

Alkermes plc.  
Form 10-Q  
July 31, 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 June 30, 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

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 the registrant's ordinary shares, \$0.01 par value, outstanding as of July 25, 2014 was 145,827,889 shares.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2014**

	<b>Page No.</b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	
<u>Condensed Consolidated Financial Statements (unaudited):</u>	
<u>Condensed Consolidated Balance Sheets June 30, 2014 and December 31, 2013</u>	5
<u>Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income For the Three and Six Months Ended June 30, 2014 and 2013</u>	6
<u>Condensed Consolidated Statements of Cash Flows For the Six Months Ended June 30, 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>	
	27
<u>Item 4.</u>	
<u>Controls and Procedures</u>	
	27
 <b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	
	28
<u>Item 1A.</u>	
<u>Risk Factors</u>	
	28
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
	28
<u>Item 5.</u>	
<u>Other Information</u>	
	28
<u>Item 6.</u>	
<u>Exhibits</u>	
	28
<u>Signatures</u>	29
<u>Exhibit Index</u>	
Ex-31.1 Section 302 Certification of Chief Executive Officer	
Ex-31.2 Section 302 Certification of Chief Financial Officer	
Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer	
Ex-101 Instance Document	
Ex-101 Schema Document	
Ex-101 Calculation Linkbase Document	
Ex-101 Labels Linkbase Document	
Ex-101 Definition Linkbase Document	
Ex-101 Presentation Linkbase Document	

Table of Contents

**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, including our development programs;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations and other significant agreements relating to our products, including our development programs;
- our expectations regarding the impact of adoption 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 in this Form 10-Q, 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

## Edgar Filing: Alkermes plc. - Form 10-Q

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.

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, 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.

Table of Contents

**Note Regarding Trademarks**

We are the owner of various U.S. federal trademark registrations (®) and registration applications (TM), including LinkeRx® and VIVITROL®. The following are trademarks of the respective companies listed: ABILIFY® Otsuka Pharmaceutical Co., Ltd.; AMPYRA® and FAMPYRA® Acorda Therapeutics, Inc.; BYDUREON® and BYETTA® Amylin Pharmaceuticals, LLC; FOCALIN XR® and RITALIN LA® Novartis AG; INVEGA® SUSTENNA®, XEPLION®, and RISPERDAL® CONSTA® Johnson & Johnson Corp. (or its affiliate); MEGACE® E.R. Squibb & Sons, LLC; TECFIDERA® Biogen Idec MA Inc.; TRICOR® Fournier Industrie et Sante Corporation; 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 TM 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)**

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 188,322	\$ 167,562
Investments short-term	450,167	194,669
Receivables	139,316	134,154
Inventory	57,066	46,218
Prepaid expenses and other current assets	52,048	27,535
Total current assets	886,919	570,138
PROPERTY, PLANT AND EQUIPMENT, NET	264,247	274,490
INTANGIBLE ASSETS NET	509,900	537,565
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	75,405	87,764
OTHER ASSETS	28,381	14,891
<b>TOTAL ASSETS</b>	<b>\$ 1,857,592</b>	<b>\$ 1,577,588</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 93,033	\$ 91,173
Long-term debt current	6,750	6,750
Deferred revenue current	2,377	2,974
Total current liabilities	102,160	100,897
LONG-TERM DEBT	354,382	357,543
DEFERRED TAX LIABILITIES, NET LONG-TERM	26,122	29,169
OTHER LONG-TERM LIABILITIES	11,596	12,580
DEFERRED REVENUE LONG-TERM	11,507	12,213
Total liabilities	505,767	512,402
<b>COMMITMENTS AND CONTINGENCIES (Note 16)</b>		
<b>SHAREHOLDERS EQUITY:</b>		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at June 30, 2014 and December 31, 2013, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 146,646,177 and 138,482,571 shares issued; 145,663,941 and 137,792,626 shares outstanding at June 30, 2014 and December 31, 2013, respectively	1,464	1,382
Treasury shares, at cost (982,236 and 689,945 shares at June 30, 2014 and December 31, 2013, respectively)	(30,861)	(17,833)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,886,827	1,553,337
Accumulated other comprehensive (loss) income	(2,712)	10,574
Accumulated deficit	(502,893)	(482,274)
Total shareholders' equity	1,351,825	1,065,186
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,857,592	\$ 1,577,588

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



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands, except per share amounts)			
<b>REVENUES:</b>				
Manufacturing and royalty revenues	\$ 130,366	\$ 119,788	\$ 241,646	\$ 266,707
Product sales, net	21,595	17,379	38,674	32,005
Research and development revenue	1,463	1,464	3,316	3,341
Total revenues	153,424	138,631	283,636	302,053
<b>EXPENSES:</b>				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	43,290	45,991	82,129	93,982
Research and development	67,207	33,462	119,347	69,262
Selling, general and administrative	50,663	32,933	93,213	67,612
Amortization of acquired intangible assets	15,089	12,716	27,665	23,038
Restructuring				12,300
Impairment of long-lived assets				3,346
Total expenses	176,249	125,102	322,354	269,540
OPERATING (LOSS) INCOME	(22,825)	13,529	(38,718)	32,513
<b>OTHER INCOME (EXPENSE), NET:</b>				
Interest income	323	161	834	332
Interest expense	(3,385)	(3,468)	(6,741)	(14,941)
Gain on sale of investment in Acceleron Pharma Inc.	15,296		15,296	
Gain on sale of property, plant and equipment	12,285		12,285	
Other income (expense), net	518	(170)	(1,332)	14
Total other income (expense), net	25,037	(3,477)	20,342	(14,595)
INCOME (LOSS) BEFORE INCOME TAXES	2,212	10,052	(18,376)	17,918
INCOME TAX (BENEFIT) PROVISION	(1,523)	2,718	2,243	7,585
NET INCOME (LOSS)	\$ 3,735	\$ 7,334	\$ (20,619)	\$ 10,333
<b>EARNINGS (LOSS) PER ORDINARY SHARE:</b>				
Basic	\$ 0.03	\$ 0.05	\$ (0.14)	\$ 0.08
Diluted	\$ 0.02	\$ 0.05	\$ (0.14)	\$ 0.07
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:</b>				
Basic	144,913	134,602	144,140	133,941
Diluted	154,300	143,369	144,140	141,822
<b>COMPREHENSIVE (LOSS) INCOME:</b>				
Net income (loss)	\$ 3,735	\$ 7,334	\$ (20,619)	\$ 10,333
Holding gains (losses), net of tax of \$6,174, none, \$7,627 and none, respectively	4,540	(408)	2,009	(265)
Reclassification of unrealized gains to realized gains	(15,296)		(15,296)	
COMPREHENSIVE (LOSS) INCOME	\$ (7,021)	\$ 6,926	\$ (33,906)	\$ 10,068

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



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30,	
	2014	2013
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net (loss) income	\$ (20,619)	\$ 10,333
Adjustments to reconcile net (loss) income to cash flows from operating activities:		
Depreciation and amortization	47,486	42,048
Share-based compensation expense	32,758	16,690
Excess tax benefit from share-based compensation	(6,984)	(11,730)
Impairment of long-lived assets		3,346
(Gain) loss on sale of property, plant and equipment	(12,160)	391
(Gain) on sale of investment of Acceleron Pharma Inc.	(15,296)	
Deferred income taxes	(10,664)	(1,732)
Loss on debt refinancing transaction		7,541
Prepayment penalty in connection with debt refinancing		(3,733)
Other non-cash charges	9,965	1,169
Changes in assets and liabilities:		
Receivables	(5,162)	(10,743)
Inventory, prepaid expenses and other assets	(19,714)	(1,036)
Accounts payable and accrued expenses	3,693	16,929
Deferred revenue	(1,304)	(974)
Other long-term liabilities	3,306	(448)
Cash flows provided by operating activities	5,305	68,051
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions of property, plant and equipment	(11,438)	(11,884)
Proceeds from the sale of property, plant and equipment	14,361	125
Purchases of investments	(433,203)	(175,619)
Sales and maturities of investments	184,446	70,149
Cash flows used in investing activities	(245,834)	(117,229)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of ordinary shares, net	248,406	
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	21,821	31,926
Excess tax benefit from share-based compensation	6,984	11,730
Employee taxes paid related to net share settlement of equity awards	(12,546)	(8,523)
Principal payments of long-term debt	(3,376)	(5,450)
Cash flows provided by financing activities	261,289	29,683
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	20,760	(19,495)
CASH AND CASH EQUIVALENTS Beginning of period	167,562	135,892
CASH AND CASH EQUIVALENTS End of period	\$ 188,322	\$ 116,397
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 1,491	\$ 1,056

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



Table of Contents

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

**1. THE COMPANY**

Alkermes plc ( Alkermes ) 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. Alkermes has a diversified portfolio of more than 20 commercial drug products and a clinical pipeline of product candidates that address 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 and six months ended June 30, 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. During the six months ended June 30, 2014, the following wholly owned subsidiaries were added: Alkermes Science Three Limited; Alkermes Science Four Limited; and Alkermes Science Five Limited. Intercompany accounts and transactions have been eliminated.

*Use of Estimates*

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an 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.

In June 2014, the FASB issued guidance that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. Existing GAAP does not contain explicit guidance on how to account for these share-based payments. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Entities have the option of prospectively applying the guidance to awards granted or modified after the effective date or retrospectively applying the guidance to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements. The guidance becomes effective for the Company in its year ending December 31, 2016 and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in its year ending December 31, 2017 and early adoption is not permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

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 (In thousands)	Greater than One Year	
<b>June 30, 2014</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 223,404	\$ 192	\$	\$	\$ 223,596
Corporate debt securities	178,720	153	(30)		178,843
International government agency debt securities	46,492	37	(2)		46,527
	448,616	382	(32)		448,966
Money market funds	1,201				1,201
Total short-term investments	449,817	382	(32)		450,167
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	42,082		(43)	(13)	42,026
Corporate debt securities	25,793		(17)	(22)	25,754
International government agency debt securities	6,080		(2)		6,078
	73,955		(62)	(35)	73,858
Held-to-maturity securities:					
Certificates of deposit	1,547				1,547
Total long-term investments	75,502		(62)	(35)	75,405
Total investments	\$ 525,319	\$ 382	\$ (94)	\$ (35)	\$ 525,572
<b>December 31, 2013</b>					
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:					
Available-for-sale securities:					



Edgar Filing: Alkermes plc. - Form 10-Q

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

Proceeds from the sales and maturities of marketable securities	\$	184,446	\$	70,149
Realized gains	\$	15,304	\$	46
Realized losses	\$	10	\$	5

During the three months ended June 30, 2014, the Company sold its investment in Acceleron Pharma Inc. ( Acceleron ), which consisted of common stock and warrants to purchase the common stock of Acceleron. The Company received net proceeds of \$24.0 million and realized a gain of \$15.3 million from the sale of this investment. The Company reclassified the gain from accumulated other comprehensive (loss) income to gain on sale of investment in Acceleron in its condensed consolidated Statements of Operations and Comprehensive (Loss) Income.

The Company's available-for-sale and held-to-maturity securities at June 30, 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	\$ 296,062	\$ 296,166	\$ 1,547	\$ 1,547
After 1 year through 5 years	226,509	226,658		
Total	\$ 522,571	\$ 522,824	\$ 1,547	\$ 1,547

At June 30, 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 June 30, 2014 and December 31, 2013, respectively, which was recorded within Other Assets in the accompanying condensed consolidated balance sheets. During the six months ended June 30, 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)	June 30, 2014	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 1,201	\$ 1,201		\$
U.S. government and agency debt securities	265,622	126,594	139,028	
Corporate debt securities	204,597		204,597	
International government agency debt securities	52,605		52,605	
<b>Total</b>	<b>\$ 524,025</b>	<b>\$ 127,795</b>	<b>\$ 396,230</b>	<b>\$</b>
<b>Liabilities:</b>				
Interest rate swap contract	\$ (92)		\$ (92)	\$
<b>Total</b>	<b>\$ (92)</b>		<b>\$ (92)</b>	<b>\$</b>
(In thousands)	December 31, 2013	Level 1	Level 2	Level 3
<b>Assets:</b>				
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
<b>Total</b>	<b>\$ 280,940</b>	<b>\$ 92,873</b>	<b>\$ 186,541</b>	<b>\$ 1,526</b>
<b>Liabilities:</b>				
Interest rate swap contract	\$ (275)		\$ (275)	\$
<b>Total</b>	<b>\$ (275)</b>		<b>\$ (275)</b>	<b>\$</b>

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 June 30, 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 June 30, 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		(383)
Sale of equity securities		(1,143)
Balance, June 30, 2014	\$	

Table of Contents

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

During the three months ended June 30, 2014, the Company sold its Level 3 investment, which consisted of warrants to purchase the common stock of Acceleron.

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 June 30, 2014:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 292,784	\$ 294,013
Term Loan B-2	\$ 68,348	\$ 68,438

**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:

(In thousands)	June 30, 2014	December 31, 2013
Raw materials	\$ 18,890	\$ 18,410

Edgar Filing: Alkermes plc. - Form 10-Q

Work in process		19,762		15,581
Finished goods		18,414		12,227
Total inventory	\$	57,066	\$	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)	June 30, 2014	December 31, 2013
Land	\$ 8,163	\$ 8,440
Building and improvements	148,298	148,044
Furniture, fixture and equipment	225,166	220,984
Leasehold improvements	24,000	23,980
Construction in progress	31,699	26,688
Subtotal	437,326	428,136
Less: accumulated depreciation	(173,079)	(153,646)
Total property, plant and equipment, net	\$ 264,247	\$ 274,490

During the three months ended June 30, 2014, the Company sold certain of its land, buildings and equipment at its Athlone, Ireland facility that had a carrying value of \$2.2 million in exchange for \$17.5 million. \$3.0 million of the sale proceeds will remain in escrow pending the completion of certain additional services the Company is obligated to perform, and will be recognized as Gain on sale of property, plant and equipment as the services are provided.

**7. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	June 30, 2014 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (102,810)	\$ 396,890
NanoCrystal technology	13	74,600	(10,760)	63,840
OCR technology	12	66,300	(17,130)	49,170
Total		\$ 640,600	\$ (130,700)	\$ 509,900

The Company recorded, as Amortization of acquired intangible assets in the accompanying condensed consolidated Statements of Operations and Comprehensive (Loss) Income, \$27.7 million and \$23.0 million of amortization expense related to its finite-lived intangible assets during



## Edgar Filing: Alkermes plc. - Form 10-Q

the six months ended June 30, 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 June 30, 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)	June 30, 2014	December 31, 2013
Accounts payable	\$ 21,261	\$ 19,493
Accrued compensation	23,196	28,101
Accrued restructuring	8,161	7,296
Accrued other	40,415	36,283
Total accounts payable and accrued expenses	\$ 93,033	\$ 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 through 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 \$5.1 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 six months ended June 30, 2014 was as follows:

(In thousands)	Severance and Outplacement Services
Balance, January 1, 2014	\$ 10,578
Payments	(2,804)
Adjustments	(106)
Balance, June 30, 2014	\$ 7,668

At June 30, 2014 and December 31, 2013, \$7.7 million and \$6.8 million, respectively, of this restructuring accrual was included within Accounts payable and accrued expenses, and none 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:

Table of Contents

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

(In thousands)	June 30, 2014	December 31, 2013
Term Loan B-1, due September 25, 2019	\$ 292,784	\$ 294,091
Term Loan B-2, due September 25, 2016	68,348	70,202
<b>Total</b>	<b>361,132</b>	<b>364,293</b>
Less: current portion	(6,750)	(6,750)
<b>Long-term debt</b>	<b>\$ 354,382</b>	<b>\$ 357,543</b>

**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 income (expense), net due to the change in fair value of this contract during the six months ended June 30, 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	June 30, 2014	Fair Value December 31, 2013
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$ (92)	\$ (275)

**12. SHARE-BASED COMPENSATION**

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of goods manufactured and sold	\$ 1,770	\$ 1,003	\$ 4,079	\$ 2,074
Research and development	4,079	2,165	7,482	4,304
Selling, general and administrative	13,489	5,641	21,197	10,312
<b>Total share-based compensation expense</b>	<b>\$ 19,338</b>	<b>\$ 8,809</b>	<b>\$ 32,758</b>	<b>\$ 16,690</b>

At June 30, 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. EARNINGS (LOSS) PER SHARE**

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

Table of Contents

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
<b>Numerator:</b>				
Net (loss) income	\$ 3,735	\$ 7,334	\$ (20,619)	\$ 10,333
<b>Denominator:</b>				
Weighted average number of ordinary shares outstanding	144,913	134,602	144,140	133,941
<b>Effect of dilutive securities:</b>				
Stock options	8,067	7,287		6,349
Restricted stock units	1,320	1,480		1,532
Dilutive ordinary share equivalents	9,387	8,767		7,881
Shares used in calculating diluted earnings (loss) per share	154,300	143,369	144,140	141,822

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Stock options	1,879	883	9,644	516
Restricted stock units	695		1,892	
Total	2,574	883	11,536	516

**15. INCOME TAXES**

The Company recorded an income tax benefit of \$1.5 million and an income tax provision of \$2.2 million for the three and six months ended June 30, 2014, respectively and an income tax provision of \$2.7 million and \$7.6 million for the three and six months ended June 30, 2013, respectively. The income tax provision in the three and six months ended June 30, 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 June 30, 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 lawsuits in the U.S. and other proceedings outside of the U.S. involving its patents in respect of FOCALIN XR, TRICOR, RITALIN LA, MEGACE ES and AMPYRA. 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.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to 7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland, which was created to carry on the business of investing exclusively in companies and businesses engaged in healthcare, pharmaceutical and life sciences sectors. The Company's commitment represents approximately 10% of the partnership's total funding. At June 30, 2014, the Company had made a payment of \$0.5 million, which is included within Other long-term assets in the accompanying condensed consolidated balance sheets.

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 income for the three months ended June 30, 2014 was \$3.7 million, or \$0.03 per ordinary share basic and \$0.02 per ordinary share diluted, as compared to net income of \$7.3 million, or \$0.05 per ordinary share basic and diluted, for the three months ended June 30, 2013. Net loss for the six months ended June 30, 2014 was \$20.6 million, or \$0.14 per ordinary share basic and diluted, as compared to net income of \$10.3 million, or \$0.08 per ordinary share basic and \$0.07 per ordinary share diluted, for the six months ended June 30, 2013.

During the three and six months ended June 30, 2014, we recorded total revenues of \$153.4 million and \$283.6 million, respectively, as compared to \$138.6 million and \$302.1 million in the three and six months ended June 30, 2013, respectively. Included in revenue for the six months ended June 30, 2013 was \$30.0 million of intellectual property ( IP ) license revenue unrelated to key development programs.

Our operating expenses for the three and six months ended June 30, 2014 were \$176.2 million and \$322.4 million, respectively, reflecting increased investment in our rapidly advancing development pipeline, such as the initiation of the pivotal clinical development program for ALKS 5461, and prelaunch activities for aripiprazole lauroxil. We announced positive phase 3 results for aripiprazole lauroxil in April 2014 and are preparing to submit our New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) in the third quarter of this year.

Also during the six months ended June 30, 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.

**Marketed Products**

We earn manufacturing and/or royalty revenues on net sales from a diversified portfolio of more than 20 products marketed by our partners, and earn revenue on net sales of VIVITROL (naltrexone for extended-release injectable suspension), which is a proprietary product that we manufacture, market and sell in the U.S. Our key marketed products, which are expected to contribute meaningfully to our revenues are discussed below. We expect revenues from our other marketed products, taken together, to decrease in the future due to existing and expected competition from generic manufacturers.



***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

Table of Contents

January 2010, the FDA approved AMPYRA as a treatment to improve walking in patients with multiple sclerosis ( 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 ( EMA ) 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 oral controlled release technology. AMPYRA and FAMPYRA are manufactured by us.

**BYDUREON**

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 announced that they plan to make the BYDUREON Pen available for patients in the second half of 2014.

**VIVITROL**

VIVITROL 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 Commonwealth of Independent States. The Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence in 2008 and for the treatment of opioid dependence in 2011.

**Key Development Programs**

We also have several proprietary and partnered product candidates in various stages of development, as discussed below.

***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.

## Edgar Filing: Alkermes plc. - Form 10-Q

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 and presented the comprehensive data from the phase 3 study in June 2014. 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.

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.

### *Samidorphan /ALKS 33*

Samidorphan, formerly referred to as ALKS 33, is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. A phase 2 study of samidorphan in alcohol dependence was completed, and samidorphan is currently being evaluated as a component of ALKS 5461 and ALKS 3831.

### *ALKS 5461*

ALKS 5461 is a proprietary combination of samidorphan and buprenorphine that we are developing for the treatment of

Table of Contents

major depressive disorder ( MDD ) in patients who have an inadequate response to standard antidepressant therapies. In March 2014, we announced the initiation of the pivotal clinical development program for ALKS 5461. The comprehensive pivotal program, named FORWARD (Focused On Results With A Rethinking of Depression), includes a total of 12 studies, including three core phase 3 efficacy studies and nine supportive studies. We announced initiation of two core efficacy studies in June 2014, and announced initiation of the third core efficacy study in July 2014. The core efficacy studies are designed to evaluate the safety and efficacy of ALKS 5461 as adjunctive treatment in patients with MDD and incorporate sophisticated design features. 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. Data from these three core efficacy studies are expected in 2016.

***ALKS 3831***

ALKS 3831 is a proprietary investigational medicine designed as a broad-spectrum treatment for schizophrenia. ALKS 3831 is composed of samidorphan 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. We expect to complete enrollment of an ongoing phase 2 study designed to assess ALKS 3831's magnitude of effect on olanzapine-induced weight gain, in 2014. In June 2014, we announced initiation of a second phase 2 study, which is a randomized, double-blind, active-controlled study that will assess ALKS 3831's efficacy, safety and tolerability in treating patients with schizophrenia and alcohol use, compared to olanzapine. We expect to have topline results from this study in mid 2017

***MMF Prodrug ALKS 8700***

ALKS 8700 is an oral, novel and proprietary molecule in development for the treatment of MS, designed to rapidly and efficiently convert to monomethyl fumarate ( MMF ) in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In July 2014, we announced that we had initiated a randomized, double-blind phase 1 study of ALKS 8700, designed to evaluate the safety, tolerability and pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups.

***ALKS 7106***

ALKS 7106 is our novel and proprietary small-molecule investigational product 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 investigational product 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, as licensee to our proprietary technology for nanoparticles.

In July 2014, Janssen Pharmaceuticals, Inc. announced the submission of a supplemental New Drug Application ( sNDA ) to the FDA seeking a label change that, if approved, is expected to include new data showing delayed time to relapse in patients prescribed once-monthly atypical long-acting antipsychotic INVEGA SUSTENNA (paliperidone palmitate) compared to selected oral antipsychotic therapies in the treatment of schizophrenia. Janssen Pharmaceuticals, Inc. also announced the submission of sNDAs to the FDA for once-monthly INVEGA SUSTENNA for approval to treat schizoaffective disorder as either monotherapy or adjunctive therapy in May 2014.

Table of Contents

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 its 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. AstraZeneca expects to file for approval of the BYDUREON once-weekly suspension in the U.S. and EU in 2015.

**Patents and Proprietary Rights**

In June 2014, we announced that the United States Patent and Trademark Office ( USPTO ) had issued Notices of Allowance, which are issued after the USPTO makes a determination that a patent can be granted from an application, for four of our key development program candidates for the treatment of CNS disorders as follows:

Aripiprazole lauroxil: The USPTO issued a Notice of Allowance for U.S. Patent Application 13/607,066, entitled Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders. We expect this patent to issue within the next few months and expire no earlier than September 2030.

ALKS 5461: The USPTO issued a Notice of Allowance for U.S. Patent Application 13/715,198, entitled Compositions of Buprenorphine and a Mu Antagonist. We expect this patent to issue within the next few months and expire no earlier than December 2032.

ALKS 3831: On July 15, 2014, following our announcement of the Notice of Allowance relating to ALKS 3831, the USPTO issued U.S. Patent No. 8,778,960, entitled Methods for Treating Antipsychotic-Induced Weight Gain. We expect this patent to expire no earlier than August 2031.

ALKS 7106: The USPTO issued a Notice of Allowance for U.S. Patent Application 14/169,305, entitled 4-Hydroxybenzomorphans. We expect this patent to issue within the next few months and expire no earlier than November 2025.

**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 June 30, 2014, as compared to the three and six months ended June 30, 2013:

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Manufacturing and royalty revenues:						
RISPERDAL CONSTA	\$ 26.9	\$ 34.4	\$ (7.5)	\$ 55.5	\$ 65.2	\$ (9.7)
INVEGA SUSTENNA/XEPLION	33.1	21.8	11.3	54.1	36.6	17.5
AMPYRA/FAMPYRA	19.5	19.9	(0.4)	40.1	44.5	(4.4)
RITALIN LA/FOCALIN XR	10.9	11.2	(0.3)	20.6	21.8	(1.2)
BYDUREON	8.8	5.4	3.4	16.5	10.1	6.4
Other	31.2	27.1	4.1	54.8	88.5	(33.7)
Manufacturing and royalty revenues	\$ 130.4	\$ 119.8	\$ 10.6	\$ 241.6	\$ 266.7	\$ (25.1)

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the three and six months ended June 30, 2014 as compared to the three and six months ended June 30, 2013 was primarily due to a 10% and 9% decrease in royalty revenues, respectively, and an 16% and 13% decrease in the number of units shipped to Janssen, respectively. Janssen's end-market sales of RISPERDAL CONSTA were \$302.0 million and \$612.0 million for the three and six months ended June 30, 2014, respectively, and \$336.0 million and \$671.0 million for the three and six months ended June 30, 2013, respectively. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen's end-market net sales of RISPERDAL CONSTA.

Table of Contents

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three and six months ended June 30, 2014, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$394.0 million and \$767.0 million, respectively, as compared to \$290.0 million and \$574.0 million in the three and six months ended June 30, 2013, respectively. 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 BYDUREON royalty revenues in the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, was due to an increase in end-market sales of BYDUREON by AstraZeneca. During the three and six months ended June 30, 2014, our estimate of AstraZeneca's end-market sales of BYDUREON was \$103.0 million and \$199.0 million, respectively, as compared to \$66.9 million and \$127.9 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the three and six months ended June 30, 2013, respectively.

Included in other manufacturing and royalty revenues during the six months ended June 30, 2013 was \$30.0 million of IP license revenue unrelated to key development programs.

*Product Sales, net*

Our product sales, net consist of sales of VIVITROL in the U.S. to wholesalers, a specialty distributor 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 June 30, 2014 and 2013:

(In millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2014	% of Sales	2013	% of Sales	2014	% of Sales	2013	% of Sales
Product sales, gross	\$ 31.6	100.0%	\$ 24.3	100.0%	\$ 57.5	100.0%	\$ 44.6	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(2.8)	(8.9)%	(1.8)	(7.4)%	(4.4)	(7.7)%	(3.3)	(7.4)%
Product discounts	(2.2)	(7.0)%	(1.7)	(7.0)%	(4.1)	(7.1)%	(2.7)	(6.1)%
Chargebacks	(2.1)	(6.6)%	(1.7)	(7.0)%	(3.6)	(6.3)%	(3.0)	(6.7)%
Co-pay assistance	(1.6)	(5.1)%	(1.3)	(5.3)%	(2.9)	(5.0)%	(2.1)	(4.7)%
Product returns	(0.9)	(2.8)%	0.1	0.4%	(1.4)	(2.4)%	(0.2)	(0.4)%
Other	(0.4)	(1.2)%	(0.5)	(2.1)%	(2.4)	(4.2)%	(1.3)	(2.9)%
Total adjustments	(10.0)	(31.6)%	(6.9)	(28.4)%	(18.8)	(32.7)%	(12.6)	(28.3)%
Product sales, net	\$ 21.6	68.4%	\$ 17.4	71.6%	\$ 38.7	67.3%	\$ 32.0	71.7%

The increase in product sales, gross for the three and six months ended June 30, 2014, as compared to the three and six months ended June 30, 2013, was due to a 24% and 26% increase in the number of units sold, respectively, as well as a 5% price increase, effective April 1, 2014. 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 during the six months ended June 30, 2014 was primarily due to a \$1.4 million charge in the three months ended



## Edgar Filing: Alkermes plc. - Form 10-Q

March 31, 2014 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 June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Cost of goods manufactured and sold	\$ 43.3	\$ 46.0	\$ 2.7	\$ 82.1	\$ 94.0	\$ 11.9

The decrease in cost of goods manufactured and sold during the three months ended June 30, 2014 as compared to the three months ended June 30, 2013, was primarily due to a 16% decrease in the number of RISPERDAL CONSTA units shipped to Janssen, partially offset by a 9% increase in shipments of our legacy products. The decrease in cost of goods manufactured and sold during the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 was primarily due to a 13%

Table of Contents

decrease in the number of RISPERDAL CONSTA units shipped to Janssen and a 13% 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.

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 June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
External R&D Expenses:						
Key development programs:						
ALKS 5461	\$ 20.7	\$ 1.8	\$ (18.9)	\$ 31.7	\$ 4.1	\$ (27.6)
Aripiprazole lauroxil	5.8	4.7	(1.1)	13.2	14.9	1.7
ALKS 3831	6.0	2.3	(3.7)	11.1	2.3	(8.8)
ALKS 8700	2.3		(2.3)	3.8		(3.8)
ALKS 7106	2.4		(2.4)	3.6		(3.6)
Other development programs	4.2	5.2	1.0	6.7	9.7	3.0
Total external R&D expenses	41.4	14.0	(27.4)	70.1	31.0	(39.1)
Internal R&D expenses:						
Employee-related	19.4	13.3	(6.1)	36.8	27.1	(9.7)
Occupancy	1.8	1.4	(0.4)	3.4	2.7	(0.7)
Depreciation	2.0	2.2	0.2	4.1	3.7	(0.4)
Other	2.6	2.6		4.9	4.8	(0.1)
Total internal R&D expenses	25.8	19.5	(6.3)	49.2	38.3	(10.9)
Research and development expenses	\$ 67.2	\$ 33.5	\$ (33.7)	\$ 119.3	\$ 69.3	\$ (50.0)

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 was the result of the initiation and start-up activities associated with the multiple phase 3 studies in 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 initiation of a second phase 2 study to investigate the potential utility of ALKS 3831 for patients with schizophrenia exacerbated by alcohol use in 2014. ALKS 8700 and ALKS 7106 were added to our key development program portfolio in 2013. In July 2014, we initiated a phase 1 study for ALKS 8700 and plan to file an IND for ALKS 7106 in mid 2014. The increase in employee-related expenses was primarily due to an increase in headcount and share-based compensation expense. Expenses incurred under the samidorphan, which was formerly referred to as

## Edgar Filing: Alkermes plc. - Form 10-Q

ALKS 33, and the RDB 1419 program were not material in the three and six months ended June 30, 2014 and 2013.

### *Selling, General and Administrative Expense*

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Selling, general and administrative expense	\$ 50.7	\$ 32.9	\$ (17.8)	\$ 93.2	\$ 67.6	\$ (25.6)

The increase in selling, general and administrative ( SG&A ) expense for the three and six months ended June 30, 2014 as compared to the three and six months ended June 30, 2013, was primarily due to a \$10.8 million and \$14.0 million increase in employee-related expenses, respectively, and a \$5.8 million and \$9.9 million increase in professional service fees and marketing

Table of Contents

expenses, respectively. The increase in employee-related expenses was primarily due to an increase in share-based compensation of \$7.9 million and \$10.9 million in the three and six months ended June 30, 2014, respectively, due to an increase in our stock price and an increase in headcount. The increases 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 2014 as launch planning activities accelerate for aripiprazole lauroxil.

*Amortization of Acquired Intangible Assets*

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	2014	June 30, 2013		2014	June 30, 2013	
Amortization of acquired intangible assets	\$ 15.1	\$ 12.7	\$ (2.4)	\$ 27.7	\$ 23.0	\$ (4.7)

The intangible assets being amortized in the three and six months ended June 30, 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 June 30, 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.

*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 Income (Expense), Net*

	Three Months Ended June 30,	Change Favorable/	Six Months Ended June 30,	Change Favorable/
--	--------------------------------	----------------------	------------------------------	----------------------

Edgar Filing: Alkermes plc. - Form 10-Q

(In millions)	2014	2013	(Unfavorable)	2014	2013	(Unfavorable)
Interest income	\$ 0.3	\$ 0.2	\$ 0.1	\$ 0.8	\$ 0.3	\$ 0.5
Interest expense	(3.4)	(3.5)	0.1	(6.7)	(14.9)	8.2
Gain on sale of investment in Acceleron Pharma Inc.	15.3		15.3	15.3		15.3
Gain on sale of property, plant and equipment	12.3		12.3	12.3		12.3
Other income (expense), net	0.5	(0.2)	0.7	(1.4)		(1.4)
Total other income (expense), net	\$ 25.0	\$ (3.5)	\$ 28.5	\$ 20.3	\$ (14.6)	\$ 34.9

The decrease in interest expense in the six months ended June 30, 2014, as compared to the six months ended June 30, 2013, 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 six months ended June 30, 2013. During the three months ended June 30, 2014, we sold our investment in Acceleron, which consisted of equity securities, resulting in a realized gain of \$15.3 million. During the three months ended June 30, 2014, we sold certain of our land, buildings and equipment at our Athlone, Ireland facility that had a carrying value of \$2.2 million in exchange for \$17.5 million. We recorded a gain of \$12.3 million in the three months ended June 30, 2014, as \$3.0 million of the sale proceeds were placed in escrow pending the completion of certain additional services we are obligated to perform.

Table of Contents**Liquidity and Financial Condition**

Our financial condition is summarized as follows:

(In millions)	June 30, 2014		December 31, 2013	
Cash and cash equivalents	\$	188.3	\$	167.6
Investments short-term		450.2		194.6
Investments long-term		75.4		87.8
Total cash, cash equivalents and investments	\$	713.9	\$	450.0
Working capital	\$	784.8	\$	469.2
Outstanding borrowings current and long-term	\$	361.1	\$	364.3

*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 at least the next twelve months. 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 six months ended June 30, 2014 and 2013:

(In millions)	Six Months Ended June 30,			
	2014		2013	
Cash and cash equivalents, beginning of period	\$	167.6	\$	135.9
Cash provided by operating activities		5.3		68.0
Cash used in investing activities		(245.8)		(117.2)
Cash provided by financing activities		261.2		29.7
Cash and cash equivalents, end of period	\$	188.3	\$	116.4

The decrease in cash flows provided by operating activities in the six months ended June 30, 2014, as compared to the six months ended June 30, 2013, was primarily due to a decrease in cash provided by net (loss) income of \$39.8 million and an increase in cash used for working capital of \$22.9 million. The decrease in cash provided from net (loss) income was partially due to a \$20.6 million net loss in the six months ended June 30, 2014, as compared to \$10.3 million of net income in the prior period. 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 \$18.7 million and a decrease in cash provided by accounts payable and accrued expenses of \$13.2 million, partially offset by an increase in cash provided by accounts receivable of \$5.6 million. The increase to inventory, prepaid expenses and other assets relates primarily to an increase in prepaid taxes of \$22.9 million. The changes in accounts payable and accrued expenses and accounts receivable are primarily related to the timing of payments and receipts, respectively.

## Edgar Filing: Alkermes plc. - Form 10-Q

The increase in cash flows used in investing activities in the six months ended June 30, 2014, as compared to the six months ended June 30, 2013, was primarily due to an increase in the net purchase of investments of \$143.3 million, partially offset by an increase in proceeds from the sale of property, plant and equipment of \$14.2 million. The proceeds from the sale of property, plant and equipment was primarily related to the sale of certain of our land, buildings and equipment at our Athlone, Ireland facility.

The increase in cash flows provided by financing activities in the six months ended June 30, 2014, as compared to the six months ended June 30, 2013, was primarily 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. This was partially offset by a \$10.1 million decrease in cash received from our employees upon the exercise of stock awards and a \$4.0 million increase in employee taxes paid related to the net share settlement of equity awards.

Table of Contents

Our investments at June 30, 2014 consist of the following:

(In millions)		Amortized	Gross Unrealized			Estimated
		Cost	Gains	Losses	Fair Value	
Investments	short-term	\$ 449.8	\$ 0.4		\$ 450.2	
Investments	long-term available-for-sale	74.0		(0.1)	73.9	
Investments	long-term held-to-maturity	1.5			1.5	
Total		\$ 525.3	\$ 0.4	\$ (0.1)	\$ 525.6	

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

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At June 30, 2014, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At June 30, 2014 and December 31, 2013, none and \$1.5 million of our investments were valued using Level 3 inputs, respectively. The investments valued at Level 3 consisted of warrants to purchase the common stock of Acceleron, which were sold during the three months ended June 30, 2014. Level 3 inputs are unobservable and are significant to the overall fair value measurement and require a significant degree of judgment.

*Borrowings*

At June 30, 2014, our borrowings consisted of \$363.2 million outstanding under our Term Loan Facility. Refer to Note 10, *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 June 30, 2014 were not materially changed from the date of that report.



*Off-Balance Sheet Arrangements*

At June 30, 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.

Table of Contents

**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.

**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 June 30, 2014. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 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 lawsuits in the U.S. and other proceedings outside of the U.S. involving our patents in respect of FOCALIN XR, TRICOR, RITALIN LA, MEGACE ES and AMPYRA. 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 six months ended June 30, 2014. As of June 30, 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 June 30, 2014, Ms. Kathryn L. Biberstein, Dr. Elliot W. Ehrich and Messrs. James M. Frates, Michael J. Landine, Richard F. Pops, and Gordon G. Pugh, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

**Item 6. Exhibits**

## Edgar Filing: Alkermes plc. - Form 10-Q

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

Table of Contents

**SIGNATURES**

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

ALKERMES plc

(Registrant)

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

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

Date: July 31, 2014

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.1+*	Alkermes plc 2011 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 May 28, 2014).
10.2	Third Amendment to Lease Agreement between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014.
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 June 30, 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).
<hr/>	
*	Previously filed
+	Indicates a management contract or any compensating plan, contract, or arrangement.