

Alkermes plc.  
Form 10-Q  
October 29, 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 September 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 October 24, 2014 was 146,231,502 shares.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 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 September 30, 2014 and December 31, 2013</u>
	5
	<u>Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income For the Three and Nine Months Ended September 30, 2014 and 2013</u>
	6
	<u>Condensed Consolidated Statements of Cash Flows For the Nine Months Ended September 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>
	28
<u>Item 4.</u>	<u>Controls and Procedures</u>
	28
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings</u>
	29
<u>Item 1A.</u>	<u>Risk Factors</u>
	29
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	29
<u>Item 5.</u>	<u>Other Information</u>
	29
<u>Item 6.</u>	<u>Exhibits</u>
	29
<u>Signatures</u>	30
<u>Exhibit Index</u>	31
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 risks 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 U.S. Securities and Exchange Commission ("SEC").

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

### **Note Regarding Company**

Alkermes plc (as used in this report, together with our subsidiaries, "Alkermes," "the Company," "us," "we" and "our") is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on 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® 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; ZOXYDRO® ER Zogenix, Inc.; and ZYPREXA® Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and 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)**

	September 30, 2014 (In thousands, except share and per share amounts)	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 136,182	\$ 167,562
Investments short-term	436,387	194,669
Receivables	143,692	134,154
Inventory	50,471	46,218
Prepaid expenses and other current assets	46,174	27,535
Total current assets	812,906	570,138
PROPERTY, PLANT AND EQUIPMENT, NET	262,128	274,490
INTANGIBLE ASSETS NET	494,656	537,565
GOODWILL	92,740	92,740
INVESTMENTS LONG-TERM	143,747	87,764
OTHER ASSETS	31,678	14,891
TOTAL ASSETS	\$ 1,837,855	\$ 1,577,588
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 100,329	\$ 91,173
Long-term debt current	6,750	6,750
Deferred revenue current	3,061	2,974
Total current liabilities	110,140	100,897
LONG-TERM DEBT	352,801	357,543
DEFERRED TAX LIABILITIES, NET LONG-TERM	21,258	29,169
DEFERRED REVENUE LONG-TERM	11,519	12,213
OTHER LONG-TERM LIABILITIES	8,545	12,580
Total liabilities	504,263	512,402
COMMITMENTS AND CONTINGENCIES (Note 16)		
SHAREHOLDERS EQUITY:		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 147,071,192 and 138,482,571 shares issued; 146,088,467 and 137,792,626 shares outstanding at September 30, 2014 and December 31, 2013, respectively	1,468	1,382
Treasury shares, at cost (982,725 and 689,945 shares at September 30, 2014 and December 31, 2013, respectively)	(30,881)	(17,833)

Edgar Filing: Alkermes plc. - Form 10-Q

Additional paid-in capital	1,908,721	1,553,337
Accumulated other comprehensive (loss) income	(2,866)	10,574
Accumulated deficit	(542,850)	(482,274)
Total shareholders' equity	1,333,592	1,065,186
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,837,855	\$ 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 132,028	\$ 118,571	\$ 373,674	\$ 385,278
Product sales, net	25,802	19,227	64,476	51,232
Research and development revenue	2,162	2,004	5,478	5,345
Total revenues	159,992	139,802	443,628	441,855
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	47,335	45,423	129,464	139,407
Research and development	78,263	45,947	197,610	115,209
Selling, general and administrative	51,888	39,454	145,101	107,066
Amortization of acquired intangible assets	15,244	12,856	42,909	35,894
Restructuring				12,300
Impairment of long-lived assets				3,346
Total expenses	192,730	143,680	515,084	413,222
OPERATING (LOSS) INCOME	(32,738)	(3,878)	(71,456)	28,633
OTHER (EXPENSE) INCOME, NET:				
Interest income	546	295	1,380	627
Interest expense	(3,356)	(3,477)	(10,097)	(18,418)
Gain on sale of investment in Acceleron Pharma Inc.			15,296	
Gain on sale of property, plant and equipment	36		12,321	
Other (expense) income, net	(921)	(469)	(2,253)	(455)
Total other (expense) income, net	(3,695)	(3,651)	16,647	(18,246)
(LOSS) INCOME BEFORE INCOME TAXES	(36,433)	(7,529)	(54,809)	10,387
INCOME TAX PROVISION	3,523	233	5,766	7,818
NET (LOSS) INCOME	\$ (39,956)	\$ (7,762)	\$ (60,575)	\$ 2,569
(LOSS) EARNINGS PER ORDINARY SHARE:				
Basic	\$ (0.27)	\$ (0.06)	\$ (0.42)	\$ 0.02
Diluted	\$ (0.27)	\$ (0.06)	\$ (0.42)	\$ 0.02
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	145,896	136,106	144,732	134,670
Diluted	145,896	136,106	144,732	143,022
COMPREHENSIVE (LOSS) INCOME:				
Net (loss) income	\$ (39,956)	\$ (7,762)	\$ (60,575)	\$ 2,569
Holding (losses) gains, net of tax of \$89, none, \$7,715 and none, respectively	(154)	8,506	1,855	8,241
Reclassification of unrealized gains to realized gains			(15,296)	
COMPREHENSIVE (LOSS) INCOME	\$ (40,110)	\$ 744	\$ (74,016)	\$ 10,810

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)**

	Nine Months Ended September 30,		
	2014		2013
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	\$	(60,575)	\$ 2,569
Adjustments to reconcile net (loss) income to cash flows from operating activities:			
Depreciation and amortization		72,719	65,722
Share-based compensation expense		46,240	30,899
Excess tax benefit from share-based compensation		(22,444)	(12,969)
Impairment of long-lived assets			3,346
(Gain) loss on sale of property, plant and equipment		(11,942)	391
Gain on sale of investment of Acceleron Pharma Inc.		(15,296)	
Deferred income taxes		(18,731)	(2,049)
Loss on debt refinancing transaction			7,541
Prepayment penalty in connection with debt refinancing			(3,733)
Other non-cash charges		9,921	2,177
Changes in assets and liabilities:			
Receivables		(9,538)	(613)
Inventory, prepaid expenses and other assets		(17,774)	(2,530)
Accounts payable and accrued expenses		25,103	18,869
Deferred revenue		(607)	(208)
Other long-term liabilities		420	7
Cash flows (used in) provided by operating activities		(2,504)	109,419
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment		(20,326)	(17,457)
Proceeds from the sale of property, plant and equipment		14,361	125
Investment in Civitas			(1,191)
Purchases of investments		(550,102)	(196,525)
Sales and maturities of investments		246,540	95,149
Cash flows used in investing activities		(309,527)	(119,899)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares, net		248,406	
Proceeds from the issuance of ordinary shares under share-based compensation arrangements		27,431	50,790
Excess tax benefit from share-based compensation		22,444	12,969
Employee taxes paid related to net share settlement of equity awards		(12,566)	(8,529)
Principal payments of long-term debt		(5,064)	(7,137)
Cash flows provided by financing activities		280,651	48,093
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS		(31,380)	37,613
CASH AND CASH EQUIVALENTS Beginning of period		167,562	135,892
CASH AND CASH EQUIVALENTS End of period	\$	136,182	\$ 173,505
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$	691	\$ 1,184

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 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 nine months ended September 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, which is presented for comparative purposes, 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-KT, which has been filed with the 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 nine months ended September 30, 2014, the following wholly owned subsidiaries were added: Alkermes Science Three Limited; Alkermes Science Four Limited; Alkermes Science Five Limited; and Alkermes Science Six 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 April 2014, the FASB adopted guidance that amends the requirements for reporting discontinued operations. Under the amendment, only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results will be reported as discontinued operations in the financial statements. Currently, many disposals, some of which may be routine in nature and not a change in an entity's strategy, are reported in discontinued operations. The guidance also requires expanded disclosures for discontinued operations. This guidance becomes effective for the Company in its year ending December 31, 2015 and early adoption is permitted, but only for disposals that have not been reported in financial statements previously issued or available for issuance. The adoption of this standard is not expected to have a material impact on the Company's results of operations, cash flows or financial condition.

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 Less than One Year (In thousands)	Greater than One Year	Estimated Fair Value
<b>September 30, 2014</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 220,312	\$ 170	\$	\$	\$ 220,482
Corporate debt securities	178,312	97	(46)		178,363
International government agency debt securities	36,321	20			36,341
	434,945	287	(46)		435,186
Money market funds	1,201				1,201
Total short-term investments	436,146	287	(46)		436,387
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	101,464		(163)	(22)	101,279
Corporate debt securities	31,390		(37)	(4)	31,349
International government agency debt securities	9,577		(4)	(1)	9,572
	142,431		(204)	(27)	142,200
Held-to-maturity securities:					
Certificates of deposit	1,547				1,547
Total long-term investments	143,978		(204)	(27)	143,747
Total investments	\$ 580,124	\$ 287	\$ (250)	\$ (27)	\$ 580,134
<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:

(In thousands)	Nine Months Ended September 30,			
	2014		2013	
Proceeds from the sales and maturities of marketable securities	\$	246,540	\$	95,149
Realized gains	\$	15,352	\$	54
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 September 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	\$ 298,878	\$ 298,972	\$ 1,547	\$ 1,547
After 1 year through 5 years	278,498	278,414		
Total	\$ 577,376	\$ 577,386	\$ 1,547	\$ 1,547

At September 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 September 30, 2014 and December 31, 2013, respectively, which was recorded within Other Assets in the accompanying Condensed Consolidated Balance Sheets. During the nine months ended September 30, 2014, the Company invested an additional \$1.0 million in Civitas and 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 no longer records 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 is suspended.

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

In October 2014, Civitas was acquired by Acorda Therapeutics, Inc. ( Acorda ) for approximately \$525.0 million. As a result of this transaction, the Company received \$30.0 million for the sale of certain commercial-scale pulmonary manufacturing equipment used by Civitas. The Company also received \$27.2 million and will receive an additional \$2.3 million, subject to release of all amounts held in escrow, for its approximate 6% equity interest in Civitas.

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 ( Fountain ), 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, and the Company is accounting for its investment in Fountain under the equity method. At September 30, 2014, the Company had made payments of, and its investment is equal to, \$1.2 million ( 0.9 million), which is included within Other assets in the accompanying Condensed Consolidated Balance Sheets.

[Table of Contents](#)

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

**4. FAIR VALUE MEASUREMENTS**

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

(In thousands)	September 30, 2014	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 1,201	\$ 1,201		\$
U.S. government and agency debt securities	321,761	169,120	152,641	
Corporate debt securities	209,712		209,712	
International government agency debt securities	45,913		45,913	
Total	\$ 578,587	\$ 170,321	\$ 408,266	\$
(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
Total	\$ 280,940	\$ 92,873	\$ 186,541	\$ 1,526
<b>Liabilities:</b>				
Interest rate swap contract	\$ (275)	\$	(275)	\$
Total	\$ (275)	\$	(275)	\$

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period.

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the nine months ended September 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 September 30, 2014:

(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)

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

Balance, September 30, 2014

\$

As disclosed in Note 3, *Investments*, 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.

Table of Contents

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

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 September 30, 2014:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 292,130	\$ 289,346
Term Loan B-2	\$ 67,421	\$ 66,825

**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)	September 30, 2014	December 31, 2013
Raw materials	\$ 18,594	\$ 18,410
Work in process	24,106	15,581
Finished goods	7,771	12,227
Total inventory	\$ 50,471	\$ 46,218

**6. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2014	December 31, 2013
Land	\$ 8,163	\$ 8,440
Building and improvements	148,856	148,044
Furniture, fixture and equipment	231,426	220,984
Leasehold improvements	24,251	23,980
Construction in progress	32,462	26,688
Subtotal	445,158	428,136

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

Less: accumulated depreciation		(183,030)		(153,646)
Total property, plant and equipment, net	\$	262,128	\$	274,490

In April 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.



Table of Contents

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

**7. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	September 30, 2014 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (115,102)	\$ 384,598
NanoCrystal technology	13	74,600	(12,001)	62,599
OCR technology	12	66,300	(18,841)	47,459
Total		\$ 640,600	\$ (145,944)	\$ 494,656

Based on the Company's most recent analysis, amortization of intangible assets included within its Condensed Consolidated Balance Sheets at September 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.

**8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2014	December 31, 2013
Accounts payable	\$ 27,233	\$ 19,493
Accrued compensation	25,121	28,101
Accrued restructuring	4,268	7,296
Accrued other	43,707	36,283
Total accounts payable and accrued expenses	\$ 100,329	\$ 91,173

**9. RESTRUCTURING**

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

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 \$8.6 million and recorded an adjustment of \$0.1 million due to changes in foreign currency since inception of this restructuring plan. Restructuring activity during the nine months ended September 30, 2014 was as follows:

Table of Contents

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

(In thousands)	Severance and Outplacement Services
Balance, January 1, 2014	\$ 10,578
Payments	(6,320)
Adjustments	(441)
Balance, September 30, 2014	\$ 3,817

At September 30, 2014 and December 31, 2013, \$3.8 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:

(In thousands)	September 30, 2014	December 31, 2013
Term Loan B-1, due September 25, 2019	\$ 292,130	\$ 294,091
Term Loan B-2, due September 25, 2016	67,421	70,202
Total	359,551	364,293
Less: current portion	(6,750)	(6,750)
Long-term debt	\$ 352,801	\$ 357,543

**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, had a notional value of \$65.0 million and expired in September 2014. 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 nine months ended September 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	Fair Value September 30, 2014	December 31, 2013
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$	\$ (275)

**12. SHARE-BASED COMPENSATION**

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014		2013		2014		2013	
Cost of goods manufactured and sold	\$	1,557	\$	1,149	\$	5,636	\$	3,223
Research and development		3,403		2,825		10,886		7,129
Selling, general and administrative		8,521		10,235		29,718		20,547
Total share-based compensation expense	\$	13,481	\$	14,209	\$	46,240	\$	30,899

At September 30, 2014 and December 31, 2013, \$0.7 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the accompanying Condensed Consolidated Balance Sheets.

Table of Contents

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

**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 ordinary share sale.

**14. (LOSS) EARNINGS PER SHARE**

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Numerator:</b>				
Net (loss) income	\$ (39,956)	\$ (7,762)	\$ (60,575)	\$ 2,569
<b>Denominator:</b>				
Weighted average number of ordinary shares outstanding	145,896	136,106	144,732	134,670
<b>Effect of dilutive securities:</b>				
Stock options				6,929
Restricted stock units				1,423
Dilutive ordinary share equivalents				8,352
Shares used in calculating diluted earnings (loss) per share	145,896	136,106	144,732	143,022

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Stock options	9,721	9,241	9,605	1,084
Restricted stock units	1,683	1,229	1,821	
Total	11,404	10,470	11,426	1,084

**15. INCOME TAXES**

The Company recorded an income tax provision of \$3.5 million and \$5.8 million for the three and nine months ended September 30, 2014, respectively and an income tax provision of \$0.2 million and \$7.8 million for the three and nine months ended September 30, 2013, respectively. The income tax provision in the three and nine months ended September 30, 2014 primarily relates to U.S. federal and state taxes on income, partially offset by deferred tax benefits in Ireland. The income tax provision in the three and nine months ended September 30, 2013 primarily relates to U.S. federal and state taxes on income, partially offset by a discrete benefit of \$3.0 million from the settlement of uncertain tax benefits.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At September 30, 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.

Table of Contents

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

**16. COMMITMENTS AND CONTINGENCIES**

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. For example, the Company is currently involved in various Paragraph IV lawsuits in the U.S. and other proceedings outside of the U.S. involving its patents in respect of FOCALIN XR, TRICOR, MEGACE ES, AMPYRA and ZOXYDOL ER. 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.

Table of Contents

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 5 of this Form 10-Q, and Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included in our Transition Report, which has been filed with the SEC.

**Executive Summary**

Net loss for the three months ended September 30, 2014 was \$40.0 million, or \$0.27 per ordinary share basic and diluted, as compared to net loss of \$7.8 million, or \$0.06 per ordinary share basic and diluted, for the three months ended September 30, 2013. Net loss for the nine months ended September 30, 2014 was \$60.6 million, or \$0.42 per ordinary share basic and diluted, as compared to net income of \$2.6 million, or \$0.02 per ordinary share basic and diluted, for the nine months ended September 30, 2013.

During the three and nine months ended September 30, 2014, we recorded total revenues of \$160.0 million and \$443.6 million, respectively, as compared to \$139.8 million and \$441.9 million in the three and nine months ended September 30, 2013, respectively. Included in revenue for the nine months ended September 30, 2013 was \$30.0 million of intellectual property ( IP ) license revenue unrelated to key development programs.

Our operating expenses for the three and nine months ended September 30, 2014 were \$192.7 million and \$515.1 million, respectively, as compared to \$143.7 million and \$413.2 million in the three and nine months ended September 30, 2013. This increase reflects increased investment in our rapidly advancing development pipeline, such as the initiation of the pivotal clinical development programs for ALKS 5461, and informative studies for ALKS 3831, ALKS 8700 and ALKS 7106. We have also begun prelaunch activities for aripiprazole lauroxil, as we submitted our New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) in August 2014, which was accepted by the FDA in October 2014.

Also during the nine months ended September 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 Pharmaceutica, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (taken together, 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.

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

Table of Contents

prescribed the 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 in May 2014 the submission of sNDAs to the FDA for once-monthly INVEGA SUSTENNA for approval to treat schizoaffective disorder as either monotherapy or adjunctive therapy.

**AMPYRA/FAMPYRA**

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. In January 2010, the FDA approved AMPYRA as a treatment to improve walking in patients with multiple sclerosis ( MS ) as demonstrated by an increase in walking speed. To our knowledge, 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 International GmbH. 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 May 2014. 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 plc ( 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 September 2014, AstraZeneca announced that the once-weekly BYDUREON Pen 2 mg, which is a pre-filled, single-use pen injector that contains the same formulation and dose as the original BYDUREON single-dose tray, was available by prescription in pharmacies in the U.S. AstraZeneca stated that it received a positive opinion from the Committee for Medicinal Products for Human Use ( CHMP ) on the BYDUREON dual-chamber pen and that it filed for approval of the dual-chamber pen in Japan in April 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 GmbH International 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 product candidates in various stages of development, as discussed below.

***Aripiprazole Lauroxil***

Aripiprazole lauroxil is an injectable atypical antipsychotic with one-month and two-month formulations in development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts into aripiprazole, which is commercially available under the name ABILIFY. As a long-acting investigational medication based on our proprietary LinkeRx technology, aripiprazole lauroxil is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format. Aripiprazole lauroxil is our first product candidate to leverage our proprietary LinkeRx technology.

In April 2014, we announced positive topline results from a randomized, double-blind, placebo-controlled phase 3 clinical trial of aripiprazole lauroxil in patients with schizophrenia and presented the comprehensive data from the phase 3 study in June 2014. In August 2014, we announced submission of an NDA to the FDA for aripiprazole lauroxil for the treatment of schizophrenia. In October 2014, we announced that the FDA had accepted for filing the NDA for aripiprazole lauroxil, with a Prescription Drug User Fee Act ( PDUFA ) date of August 22, 2015.

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

Table of Contents

***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 major depressive disorder ( MDD ) in patients who have an inadequate response to standard antidepressant therapies. An oral investigational medicine, ALKS 5461 acts as a balanced neuromodulator in the brain and represents a new approach with a novel mechanism of action for treating MDD. 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. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies.

***ALKS 3831***

ALKS 3831 is a novel, proprietary investigational medicine designed as a broad-spectrum antipsychotic for the treatment of 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 the treatment of schizophrenia in patients with alcohol use. In September 2014, we announced completion of patient enrollment in an ongoing phase 2 study designed to assess ALKS 3831's efficacy, safety and tolerability in the treatment of schizophrenia and its attenuation of weight gain, compared to olanzapine, and we expect topline results from this study in early 2015. 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 schizophrenia in patients with alcohol use, compared to olanzapine. We expect topline results from this study in mid-2017.

***ALKS 8700***

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate ( MMF ) molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to 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. We expect topline results from this study in the first quarter of 2015.

***ALKS 7106***

ALKS 7106 is our novel, oral opioid analgesic drug candidate designed for the treatment of pain with intrinsically low potential for abuse and overdose death, which are two liabilities associated with opioid analgesics. In August 2014, we announced that we had initiated a randomized, double-blind, placebo-controlled phase 1 study designed to evaluate the safety, tolerability and pharmacokinetics of ALKS 7106. We expect topline results from this study in the first half of 2015.

***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 Investigational New Drug ( IND ) enabling activities for RDB 1419 in 2014.

Table of Contents

***Other Partnered Product Candidates***

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.

AstraZeneca is developing line extensions for BYDUREON for the treatment of type 2 diabetes, including weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. AstraZeneca has stated that it expects to file for approval of the BYDUREON once-weekly suspension in the U.S. and EU in 2015.

**Patents and Proprietary Rights**

In July 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. Following our announcement of the four Notices of Allowance, the USPTO issued the patents as follows:

Aripiprazole lauroxil: On August 5, 2014, the USPTO issued U.S. Patent No. 8,796,276, entitled Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders. We expect this patent to expire no earlier than June 2030.

ALKS 5461: On September 2, 2014, the USPTO issued U.S. Patent No. 8,822,488, entitled Compositions of Buprenorphine and  $\mu$  Antagonists. We expect this patent to expire no earlier than December 2032.

ALKS 3831: On July 15, 2014, 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 February 2032.

ALKS 7106: On August 12, 2014, the USPTO issued U.S. Patent No. 8,802,655, entitled 4-Hydroxybenzomorphans. We expect this patent to expire no earlier than November 2025.



Table of Contents**Results of Operations***Manufacturing and Royalty Revenues*

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues from continuing operations earned in the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013:

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Nine Months Ended September 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION	\$ 36.1	\$ 29.2	\$ 6.9	\$ 90.2	\$ 65.8	\$ 24.4
RISPERDAL CONSTA	32.3	33.4	(1.1)	87.9	98.6	(10.7)
AMPYRA/FAMPYRA	16.5	12.6	3.9	56.7	57.1	(0.4)
BYDUREON	10.3	7.0	3.3	26.7	17.1	9.6
RITALIN LA/FOCALIN XR	8.7	9.2	(0.5)	29.4	31.0	(1.6)
Other	28.1	27.2	0.9	82.8	115.7	(32.9)
Manufacturing and royalty revenues	\$ 132.0	\$ 118.6	\$ 13.4	\$ 373.7	\$ 385.3	\$ (11.6)

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three and nine months ended September 30, 2014, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$403.0 million and \$1,170.0 million, respectively, as compared to \$324.0 million and \$898.0 million in the three and nine months ended September 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 to 5% at the beginning of each calendar year.

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the three months ended September 30, 2014 as compared to the three months ended September 30, 2013, was primarily due to a 13% decrease in royalty revenues. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013, was primarily due to an 11% decrease in manufacturing revenues and an 11% decrease in royalty revenues. The decrease in manufacturing revenues was primarily due to a 7% decrease in our selling price of RISPERDAL CONSTA to Janssen and a 2% decrease in the number of units shipped. Janssen's end-market sales of RISPERDAL CONSTA were \$283.8 million and \$892.0 million for the three and nine months ended September 30, 2014, respectively, and \$325.4 million and \$996.7 million for the three and nine months ended September 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.

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended September 30, 2014, as compared to the three months ended September 30, 2013 was primarily due to \$3.7 million in royalties earned on third-party shipments of AMPYRA to Acorda.



The increase in BYDUREON royalty revenues in the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013, was due to an increase in end-market sales of BYDUREON by AstraZeneca. During the three and nine months ended September 30, 2014, our estimate of AstraZeneca's end-market sales of BYDUREON was \$125.0 million and \$334.3 million, respectively, as compared to \$87.6 million and \$215.5 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the three and nine months ended September 30, 2013, respectively.

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

Table of Contents*Product Sales, net*

Our product sales, net consist of sales of VIVITROL in the U.S. to wholesalers, 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 nine months ended September 30, 2014 and 2013:

(In millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	% of Sales	2013	% of Sales	2014	% of Sales	2013	% of Sales
Product sales, gross	\$ 37.9	100.0%	\$ 26.3	100.0%	\$ 95.4	100.0%	\$ 70.9	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(3.5)	(9.2)%	(2.0)	(7.6)%	(7.9)	(8.3)%	(5.3)	(7.5)%
Product discounts	(2.7)	(7.1)%	(1.6)	(6.1)%	(6.8)	(7.1)%	(4.4)	(6.2)%
Chargebacks	(2.9)	(7.7)%	(1.7)	(6.5)%	(6.4)	(6.7)%	(4.7)	(6.6)%
Co-pay assistance	(1.6)	(4.2)%	(1.2)	(4.5)%	(4.5)	(4.7)%	(3.4)	(4.8)%
Product returns	(0.8)	(2.1)%	(0.4)	(1.5)%	(2.2)	(2.3)%	(0.5)	(0.7)%
Other	(0.6)	(1.6)%	(0.2)	(0.8)%	(3.1)	(3.3)%	(1.4)	(2.0)%
Total adjustments	(12.1)	(31.9)%	(7.1)	(27.0)%	(30.9)	(32.4)%	(19.7)	(27.8)%
Product sales, net	\$ 25.8	68.1%	\$ 19.2	73.0%	\$ 64.5	67.6%	\$ 51.2	72.2%

The increase in product sales, gross for the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013, was due to a 38% and 30% 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 nine months ended September 30, 2014 was primarily due to a \$1.4 million charge in the three months ended 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 September 30,		Change Favorable/ (Unfavorable)	Nine Months Ended September 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Cost of goods manufactured and sold	\$ 47.3	\$ 45.4	\$ (1.9)	\$ 129.5	\$ 139.4	\$ 9.9

The decrease in cost of goods manufactured and sold during the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013 was primarily due to the decrease in the number of RISPERDAL CONSTA units shipped to Janssen and a decrease in shipments of our legacy products. The decrease in shipments of our legacy products is primarily due to decreasing demand from our customers due to generic competition. 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. As a result of the termination of these services,

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

we began a corresponding reduction in headcount of up to 130 employees and we expect that by the end of 2014, our restructuring plan at our Athlone, Ireland manufacturing facility will have been completed.

### *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.

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

## Table of Contents

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

	Three Months Ended September 30,			Change Favorable/ (Unfavorable)	Nine Months Ended September 30,			Change Favorable/ (Unfavorable)				
(In millions)	2014	2013			2014	2013						
External R&D Expenses:												
Key development programs:												
ALKS 5461	\$	21.1	\$	1.2	\$	(19.9)	\$	52.8	\$	5.3	\$	(47.5)
ALKS 3831		10.3		2.3		(8.0)		21.4		4.6		(16.8)
Aripiprazole lauroxil		9.8		17.6		7.8		23.0		32.5		9.5
ALKS 8700		3.8				(3.8)		7.6				(7.6)
ALKS 7106		1.7				(1.7)		5.3				(5.3)
Other development programs		5.6		4.2		(1.4)		12.3		13.9		1.6
Total external R&D expenses		52.3		25.3		(27.0)		122.4		56.3		(66.1)
Internal R&D expenses:												
Employee-related		19.4		14.4		(5.0)		56.2		41.5		(14.7)
Depreciation		2.1		2.1				6.2		5.8		(0.4)
Occupancy		1.8		2.2		0.4		5.2		4.9		(0.3)
Other		2.7		1.9		(0.8)		7.6		6.7		(0.9)
Total internal R&D expenses		26.0		20.6		(5.4)		75.2		58.9		(16.3)
Research and development expenses	\$	78.3	\$	45.9	\$	(32.4)	\$	197.6	\$	115.2	\$	(82.4)

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, initiated in July 2013, and the initiation of a second phase 2 study in June 2014 to investigate the potential utility of ALKS 3831 for patients with schizophrenia exacerbated by alcohol use disorders. ALKS 8700 and ALKS 7106 were added to our key development program portfolio in 2013 and we initiated phase 1 studies for these programs in July 2014 and August 2014, respectively. Expenses incurred under the samidorphan development program, which was formerly referred to as ALKS 33, and the RDB 1419 development program were not material in the three and nine months ended September 30, 2014 and 2013. The increase in employee-related expenses was primarily due to an increase in headcount and share-based compensation expense.

## Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30,			Change Favorable/ (Unfavorable)	Nine Months Ended September 30,			Change Favorable/ (Unfavorable)
	2014	2013			2014	2013		
Selling, general and administrative expense	\$ 51.9	\$ 39.5	\$ (12.4)	\$	145.1	\$ 107.1	\$ (38.0)	

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

The increase in selling, general and administrative ( SG&A ) expense for the three months ended September 30, 2014 as compared to the three months ended September 30, 2013, was primarily due to an \$8.8 million increase in professional service fees and marketing expenses. The increases in professional service fees and marketing expenses were primarily due to prelaunch activities for aripiprazole lauroxil, as we submitted our NDA to the FDA in August 2014.

The increase in SG&A expense for the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013, was primarily due to an \$18.6 million increase in professional service fees and marketing expenses and a \$15.7 million increase in employee-related expenses. The increases in professional service fees and marketing expenses were primarily due to prelaunch activities for aripiprazole lauroxil and increased marketing activities related to VIVITROL. The increase in employee-related expenses is primarily related to an increase in share-based compensation of \$9.2 million, which is primarily due to recent equity grants being awarded with higher grant-date fair values than older grants due to the increase in our stock price, and an increase in labor and benefit expenses of \$5.8 million due to an increase in headcount.

We expect SG&A expenses to continue to increase in 2015 as launch planning activities accelerate for aripiprazole lauroxil.

Table of Contents*Amortization of Acquired Intangible Assets*

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Nine Months Ended September 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Amortization of acquired intangible assets	\$ 15.2	\$ 12.9	\$ (2.3)	\$ 42.9	\$ 35.9	\$ (7.0)

The intangible assets being amortized in the three and nine months ended September 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 September 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.

*Other (Expense) Income, Net*

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Nine Months Ended September 30,		Change Favorable/ (Unfavorable)
	2014	2013		2014	2013	
Interest income	\$ 0.5	\$ 0.3	\$ 0.2	\$ 1.4	\$ 0.6	\$ 0.8
Interest expense	(3.4)	(3.5)	0.1	(10.1)	(18.4)	8.3
Gain on sale of investment in Acceleron Pharma Inc.				15.3		15.3
Gain on sale of property, plant and equipment				12.3		12.3
Other (expense) income, net	(0.8)	(0.5)	(0.3)	(2.3)	(0.4)	(1.9)
Total other (expense) income, net	\$ (3.7)	\$ (3.7)	\$	\$ 16.6	\$ (18.2)	\$ 34.8

The decrease in interest expense in the nine months ended September 30, 2014, as compared to the nine months ended September 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 nine months ended September 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. Also, 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 and recorded a gain of \$12.3 million, as \$3.0 million of the sale proceeds were placed in escrow pending the completion of certain additional services we are obligated to perform.

In October 2014, Civitas was acquired by Acorda Therapeutics, Inc. ( Acorda ) for approximately \$525.0 million. As a result of this transaction, we received \$30.0 million for the sale of certain commercial-scale pulmonary manufacturing equipment used by Civitas. We also received \$27.2 million and will receive an additional \$2.3 million, subject to release of all amounts held in escrow, for our approximate 6% equity interest in Civitas.

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

## Income Tax Provision

	Three Months Ended			Change	Nine Months Ended			Change				
	September 30,			Favorable/	September 30,			Favorable/				
(In millions)	2014		2013	(Unfavorable)	2014		2013	(Unfavorable)				
Income tax provision	\$	3.5	\$	0.2	\$	(3.3)	\$	5.8	\$	7.8	\$	2.0

The income tax provision in the three and nine months ended September 30, 2014 primarily relates to U.S. federal and state taxes on income earned in the U.S., partially offset by deferred tax benefits in Ireland. The income tax provision for the three and nine months ended September 30, 2013 relates primarily to U.S. federal and state taxes on income, partially offset by a \$3.0 million discrete tax benefit from the settlement of uncertain tax benefits.

Table of Contents**Liquidity and Financial Condition**

Our financial condition is summarized as follows:

(In millions)		September 30, 2014		December 31, 2013
Cash and cash equivalents	\$	136.2	\$	167.6
Investments short-term		436.4		194.6
Investments long-term		143.7		87.8
Total cash, cash equivalents and investments	\$	716.3	\$	450.0
Working capital	\$	702.8	\$	469.2
Outstanding borrowings current and long-term	\$	359.6	\$	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 nine months ended September 30, 2014 and 2013:

(In millions)		Nine Months Ended September 30, 2014		2013
Cash and cash equivalents, beginning of period	\$	167.6	\$	135.9
Cash (used in) provided by operating activities		(2.5)		109.4
Cash used in investing activities		(309.5)		(119.9)
Cash provided by financing activities		280.6		48.1
Cash and cash equivalents, end of period	\$	136.2	\$	173.5

The decrease in cash flows provided by operating activities in the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013, was primarily due to a decrease in cash provided by net (loss) income of \$94.0 million and an increase in cash used for working capital of \$17.9 million. The decrease in cash provided from net (loss) income was partially due to a \$60.6 million net loss in the nine months ended September 30, 2014, as compared to \$2.6 million of net income in the prior period. The increase in cash used in working capital was primarily due to a decrease in cash provided by accounts receivable of \$8.9 million and an increase in cash used for inventory, prepaid expenses and other assets of \$15.2 million, partially offset by an increase in cash provided by accounts payable and accrued expenses of \$6.2 million.



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

The increase in cash flows used in investing activities in the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013, was primarily due to an increase in the net purchase of investments of \$202.2 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 nine months ended September 30, 2014, as compared to the nine months ended September 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 and a \$10.0 million increase in the excess tax benefit from share-based compensation. This was partially offset by a \$23.4 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 September 30, 2014 consisted of the following:

(In millions)		Amortized Cost		Gains		Gross Unrealized Losses		Estimated Fair Value	
Investments	short-term	\$	436.2	\$	0.3	\$	(0.1)	\$	436.4
Investments	long-term available-for-sale		142.4				(0.2)		142.2
Investments	long-term held-to-maturity		1.5						1.5
Total		\$	580.1	\$	0.3	\$	(0.3)	\$	580.1

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 September 30, 2014, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At September 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 September 30, 2014, our borrowings consisted of \$361.5 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. With the exception of our agreement with Fountain as disclosed in footnote 3, *Investments*, our contractual obligations as of September 30, 2014 have not materially changed from the date of that report.

*Off-Balance Sheet Arrangements*

At September 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 September 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 September 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, MEGACE ES, AMPYRA and ZOHYDRO ER. 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 nine months ended September 30, 2014. As of September 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 September 30, 2014, Messrs. James M. Frates 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: October 29, 2014

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.1	Amendment No. 3 and Waiver, dated as of May 22, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended as of February 14, 2013 among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.
31.1	Rule 13a-14(a)/15d-14(a) Certification.
31.2	Rule 13a-14(a)/15d-14(a) Certification.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101	The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the quarter ended September 30, 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.