abbott Laboratories; MEGACE® E.R. Squibb & Sons, LLC; NAPRELAN® Alvogen Pharma US, Inc.; RAPAMUNE® Wyeth LLC; SUPRALIP® and TRICOR® Fournier Industrie et Sante Corporation; TECFIDERA® Biogen Idec MA, Inc.; UNIVER® various non-Alkermes entities (depending on the jurisdiction); ZOXYDRO ER Zogenix, Inc.; and ZYPREXA® Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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

	March 31, 2014 (In thousands, except share and per share amounts)	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 156,325	\$ 167,562
Investments short-term	395,948	194,669
Receivables	123,154	134,154
Inventory	55,403	46,218
Prepaid expenses and other current assets	45,941	27,535
Total current assets	776,771	570,138
PROPERTY, PLANT AND EQUIPMENT, NET	268,992	274,490
INTANGIBLE ASSETS NET	524,989	537,565
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	149,491	87,764
OTHER ASSETS	22,495	14,891
TOTAL ASSETS	\$ 1,835,478	\$ 1,577,588
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 83,750	\$ 91,173
Long-term debt current	6,750	6,750
Deferred revenue current	2,259	2,974
Total current liabilities	92,759	100,897
LONG-TERM DEBT	355,963	357,543
DEFERRED TAX LIABILITIES, NET LONG-TERM	25,061	29,169
OTHER LONG-TERM LIABILITIES	10,230	12,580
DEFERRED REVENUE LONG-TERM	11,964	12,213
Total liabilities	495,977	512,402
COMMITMENTS AND CONTINGENCIES (Note 16)		
SHAREHOLDERS EQUITY:		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at March 31, 2014 and December 31, 2013, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 145,137,639 and 138,482,571 shares issued; 144,444,951 and 137,792,626 shares outstanding at March 31, 2014 and December 31, 2013, respectively		
	1,448	1,382
Treasury shares, at cost (692,688 and 689,945 shares at March 31, 2014 and December 31, 2013, respectively)	(17,959)	(17,833)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,854,596	1,553,337
Accumulated other comprehensive income	8,044	10,574
Accumulated deficit	(506,628)	(482,274)
Total shareholders' equity	1,339,501	1,065,186
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,835,478	\$ 1,577,588

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

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME****(unaudited)**

	Three Months Ended March 31,	
	2014	2013
	(In thousands, except per share amounts)	
REVENUES:		
Manufacturing and royalty revenues	\$ 111,280	\$ 146,919
Product sales, net	17,079	14,626
Research and development revenue	1,853	1,877
Total revenues	130,212	163,422
EXPENSES:		
Cost of goods manufactured and sold	38,839	47,991
Research and development	52,140	35,800
Selling, general and administrative	42,550	34,679
Amortization of acquired intangible assets	12,576	10,322
Restructuring		12,300
Impairment of long-lived assets		3,346
Total expenses	146,105	144,438
OPERATING (LOSS) INCOME	(15,893)	18,984
OTHER (EXPENSE), NET:		
Interest income	511	171
Interest expense	(3,356)	(11,473)
Other (expense) income, net	(1,850)	184
Total other (expense), net	(4,695)	(11,118)
(LOSS) INCOME BEFORE INCOME TAXES	(20,588)	7,866
INCOME TAX PROVISION	3,766	4,867
NET (LOSS) INCOME	\$ (24,354)	\$ 2,999
(LOSS) EARNINGS PER ORDINARY SHARE:		
Basic	\$ (0.17)	\$ 0.02
Diluted	\$ (0.17)	\$ 0.02
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic	143,358	133,272
Diluted	143,358	139,677
COMPREHENSIVE (LOSS) INCOME:		
Net (loss) income	\$ (24,354)	\$ 2,999
Holding (losses) gains, net of tax of \$1,453 and none, respectively	(2,531)	143
COMPREHENSIVE (LOSS) INCOME	\$ (26,885)	\$ 3,142

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

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	\$ (24,354)	\$ 2,999
Adjustments to reconcile net (loss) income to cash flows from operating activities:		
Depreciation and amortization	22,553	18,321
Share-based compensation expense	13,420	7,881
Excess tax benefit from share-based compensation	(7,163)	(4,513)
Impairment of long-lived assets		3,346
Deferred income taxes	(4,916)	(533)
Loss on debt refinancing transaction		7,541
Prepayment penalty in connection with debt refinancing		(3,733)
Other non-cash charges	3,702	795
Changes in assets and liabilities:		
Receivables	11,000	(4,785)
Inventory, prepaid expenses and other assets	(13,678)	1,176
Accounts payable and accrued expenses	(3,084)	26,596
Deferred revenue	(965)	(878)
Other long-term liabilities	13	1,091
Cash flows (used in) provided by operating activities	(3,472)	55,304
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(5,685)	(8,259)
Proceeds from the sale of equipment		119
Purchases of investments	(351,489)	(142,437)
Sales and maturities of investments	84,500	38,749
Cash flows used in by investing activities	(272,674)	(111,828)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares, net	248,406	
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	11,028	16,847
Excess tax benefit from share-based compensation	7,163	4,513
Proceeds from the issuance of long-term debt		(2,074)
Employee taxes paid related to net share settlement of equity awards		(5)
Principal payments of long-term debt	(1,688)	(1,688)
Cash flows provided by provided by financing activities	264,909	17,593
NET DECREASE IN CASH AND CASH EQUIVALENTS	(11,237)	(38,931)
CASH AND CASH EQUIVALENTS Beginning of period	167,562	135,892
CASH AND CASH EQUIVALENTS End of period	\$ 156,325	\$ 96,961
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 787	\$ 2,450

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 research, develop and commercialize, both with partners and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. 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, Alkermes 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three months ended March 31, 2014 and 2013 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the nine-month transition period ended December 31, 2013 (the Transition Period). 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 audited consolidated financial statements and notes thereto of Alkermes, which are contained in the Company's Transition Report on Form 10-K, 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, including the Transition 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 as disclosed in Note 2: *Summary of Significant Accounting Policies* within Part II, Item 8 of our Transition 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.

In July 2013, the FASB adopted clarifying guidance on the presentation of unrecognized tax benefits when various qualifying tax credits exist. The amendment requires that unrecognized tax benefits be presented on the consolidated balance sheet as a reduction to deferred tax assets created by net operating losses (NOLs) or other tax credits from prior periods that occur in the same taxing jurisdiction. To the extent that the unrecognized tax benefit exceeds these NOLs or other tax credits, it shall be presented as a liability. This update, required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, was adopted by the Company on January 1, 2014. The adoption of this standard did not have a material impact on the presentation of the Company's financial position.

Table of Contents

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

3. INVESTMENTS

Investments consisted of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year	Greater than One Year	
March 31, 2014					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 230,853	\$ 155	\$ (17)	\$	\$ 230,991
Corporate debt securities	109,986	91	(101)		109,976
International government agency debt securities	27,718	12	(54)		27,676
Equity securities	8,732	17,372			26,104
	377,289	17,630	(172)		394,747
Money market funds	1,201				1,201
Total short-term investments	378,490	17,630	(172)		395,948
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	81,050		(163)	(1)	80,886
Corporate debt securities	42,278		(40)	(46)	42,192
International government agency debt securities	24,890		(24)		24,866
	148,218		(227)	(47)	147,944
Held-to-maturity securities:					
Certificates of deposit	1,547				1,547
Total long-term investments	149,765		(227)	(47)	149,491
Total investments	\$ 528,255	\$ 17,630	\$ (399)	\$ (47)	\$ 545,439
December 31, 2013					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 130,669	\$ 80	\$ (1)	\$	\$ 130,748
Corporate debt securities	38,614	64	(30)		38,648
International government agency debt securities	24,097	8	(33)		24,072
	193,380	152	(64)		193,468
Money market funds	1,201				1,201
Total short-term investments	194,581	152	(64)		194,669
Long-term investments:					

Edgar Filing: Alkermes plc. - Form 10-Q

Available-for-sale securities:

Equity securities	8,732	21,253			29,985
U.S. government and agency debt securities	28,503		(61)	(3)	28,439
Corporate debt securities	20,266		(30)	(75)	20,161
International government agency debt securities	7,691		(5)		7,686
	65,192	21,253	(96)	(78)	86,271

Held-to-maturity securities:

Certificates of deposit	1,493				1,493
Total long-term investments	66,685	21,253	(96)	(78)	87,764
Total investments	\$ 261,266	\$ 21,405	\$ (160)	\$ (78)	\$ 282,433

Table of Contents

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

The Company's equity securities at March 31, 2014 included common stock and warrants in Acceleron Pharma, Inc. (Acceleron), which the Company accounts for as available-for-sale marketable securities. 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)	Three Months Ended March 31,	
	2014	2013
Proceeds from the sales and maturities of marketable securities	\$ 84,500	\$ 38,749
Realized gains	\$	\$ 39
Realized losses	\$ (3)	\$ (5)

The Company's available-for-sale and held-to-maturity securities at March 31, 2014 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	\$ 225,758	\$ 225,679	\$ 1,547	\$ 1,547
After 1 year through 5 years	291,017	290,908		
Total	\$ 516,775	\$ 516,587	\$ 1,547	\$ 1,547

At March 31, 2014, 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 investment in Civitas Therapeutics, Inc. (Civitas) was zero and \$2.0 million at March 31, 2014 and December 31, 2013, respectively, which was recorded within Other Assets in the accompanying condensed consolidated balance sheets. During the three months ended March 31, 2014, the Company recorded a reduction in its investment in Civitas of \$2.0 million, which represented the Company's proportionate share of Civitas' net losses for this period. As the Company's interest in Civitas has reached zero, the Company will no longer record its proportionate share of Civitas' net losses until such time as the Company's share of Civitas' net income exceeds its share of Civitas' net losses not recognized during the period the equity method was suspended.

[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)	March 31, 2014	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201		\$
U.S. government and agency debt securities	311,877	144,046	167,831	
Corporate debt securities	152,168		152,168	
International government agency debt securities	52,542		52,542	
Equity securities	26,104	24,794		1,310
Total	\$ 543,892	\$ 170,041	\$ 372,541	\$ 1,310
Liabilities:				
Interest rate swap contract	\$ (185)	\$	(185)	\$
Total	\$ (185)	\$	(185)	\$

(In thousands)	December 31, 2013	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201		\$
U.S. government and agency debt securities	159,187	63,213	95,974	
Corporate debt securities	58,809		58,809	
International government agency debt securities	31,758		31,758	
Equity securities	29,985	28,459		1,526
Total	\$ 280,940	\$ 92,873	\$ 186,541	\$ 1,526
Liabilities:				
Interest rate swap contract	\$ (275)	\$	(275)	\$
Total	\$ (275)	\$	(275)	\$

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 three months ended March 31, 2014. 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 March 31, 2014:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Fair Value
Balance, January 1, 2014	\$ 1,526
Total unrealized losses included in other comprehensive (loss) income	(216)
Balance, March 31, 2014	\$ 1,310

Table of Contents

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

During the three months ended March 31, 2014, the Company's Level 3 investment 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 the following:

Current stock price	\$	34.50
Warrant strike price	\$	5.88
Expected term (years)		6.28
Risk-free rate		2.31%
Volatility		71.2%

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 within the fair value hierarchy 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 included reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validated 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, which is described in greater detail in Note 11, *Derivative Instruments*. The fair value of the Company's interest rate swap agreement was 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 condensed consolidated balance sheets consisted 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) and together with Term Loan B-1, the 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, was as follows at March 31, 2014:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 293,438	\$ 295,408
Term Loan B-2	\$ 69,275	\$ 69,375

5. INVENTORY

Edgar Filing: Alkermes plc. - Form 10-Q

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

(In thousands)	March 31, 2014	December 31, 2013
Raw materials	\$ 19,251	\$ 18,410
Work in process	21,076	15,581
Finished goods	15,076	12,227
Total inventory	\$ 55,403	\$ 46,218

[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)	March 31, 2014	December 31, 2013
Land	\$ 8,440	\$ 8,440
Building and improvements	148,321	148,044
Furniture, fixture and equipment	223,013	220,984
Leasehold improvements	23,969	23,980
Construction in progress	28,855	26,688
Subtotal	432,598	428,136
Less: accumulated depreciation	(163,606)	(153,646)
Total property, plant and equipment, net	\$ 268,992	\$ 274,490

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	March 31, 2014 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (90,641)	\$ 409,059
NanoCrystal technology	13	74,600	(9,531)	65,069
OCR technology	12	66,300	(15,439)	50,861
Total		\$ 640,600	\$ (115,611)	\$ 524,989

The Company recorded, as Amortization of acquired intangible assets in the accompanying condensed consolidated Statements of Operations and Comprehensive (Loss) Income, \$12.6 million and \$10.3 million of amortization expense related to its finite-lived intangible assets during the three months ended March 31, 2014 and 2013, respectively, all of which related to cost of goods manufactured and sold. Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at March 31, 2014 is expected to be approximately \$60.0 million, \$65.0 million, \$70.0 million, \$70.0 million and \$70.0 million in the years ending December 31, 2014 through 2018, 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.

Table of Contents

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

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	March 31, 2014	December 31, 2013
Accounts payable	\$ 24,297	\$ 19,493
Accrued compensation	14,210	28,101
Accrued restructuring	8,537	7,296
Accrued other	36,706	36,283
Total accounts payable and accrued expenses	\$ 83,750	\$ 91,173

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 year ending December 31, 2015.

As a result of the termination of these services, the Company also implemented a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the twelve months ended March 31, 2013, the Company recorded a restructuring charge of \$12.3 million, which consisted of severance and outplacement services. The Company has paid in cash \$3.2 million in connection with this restructuring plan and recorded an adjustment of \$0.5 million to the restructuring accrual due to changes in foreign currency. Restructuring activity during the three months ended March 31, 2014 was as follows:

(In thousands)	Severance and Outplacement Services
Balance, January 1, 2014	\$ 10,578
Payments	(946)
Adjustments	(12)
Balance, March 31, 2014	\$ 9,620

At March 31, 2014 and December 31, 2013, \$8.0 million and \$6.8 million, respectively, of this restructuring accrual was included within Accounts payable and accrued expenses, and \$1.6 million and \$3.8 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:

(In thousands)	March 31, 2014	December 31, 2013
Term Loan B-1, due September 25, 2019	\$ 293,438	\$ 294,091
Term Loan B-2, due September 25, 2016	69,275	70,202
Total	362,713	364,293
Less: current portion	(6,750)	(6,750)
Long-term debt	\$ 355,963	\$ 357,543

Table of Contents

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

11. DERIVATIVE INSTRUMENTS

In September 2011, the Company entered into an interest rate swap agreement with Morgan Stanley Capital Services LLC 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 swap agreement became effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. The Company recorded an immaterial loss and a gain of \$0.1 million within Other (expense) income, net due to the change in fair value of this contract during the three months ended March 31, 2014 and 2013, respectively. The fair value and presentation in the condensed consolidated balance sheets for the Company's interest rate swap was as follows:

(In thousands)	Balance Sheet Location	Fair Value	
		March 31, 2014	December 31, 2013
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$ (185)	\$ (275)

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)		Three Months Ended	
		March 31, 2014	March 31, 2013
Cost of goods manufactured and sold	\$	2,310	\$ 1,071
Research and development		3,403	2,139
Selling, general and administrative		7,707	4,671
Total share-based compensation expense	\$	13,420	\$ 7,881

At March 31, 2014 and December 31, 2013, \$0.6 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the accompanying condensed consolidated balance sheets.

13. SHAREHOLDERS' EQUITY

In January 2014, the Company sold 5,917,160 ordinary shares, \$0.01 par value per share, pursuant to its shelf registration statement on Form S-3 at a price of \$42.25 per share. The Company received total gross proceeds of \$250.0 million, before deducting expenses of \$1.6 million associated with the offering.

14. (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.

Table of Contents

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

(In thousands)	2014	Three Months Ended March 31,	2013
Numerator:			
Net (loss) income	\$	(24,354)	\$ 2,999
Denominator:			
Weighted average number of ordinary shares outstanding		143,358	133,272
Effect of dilutive securities:			
Stock options			4,866
Restricted stock units			1,539
Dilutive ordinary share equivalents			6,405
Shares used in calculating diluted (loss) earnings per share		143,358	139,677

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)	2014	Three Months Ended March 31,	2013
Stock options	9,342		2,084
Restricted stock units	1,763		
Total	11,105		2,084

15. INCOME TAXES

The Company recorded an income tax provision of \$3.8 million and \$4.9 million for the three months ended March 31, 2014 and 2013, respectively. The income tax provision in the three months ended March 31, 2014 and 2013 primarily relates to U.S. Federal and state taxes on income.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At March 31, 2014, the Company maintained a valuation allowance against certain of its U.S. and foreign deferred tax assets. The Company evaluates, at each reporting period, the need for a valuation allowance on its deferred tax assets on a jurisdiction by jurisdiction basis.

16. COMMITMENTS AND CONTINGENCIES

Edgar Filing: Alkermes plc. - Form 10-Q

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 litigations in the U.S. and other proceedings outside of the U.S. involving its patents in respect of FOCALIN XR, TRICOR, RITALIN LA and MEGACE ES. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition, cash flows and results of operations.

17. SUBSEQUENT EVENTS

In April 2014, the Company closed on the sale of certain of its land, buildings and equipment at its Athlone, Ireland facility.

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 5 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 Transition Report, which has been filed with the SEC.

Executive Summary

Net loss for the three months ended March 31, 2014 was \$24.4 million, or \$0.17 per ordinary share – basic and diluted, as compared to net income of \$3.0 million, or \$0.02 per ordinary share – basic and diluted, for the three months ended March 31, 2013.

During the three months ended March 31, 2014, we recorded total revenues of \$130.2 million as compared to \$163.4 million in the three months ended March 31, 2013. Included in revenue for the three months ended March 31, 2013 was \$30.0 million of intellectual property (IP) license revenue unrelated to key development programs. Our operating expenses for the three months ended March 31, 2014 were \$146.1 million, reflecting increased investment in our development pipeline, such as the initiation of the pivotal clinical development program for ALKS 5461, and prelaunch activities for aripiprazole lauroxil as we announced positive phase 3 results for this drug candidate in April 2013. Also during the three months ended March 31, 2014, we sold approximately 5.9 million ordinary shares, through a registered direct offering, to Invesco Perpetual Income Fund (IPI Fund) and the Invesco Perpetual High Income Fund (IPHI Fund) and together with the IPI Fund, the Invesco Funds), for gross proceeds of \$250.0 million.

ProductsMarketed Products

We earn manufacturing and/or royalty revenues on net sales of products marketed by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our marketed 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(s)	Technology	Territory	Revenue Source	Marketer
<i>RISPERDAL CONSTA</i>	Schizophrenia bipolar I disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen Pharmaceutica, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (taken together, Janssen)
<i>INVEGA SUSTENNA /</i>	Schizophrenia	NanoCrystal	U.S.	Royalty	Janssen

Edgar Filing: Alkermes plc. - Form 10-Q

XEPLION					
			Rest of World (ROW)		
AMPYRA /	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)
FAMPYRA			ROW		Biogen Idec International GmbH (Biogen Idec) under sublicense from Acorda
BYDUREON	Type 2 diabetes	Extended-release microsphere	Worldwide	Royalty	AstraZeneca plc (AstraZeneca)

Edgar Filing: Alkermes plc. - Form 10-Q

Table of Contents

VIVITROL	Alcohol and opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States (CIS)	Product sales Manufacturing and Royalty	Alkermes Cilag GmbH International (Cilag)
TRICOR LIPANTHYL LIPIDIL SUPRALIP (and other trade names under which fenofibrate 48 mg and 145 mg are sold)	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	AbbVie Inc. Abbott Laboratories
ZANAFLEX CAPSULES ZANAFLEX TABLETS TIZANIDINE HYDROCHLORIDE (AB Rated to ZANAFLEX CAPSULES)	Muscle spasticity	OCR Spheroidal Oral Drug Absorption System (SODAS)	U.S.	Manufacturing (capsules only) and Royalty	Acorda; Actavis, Inc. (formerly Watson Pharmaceutical) (Actavis)
AVINZA	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer Inc. (Pfizer)
EMEND	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck & Co. Inc. (Merck)
FOCALIN XR / RITALIN LA	Attention deficit hyperactivity disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis AG (Novartis)
MEGACE ES	Anorexia, Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)
LUVOX CR	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Royalty	Jazz Pharmaceuticals plc (Jazz)
RAPAMUNE	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
NAPRELAN	Various mild to moderate pain indications	OCR Intestinal Protective Drug Absorption System (IPDAS)	U.S.	Manufacturing	Alvogen Pharma U.S., Inc.
VERAPAMIL SR VERELAN VERELAN PM VERAPAMIL PM UNIVER	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (on select formulations)	Kremers Urban Pharmaceuticals, Inc.; Cephalon, Inc. (Cephalon); Actavis
DILZEM SR DILZEM XL DILTELAN	Hypertension and/or angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing	Cephalon; Kun-Wha Pharmaceutical Co. Ltd;

Edgar Filing: Alkermes plc. - Form 10-Q

<i>AFEDITAB CR AB Rated to ADALAT CC)</i>	Hypertension	OCR (MXDAS)	U.S.	Manufacturing	Actavis
<i>ZOHYDRO ER</i>	Severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Zogenix, Inc.

Table of Contents

KEY MARKETED PRODUCTS

Our key marketed products 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 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 over 25 other countries worldwide.

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 for the acute and maintenance treatment of schizophrenia in adults in the U.S. in 2009. Paliperidone palmitate extended-release injectable suspension is also approved in the European Union (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. In January 2010, the FDA approved AMPYRA as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed. It is the first and, currently, only product to be approved for this indication. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. In July 2011, the European Medicines Agency conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of July 2013. The product incorporates our OCR technology. AMPYRA and FAMPYRA are manufactured by us.

BYDUREON

Edgar Filing: Alkermes plc. - Form 10-Q

BYDUREON (exenatide extended-release for injectable suspension) 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, uses our polymer-based microsphere injectable extended-release technology. From August 2012 until February 2014, Bristol-Myers Squibb Company (Bristol-Myers) and AstraZeneca co-developed and marketed BYDUREON through their diabetes collaboration. In February 2014, AstraZeneca assumed sole responsibility for the development and commercialization of BYDUREON. In March 2014, AstraZeneca announced FDA approval of the BYDUREON Pen 2 mg. AstraZeneca said that they plan to make the BYDUREON Pen available for patients in the second half of 2014.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly injectable medication approved by the FDA 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. The Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence in 2008 and for the treatment of opioid dependence in 2011.

Other Marketed Products

Except for ZOHYDRO ER, which received FDA approval in October 2013, we generally expect revenues from our other commercial products, taken together, to 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 Transition Report, which has been filed with the SEC.

Table of Contents

KEY DEVELOPMENT PROGRAMS

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

Aripiprazole Lauroxil

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 technology.

In April 2014, we announced positive topline results from a randomized, double-blind, placebo-controlled phase 3 clinical trial of aripiprazole lauroxil in patients with schizophrenia. Patients treated once monthly with either 441 mg or 882 mg of aripiprazole lauroxil demonstrated statistically significant reductions from baseline in Positive and Negative Syndrome Scale (PANSS) total scores, compared to placebo, which was the prespecified primary endpoint in the study. In addition to meeting the prespecified primary efficacy endpoint, the study also met the prespecified key secondary endpoint of improvement on the Clinical Global Impression – Improvement scale (CGI-I) versus placebo. Aripiprazole lauroxil was generally well tolerated in the phase 3 study, and the safety profile of aripiprazole lauroxil was similar to that reported with oral aripiprazole. The most common adverse events in the study were insomnia, akathisia and headache. Based on the positive results from this phase 3 study, we plan to submit an NDA to the FDA in the third quarter of 2014. We will present comprehensive data from the phase 3 study at an upcoming medical meeting and submit the results for publication in a peer-reviewed journal.

In January 2014, we announced plans to commence clinical testing of aripiprazole lauroxil two-month, a new product candidate for the treatment of schizophrenia. If approved, aripiprazole lauroxil would be the first and only long-acting atypical antipsychotic medication dosed every two months.

ALKS 33

ALKS 33 is a proprietary 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 ALKS 5461 and ALKS 3831.

ALKS 5461

ALKS 5461 is a proprietary 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 March 2014, we

Edgar Filing: Alkermes plc. - Form 10-Q

announced the initiation of the pivotal clinical development program for ALKS 5461. The comprehensive pivotal program, named FORWARD (**F**ocused **O**n **R**esults **W**ith **A** **R**ethinking of **D**epression), includes a total of 12 studies, including three core phase 3 efficacy studies and nine supportive studies. The first FORWARD study, evaluating the onset of clinical effect, safety and tolerability of ALKS 5461 in patients with MDD, has begun, and the three core efficacy studies are expected to begin in mid-2014. The FORWARD pivotal program will include studies to evaluate the long-term safety, dosing, pharmacokinetic profile and human abuse liability of ALKS 5461. The three core efficacy studies will utilize state-of-the-art methodologies intended to reduce the impact of clinically meaningful placebo response.

ALKS 3831

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is composed of ALKS 33 in combination with the established antipsychotic drug olanzapine, which is 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 with schizophrenia exacerbated by alcohol use disorders. We expect to complete enrollment of the ongoing phase 2 study, assessing ALKS 3831's magnitude of effect on olanzapine-induced weight gain in 2014. A second, planned phase 2 study will investigate the potential utility of ALKS 3831 for the large number of patients with schizophrenia exacerbated by alcohol use disorders, and enrollment for this study is expected to begin in the second half of 2014.

MMF Prodrug ALKS 8700

ALKS 8700 is a proprietary, small-molecule prodrug of monomethyl fumarate (MMF) for the treatment of multiple sclerosis. It is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated dosing and tolerability as compared to the currently marketed dimethyl fumarate prodrug, TECFIDERA. We expect to file an Investigational New Drug

Table of Contents

(IND) application with the FDA and initiate a phase 1 study of ALKS 8700 in mid-2014.

ALKS 7106

ALKS 7106 is our novel and proprietary small-molecule product 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, which are two liabilities associated with opioid medicines. We expect to file an IND and initiate clinical studies in mid-2014.

RDB 1419

RDB 1419 is a proprietary biologic cancer immunotherapy candidate based on interleukin-2 and its receptors. RDB 1419 was engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic. We expect to conduct IND-enabling activities for RDB 1419 in 2014.

Other

A phase 3 clinical research program for a three-month formulation of INVEGA SUSTENNA (paliperidone palmitate 3-month formulation), an investigational treatment for symptoms of schizophrenia in adults, was initiated by Janssen Research & Development, LLC (Janssen R&D) in 2012. In March 2014, Janssen R&D announced that, following an Independent Data Monitoring Committee recommendation based on positive efficacy, it halted early a phase 3 clinical study of paliperidone palmitate 3-month formulation. Janssen R&D has stated that, following a final analysis of the study and discussions with the FDA, it plans to file an NDA with the FDA for paliperidone palmitate 3-month formulation by the end of 2014 and that the study results will be presented at a future medical congress and will also be submitted for publication in a peer-reviewed journal. This investigational product is being developed by Janssen Pharmaceutica, NV, licensee to our proprietary technology for nanoparticles.

AstraZeneca is developing line extensions for BYDUREON for the treatment of type 2 diabetes, including a dual-chamber pen device, and weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. AstraZeneca stated that they expect the Committee for Medicinal Products for Human Use (CHMP) to issue their opinion on the BYDUREON dual-chamber pen in the fourth quarter of 2014, and that they plan to file for approval of the dual-chamber pen in Japan during the second quarter of 2014. AstraZeneca expects to file for approval of the BYDUREON once-weekly suspension in the U.S. and EU in 2015.

Table of Contents**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 March 31, 2014, as compared to the three months ended March 31, 2013:

(In millions)	Three Months Ended March 31,		Change Favorable/ (Unfavorable)	
	2014	2013		
Manufacturing and royalty revenues:				
RISPERDAL CONSTA	\$ 28.6	\$ 30.7	\$	(2.1)
INVEGA SUSTENNA/XEPLION	21.0	14.8		6.2
AMPYRA/FAMPYRA	20.6	24.7		(4.1)
RITALIN LA/FOCALIN XR	9.7	10.6		(0.9)
BYDUREON	7.7	4.8		2.9
Other	23.7	61.3		(37.6)
Manufacturing and royalty revenues	\$ 111.3	\$ 146.9	\$	(35.6)

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three months ended March 31, 2014, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$373.0 million, as compared to \$284.0 million in the three months ended March 31, 2013. The increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION resulted in our achieving a higher royalty rate earlier in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. 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 decrease in AMPYRA/FAMPYRA manufacturing and royalty revenue in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was due to a \$2.4 million decrease in manufacturing revenues and a \$1.7 million decrease in royalty revenues. The decrease in manufacturing revenues was primarily due to a 49% decrease in the amount of product shipped to Acorda and Biogen Idec, partially offset by an 11% increase in the price of AMPYRA. The decrease in royalty revenues was primarily due to a decrease in end-market sales of FAMPYRA in Europe.

The increase in BYDUREON royalty revenues in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to an increase in end-market sales of BYDUREON by AstraZeneca. During the three months ended March 31, 2014, our estimate of AstraZeneca's end-market sales of BYDUREON was \$96.0 million, as compared to \$61.0 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the three months ended March 31, 2013.

Edgar Filing: Alkermes plc. - Form 10-Q

Included in other manufacturing and royalty revenues during the three months ended March 31, 2013 was \$30.0 million of IP license revenue unrelated to key development programs.

Table of Contents*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 months ended March 31, 2014 and 2013:

(In millions)	Three Months Ended March 31,			
	2014	% of Sales	2013	% of Sales
Product sales, gross	\$ 25.9	100.0%	\$ 20.3	100.0%
Adjustments to product sales, gross:				
Medicaid rebates	(1.6)	(6.2)%	(1.5)	(7.4)%
Chargebacks	(1.5)	(5.8)%	(1.3)	(6.4)%
Product Discounts	(1.9)	(7.3)%	(1.1)	(5.4)%
Co-pay assistance	(1.3)	(5.0)%	(0.9)	(4.4)%
Product Returns	(0.5)	(1.9)%	(0.3)	(1.5)%
Other	(2.0)	(7.8)%	(0.6)	(3.0)%
Total adjustments	(8.8)	(34.0)%	(5.7)	(28.1)%
Product sales, net	\$ 17.1	66.0%	\$ 14.6	71.9%

The increase in product sales, gross for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was due to a 27% increase in the number of units sold. The increase in Medicaid rebates, chargebacks and co-pay assistance were all primarily due to the increase in VIVITROL gross product sales. The increase in other adjustments was primarily due to a \$1.4 million charge against product sales, net, related to a limited VIVITROL recall for a needle clog issue.

Costs and Expenses*Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended March 31,		Change Favorable/ (Unfavorable)
	2014	2013	
Cost of goods manufactured and sold:			
RISPERDAL CONSTA	\$ 7.1	\$ 9.0	\$ 1.9
VIVITROL	3.7	4.1	0.4
AMPYRA/FAMPYRA	1.5	2.2	0.7
Other	26.5	32.7	6.2
Cost of goods manufactured and sold	\$ 38.8	\$ 48.0	\$ 9.2

The decrease in other cost of goods manufactured and sold during the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to a 25% decrease in shipments of our legacy products.

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 (CROs), 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.

Table of Contents

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:

(In millions)	Three Months Ended March 31,		Change Favorable/ (Unfavorable)
	2014	2013	
External R&D Expenses:			
Key development programs:			
ALKS 5461	\$ 11.0	\$ 2.3	\$ (8.7)
Aripiprazole lauroxil	7.4	10.2	2.8
ALKS 3831	5.1		(5.1)
ALKS 8700	1.5		(1.5)
ALKS 7106	1.2		(1.2)
Other development programs	2.5	4.5	2.0
Total external R&D expenses	28.7	17.0	(11.7)
Internal R&D expenses:			
Employee-related	17.4	13.8	(3.6)
Occupancy	1.6	4.3	2.7
Depreciation	2.1	1.5	(0.6)
Other	2.3	(0.8)	(3.1)
Total internal R&D expenses	23.4	18.8	(4.6)
Research and development expenses	\$ 52.1	\$ 35.8	\$ (16.3)

These amounts are not necessarily predictive of future R&D expenses. In an effort to allocate our spending most effectively, we continually evaluate the products under development, based on the performance of such products in pre-clinical 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 expenses related to ALKS 5461 is a result of the initiation and start-up activities associated with the multiple phase 3 studies. The decrease in R&D expenses related to the aripiprazole lauroxil program was primarily due to the completion of the phase 3 clinical trial, which we announced the top line results for in April 2014. The increase in expenses related to the ALKS 3831 program was due to an ongoing phase 2 study that was initiated in July 2013, and the preparation of a second phase 2 study to investigate the potential utility of ALKS 3831 for patients with schizophrenia exacerbated by alcohol use disorders, which is expected to begin in the second half of 2014. ALKS 8700 and ALKS 7106 were added to our key development program portfolio in 2013, and we plan to file INDs and initiate clinical studies for both programs in mid-2014. The increase in employee-related expenses is primarily due to an increase in headcount and share-based compensation expense. Expense incurred under the RDB 1419 program was not material in the three months ended March 31, 2014 and 2013.

Selling, General and Administrative Expense

(In millions)	Three Months Ended March 31,		Change Favorable/ (Unfavorable)
	2014	2013	
Selling, general and administrative expense	\$ 42.6	\$ 34.7	\$ (7.9)

The increase in selling, general and administrative (SG&A) expense for the three months ended March 31, 2014 as compared to the three months ended March 31, 2013, was primarily due to a \$3.3 million increase in employee-related expenses and a \$3.3 million increase in professional

Edgar Filing: Alkermes plc. - Form 10-Q

service fees and marketing expenses. The increase in employee-related expenses was primarily due to an increase in share-based compensation of \$3.0 million in the three months ended March 31, 2014, due to an increase in our stock price and an increase in headcount. The increase in professional service fees and marketing expenses were primarily due to an increase in activity related to the anticipated launch of aripiprazole lauroxil and increased marketing activities related to VIVITROL. We expect SG&A expenses to continue to increase in calendar-year 2014 as launch planning activities accelerate for aripiprazole lauroxil.

Table of Contents*Amortization of Acquired Intangible Assets*

(In millions)	Three Months Ended March 31,				Change Favorable/ (Unfavorable)
	2014		2013		
Amortization of acquired intangible assets	\$	12.6	\$	10.3	\$ (2.3)

The intangible assets being amortized in the three months ended March 31, 2014 and 2013 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 March 31, 2014 is expected to be approximately \$60.0 million, \$65.0 million, \$70.0 million, \$70.0 million and \$70.0 million in the years ended December 31, 2014 through 2018, 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 us to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from our customers resulting from generic competition. We expect to continue to generate revenues from the manufacturing of these products into the year ending December 31, 2015.

As a result of the termination of these services, we began a corresponding reduction in headcount of up to 130 employees. During the three months ended March 31, 2013, we recorded a one-time restructuring charge, expected to be settled in cash payments, consisting solely of severance and outplacement services of \$12.3 million.

Other (Expense), Net

(In millions)	Three Months Ended March 31,				Change Favorable/ (Unfavorable)
	2014		2013		
Interest income	\$	0.5	\$	0.2	\$ 0.3
Interest expense		(3.4)		(11.5)	8.1
Other (expense) income, net		(1.8)		0.2	(2.0)
Total other (expense), net	\$	(4.7)	\$	(11.1)	\$ 6.4

The decrease in interest expense was primarily due to an amendment of our long-term debt in February 2013, which resulted in a \$7.5 million charge to interest expense during the three months ended March 31, 2013.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	March 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 156.3	\$ 167.6
Investments short-term	396.0	194.6
Investments long-term	149.5	87.8
Total cash, cash equivalents and investments	\$ 701.8	\$ 450.0
Working capital	\$ 684.0	\$ 469.2
Outstanding borrowings current and long-term	\$ 362.7	\$ 364.3

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 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 three months ended March 31, 2014 and 2013:

(In millions)	Three Months Ended March 31,	
	2014	2013
Cash and cash equivalents, beginning of period	\$ 167.6	\$ 135.9
Cash (used in) provided by operating activities	(3.5)	55.3
Cash used in investing activities	(272.7)	(111.8)
Cash provided by financing activities	264.9	17.6
Cash and cash equivalents, end of period	\$ 156.3	\$ 97.0

The increase in cash flows used in operating activities in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to a decrease in cash provided by net (loss) income of \$28.9 million and an increase in cash used for working capital of \$29.9 million. The decrease in cash provided from net (loss) income was partially due to a \$24.4 million net loss in the three months ended March 31, 2014, as compared to \$3.0 million of net income in the prior period. There was an increase in excess tax-benefit from share-based compensation of \$2.7 million related to an increase in our stock price. The increase in cash used in working capital was primarily due to an increase in cash used for inventory, prepaid expenses and other assets of \$14.9 million and a decrease in cash provided by accounts payable and accrued expenses of \$29.7 million, partially offset by an increase in cash provided by accounts receivable of \$15.8 million. The increase to inventory, prepaid expenses and other assets relates primarily to an increase in prepaid taxes of \$21.5 million. The changes in accounts payable and accrued expenses and accounts receivable are primarily related to the timing of payments and receipts, respectively.

The increase in cash flows used in investing activities in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to an increase in the net purchase of investments of \$163.3 million.

The increase in cash flows provided by financing activities in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was due to the sale of approximately 5.9 million ordinary shares, through a registered direct offering to the Invesco Funds, for gross proceeds of \$250.0 million and a \$2.7 million increase in the excess tax-benefit from share-based compensation due to an increase in our stock price.

Our investments at March 31, 2014 consist of the following:

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)		Amortized		Gross Unrealized		Estimated	
		Cost		Gains		Fair Value	
				Losses			
Investments	short-term	\$	378.5	\$	17.6	\$	395.9
Investments	long-term available-for-sale		148.2			(0.3)	147.9
Investments	long-term held-to-maturity		1.6				1.6
Total		\$	528.3	\$	17.6	\$	545.4

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, corporate debt securities and equity securities. The equity securities consist of common stock and warrants of Acceleron. 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.

Table of Contents

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 March 31, 2014, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At March 31, 2014 and December 31, 2013, \$1.3 million and \$1.5 million of our investments, consisting of warrants to purchase the common stock of Acceleron, 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 March 31, 2014, our borrowings consisted of \$364.9 million outstanding under our Term Loan Facility. Refer to Note 11, *Long-Term Debt*, within Part II, Item 8 of our Transition Report, for a discussion of our outstanding term loans.

Contractual Obligations

Refer to Part II, Item 7 of our Transition Report in the *Contractual Obligations* section for a discussion of our contractual obligations. Our contractual obligations as of March 31, 2014 were not materially changed from the date of that report.

Off-Balance Sheet Arrangements

At March 31, 2014, 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 Transition 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 Transition 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 December 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 Transition Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since December 31, 2013.

Table of Contents

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 March 31, 2014. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2014 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 other proceedings outside of the U.S. involving our patents in respect of FOCALIN XR, TRICOR, RITALIN LA and MEGACE ES. 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, financial condition, cash flows and results of operations.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in our Transition Report. For a further discussion of our Risk Factors, refer to Part I, Item 1A *Risk Factors* of our Transition 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 three months ended March 31, 2014. As of March 31, 2014, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million.

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 March 31, 2014, Dr. Floyd E. Bloom, Mr. Robert A. Breyer and Mr. Paul J. Mitchell, each a director of the Company and Mr. Gordon G. Pugh, 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

Edgar Filing: Alkermes plc. - Form 10-Q

(a) List of Exhibits:

- 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 March 31, 2014, 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 compensating 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: April 30, 2014