Alkermes plc. Form 10-Q July 25, 2013 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

OR

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

Commission File Number 001-35299

# ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland

98-1007018

(State or other jurisdiction of incorporation or organization)

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

Connaught Ho	ouse
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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 x No o

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 x No o

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 x Accelerated filer o Non-accelerated filer o Smaller reporting company o (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 o No x

The number of shares of the issuer s ordinary shares, \$0.01 par value, outstanding as of July 22, 2013, was 135,692,171 shares.

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



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### **Forward-Looking Statements**

This report contains and incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, would, expect, anticipate, continue or other similar words. These statements discuss a expectations, contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Form 10-Q include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes:
- our expectations regarding the commercialization of our products;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products;
- our expectations regarding our collaborations and other significant agreements relating to our products;
- our expectations regarding the impact of new accounting pronouncements;
- our expectations regarding our intellectual property rights, including our ability to protect our intellectual property rights and not infringe upon third-party intellectual property rights;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management s objectives and strategies with respect to managing such exposures; and
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including the risks and uncertainties described or discussed in this Form 10-Q and in our Annual Report on Form 10-K and Form 10-K/A for the year ended March 31, 2013 (Annual Report) (including, without limitation, in Item 1A Risk Factors thereof).

The forward-looking statements contained and incorporated herein represent our judgment as of the date of this Form 10-Q, and we caution readers not to place undue reliance on such statements. The information contained in this Form 10-Q is provided by us as of the date of this Form 10-Q and, except as required by law, we do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

### **Note Regarding Company**

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

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products.

# PART I. FINANCIAL INFORMATION

# **Item 1. Condensed Consolidated Financial Statements:**

# ALKERMES PLC AND SUBSIDIARIES

### CONDENSED CONSOLIDATED BALANCE SHEETS

### (unaudited)

	June 30, 2013 (In thousands, o and per share		
ASSETS			,
CURRENT ASSETS:			
Cash and cash equivalents	\$ 116,397	\$	96,961
Investments short-term	112,144		124,391
Receivables	130,578		124,620
Inventory	39,128		43,483
Prepaid expenses and other current assets	23,838		19,133
Total current assets	422,085		408,588
PROPERTY, PLANT AND EQUIPMENT, NET	281,253		288,435
INTANGIBLE ASSETS NET	563,277		575,993
GOODWILL	92,740		92,740
INVESTMENTS LONG-TERM	96,449		82,827
OTHER ASSETS	22,050		21,708
TOTAL ASSETS	\$ 1,477,854	\$	1,470,291
LIABILITIES AND SHAREHOLDERS EQUITY			
CURRENT LIABILITIES:			
Accounts payable and accrued expenses	\$ 63,719	\$	76,910
Deferred revenue current	2,129		2,270
Long-term debt current	6,750		6,750
Total current liabilities	72,598		85,930
LONG-TERM DEBT	360,690		362,258
DEFERRED REVENUE LONG-TERM	8,911		8,866
DEFERRED TAX LIABILITIES, NET LONG-TERM	36,404		37,603
OTHER LONG-TERM LIABILITIES	17,311		23,260
Total liabilities	495,914		517,917
COMMITMENTS AND CONTINGENCIES (Note 15)			
SHAREHOLDERS EQUITY:			
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and			
outstanding at June 30, 2013 and March 31, 2013, respectively			
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 135,843,440			
and 134,065,107 shares issued; 135,262,090 and 133,751,610 shares outstanding at			
June 30, 2013 and March 31, 2013, respectively	1,354		1,338
Treasury stock, at cost (581,350 and 313,497 shares at June 30, 2013 and March 31, 2013,			
respectively)	(13,898)		(5,380)

Additional paid-in capital	1,489,998	1,458,857
Accumulated other comprehensive loss	(2,925)	(2,518)
Accumulated deficit	(492,589)	(499,923)
Total shareholders equity	981,940	952,374
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 1,477,854	\$ 1,470,291

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

#### ALKERMES PLC AND SUBSIDIARIES

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

#### (unaudited)

Three Months Ended June 30, 2013 2012 (In thousands, except per share amounts) **REVENUES:** Manufacturing and royalty revenues \$ 119,788 \$ 138,380 12,372 Product sales, net 17,379 Research and development revenue 1,464 1,487 Total revenues 138,631 152,239 **EXPENSES:** 45,991 Cost of goods manufactured and sold 42,070 Research and development 33,462 37,806 Selling, general and administrative 32,933 29,784 Amortization of acquired intangible assets 12,716 10,434 Total expenses 125,102 120,094 OPERATING INCOME 13,529 32,145 OTHER EXPENSE, NET: 161 299 Interest income (3,468)(10,170)Interest expense Other (expense) income, net 923 (170)Total other expense, net (3,477)(8,948)23,197 INCOME BEFORE INCOME TAXES 10,052 PROVISION FOR INCOME TAXES 764 2,718 NET INCOME \$ \$ 22,433 7,334 EARNINGS PER COMMON SHARE: \$ Basic 0.05 0.17 Diluted \$ 0.05 \$ 0.17 WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: 134,602 130,434 Basic Diluted 143,369 134,945 COMPREHENSIVE INCOME: \$ 7,334 \$ 22,433 Net income Unrealized holding losses on marketable securities (141)(408)Unrealized losses on derivative contracts (72)COMPREHENSIVE INCOME \$ 6,926 \$ 22,220

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

# ALKERMES PLC AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (unaudited)

	Three Months End June 30,	
	2013 (In thousands)	2012
CASH FLOWS FROM OPERATING ACTIVITIES:	(III tilousalius)	
Net income	\$ 7,334 \$	22,433
Adjustments to reconcile net income to cash flows from operating activities:	 .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,
Depreciation and amortization	23,727	18,018
Share-based compensation expense	8,809	8,162
Excess tax benefit from share-based compensation	(7,217)	(105)
Deferred income taxes	(1,199)	(313)
Other non-cash charges	765	1,772
Changes in assets and liabilities:		
Receivables	(5,958)	(39,275)
Inventory, prepaid expenses and other assets	(2,212)	(242)
Accounts payable and accrued expenses	(9,667)	(18,826)
Deferred revenue	(96)	3,671
Other long-term liabilities	(1,539)	6
Cash flows provided by (used in) operating activities	12,747	(4,699)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(3,625)	(6,733)
Proceeds from the sale of equipment	6	18
Purchases of investments	(33,182)	(40,621)
Sales and maturities of investments	31,400	56,686
Cash flows (used in) provided by investing activities	(5,401)	9,350
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation		
arrangements	15,079	1,340
Excess tax benefit from share-based compensation	7,217	105
Employee taxes paid related to net share settlement of equity awards	(8,518)	(3,323)
Principal payments of long-term debt	(1,688)	(775)
Cash flows provided by (used in) financing activities	12,090	(2,653)
NET INCREASE IN CASH AND CASH EQUIVALENTS	19,436	1,998
CASH AND CASH EQUIVALENTS Beginning of period	96,961	83,601
CASH AND CASH EQUIVALENTS End of period	\$ 116,397 \$	85,599
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 1,056 \$	827

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

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

### 1. THE COMPANY

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

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three months ended June 30, 2013 and 2012 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2013. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (U.S.) (commonly referred to as GAAP). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

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

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

Principles of Consolidation

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

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments, litigation and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Segment Information

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

Reclassifications

An amount equal to \$(0.1) million that was previously classified as Accounts payable and accrued expenses has been reclassified to Excess tax benefit from share-based compensation in the accompanying condensed consolidated statements of cash flows to conform to current period presentation.

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

New Accounting Pronouncements

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

### 3. INVESTMENTS

Investments consisted of the following:

1 20 2012										
June 30, 2013										
Short-term investments:										
Available-for-sale securities:										
U.S. government and agency debt	ф	04.005	Ф	20	Ф	(10)	Ф		Ф	05.005
securities	\$	94,995	\$	28	\$	(18)	\$		\$	95,005
Corporate debt securities		8,928		6						8,934
International government agency debt		< 000								
securities		6,999		11		(6)				7,004
		110,922		45		(24)				110,943
Money market funds		1,201								1,201
Total short-term investments		112,123		45		(24)				112,144
Long-term investments:										
Available-for-sale securities:										
U.S. government and agency debt										
securities		57,332				(176)				57,156
Corporate debt securities		29,363				(226)		(158)		28,979
International government agency debt										
securities		9,125				(11)				9,114
		95,820				(413)		(158)		95,249
Held-to-maturity securities:										
Certificates of deposit		1,200								1,200
Total long-term investments		97,020				(413)		(158)		96,449
Total investments	\$	209,143	\$	45	\$	(437)	\$	(158)	\$	208,593
N 1 21 2012										
March 31, 2013										
Short-term investments:										
Available-for-sale securities:										

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U.S. government and agency debt					
securities	\$ 102,093	\$ 29	\$ (1)	\$	\$ 102,121
Corporate debt securities	10,946	27			10,973
International government agency debt					
securities	10,089	8	(1)		10,096
	123,128	64	(2)		123,190
Money market funds	1,201				1,201
Total short-term investments	124,329	64	(2)		124,391
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt					
securities	60,047		(17)		60,030
Corporate debt securities	18,725		(26)	(162)	18,537
International government agency debt					
securities	3,060				3,060
	81,832		(43)	(162)	81,627
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	83,032		(43)	(162)	82,827
Total investments	\$ 207,361	\$ 64	\$ (45)	\$ (162)	\$ 207,218

# 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:

	Three Moi Jun	ded
(In thousands)	2013	2012
Proceeds from the sales and maturities of marketable		
securities	\$ 31,400	\$ 56,686
Realized gains	\$ 7	\$ 3
Realized losses	\$	\$

The Company s available-for-sale and held-to-maturity securities at June 30, 2013 had contractual maturities in the following periods:

	Availabl	le	Held-to-	maturity		
	Amortized		Estimated	Amortized		Estimated
(In thousands)	Cost		Fair Value	Cost		Fair Value
Within 1 year	\$ 85,717	\$	85,714	\$ 1,200	\$	1,200
After 1 year through 5 years	121,025		120,478			
Total	\$ 206,742	\$	206,192	\$ 1,200	\$	1,200

At June 30, 2013, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of U.S. government and agency debt securities and corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company s intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company s investment in Acceleron Pharma, Inc. (Acceleron) was \$8.7 million at June 30, 2013 and March 31, 2013, which was recorded within Other assets in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company will continue to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

The Company s investment in Civitas Therapeutics, Inc. (Civitas) was \$0.4 million and \$0.8 million at June 30, 2013 and March 31, 2013, respectively, which was recorded within Other assets in the accompanying condensed consolidated balance sheets. The Company accounts for its investment in Civitas under the equity method as the Company has an approximate 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the three months ended June 30, 2013 and 2012, the Company recorded a reduction in its investment in Civitas of \$0.4 million and \$0.3 million,

respectively, which represented the Company s proportionate share of Civitas net losses for these periods.

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

### 4. FAIR VALUE MEASUREMENTS

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

(In thousands)	June 30, 2013	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	152,161	65,407	86,754	
Corporate debt securities	37,913		37,913	
International government agency debt securities	16,118		16,118	
Total	\$ 207,393	\$ 66,608	\$ 140,785	\$
Liabilities:				
Interest rate swap contract	\$ (454)	\$	\$ (454)	\$
Total	\$ (454)	\$	\$ (454)	\$

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

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

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

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the three months ended June 30, 2013. During the three months ended June 30, 2013, there were no securities valued as Level 3.

A third-party pricing service was used to determine the estimated fair value of the Company s securities. The third-party pricing service develops its estimates of fair value through a proprietary model using variables including reportable trades and last trade date, bids and offers, trading frequency, benchmark yields, credit spreads and other industry and economic events. The Company validates the prices provided by its third-party pricing service by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming the activity in the relevant markets. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its pricing service at June 30, 2013.

The Company s investments in U.S. government and agency debt securities, international government agency debt securities and corporate debt securities classified as Level 2 were initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market observable data. The market observable data includes reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company entered into an interest rate swap agreement in September 2011 and interest rate cap agreement in December 2011. These agreements are described in greater detail in Note 11, *Derivative Instruments*. The fair value of the Company s interest rate cap and interest rate swap agreements were based on an income approach, which excludes accrued interest, and takes into consideration then-current interest rates and then-current creditworthiness of the Company or the counterparty, as applicable.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company s consolidated balance sheets consists of the \$300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% ( Term Loan B-1 ) and the \$75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor ( Term Loan B-2 ). The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future at June 30, 2013, was as follows:

(In thousands)	arrying Value	Estimated Fair Value
Term Loan B-1	\$ 295,386	\$ 294,275
Term Loan B-2	\$ 72,054	\$ 72.188

## 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)	=	ine 30, 2013	March 31, 2013
Raw materials	\$	12,395	\$ 13,506
Work in process		13,261	13,842
Finished goods(1)		13,472	16,135
Total inventory	\$	39,128	\$ 43,483

<sup>(1)</sup> At June 30, 2013 and March 31, 2013, the Company had \$1.1 million and \$0.6 million, respectively, of VIVITROL finished goods inventory located at its third-party warehouse and shipping service provider.

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

### 6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	June 30, 2013	March 31, 2013		
Land	\$ 8,457	\$ 8,3	357	
Building and improvements	147,388	141,0	092	
Furniture, fixture and equipment	208,138	197,7	743	
Leasehold improvements	23,960	24,	137	
Construction in progress	26,347	39,3	399	
Subtotal	414,290	410,7	728	
Less: accumulated depreciation	(133,037)	(122,2	293)	
Total property, plant and equipment, net	\$ 281,253	\$ 288,4	435	

#### 7. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life	Cai	Gross rrying Amount	June 30, 2013 Accumulated Amortization	Cai	Net rrying Amount
Goodwill		\$	92,740	\$	\$	92,740
Finite-lived intangible assets:						
Collaboration agreements	12	\$	499,700	\$ (60,240)	\$	439,460
NanoCrystal technology	13		74,600	(6,410)		68,190
OCR technology	12		66,300	(10,673)		55,627
Total		\$	640,600	\$ (77,323)	\$	563,277

The Company recorded \$12.7 million of amortization expense related to its finite-lived intangible assets during the three months ended June 30, 2013. Based on the Company s most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at June 30, 2013 is expected to be approximately \$40.0 million for the nine months ended December 31, 2013, and \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the years ended December 31, 2015 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 asset will change in proportion to the change in revenues.

# 8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	Jui	June 30,		
(In thousands)	2	013		2013
Accounts payable	\$	14,209	\$	18,282
Accrued compensation		15,393		30,432
Accrued interest		939		970
Accrued other		33,178		27,226
Total accounts payable and accrued expenses	\$	63,719	\$	76,910

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

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

### 9. RESTRUCTURING

On April 4, 2013, the Company approved a restructuring plan at its Athlone, Ireland manufacturing facility consistent with the evolution of the Company s product portfolio and designed to improve operational performance for the future. Under the restructuring plan, the Company will terminate manufacturing services for certain older products becoming uneconomic to produce due to decreasing demand from its customers resulting from generic competition. The Company expects to continue to generate revenues from the manufacturing of these products during the nine months ending December 31, 2013 and, for certain of these products, into the year ending December 31, 2015.

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

	Severance and	
(In thousands)	outplacement servi	ices
Balance, April 1, 2013	\$	12,300
Payments		(272)
Adjustments		70
Balance, June 30, 2013	\$	12.098

At June 30, 2013 \$4.0 million and \$8.1 million of the restructuring accrual was included in accounts payable and accrued expenses, and other long-term liabilities, respectively, in the accompanying condensed consolidated balance sheet.

#### 10. LONG-TERM DEBT

Long-term debt consisted of the following:

June 30, March 31,

(In thousands)	2013	2013
Term Loan B-1, due September 25, 2019	\$ 295,386 \$	296,029
Term Loan B-2, due September 25, 2016	72,054	72,979
Total	367,440	369,008
Less: current portion	(6,750)	(6,750)
Long-term debt	\$ 360,690 \$	362,258

#### 11. DERIVATIVE INSTRUMENTS

In December 2011, the Company entered into an interest rate cap agreement with Morgan Stanley Capital Services LLC (MSCS) at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company s long-term debt bears interest. The interest rate cap agreement expires in December 2013, has a notional value of \$160.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss as Other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive income due to the decrease in value of this contract during the three months ended June 30, 2013. At June 30, 2013, this contract had an immaterial balance included within Other assets in the accompanying condensed consolidated balance sheet.

In September 2011, the Company entered into an interest rate swap agreement with MSCS to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company s long-term debt bear interest. The interest rate swap agreement became effective in December 2012, expires in December 2014, has a notional value of \$65.0 million and is not designated as a hedging instrument. Included within Interest expense in the accompanying condensed consolidated statements of operations and comprehensive income is \$0.1 million related to income for the increase in value of this contract during the three months ended June 30, 2013. At June 30, 2013, this contract had a fair value of \$0.5 million and is included within Other long-term liabilities in the accompanying condensed consolidated balance sheet.

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

### 12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

	Three Months Ended June 30,				
(In thousands)		2013		2012	
Cost of goods manufactured and sold	\$	1,003	\$	1,081	
Research and development		2,165		2,310	
Selling, general and administrative		5,641		4,771	
Total share-based compensation expense	\$	8,809	\$	8,162	

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

### 13. EARNINGS PER SHARE

Basic earnings per ordinary share is calculated based upon net income available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the calculation of diluted 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.

	Three Months Ended June 30,			
(In thousands)		2013		2012
Numerator:				
Net income	\$	7,334	\$	22,433
Denominator:				
Weighted average number of ordinary shares outstanding		134,602		130,434
Effect of dilutive securities:				
Stock options		7,287		3,276
Restricted stock units		1,480		1,235
Dilutive ordinary share equivalents		8,767		4,511
Shares used in calculating diluted earnings per share		143,369		134,945

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

### Three Months Ended June 30,

	Julie 30,		
(In thousands)	2013	2012	
Stock options	883	6,165	
Restricted stock units			
Total	883	6,165	

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

#### 14. INCOME TAXES

The Company recorded an income tax provision of \$2.7 million and \$0.8 million for the three months ended June 30, 2013 and 2012, respectively. The income tax provision in the three months ended June 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 income tax provision in the three months ended June 30, 2012 primarily relates to foreign taxes on income.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At June 30, 2013, the Company determined, based on the weight of all available positive and negative evidence, on a jurisdiction by jurisdiction basis, that it is more likely than not that a significant portion of the net deferred tax assets will not be realized, and a valuation allowance has been recorded. However, if the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of the deferred tax asset could change and the valuation allowance could be released in part or in whole.

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

### 15. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any current proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 3 of this Quarterly Report on Form 10-Q ( Form 10-Q ), and Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included in our Annual Report, which has been filed with the Securities and Exchange Commission ( SEC ).

#### **Executive Summary**

Net income for the three months ended June 30, 2013, was \$7.3 million or \$0.05 per ordinary share basic and diluted, as compared to a net income of \$22.4 million, or \$0.17 per ordinary share basic and diluted for the three months ended June 30, 2012. During the three months ended June 30, 2013 and 2012, we recorded total revenues of \$138.6 million and \$152.2 million, respectively. Included in the three months ended June 30, 2012 was \$20.0 million of intellectual property license revenue, unrelated to key development programs. Revenues from our five key commercial products, as summarized below, accounted for 71% and 53% of our total revenues in the three months ended June 30, 2013 and 2012, respectively.

### COMMERCIAL PRODUCT PORTFOLIO

Our primary commercial products are described in the table below, including, among other things, the territory in which the marketer has the right to sell the product and the source of revenues for us:

Product	Indication	Technology	Territory	Revenue Source	Marketer
RISPERDAL®	Schizophrenia	Extended-release	Worldwide	Manufacturing and	Ortho-McNeil-Janssen
CONSTA®	Bipolar I Disorder	microsphere		Royalty	Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG
					( Janssen )
INVEGA®	Schizophrenia	NanoCrystal®	United States (U.S.)	Royalty	Janssen
SUSTENNA®/					
<i>XEPLION</i> ®			Worldwide		
AMPYRA®/	Treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking	Oral Controlled Release (OCR) (MXDAS®)	U.S.	Manufacturing and Royalty	Acorda Therapeutics, Inc. ( Acorda )

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FAMPYRA®	speed		Worldwide		Biogen Idec International GmbH (Biogen Idec), under sublicense from Acorda
BYDUREON®	Type 2 diabetes	Extended-release microsphere	Worldwide	Royalty	Bristol-Myers Squibb Company ( Bristol-Myers ) and AstraZeneca PLC ( Astra Zeneca )
VIVITROL®	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States ( CIS )	Product sales Manufacturing and Royalty	Alkermes plc Janssen
TRICOR®	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	AbbVie Inc. Abbott Laboratories
LIPANTHYL®					
LIPIDIL					
SUPRALIP (and other trade					
names under which <i>fenofibrate</i> 145mg is sold)					
ZANAFLEX®	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing (capsules only) and	Acorda; Actavis, Inc. (formerly Watson
CAPSULES®				Royalty	Pharmaceutical)
ZANAFLEX®					
TABLETS					
TIZANIDINE					
HYDROCHLORIDE (AB					
Rated to ZANAFLEX CAPSULES)					
AVINZA®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer, Inc. ( Pfizer )
EMEND®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck & Co. Inc. ( Merck )

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FOCALIN® XR  RITALIN LA®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis AG ( Novartis )
MEGACE® ES	Anorexia, Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)
LUVOX CR®	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Manufacturing and Royalty	Jazz Pharmaceuticals plc ( Jazz )
RAPAMUNE®	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
NAPRELAN®	Various mild to moderate pain indications	OCR (IPDAS®)	U.S.	Manufacturing	Shionogi
			Canada		Sunovion Pharmaceuticals Canada, Inc.
VERAPAMIL SR  VERELAN®	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout	Manufacturing and Royalty (on select	UCB Kremers-Urban; Cephalon; Aspen
VERELAN® PM			the world	formulations)	Pharma; Orient Europharma;
VERAPAMIL PM					
VERECAPS®					Actavis, Inc.
UNIVER DILZEM	Hypertension and/or	OCR	Licensed on	Manufacturing	Cephalon; Pfizer;
DILZEM SR	Angina	(SODAS)	country/region basis throughout the world	and Royalty (for CARDIZEM CD only)	Roemmers; Kun Wha; Orient Europharma; Sanofi;
DILZEM XL				3,	Valeant Pharmaceuticals
DILTELAN					International Inc.
ACALIX CD					
DINISOR					
TILAZEM CR					
CARDIZEM® CD					
AFEDitab® CR (AB Rated to Adalat CC®)	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Actavis, Inc.
ADVATE®	Hemophilia A		Worldwide	Royalty	Baxter

### KEY COMMERCIAL PRODUCTS

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

### RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION

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

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

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 for injectable suspension is also approved in the EU and other countries worldwide, and is marketed and sold in the EU under the trade name XEPLION. INVEGA

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SUSTENNA/XEPLION is manufactured and commercialized worldwide by Janssen.

#### AMPYRA/FAMPYRA

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. AMPYRA was approved by the FDA as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed in January 2010 and received conditional approval in the EU in July 2011. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). It is the first and, currently, only product to be approved for this indication. The product incorporates our OCR technology. AMPYRA and FAMPYRA are manufactured by us.

#### **BYDUREON**

We collaborated with Amylin Pharmaceuticals, Inc., now a wholly-owned subsidiary of Bristol-Myers, on the development of a once-weekly formulation of exenatide, BYDUREON, which was approved by the FDA in January 2012 and received marketing authorization in the EU in June 2011 for the treatment of type 2 diabetes. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology. Through their diabetes collaboration, Bristol-Myers and AstraZeneca co-develop and market Amylin s portfolio of products, including BYDUREON. BYDUREON is manufactured by Bristol-Myers.

### **VIVITROL**

VIVITROL is the first and only once-monthly injectable medication approved by the FDA for the treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification. The FDA approved VIVITROL for the treatment of alcohol dependence in April 2006 and for the prevention of relapse to opioid dependence, following opioid detoxification in October 2010. The medication uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently market and sell, VIVITROL in the U.S., and Cilag sells VIVITROL in Russia and the CIS where it was approved for the treatment of alcohol dependence in 2008 and for opioid dependence in 2011. VIVITROL is manufactured by us.

### Other Commercial Products

We expect that revenues from our other commercial products will decrease in the future due to existing and expected competition from generic manufacturers, as discussed in greater detail herein and within Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report, which has been filed with the SEC.

#### KEY DEVELOPMENT PROGRAMS

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

We are studying aripiprazole lauroxil for the treatment of schizophrenia. Aripiprazole lauroxil is designed to provide once-monthly dosing of a medication that converts *in vivo* into aripiprazole, a molecule that is commercially available under the name ABILIFY®. Aripiprazole lauroxil is our first product candidate to leverage our proprietary LinkeRx® product platform. A phase 3 trial designed to assess the efficacy, safety and tolerability of aripiprazole lauroxil in approximately 690 patients experiencing acute exacerbation of schizophrenia is currently on-going, and the clinical data from this study, expected in the first half of calendar-year 2014, will form the basis of a New Drug Application (NDA) to the FDA for aripiprazole lauroxil for the treatment of schizophrenia.

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

ALKS 5461 is a combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for the treatment of major depressive disorder (MDD) in patients who have an inadequate response to standard antidepressant therapies. In April 2013, we announced positive results from a phase 2 study conducted in patients with MDD and inadequate response to standard therapies. In the phase 2 study, ALKS 5461 met its primary endpoint, met key secondary endpoints and demonstrated significant reduction in depressive symptoms versus placebo. Based on these results, as well as positive phase 1/2 results previously reported, we plan to meet with the FDA and to advance ALKS 5461 into a pivotal development program in early calendar-year 2014.

ZOHYDRO ER (hydrocodone bitartrate extended-release capsule) is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. ( Zogenix ) for the U.S. market. ZOHYDRO ER utilizes our oral

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controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. We have also entered into a license and distribution agreement with Paladin Labs Inc. in respect of ZOHYDRO ER in Canada. We have maintained all rights to the product in territories outside the U.S. and Canada and expect to seek to develop and license the product through commercial partnerships in those territories.

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

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

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

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

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

Line extensions for BYDUREON are in development by Bristol-Myers. These line extensions include a dual-chamber pen device and weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres.

# **Results of Operations**

Manufacturing and Royalty Revenues

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators—sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues earned in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012:

	Three Months Ended June 30,				Change Favorable/		
(In millions)		2013		2012	(Ur	favorable)	
Manufacturing and royalty							
revenues:							
RISPERDAL CONSTA	\$	34.4	\$	36.8	\$	(2.4)	
INVEGA SUSTENNA/XEPLION		21.8		11.8		10.0	
AMPYRA/FAMPYRA		19.9		17.2		2.7	
RITALIN LA/FOCALIN XR		11.2		10.9		0.3	
BYDUREON		5.4		3.0		2.4	
TRICOR 145		4.1		12.0		(7.9)	
Other		23.0		46.7		(23.7)	
Manufacturing and royalty revenues	\$	119.8	\$	138.4	\$	(18.6)	

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to a 10% decrease in the net per-unit price we received on shipments of RISPERDAL CONSTA to Janssen and a 5% decrease in royalty revenues, partially offset by a 2% increase in the number of units shipped to Janssen. The decrease in the net per-unit price is due a change in the mix of products shipped to Janssen. In the three months ended June 30, 2013, we shipped fewer units for resale in the U.S. and more units for resale in other countries, as compared to the three months ended June 30, 2012. Units shipped for resale in the U.S. have a higher selling price than units shipped for resale in other countries. The decrease in royalty revenues was due to a decrease in Janssen s end-market sales of RISPERDAL CONSTA from \$354.8 million in the three months ended June 30, 2012 to \$336.3 million in the three months ended June 30, 2013. The increase in INVEGA SUSTENNA/XEPLION royalty revenue in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was due to an increase in Janssen s end-market sales of INVEGA SUSTENNA/XEPLION from \$194.6 million in the three months ended June 30, 2012 to \$290.4 million in the three months ended June 30, 2013.

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, our long-acting atypical antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen s unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen s end-market net sales of RISPERDAL CONSTA. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION of 5% up to the first \$250 million in calendar-year net sales; 7% on calendar-year net sales of between \$250 million and \$500 million; and 9% on calendar-year net sales exceeding \$500 million. The royalty rate resets at the beginning of each calendar-year to 5%.

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to an increase in royalty revenues, which was due to an increase in end-market sales of AMPYRA/FAMPYRA in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012.

The decrease in TRICOR 145 royalty revenue in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was due to a decrease in end-market net sales of TRICOR 145 by Abbott from \$240.9 million in the three months ended June 30, 2012 to \$54.5 million in the three months ended June 30, 2013, due primarily to the introduction of a generic version of this product in November 2012.

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

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

Product Sales, net

Our product sales, net consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three months ended June 30, 2013 and 2012:

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	Three Months Ended June 30,						
(In millions)	2013		% of Sales		2012	% of Sales	
Product sales, gross	\$	24.3	100.0%	\$	17.7	100.0%	
Adjustments to product sales,							
gross:							
Medicaid rebates		(1.8)	(7.4)%		(1.3)	(7.3)%	
Chargebacks		(1.7)	(7.0)%		(1.3)	(7.3)%	
Co-pay assistance		(1.3)	(5.3)%		(0.6)	(3.4)%	
Other		(2.1)	(8.6)%		(2.1)	(11.9)%	
Total adjustments		(6.9)	(28.3)%		(5.3)	(29.9)%	
Product sales, net	\$	17.4	71.7%	\$	12.4	70.1%	

The increase in product sales, gross for the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was due to a 37% increase in the number of units sold. The increase in Medicaid rebates, chargebacks and co-pay assistance are all primarily due to the increase in VIVITROL gross product sales. We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S.

### **Costs and Expenses**

Cost of Goods Manufactured and Sold

	Three Months Ended June 30,					Change Favorable/		
(In millions)		2013		2012	(Unfavorable)			
Cost of goods manufactured and								
sold	\$	46.0	\$	42.1	\$	(3.9)		

The increase in cost of goods manufactured and sold in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to a \$2.0 million increase in depreciation expense at our Athlone facility and a \$1.4 million increase in cost of goods manufactured for RISPERDAL CONSTA. The increase in the depreciation expense at our Athlone facility is primarily due to the acceleration of depreciation of certain of our manufacturing assets that will have no future use at the completion of the restructuring plan in the year ended December 31, 2015. The increase in the RISPERDAL CONSTA cost of goods manufactured is due to an increase in the number of units shipped to Janssen.

### Research and Development Expense

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

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

	Three Months	Ended I			Change Favorable/
(In millions)	2013	2012	(Unfavorable)		
External R&D Expenses:					
Key development programs:					
Aripiprazole lauroxil	\$ 4.7	\$	11.7	\$	7.0
ALKS 3831	2.3				(2.3)
ALKS 5461	1.8		1.6		(0.2)
ALKS 37			2.4		2.4
Other development programs	5.2		3.7		(1.5)
Total external expenses	14.0		19.4		5.4
Internal R&D expenses:					
Employee-related	13.3		12.8		(0.5)
Occupancy	2.3		1.2		(1.1)
Depreciation	2.2		1.4		(0.8)
Other	1.7		3.0		1.3
Total internal R&D expenses	19.5		18.4		(1.1)
Research and development					
expenses	\$ 33.5	\$	37.8	\$	4.3

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

The decrease in expense related to the aripiprazole lauroxil program in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to the timing of patient enrollments in our phase 3 study, which began in December 2011.

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During the three months ended June 30, 2012, our focus was on the enrollment of U.S. patients, which on average carry a higher per patient cost, as compared to ex-U.S. patient enrollments, which was our primary focus during the three months ended June 30, 2013.

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

Selling, General and Administrative Expense

	Three Mon	nded	Change Favorable/		
(In millions)	2013		2012	(Unfavo	orable)
Selling, general and administrative					
expense	\$ 32.9	\$	29.8	\$	(3.1)

The increase in selling, general and administrative (SG&A) expense for the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to a \$2.1 million increase in employee-related expenses. The increase in employee-related expenses was primarily due to an increase in headcount and an increase in share-based compensation due to an increase in the number of eligible participants in our equity plans and an increase in our stock price.

Amortization of Acquired Intangible Assets

	Three Months Ended			nded	Change	
		June 30,			Favorable/	
(In millions)		2013		2012	(Unfa	avorable)
Amortization of acquired intangible assets	\$	12.7	\$	10.4	\$	(2.3)

The intangible assets being amortized in the three months ended June 30, 2013 and 2012 were acquired as part of the acquisition of Elan Drug Technologies (EDT) in September 2011. In connection with the acquisition of EDT, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which were expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at June 30, 2013 is expected to be approximately \$40.0 million for the nine months ended December 31, 2013, and \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the years ended December 31, 2015 through 2018, respectively.

Restructuring

On April 4, 2013, we approved a restructuring plan at our Athlone, Ireland manufacturing facility consistent with the evolution of our product portfolio and designed to improve operational performance in the future. Under the restructuring plan, we will terminate manufacturing services for certain older products becoming uneconomic to produce due to decreasing demand from our customers resulting from generic competition. We expect to continue to generate revenues from the manufacturing of these products during the nine months ending December 31, 2013 and, for certain of these products, into the year ending December 31, 2015.

As a result of the termination of these services, we expect a corresponding reduction in headcount of up to 130 employees. The restructuring plan commenced on March 31, 2013 and will be implemented over a period of approximately two years. During the year ended March 31, 2013, we recorded a one-time restructuring charge, expected to be settled in cash payments, consisting solely of severance and other employee-related expenses of \$12.3 million. During the three months ended June 30, 2013, we reduced the restructuring accrual by \$0.2 million primarily due to payments to our former employees. We expect the restructuring plan will result in annual cost savings of between \$15.0 and \$20.0 million by the year ending December 31, 2016 and beyond. As part of the restructuring plan, we expect to incur non-cash charges resulting from the acceleration of depreciation of certain of our manufacturing assets of \$7.5 million in the nine months ending December 31, 2013 and \$7.8 million in the year ending December 31, 2014.

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Other (Expense), Net

		Change Favorable/			
(In millions)		2013	2012	(Unfa	vorable)
Interest income	\$	0.2	\$ 0.3	\$	(0.1)
Interest expense		(3.5)	(10.2)		6.7
Other (expense) income, net		(0.2)	0.9		(1.1)
Total other (expense), net	\$	(3.5)	\$ (9.0)	\$	5.5

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

## **Liquidity and Financial Condition**

Our financial condition is summarized as follows:

(In millions)	June 30, 2013	March 31, 2013
Cash and cash equivalents	\$ 116.4	\$ 97.0
Investments short-term	112.2	124.4
Investments long-term	96.4	82.8
Total cash, cash equivalents and investments	\$ 325.0	\$ 304.2
Working capital	\$ 349.5	\$ 322.7
Outstanding borrowings current and long-term	\$ 367.4	\$ 369.0

Sources and Uses of Cash

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

Information about our cash flows, by category, is presented in the condensed consolidated statements of cash flows. The following table summarizes our cash flows for the three months ended June 30, 2013 and 2012:

	Three Months Ended June 30,					
(In millions)		2013		2012		
Cash and cash equivalents, beginning of						
period	\$	97.0	\$	83.6		
Cash provided by (used in) operating						
activities		12.7		(4.7)		
Cash (used in) provided by investing						
activities		(5.4)		9.4		
Cash provided by (used in) financing						
activities		12.1		(2.7)		
Cash and cash equivalents, end of period	\$	116.4	\$	85.6		

The increase in cash flows provided by operating activities in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to an increase in cash provided from working capital of \$35.2 million. The increase in cash provided from working capital was primarily due to a decrease in our accounts receivable of \$33.3 million, partially offset by a decrease in cash provided from net income of \$17.7 million. The decrease in cash provided from net income was partially due to a \$15.1 million decrease in net income.

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The increase in cash flows used in investing activities in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to an increase in the net purchase of investments of \$17.8 million, partially offset by a decrease in cash used to purchase property, plant and equipment of \$3.1 million.

The increase in cash flows provided by financing activities in the three months ended June 30, 2013, as compared to the three months ended June 30, 2012, was primarily due to a \$13.7 million increase in cash received from our employees upon the exercise of stock awards and a \$7.1 million increase in the excess tax-benefit from share-based compensation. This was partially offset by an increase in employee taxes paid related to the net share settlement of equity awards in the amount of \$5.2 million.

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

		A	Amortized		<b>Gross Unrealized</b>		Estimated
(In millions)			Cost	Gains	]	Losses	Fair Value
Investments	short-term	\$	112.1	\$	\$	\$	112.1
Investments	long-term available-for-sale		95.8			(0.5)	95.3
Investments	long-term held-to-maturity		1.2				1.2
Total		\$	209.1	\$	\$	(0.5) \$	208.6

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

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At June 30, 2013, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

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

#### **Borrowings**

At June 30, 2013, our borrowings consisted of a term loan facility with an outstanding principal balance of \$369.9 million. Please refer to Note 10 *Long-Term Debt* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of our outstanding long-term

debt.	

Contractual Obligations

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

Off-Balance Sheet Arrangements

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

Critical Accounting Estimates

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

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New Accounting Standards

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

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

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks since March 31, 2013, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management s objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products as well as certain operating costs arising from expenses and payables at our Irish operations that are settled in Euro. These foreign currency exchange rate risks are summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since March 31, 2013.

## Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act ), on June 30, 2013. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2013 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported 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.

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#### PART II. OTHER INFORMATION

## Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various Paragraph IV litigation in the U.S. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations, cash flows or financial position.

## Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in our Annual Report. For a further discussion of our Risk Factors, refer to Part I, Item 1A *Risk Factors* of our Annual Report.

## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the quarter ended June 30, 2013. As of June 30, 2013, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million under this program.

## Item 5. Other Information

The Company s policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2013, Mr. Paul J. Mitchell, a director of the Company, and Mr. Gordon G. Pugh, an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1 and the Company s policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

## Item 6. Exhibits

(a) List of Exhibits:

# Exhibit No. 31.1 Rule 13a-14(a)/15d-14(a) Certification. 31.2 Rule 13a-14(a)/15d-14(a) Certification. 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith). 101 The following materials from Alkermes plc s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the

Condensed Consolidated Financial Statements (furnished herewith).

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## **SIGNATURES**

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

# ALKERMES plc

(Registrant)

By: /s/ Richard F. Pops

Chairman and Chief Executive

Officer

(Principal Executive Officer)

By: /s/ James M. Frates

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting

Officer)

Date: July 25, 2013