

Alkermes plc.  
Form 10-Q  
February 02, 2012  
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 December 31, 2011

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)

**Ireland**

(State or other jurisdiction of incorporation or organization)

**98-1007018**

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

Edgar Filing: Alkermes plc. - Form 10-Q

**Treasury Building, Lower Grand Canal Street  
Dublin 2, Ireland**

(Address of principal executive offices)

**+ 353-1-772-8000**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

The number of shares of the issuer's Common Stock, \$0.01 par value, outstanding as of January 30, 2012, was 129,736,507 shares.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES  
QUARTERLY REPORT ON FORM 10-Q  
FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2011**

		<b>Page No.</b>
	<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u>	3
	<u>Condensed Consolidated Balance Sheets December 31, 2011 and March 31, 2011</u>	3
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss For the Three and Nine Months Ended December 31, 2011 and 2010</u>	4
	<u>Condensed Consolidated Statement of Shareholders Equity For the Nine Months Ended December 31, 2011</u>	5
	<u>Condensed Consolidated Statements of Cash Flows For the Nine Months Ended December 31, 2011 and 2010</u>	6
	<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	35
<u>Item 4.</u>	<u>Controls and Procedures</u>	36
	<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	37
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>Item 5.</u>	<u>Other Information</u>	37
<u>Item 6.</u>	<u>Exhibits</u>	37
<u>Signatures</u>		38
Exhibit Index		
	Ex-31.1 Section 302 Certification of Chief Executive Officer	
	Ex-31.2 Section 302 Certification of Chief Financial Officer	
	Ex-32.1 Section 906 Certification of Chief Executive Officer and Chief Financial Officer	
	Ex-101 Instance Document	
	Ex-101 Schema Document	
	Ex-101 Calculation Linkbase Document	
	Ex-101 Labels Linkbase Document	
	Ex-101 Definition Linkbase Document	
	Ex-101 Presentation Linkbase Document	

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

	December 31, 2011		March 31, 2011
	(In thousands, except share and per share amounts)		
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	\$ 85,331	\$	38,394
Investments short-term	128,096		162,928
Receivables	104,684		22,969
Inventory	46,109		20,425
Prepaid expenses and other current assets	10,916		8,244
Total current assets	375,136		252,960
PROPERTY, PLANT AND EQUIPMENT, NET	302,612		95,020
INTANGIBLE ASSETS, NET	675,287		
GOODWILL	105,700		
INVESTMENTS LONG-TERM	20,525		93,408
OTHER ASSETS	26,567		11,060
<b>TOTAL ASSETS</b>	<b>\$ 1,505,827</b>	<b>\$</b>	<b>452,448</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Accounts payable and accrued expenses	\$ 88,976	\$	44,934
Deferred revenue current	5,120		3,123
Long-term debt current	3,100		
Total current liabilities	97,196		48,057
LONG-TERM DEBT	441,668		
DEFERRED REVENUE LONG-TERM	4,697		4,837
DEFERRED TAX LIABILITIES LONG-TERM	48,969		
OTHER LONG-TERM LIABILITIES	8,444		7,536
Total liabilities	600,974		60,430
<b>COMMITMENTS AND CONTINGENCIES (Note 15)</b>			
<b>SHAREHOLDERS EQUITY:</b>			
Preferred stock, par value, \$0.01 per share; 50,000,000 and zero shares authorized; none issued and outstanding at December 31, 2011 and March 31, 2011, respectively			
Common stock, par value, \$0.01 per share; 450,000,000 and 160,000,000 shares authorized; 129,774,455 and 105,771,507 shares issued; 129,747,422 and 95,702,299 shares outstanding at December 31, 2011 and March 31, 2011, respectively	1,296		1,055
Non-voting common stock, par value, \$0.01 per share; none and 450,000 shares authorized; none and 382,632 shares issued and outstanding at December 31, 2011 and March 31, 2011, respectively			4

Edgar Filing: Alkermes plc. - Form 10-Q

Treasury stock, at cost (27,033 and 10,069,208 shares at December 31, 2011 and March 31, 2011, respectively)	(417)	(131,095)
Additional paid-in capital	1,368,444	936,295
Accumulated other comprehensive loss	(2,921)	(3,013)
Accumulated deficit	(461,549)	(411,228)
Total shareholders' equity	904,853	392,018
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 1,505,827</b>	<b>\$ 452,448</b>

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

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

(unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2011	2010	2011	2010
	(In thousands, except per share amounts)			
<b>REVENUES:</b>				
Manufacturing and royalty revenues	\$ 112,780	\$ 35,932	\$ 215,759	\$ 114,363
Product sales, net	10,597	7,729	30,170	20,402
Research and development revenue	2,266	314	13,575	737
Total revenues	125,643	43,975	259,504	135,502
<b>EXPENSES:</b>				
Cost of goods manufactured and sold	42,752	12,860	76,501	39,436
Research and development	40,493	22,503	96,703	69,412
Selling, general and administrative	35,469	20,521	103,200	58,683
Amortization of acquired intangible assets	11,896		13,713	
Total expenses	130,610	55,884	290,117	167,531
OPERATING LOSS	(4,967)	(11,909)	(30,613)	(32,029)
<b>OTHER (EXPENSE) INCOME, NET:</b>				
Interest income	350	650	1,235	2,175
Interest expense	(10,458)		(18,019)	(3,298)
Other income (expense), net	345	(83)	770	(266)
Total other (expense) income, net	(9,763)	567	(16,014)	(1,389)
LOSS BEFORE INCOME TAXES	(14,730)	(11,342)	(46,627)	(33,418)
INCOME TAX PROVISION (BENEFIT)	98	41	3,694	(960)
NET LOSS	\$ (14,828)	\$ (11,383)	\$ (50,321)	\$ (32,458)
<b>LOSS PER COMMON SHARE:</b>				
Basic and diluted	\$ (0.11)	\$ (0.12)	\$ (0.46)	\$ (0.34)
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				
Basic and diluted	129,670	95,667	109,645	95,502
<b>COMPREHENSIVE LOSS:</b>				
Net loss	\$ (14,828)	\$ (11,383)	\$ (50,321)	\$ (32,458)
<b>Unrealized gains (losses) on marketable securities:</b>				
Holding gains (losses), net of tax	27	(516)	368	431
Unrealized gains (losses) on marketable securities	27	(516)	368	431
Unrealized losses on derivative contracts	(33)		(276)	
COMPREHENSIVE LOSS	\$ (14,834)	\$ (11,899)	\$ (50,229)	\$ (32,027)

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

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(unaudited)

	Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount	Shares	Amount		(Loss)		Shares	Amount	
	(In thousands, except share data)									
<b>BALANCE</b>										
March 31, 2010	104,815,328	\$ 1,047	382,632	\$ 4	\$ 910,326	\$ (3,392)	\$ (365,688)	(9,945,265)	\$ (129,681)	\$ 412,616
Issuance of common stock under employee stock plans	580,313	4			594					598
Receipt of Alkermes stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards					1,384			(121,550)	(1,384)	
Share-based compensation expense					15,131					15,131
Unrealized gains on marketable securities, net of tax of \$255						431				431
Net loss							(32,458)			(32,458)
<b>BALANCE</b>										
December 31, 2010	105,395,641	\$ 1,051	382,632	\$ 4	\$ 927,435	\$ (2,961)	\$ (398,146)	(10,066,815)	\$ (131,065)	\$ 396,318
<b>BALANCE</b>										
March 31, 2011	105,771,507	\$ 1,055	382,632	\$ 4	\$ 936,295	\$ (3,013)	\$ (411,228)	(10,069,208)	\$ (131,095)	\$ 392,018
Issuance of common stock to Elan Corporation, plc in connection with the purchase of Elan Drug Technologies	31,900,000	319			524,755					525,074
Issuance of common stock under employee stock plans	1,960,347	20			13,031					13,051
Receipt of Alkermes stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards					3,522			(197,856)	(3,522)	
					21,812					21,812

Edgar Filing: Alkermes plc. - Form 10-Q

Share-based compensation expense									
Excess tax benefit from share-based compensation				3,127					3,127
Conversion of non-voting common stock to common stock	382,632	4	(382,632)	(4)					
Cancellation of treasury stock	(10,240,031)	(102)		(134,098)			10,240,031	134,200	
Unrealized gains on marketable securities, net of tax of \$199					368				368
Unrealized loss on cash flow hedge, net of tax of \$145					(276)				(276)
Net loss						(50,321)			(50,321)
BALANCE									
December 31, 2011	129,774,455	\$ 1,296	\$	\$ 1,368,444	\$ (2,921)	\$ (461,549)	(27,033)	\$	(417) \$ 904,853

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



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended December 31,	
	2011	2010
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (50,321)	\$ (32,458)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	27,251	6,210
Share-based compensation expense	21,743	15,196
Deferred income taxes	(11,239)	
Other non-cash charges	2,664	2,273
Changes in assets and liabilities, excluding the effect of acquisitions:		
Receivables	(22,050)	1,147
Inventory, prepaid expenses and other assets	(8,052)	4,059
Accounts payable and accrued expenses	20,844	(4,928)
Deferred revenue	1,398	1,007
Other long-term liabilities		(75)
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal attributable to original issue discount		(6,611)
Cash flows used in operating activities	(17,762)	(14,180)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment	(8,859)	(8,029)
Sales of property, plant and equipment	3	260
Acquisition of Elan Drug Technologies, net of cash acquired	(494,774)	
Investment in Acceleron Pharmaceuticals, Inc.	(231)	(501)
Purchases of investments	(159,322)	(324,143)
Sales and maturities of investments	267,604	349,546
Cash flows (used in) provided by investing activities	(395,579)	17,133
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of common stock for share-based compensation arrangements	13,051	1,982
Excess tax benefit from share-based compensation	3,127	
Proceeds from the issuance of long-term debt	444,100	
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal		(45,397)
Cash flows provided by (used in) financing activities	460,278	(43,415)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>46,937</b>	<b>(40,462)</b>
<b>CASH AND CASH EQUIVALENTS</b> Beginning of period	<b>38,394</b>	<b>79,324</b>
<b>CASH AND CASH EQUIVALENTS</b> End of period	<b>\$ 85,331</b>	<b>\$ 38,862</b>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 2,139	\$ 550
Investment in Civitas Therapeutics, Inc.	\$ 1,547	\$ 1,320

See Note 3 for supplemental disclosure of non-cash investing activities.

Edgar Filing: Alkermes plc. - Form 10-Q

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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1. THE COMPANY**

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

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business ( EDT ) of Elan Corporation, plc ( Elan ) were combined (this combination is referred to as the Business Combination , the acquisition of EDT or the EDT acquisition ) in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the historical financial statements of Alkermes, Inc. are included in the comparative prior periods. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of the Company, merged with and into Alkermes, Inc. (the Merger ), with Alkermes, Inc. surviving as a wholly owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company. At the effective time of the Merger, (i) each share of Alkermes, Inc. common stock then issued and outstanding and all associated rights were canceled and automatically converted into the right to receive one ordinary share of the Company; (ii) all then issued and outstanding options to purchase Alkermes, Inc. common stock granted under any stock option plan were converted into options to purchase, on substantially the same terms and conditions, the same number of ordinary shares of the Company at the same exercise price; and (iii) all then issued and outstanding awards of Alkermes, Inc. common stock were converted into awards of the same number, on substantially the same terms and conditions, of ordinary shares of the Company. As a result, upon consummation of the Merger and the issuance of the ordinary shares of the Company in exchange for the canceled shares of Alkermes, Inc. common stock, the former shareholders of Alkermes, Inc. owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan pursuant to the terms of a shareholder s agreement.

Use of the terms such as us, we, our, Alkermes or the Company in this Quarterly Report on Form 10-Q is meant to refer to Alkermes plc and its subsidiaries, except when the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market under the symbol ALKS.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of Presentation*

The accompanying condensed consolidated financial statements of Alkermes for the three and nine months ended December 31, 2011 and 2010 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2011. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all

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

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, Inc. which are contained, or incorporated by reference, in Alkermes, Inc. s Annual Report on Form 10-K for the year ended March 31, 2011, as amended, and the audited financial statements and notes thereto, which has been filed with the U.S. Securities and Exchange Commission ( SEC ) and Alkermes Registration Statement on Form S-4, as amended (Registration No. 333-175078), which was declared effective by the SEC on August 4, 2011. 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.

### *Principles of Consolidation*

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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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.

*Risk-management Instruments*

On September 16, 2011, the Company entered into a \$310.0 million first lien term loan facility (the "First Lien Term Loan") and a \$140.0 million second lien term loan facility (the "Second Lien Term Loan" and, together with the First Lien Term Loan, the "Term Loans"). Interest on the Term Loans is at a rate equal to an applicable margin plus three-month LIBOR. The Company addressed its risk to exposure to fluctuations in interest rates by entering into certain derivative financial instruments, the objective of which is to limit the impact of fluctuations in interest rates on earnings. The Company's derivative activities are initiated within the guidelines of documented corporate risk management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the liabilities being hedged.

During the nine months ended December 31, 2011, the Company entered into an interest rate swap contract that was designated and qualified as a cash flow hedge. The Company reviews the effectiveness of its derivatives on a quarterly basis. The effective portion of gains or losses on the Company's cash flow hedge is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings.

During the nine months ended December 31, 2011, the Company entered into two interest rate cap contracts that were not designated as hedging instruments. The interest rate caps are recorded at fair value with associated gains or losses recognized in other income/(expense) during the period of change.

*Segment Information*

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

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.

### *Business Acquisitions*

The Company's condensed consolidated financial statements include the operations of an acquired business after the completion of the acquisition. The Company accounts for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired in-process research and development (IPR&D) be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved. Changes in fair value are recognized in earnings.

### *Goodwill and Intangible Assets*

Goodwill represents the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. The Company's goodwill balance solely relates to the EDT acquisition in the fiscal year ended March 31, 2012, as described in Note 3, *Acquisitions*. Goodwill is not amortized but is tested for impairment annually or when events or circumstances indicate the fair value of a reporting unit may be below its carrying value. A reporting unit is an operating segment or sub-segment to which goodwill is assigned when initially recorded.

In September 2011, the Financial Accounting Standards Board (FASB) issued guidance related to testing goodwill for impairment. This accounting standard allows an entity to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. An entity can choose to perform the qualitative assessment on none, some or all of its reporting units. Moreover, an entity can bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the impairment test, and then resume performing the qualitative assessment in any subsequent period. This standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. However, an entity can choose to early adopt the standard if its annual test date is before the issuance of the final standard, provided that the entity has not yet performed its 2011 annual impairment test or issued its financial statements. The Company chose to early adopt the provisions of this standard as it had not yet performed its annual impairment test, which the Company performs as of October 31 each year. The adoption of this standard did not impact the Company's financial position or results of operations. As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of the Company's goodwill was not recorded.

The Company's finite-lived intangible assets consist of core developed technology and collaboration agreements and are recorded at fair value at the time of their acquisition and are stated within its condensed consolidated balance sheets net of accumulated amortization and impairments. The finite-lived intangible assets are amortized over their estimated useful life 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. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent. IPR&D represents the fair value assigned to research and development assets that were acquired prior to its completion. IPR&D is considered an indefinite-lived asset and is not amortized but is tested for impairment annually or when events or circumstances indicate the fair value may be below its carrying value. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. The Company's intangible assets were all acquired as part of the EDT acquisition in the fiscal year ended March 31, 2012, as described in Note 3, *Acquisitions*.

*Foreign Currency*

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within Other income (expense) in the accompanying condensed consolidated statement of operations and comprehensive loss.

*New Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the 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 January 2010, the Company adopted accounting guidance issued by the FASB related to fair value measurements that requires additional disclosure related to transfers in and out of Levels 1 and 2 of the fair value hierarchy. In addition, effective for the Company beginning on April 1, 2011, this standard further requires an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount. As this accounting standard only requires enhanced disclosure, the adoption of this newly issued accounting standard did not impact the Company's financial position or results of operations.

On April 1, 2011, the Company prospectively adopted the accounting guidance related to the milestone method of revenue recognition for research and development arrangements. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various licensing and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone, or the increase in value to the collaboration resulting from the Company's performance, relates solely to the Company's past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The Company's license and collaboration agreements with its partners provide for payments to the Company upon the achievement of development milestones, such as the completion of clinical trials or regulatory approval for drug candidates. As of April 1, 2011, the Company's agreements with partners included potential future payments for development milestones aggregating \$17.0 million. Given the challenges inherent in developing and obtaining approval for pharmaceutical



Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time these licensing and collaboration agreements were entered into. In addition, the Company evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of the Company's analysis, the Company considers its development milestones to be substantive and, accordingly, the Company expects to recognize as revenue future payments received from such milestones as it achieves each milestone. The election to adopt the milestone method did not impact the Company's historical financial position at April 1, 2011. This policy election may result in revenue recognition patterns for future milestones that are materially different from those recognized for milestones received prior to adoption. During the nine months ended December 31, 2011, the Company recognized into revenue \$3.0 million upon the achievement of developmental milestones during this period. During the nine months ended December 31, 2011, the Company recognized into revenue an aggregate of \$8.0 million upon the achievement of milestones where there were no remaining performance obligations under the associated agreements.

Milestone payments received prior to April 1, 2011 from arrangements where the Company has continuing performance obligations have been deferred and are recognized through the application of a proportional performance model where the milestone payment is recognized over the related performance period or, in full, when there are no remaining performance obligations. The Company makes its best estimate of the period of time for the performance period. The Company will continue to recognize milestone payments received prior to April 1, 2011 in this manner. As of December 31, 2011, the Company has deferred revenue of \$5.0 million from milestone payments received prior to April 1, 2011 that will be recognized ratably through 2018.

In June 2011, the FASB issued guidance related to the presentation of comprehensive income. This accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this accounting standard do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact the Company's financial position or results of operations.

**3. ACQUISITIONS**

On September 16, 2011, the Company acquired EDT from Elan in a transaction accounted for under the acquisition method of accounting for business combinations, in exchange for \$500.0 million in cash and 31.9 million ordinary shares of Alkermes, valued at \$525.1 million based on a stock price of \$16.46 per share on the acquisition date. Under the acquisition method of accounting, the assets acquired and liabilities assumed were recorded as of the acquisition date, at their respective fair values. The reported consolidated financial condition and results of operations after completion of the acquisition reflect these fair values. EDT's results of operations are included in the consolidated financial statements from the date of acquisition.

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

Prior to the acquisition, EDT, which was a division of Elan, developed and manufactured pharmaceutical products that deliver clinical benefits to patients using EDT's experience and proprietary drug technologies in collaboration with other pharmaceutical companies worldwide. EDT's two principal drug technology platforms are the oral controlled release platform (OCR) and the bioavailability enhancement platform, including EDT's *NanoCrystal*® technology. The Company acquired EDT to diversify its commercialized product portfolio and pipeline candidates, enhance its financial resources in order to invest in its proprietary drug candidates, pursue additional growth opportunities and reduce its cost of capital.

During the nine months ended December 31, 2011, the Company incurred approximately \$26.7 million in expenses related to the EDT acquisition, which primarily consist of banking, legal, accounting and valuation-related expenses. These expenses have been recorded within Selling, general and administrative expense in the accompanying condensed consolidated statement of operations and comprehensive loss. During the three and nine months ended December 31, 2011, the Company's results of operations included revenues of \$74.4 million and \$83.4 million and net income of \$14.2 million and \$14.9 million from the acquired EDT business.

The purchase price of the EDT business was as follows (in thousands):

Upfront payment in accordance with the merger agreement	\$	500,000
Equity consideration in accordance with the merger agreement		525,074
Total purchase price	\$	1,025,074

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below (in thousands):

Cash	\$	5,225
Receivables		59,398
Inventory		29,669
Prepaid expenses and other current assets		1,806
Property plant and equipment		210,558
Acquired identifiable intangible assets		689,000
Goodwill		105,700
Other assets		4,360
Accounts payable and accrued expenses		(19,851)
Deferred tax liabilities		(60,207)
Other long-term liabilities		(584)
Total	\$	1,025,074

Asset categories acquired in the EDT acquisition included working capital, long-term assets and liabilities, fixed assets and identifiable intangible assets, including IPR&D. The allocation of the purchase price for the acquisition has been prepared on a preliminary basis and changes to that allocation may occur as additional information becomes available. During the three months ended December 31, 2011, the Company recorded an increase to goodwill of \$0.7 million as a result of changes to the acquisition-date fair value of working capital, property, plant and equipment and acquired identifiable intangible asset accounts.

The intangible assets acquired include the following (in thousands):

Collaboration agreements	\$	499,700
NanoCrystal technology		74,600
OCR technology		66,300
In-process research and development		45,800
Trademark		2,600
Total	\$	689,000

Intangible assets associated with collaboration agreements relate to the several collaboration agreements EDT has in place with third-party pharmaceutical companies related to the development and commercialization of products or an improvement to existing products based on EDT's experience with drug delivery systems and their technology platforms. Intangible assets associated with IPR&D relate to various preclinical EDT product candidates. The estimated fair value for the collaboration agreements and IPR&D was determined using the excess earnings approach. The excess earnings approach includes projecting revenue and costs attributable to the associated collaboration agreement or product candidate and then subtracting the required return related to other contributory assets used in the business to determine any residual excess earnings attributable to the collaboration agreement or product candidate. The after-tax excess earnings are then discounted to present value using an appropriate discount rate. The estimated useful life of the collaboration agreements is 12 years.

The NanoCrystal and OCR technologies are platform technologies that are used in both currently marketed products and potential future products currently under development. The estimated fair value of these technologies was determined using the relief from royalty method, an approach under which fair value is estimated to be the present value of royalties saved because the Company owns the intangible assets and therefore does not have to pay a royalty for its use. The estimated useful lives of the NanoCrystal and OCR technologies are 13 and 12 years, respectively.

The estimated fair value of the EDT trademark was determined using the relief from royalty method. The Company does not expect to use the EDT trademark beyond March 31, 2012 and, as a result, the Company will amortize the full value of the trademark over the remainder of the fiscal year.

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition of EDT has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill included the synergies that are specific to the Company's business and not available to market participants, including the Company's unique ability to leverage

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

its knowledge in the areas of drug delivery and development of innovative medicines to improve patients' lives, the acquisition of a talented workforce that brings translational medicine expertise to the Company's preclinical compounds and the Company's ability to utilize its research capacity to develop additional compounds using the acquired technologies.

*Pro forma financial information (unaudited)*

The following unaudited pro forma information presents the combined results of operations for the three months ended December 31, 2010 and nine months ended December 31, 2011 and 2010 as if the acquisition of EDT had been completed on April 1, 2010. The unaudited pro forma results do not reflect any material adjustments, operating efficiencies or potential cost savings which may result from the consolidation of operations but do reflect certain adjustments expected to have a continuing impact on the combined results.

<b>(In thousands, except per share data)</b>	<b>Three Months Ended December 31, 2010</b>		<b>Nine Months Ended December 31, 2010</b>	
Revenues	\$ 122,507	\$ 368,570	\$ 333,194	
Net loss	\$ (7,683)	\$ (21,705)	\$ (31,631)	
Basic and diluted loss per common share	\$ (0.06)	\$ (0.17)	\$ (0.25)	

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year (In thousands)	Greater than One Year	
<b>December 31, 2011</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 90,420	\$ 103	\$ (1)	\$	\$ 90,522
International government agency debt securities	20,580	47	(14)		20,613
Corporate debt securities	11,065	41			11,106
	122,065	191	(15)		122,241
Held-to-maturity securities:					
Certificates of deposit	4,236				4,236
U.S. government obligations	417				417
	4,653				4,653
Money market funds	1,202				1,202
Total short-term investments	127,920	191	(15)		128,096
Long-term investments:					
Available-for-sale securities:					
International government agency debt securities	11,095		(31)		11,064
Corporate debt securities	8,010			(424)	7,586
Strategic investments	644	31			675
	19,749	31	(31)	(424)	19,325
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
	1,200				1,200
Total long-term investments	20,949	31	(31)	(424)	20,525
Total investments	\$ 148,869	\$ 222	\$ (46)	\$ (424)	\$ 148,621
<b>March 31, 2011</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 117,298	\$ 129	\$ (1)	\$	\$ 117,426
Corporate debt securities	20,973	48		(4)	21,017
International government agency debt securities	23,048	236			23,284
	161,319	413	(1)	(4)	161,727
Money market funds	1,201				1,201

Edgar Filing: Alkermes plc. - Form 10-Q

Total short-term investments	162,520	413	(1)	(4)	162,928
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	57,709		(804)		56,905
International government agency debt securities	15,281		(93)		15,188
Corporate debt securities	15,140		(29)	(328)	14,783
Strategic investments	644	31			675
	88,774	31	(926)	(328)	87,551
Held-to-maturity securities:					
Certificates of deposit	5,440				5,440
U.S. government obligations	417				417
	5,857				5,857
Total long-term investments	94,631	31	(926)	(328)	93,408
Total investments	\$ 257,151	\$ 444	\$ (927)	\$ (332)	\$ 256,336

The Company's strategic investments include common stock in public companies with which the Company has or had a collaborative arrangement.

Table of Contents

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

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

(In thousands)	Nine Months Ended December 31,			
	2011		2010	
Proceeds from the sales and maturities of marketable securities	\$	267,604	\$	349,546
Realized gains	\$	37	\$	70
Realized losses	\$	(11)	\$	(31)

The Company's available-for-sale and held-to-maturity securities at December 31, 2011 have 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	\$ 70,038	\$ 70,107	\$ 5,853	\$ 5,853
After 1 year through 5 years	71,132	70,784		
Total	\$ 141,170	\$ 140,891	\$ 5,853	\$ 5,853

At December 31, 2011, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments with unrealized losses consist primarily of 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 and \$8.5 million at December 31, 2011 and March 31, 2011, respectively, which is 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 \$2.3 million and \$1.3 million at December 31, 2011 and March 31, 2011, respectively, which is 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 approximately 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.



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

During the three months ended December 31, 2011, Civitas issued 14.3 million shares of Series A preferred stock in exchange for \$12.5 million. The Company did not participate in the financing, however, it received 12.4% of these Series A preferred shares in accordance with the terms of its arrangement with Civitas and recorded an increase to its investment in Civitas of \$1.5 million. The Company has deferred the recognition of the gain on its investment in Civitas and will recognize it into other income, ratably over a period of approximately four years, in the Company's consolidated statement of operations. In addition, during the nine months ended December 31, 2011, the Company recorded a reduction in its investment in Civitas by \$0.6 million, which represented the Company's proportionate share of Civitas' net losses for this period.

Table of Contents

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

**5. 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)	December 31, 2011		Level 1		Level 2		Level 3	
<b>Assets:</b>								
Cash equivalents	\$	1,201	\$	1,201	\$	\$		
U.S. government and agency debt securities		90,522		90,522				
International government agency debt securities		31,677		26,682				4,995
Corporate debt securities		18,692				11,106		7,586
Strategic equity investments		675		675				
Interest rate cap contracts		111				111		
<b>Total</b>	<b>\$</b>	<b>142,878</b>	<b>\$</b>	<b>119,080</b>	<b>\$</b>	<b>11,217</b>	<b>\$</b>	<b>12,581</b>
<b>Liabilities:</b>								
Interest rate swap contract	\$	(421)	\$		\$	(421)	\$	
<b>Total</b>	<b>\$</b>	<b>(421)</b>	<b>\$</b>		<b>\$</b>	<b>(421)</b>	<b>\$</b>	

(In thousands)	March 31, 2011		Level 1		Level 2		Level 3	
<b>Assets:</b>								
Cash equivalents	\$	1,303	\$	1,303	\$	\$		
U.S. government and agency debt securities		174,331		174,331				
Corporate debt securities		35,801				34,754		1,047
International government agency debt securities		38,471		38,471				
Strategic equity investments		675		675				
<b>Total</b>	<b>\$</b>	<b>250,581</b>	<b>\$</b>	<b>214,780</b>	<b>\$</b>	<b>34,754</b>	<b>\$</b>	<b>1,047</b>

There were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended December 31, 2011. The following table illustrates the rollforward of the fair value of the Company's investments whose fair value is determined using Level 3 inputs:

(In thousands)	Fair Value	
Balance, April 1, 2011	\$	1,047
Investments transferred into Level 3		11,603
Total unrealized losses included in comprehensive loss		(69)
Balance, December 31, 2011	\$	12,581

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

During the nine months ended December 31, 2011, there were two investments in corporate debt securities transferred into Level 3 from Level 2 as trading in these securities ceased during the period. Also, during the nine months ended December 31, 2011, there was one investment in an international government agency debt security transferred into Level 3 from Level 1 as trading in this security ceased during the period.

In September and December 2011, the Company entered into interest rate cap agreements, and in September 2011, the Company entered into an interest rate swap agreement. 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.

Substantially all of the Company's corporate debt securities have been classified as Level 2. These securities 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.

Table of Contents

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

The Company used a discounted cash flow model to determine the estimated fair value of its Level 3 securities. The assumptions used in the discounted cash flow model included estimates for interest rates, timing of cash flows, expected holding periods and risk-adjusted discount rates, which include provisions for default and liquidity risk, which the Company believes to be the most critical assumptions utilized within the analysis.

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 consist of the Term Loans. The estimated fair value of the Term Loans, which was based on quoted market price indications, is as follows:

(In thousands)	Carrying Value	Estimated Fair Value
First Lien Term Loan	\$ 307,314	\$ 308,838
Second Lien Term Loan	\$ 137,454	\$ 138,600

**6. INVENTORY**

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

(In thousands)	December 31, 2011	March 31, 2011
Raw materials	\$ 14,259	\$ 3,100
Work in process	12,141	5,843
Finished goods (1)	19,209	11,127
Consigned-out inventory (2)	500	355
Total inventory	\$ 46,109	\$ 20,425

- 
- (1) At December 31, 2011 and March 31, 2011, the Company had \$1.2 million and \$2.0 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.
- (2) At December 31, 2011 and March 31, 2011, consigned-out inventory relates to VIVITROL® inventory in the distribution channel for which the Company has not recognized revenue.

**7. PROPERTY, PLANT AND EQUIPMENT**

Edgar Filing: Alkermes plc. - Form 10-Q

Property, plant and equipment consist of the following:

<b>(In thousands)</b>	<b>December 31,</b>		<b>March 31,</b>	
	<b>2011</b>		<b>2011</b>	
Land	\$	7,681	\$	301
Building and improvements		140,488		36,792
Furniture, fixture and equipment		176,415		62,660
Leasehold improvements		45,762		44,779
Construction in progress		37,271		42,194
Subtotal		407,617		186,726
Less: accumulated depreciation		(105,005)		(91,706)
Total property, plant and equipment, net	\$	302,612	\$	95,020

Table of Contents

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

**8. GOODWILL AND INTANGIBLE ASSETS**

Intangible assets consist of the following:

(In thousands)	Weighted Amortizable Life	Gross Carrying Amount	December 31, 2011	
			Accumulated Amortization	Net Carrying Amount
<b>Finite-lived intangible assets:</b>				
Collaboration agreements	12	\$ 499,700	\$ (9,591)	\$ 490,109
NanoCrystal technology	13	74,600	(995)	73,605
OCR technology	12	66,300	(1,721)	64,579
Trademark		2,600	(1,406)	1,194
Total finite-lived intangible assets		643,200	(13,713)	629,487
<b>Indefinite-lived intangible assets:</b>				
IPR&D		45,800		45,800
Total		\$ 689,000	\$ (13,713)	\$ 675,287

The Company recorded goodwill of \$105.7 million in September 2011 in connection with the acquisition of EDT. There were no changes to the initial carrying amount of the Company's goodwill during the nine months ended December 31, 2011. The Company recorded \$13.7 million of amortization expense related to its intangible assets during the nine months ended December 31, 2011. Based upon the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheet as of December 31, 2011 is expected to be in the range of approximately \$42.0 million to \$76.0 million annually through fiscal year 2017.

As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of the Company's goodwill was not recorded.

**9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2011		March 31, 2011	
Accounts payable	\$	23,142	\$	9,269
Accrued compensation		22,652		17,481
Accrued other		43,182		18,184

Edgar Filing: Alkermes plc. - Form 10-Q

Total accounts payable and accrued expenses                   \$                   88,976   \$                   44,934

**10. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	December 31, 2011	March 31, 2011
First Lien Term Loan, due September 16, 2017	\$ 307,314	\$
Second Lien Term Loan, due September 16, 2018	137,454	
Total	444,768	
Less: current portion	(3,100)	
Long-term debt	\$ 441,668	\$

On September 16, 2011, the Company and certain of its subsidiaries, as guarantors, entered into the Term Loans with Morgan Stanley Senior Funding, Inc. ( MSSF ), as administrative agent and as collateral agent, MSSF and HSBC Securities (USA) Inc., as co-syndication agents, joint lead arrangers and joint bookrunners, and various other financial institutions, as lenders. The First Lien Term Loan was issued with an original issue discount of \$3.1 million, has a term of six years and is secured by a first priority lien on substantially all of the assets and properties of the Company and the guarantors. The Second Lien Term Loan was issued with an original issue discount of \$2.8 million, has a term of seven years and is secured by a second priority lien on substantially all of the assets and properties of the Company and the guarantors.

Table of Contents

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

Scheduled maturities with respect to the Term Loans are as follows (in thousands):

<b>Fiscal Year:</b>		
2012	\$	775
2013		3,100
2014		3,100
2015		3,100
2016		3,100
Thereafter		436,825
<b>Total</b>	<b>\$</b>	<b>450,000</b>

The initial applicable margin for borrowings under the First Lien Term Loan is three-month LIBOR plus 5.25% with respect to LIBOR borrowings and 4.25% with respect to base rate borrowings. The initial applicable margin for borrowings under the Second Lien Term Loan is three-month LIBOR plus 8.00% with respect to LIBOR borrowings and 7.00% with respect to base rate borrowings. Under each of the Term Loans, LIBOR is subject to an interest rate floor of 1.50% and the base rate is subject to an interest rate floor of 2.50%. Commencing upon the completion of the Company's first fiscal quarter ending after the Business Combination, the applicable margin under the First Lien Term Loan is subject to adjustment each fiscal quarter, based upon meeting a certain consolidated leverage ratio during the preceding quarter. The applicable margin under the Second Lien Term Loan is not subject to adjustment.

Required quarterly principal payments of \$0.8 million on the First Lien Term Loan begin on March 31, 2012. In addition, beginning in fiscal year 2013, the Company is required to make principal payments on the First Lien Term Loan for amounts up to 50% of excess cash flows as defined in the First Lien Term Loan credit agreement. The principal amount of the Second Lien Term Loan is due and payable in full on the maturity date. The Company may make prepayments of principal without penalty; however, no principal payments may be made on the Second Lien Term Loan until the First Lien Term Loan has been repaid in full. If prepayments are made prior to September 16, 2012, the Company may be subject to prepayment premium of 1% of the amount of the term loans being repaid if the prepayment is made in connection with a refinancing transaction or 1% of the amount of the outstanding term loans if the prepayment is made in connection with an amendment to the agreement resulting in a refinancing transaction.

Each of the Term Loans has incremental capacity in an amount of \$50.0 million, plus additional amounts so long as Alkermes meets certain conditions, including a specified leverage ratio. The agreements governing the Term Loans include a number of restrictive covenants that, among other things, and subject to certain exceptions and baskets, impose operating and financial restrictions on Alkermes, Inc., the Company and the restricted subsidiaries. These financing agreements also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2011.

As part of the Term Loans, the Company is required to enter into and thereafter maintain hedge agreements to the extent necessary to provide that at least 50% of the aggregate principal amount of the Term Loans is subject to either a fixed interest rate or interest rate protection for a period of not less than three years. Pursuant to this term, the Company entered into an interest rate swap agreement and interest rate cap agreements, which are discussed in greater detail in Note 11, *Derivative Instruments*.



The Company incurred \$11.8 million of offering costs associated with the issuance of the Term Loans which were recorded under the caption "Other assets" in the accompanying condensed consolidated balance sheets. The offering costs and original issue discount related to the Term Loans are being amortized to interest expense over the estimated repayment terms using the effective interest method. During the nine months ended December 31, 2011, the Company had amortization expense of \$2.1 million related to the offering costs and original issue discount.

## 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 Term Loans bear 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 gain as other income in the accompanying condensed consolidated statements of operations and comprehensive loss due to the increase in value of this contract during the three months ended December 31, 2011.

In July 2011, the Company entered into an interest rate cap agreement with HSBC Bank USA at a cost of less than \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate cap agreement became effective upon the issuance of the Term Loans, expires in December 2012, has a notional value of \$65.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss as other expense in the accompanying condensed consolidated statements of

Table of Contents

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

operations and comprehensive loss due to the decline in value of this contract during the three and nine months ended December 31, 2011.

In July 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 Term Loans bear interest. The interest rate swap agreement becomes effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. This contract has been designated as a cash flow hedge and accordingly, to the extent effective, any unrealized gains or losses on this interest rate swap contract is reported in accumulated other comprehensive loss. To the extent the hedge is ineffective, hedge transaction gains and losses are reported in other income (expense), net when the interest payment on the related debt is recognized.

The following table summarizes the fair value and presentation in the consolidated balance sheets for derivatives designated and not designated as hedging instruments:

(In thousands)	Balance Sheet Location	Fair Value at December 31, 2011
<i>Interest rate swap</i>		
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$ (421)
<i>Interest rate caps</i>		
Asset derivatives not designated as a hedging instruments	Other long-term assets	\$ 111

The following table summarizes the effect of derivatives designated as hedging instruments on the condensed consolidated statements of operations and comprehensive loss:

(In thousands)	Amount Recognized in Accumulated Other Comprehensive Loss (Effective Portion)	Amount Reclassified from Accumulated Other Comprehensive Loss into Earnings (Effective Portion)	Amount of Loss Recorded (Ineffective Portion)
December 31, 2011	\$ (421)	\$	\$

The cash flow hedge was deemed to be effective at December 31, 2011. Accordingly, the Company included the loss incurred during the three and nine months ended December 31, 2011 within accumulated other comprehensive loss. The Company expects that when this contract matures, any amounts in accumulated other comprehensive loss is to be reported as an adjustment to interest expense. The Company considers the impact of its and MSCS' credit risk on the fair value of the contract as well as the ability of each party to execute its obligations under the contract. As of December 31, 2011, credit risk did not materially change the fair value of the Company's interest rate swap contract.

**12. SHARE-BASED COMPENSATION**

Share-based compensation expense consists of the following:

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2011	2010	2011	2010
Cost of goods manufactured and sold	\$ 801	\$ 385	\$ 1,886	\$ 1,271
Research and development	2,470	1,573	6,714	4,726
Selling, general and administrative	5,760	3,834	13,143	9,199
Total share-based compensation expense	\$ 9,031	\$ 5,792	\$ 21,743	\$ 15,196

At December 31, 2011 and March 31, 2011, \$0.7 million and \$0.6 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

Table of Contents

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

**13. LOSS PER SHARE**

Basic loss per common share is calculated based upon net loss available to holders of common shares divided by the weighted average number of shares outstanding. Diluted loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of unvested restricted stock units. Common equivalent shares have not been included in the net loss per common share calculations because the effect would have been anti-dilutive.

The potential common equivalent shares consisted of the following:

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2011	2010	2011	2010
Stock options	9,033	14,499	8,323	13,614
Restricted stock units	1,164	934	1,477	878
<b>Total</b>	<b>10,197</b>	<b>15,433</b>	<b>9,800</b>	<b>14,492</b>

**14. INCOME TAXES**

The Company recorded an income tax provision of \$0.1 million and \$3.7 million for the three and nine months ended December 31, 2011, respectively, and an income tax provision of less than \$0.1 million and an income tax benefit of \$1.0 million for the three and nine months ended December 31, 2010, respectively. During the nine months ended December 31, 2011, the Company recorded a \$13.2 million current tax expense for the taxable transfer of the BYDUREONTM intellectual property from the U.S. to Ireland and a deferred tax benefit of \$10.2 million in connection with the Business Combination, as the Company recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

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 December 31, 2011, the Company determined that it is more likely than not that its U.S. and Irish deferred tax assets may not be realized and a full valuation allowance has been recorded.

**15. COMMITMENTS AND CONTINGENCIES**

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

From time to time, we may be subject to other legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of certain of our products. 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 and financial condition.

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 3 of this Quarterly Report on 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 (i) our Registration Statement on Form S-4, as amended (Registration No. 333-175078), which was declared effective by the United States ( U.S. ) Securities and Exchange Commission ( SEC ) on August 4, 2011, (the Registration Statement ) and (ii) the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2011, as amended (the Annual Report ), which has been filed with the SEC.

Alkermes plc develops medicines that address the unmet needs and challenges of people living with chronic disease. A fully integrated global biopharmaceutical company, Alkermes applies proven scientific expertise, proprietary technologies and global development capabilities to the creation of innovative treatments for major clinical conditions with a focus on central nervous system (CNS) disorders, such as schizophrenia, addiction and depression.

We create new, proprietary pharmaceutical products for our own account, and we collaborate with other pharmaceutical and biotechnology companies. We are increasingly focused on maintaining rights to commercialize our leading product candidates in certain markets. Each of these approaches is discussed in more detail in Products and Development Programs.

Our headquarters are located in Dublin, Ireland, and we operate R&D and GMP manufacturing facilities in Ireland and the U.S. Alkermes technologies are incorporated in over 20 commercial-stage products sold in over 90 countries.

Use of the terms such as us, we, our or the Company in this Management's Discussion and Analysis of Financial Condition and Results of Operations refers to Alkermes plc and its subsidiaries, except when the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ under the symbol ALKS.

**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 and Section 21E of the Securities Exchange Act of 1934. All statements, trend analyses and other information contained herein about the markets for the services and products and trends in revenue, as well as other statements identified by the use of forward-looking terminology, including may, will, could, should, would, expect, anticipate, continue, or the negative of these terms or other similar expressions, constitute forward-looking statements. These forward-looking statements are based on estimates reflecting the best judgment of senior management. These forward-looking statements involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. Forward-looking statements should therefore be considered in light of various important factors, including those set forth herein. Important factors that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include the following:

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

- 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, including the sales and marketing efforts of our partners and, for VIVITROL® (naltrexone for extended-release injectable suspension), our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements;
- our efforts and ability to evaluate and license product candidates and build our pipeline;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial 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 successful manufacture of our products, by us or our partners for commercial sale;
- the continuation of our collaborations and other significant agreements and our ability to establish and maintain successful development collaborations;
- our expectations regarding the financial impact of health care reform legislation and foreign currency exchange rate fluctuations and valuations;
- the impact of new accounting pronouncements;

Table of Contents

- our beliefs regarding Adjusted EBITDA;
- our ability to protect our intellectual property rights and the impact of patent reform legislation;
- 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;
- our expectations concerning the status, intended use, and financial impact of, and arrangements involving, our properties, including manufacturing facilities;
- our future capital requirements and capital expenditures and our ability to finance our operations and capital requirements; and
- other risk factors included herein and under "Risk Factors" in our Registration Statement and Quarterly Report on Form 10-Q for the period ended September 30, 2011.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this document and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus might not occur.

**Executive Summary**

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business ( "EDT" ) of Elan Corporation, plc ( "Elan" ) were combined (this combination is referred to as the "Business Combination", the acquisition of EDT, or the "EDT acquisition" ) under Alkermes. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of the Company, merged with and into Alkermes, Inc. (the "Merger" ), with Alkermes, Inc. surviving as a wholly owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company. We paid Elan \$500.0 million in cash and issued Elan 31.9 million ordinary shares, which had a fair value of \$525.1 million on the closing date, for the EDT business. Upon consummation of the Merger, the former shareholders of Alkermes, Inc. owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan pursuant to the terms of a shareholder's agreement.

For a more detailed discussion of the Business Combination, please refer to the notes to our condensed consolidated financial statements, including Note 1, *The Company*, and Note 3, *Acquisitions*, in the accompanying Notes to Condensed Consolidated Financial Statements.

The Business Combination is being accounted for using the acquisition method of accounting for business combinations with Alkermes, Inc. being treated as the accounting acquirer under accounting principles generally accepted in the U.S. ( "GAAP" ), which means that the operating results of Alkermes, Inc. are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition through the end of the period. Accordingly, our financial results for the nine months ended December 31, 2011 reflect the full nine months of operations of Alkermes, Inc., and the operations of the former EDT business from September 17, 2011 through December 31, 2011, together with the consolidated balance sheet as of December 31, 2011.



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

Net loss for the three months ended December 31, 2011, was \$14.8 million, or \$0.11 per common share basic and diluted, as compared to a net loss of \$11.4 million, or \$0.12 per common share basic and diluted, for the three months ended December 31, 2010. Net loss for the nine months ended December 31, 2011, was \$50.3 million, or \$0.46 per common share basic and diluted, as compared to a net loss of \$32.5 million, or \$0.34 per common share basic and diluted, for the nine months ended December 31, 2010.

Table of Contents

As a complement to GAAP results, we are also providing a non-GAAP measure of adjusted EBITDA ( Adjusted EBITDA ), which we believe better indicates underlying trends in ongoing operations. Adjusted EBITDA excludes from GAAP results the following: interest expense, taxes, depreciation and amortization, share-based compensation expense and certain noncash or nonrecurring items. For the three and nine months ended December 31, 2011, we had Adjusted EBITDA of \$29.7 million and \$45.9 million, respectively as compared to Adjusted EBITDA of \$(4.0) million and \$(8.7) million for the three and nine months ended December 31, 2010, respectively. Refer to the reconciliation of net loss as calculated under GAAP to Adjusted EBITDA under the caption *Non-GAAP Financial Measures*.

**KEY COMMERCIAL PRODUCTS**

We have five principal commercial products with long patent protection which either currently, or in the future, are expected to, contribute meaningfully to our revenues.

*RISPERDAL® CONSTA®*

RISPERDAL CONSTA (risperidone long-acting injection) is a product of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ( Janssen ), and is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration ( FDA ) for the treatment of schizophrenia and bipolar I disorder. The medication uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through one injection every two weeks. RISPERDAL CONSTA is marketed by Janssen and is sold in more than 90 countries, and is exclusively manufactured by us. We earn manufacturing revenues and royalties on worldwide sales of RISPERDAL CONSTA.

*INVEGA® SUSTENNA®/XEPLION®*

INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension is a product of Janssen and was approved in July 2009 in the U.S. for the acute and maintenance treatment of schizophrenia in adults. It is the first once-monthly, long-acting, injectable atypical antipsychotic approved for this use in the U.S. The medication 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 is manufactured and commercialized by Janssen. Paliperidone palmitate extended-release for injectable suspension is also approved in the European Union ( EU ) and other countries worldwide, and is commercialized in the EU under the trade name XEPLION. We earn royalties on worldwide sales of INVEGA SUSTENNA and XEPLION.

*AMPYRA®/FAMPYRA®*

Dalfampridine, marketed and sold in the U.S. under the trade name AMPYRA and outside the U.S. under the trade name FAMPYRA, was approved by the FDA in January 2010 as a treatment to improve walking in patients with multiple sclerosis ( MS ). It is the first and currently only product to be approved for this indication. A product of Acorda Therapeutics, Inc. ( Acorda ), it incorporates our OCR technology. AMPYRA and FAMPYRA are manufactured by us and are marketed in the U.S. by Acorda and outside the U.S. by Biogen Idec, Inc.

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

FAMPYRA received conditional marketing approval in the EU in July 2011 and is currently being sold in select European countries, as well as Australia. We earn manufacturing revenues and royalties on worldwide sales of AMPYRA/FAMPYRA.

### *VIVITROL*

We developed, manufacture and commercialize VIVITROL as the first and only once-monthly injectable medication for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL was approved by the FDA in April 2006 for the treatment of alcohol dependence and was launched in the U.S. in June 2006. VIVITROL was approved for the prevention of relapse to opioid dependence following opioid detoxification in October 2010. We exclusively licensed the rights to commercialize VIVITROL in Russia and the Commonwealth of Independent States ( CIS ) to Cilag GmbH International in December 2007, and VIVITROL has been available in Russia for the treatment of alcohol dependence since March 2009 and for the prevention of relapse to opioid dependence following opioid detoxification, since April 2011.

Table of Contents

In November 2011, we announced positive results from a one-year, open-label extension of our six-month pivotal study of VIVITROL. This study showed sustained efficacy of VIVITROL, as measured by the number of opioid-free urine screens, in patients who received VIVITROL, in combination with psychosocial treatment, for a total of 18 months of treatment. Additionally, all safety events observed during the open-label extension were consistent with those set forth in the approved product labeling. During the total observation period of 18 months, improvements during the six-month pivotal trial observed in patients treated with VIVITROL were maintained for the duration of the subsequent one-year, open-label extension study. Approximately half of the patients (49%) who entered the one-year extension study, after receiving six months of VIVITROL in the pivotal study, were completely abstinent for the duration of the extension study, based on opioid-free urine screens.

*BYDUREONTM*

We collaborated with Amylin Pharmaceuticals, Inc. ( Amylin ) on the development of a once-weekly formulation of exenatide, called BYDUREON, for the treatment of type 2 diabetes. BYDUREON, an injectable formulation of Amylin's BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology. Amylin is responsible for commercializing exenatide products, including BYDUREON, in the U.S. Eli Lilly and Company ( Lilly ) has exclusive rights to commercialize exenatide products outside of the U.S. until December 31, 2013, or such earlier date as agreed upon between Lilly and Amylin pursuant to the terms of their transition agreement.

In June 2011, the European Commission granted marketing authorization for BYDUREON for the treatment of type 2 diabetes in adult patients in combination with metformin, a sulfonylurea, a thiazolidinedione, metformin plus a sulfonylurea or metformin plus a thiazolidinedione. In July 2011, Lilly launched BYDUREON in the United Kingdom, and in September 2011, BYDUREON was launched in Germany. We received a \$7.0 million milestone payment upon first commercial sale of BYDUREON in the EU, which was recognized during the three months ended September 30, 2011.

In January 2012, the FDA approved BYDUREON as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. We will receive an additional \$7.0 million milestone payment upon first commercial sale of BYDUREON in the U.S. BYDUREON is expected to be launched in February 2012.

Table of Contents**OTHER COMMERCIAL PRODUCTS**

We expect revenues from our other commercial products, set forth in the table below, to decrease in the future due to existing and expected competition from generic manufacturers. For a more detailed discussion of current and expected future revenue contribution of such products, please refer to the Results of Operations section in this *Management's Discussion and Analysis of Financial Condition and Results of Operation*.

Marketer	Product	Indication	Technology	Territory	Revenue Source
Abbott Laboratories	<i>TriCor</i> ®	Cholesterol lowering	NanoCrystal	Worldwide	Royalty
	<i>Lipanthyl</i> ®				
	<i>Lipidil</i>				
	<i>Supralip</i>				
Acorda Therapeutics, Inc.	<i>Zanaflex</i> ® Capsules	Muscle spasticity	OCR (SODAS)	United States	Manufacturing and Royalty
	<i>ZANAFLEX TABLETS</i>				
Pfizer Inc.	<i>Avinza</i> ®	Chronic pain	OCR (SODAS)	United States	Manufacturing and Royalty
Merck & Co., Inc.	<i>Emend</i> ®	Nausea associated with chemotherapy	NanoCrystal Technology	Worldwide	Royalty
Novartis AG	<i>Focalin XR</i> ®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty
	<i>Ritalin LA</i> ®				
Strativa (a business division of Par Pharmaceutical Companies, Inc.)	<i>Megace</i> ® ES	Cachexia associated with AIDS	NanoCrystal	United States	Royalty
Jazz	<i>LUVOX CR</i> ®		OCR	United States	Manufacturing and Royalty

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

Pharmaceuticals plc		Obsessive-compulsive (SODAS) disorder			
Pfizer Inc.	<i>Rapamune®</i>	Renal transplant  Rejection	NanoCrystal	Worldwide	Manufacturing
Shionogi Inc.	<i>Naprelan®</i>	Various mild to moderate pain indications	OCR  (IPDAS)	United States  Canada	Manufacturing
Sunovion Pharmaceuticals Canada, Inc.					
UCB, Inc.;	<i>VERAPAMIL SR</i>	Hypertension	OCR	Licensed on country/region basis throughout the world	Manufacturing
Watson;	<i>Verelan®</i>		(SODAS)		
Cephalon;	<i>Verelan® PM</i>				
Aspen;	<i>VERAPIMIL OD</i>				
Orient	<i>VERECAPS®</i>  <i>UNIVER®</i>				

### KEY DEVELOPMENT PROGRAMS

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

#### *ALKS 37*

*ALKS 37* is an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced constipation, ( *OIC* ). In May 2011, we presented positive results from a phase 2 double-blind, randomized, placebo-controlled, multi-dose clinical study of *ALKS 37* for the treatment of *OIC*. Data from the study showed that *ALKS 37* significantly improved gastrointestinal motility, demonstrated by increased frequency of bowel movements in patients with *OIC*, while simultaneously preserving the analgesic effects of opioid treatment. The study also demonstrated that *ALKS 37* was generally well tolerated with limited bioavailability and systemic exposure. In July 2011, we announced the initiation of a multicenter, randomized, double-blind, placebo-controlled, repeat-dose phase 2b study of *ALKS 37* to assess the safety, tolerability, efficacy and pharmacokinetic profile of *ALKS 37* in approximately 150 patients. In October 2011, we announced the initiation of a second phase 2b study of *ALKS 37*. This multicenter, randomized, double-blind, placebo-controlled, fixed-dose study is designed to assess the safety and efficacy of daily administration of a 100 mg dose of *ALKS 37* versus placebo for 12 weeks in approximately 80 patients with *OIC*. The results of this phase 2b study, along with those from the dose-ranging, four-week phase 2b study initiated earlier in 2011, are expected in mid-calendar year 2012.

*ALKS 9070*

We are studying ALKS 9070 for the treatment of schizophrenia. ALKS 9070 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®. ALKS 9070 is our first product candidate to leverage our proprietary LinkeRx product platform. In June 2011, we announced positive

Table of Contents

topline results from a phase 1b, double-blind, randomized, placebo-controlled, 20-week study that assessed the safety, tolerability and pharmacokinetic profile of a single administration of three ascending doses of ALKS 9070 in 32 patients with chronic, stable schizophrenia. Data from the study showed that ALKS 9070 was generally well tolerated, achieved therapeutically relevant plasma concentrations of aripiprazole with a pharmacokinetic profile that supports once-monthly dosing.

Based on these results, we announced the initiation of a phase 3 clinical trial of ALKS 9070 in December 2011. The phase 3 randomized, multicenter, double-blind study is designed to assess the efficacy, safety and tolerability of ALKS 9070 compared to placebo in patients experiencing acute exacerbation of schizophrenia. Approximately 690 subjects will be randomized to receive once-monthly intramuscular injections of ALKS 9070 300 mg, ALKS 9070 600 mg or placebo for twelve weeks. In addition, subjects will receive oral study drug for the first three weeks after randomization. Subjects randomized to one of the two ALKS 9070 treatment groups will receive oral aripiprazole, while subjects randomized to the placebo group will receive matching oral placebo. The primary efficacy endpoint of the study is the change in Positive and Negative Syndrome Scale total score from baseline. The clinical data from this study, expected mid-calendar 2013 will form the basis of a NDA to the FDA for ALKS 9070 for the treatment of schizophrenia.

*ALKS 5461*

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, and for the treatment of cocaine dependence.

*Major Depressive Disorder*

In January 2012, we announced positive results from a phase 1/2 study of ALKS 5461 compared to placebo in 32 patients with MDD who did not adequately respond to standard antidepressant therapies. In the study, ALKS 5461 was shown to significantly reduce depressive symptoms, as measured by the Hamilton Depression Rating Scale (HAM-D17; a standard, clinician-assessed measure of depression severity), in patients who received ALKS 5461 for the seven-day treatment period. In addition, data from the study showed that ALKS 5461 was generally well tolerated. Based on these results, we initiated a randomized, double-blind, multicenter, placebo-controlled phase 2 study to evaluate the efficacy and safety of ALKS 5461 when administered once daily for four weeks in approximately 130 patients with MDD who have inadequate response to antidepressant therapy. Data from the study are expected in the first half of calendar year 2013.

*Cocaine Dependence*

Our randomized, double-blind, multidose, placebo-controlled phase 1 clinical study assessed the safety, tolerability and pharmacodynamic effects of the combination of ALKS 33 and buprenorphine when administered alone, and in combination as ALKS 5461, to 12 opioid-experienced users. Data from the study showed that ALKS 5461 was generally well-tolerated and sublingual administration of ALKS 33 effectively blocked the agonist effects of buprenorphine.



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

Based on these positive results, we filed an Investigational New Drug application ("IND") for ALKS 5461 for the treatment of cocaine dependence in June 2011. In the second half of 2011, we initiated a phase 2a study of ALKS 5461 for cocaine dependence, which is being funded through a grant from the National Institute on Drug Abuse ("NIDA"). NIDA has granted us up to \$2.4 million to accelerate the clinical development of ALKS 5461 for the treatment of cocaine dependence. Currently, there are no medications approved for the treatment of cocaine dependence.

### *ALKS 33*

ALKS 33 is an oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 is currently being evaluated as a potential treatment for alcohol dependence.

We conducted two phase 1 studies and one phase 2 study of ALKS 33. The first phase 1 study was a randomized, double-blind, placebo-controlled, multidose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33. In the study, ALKS 33 demonstrated rapid oral absorption and sustained pharmacologically active plasma levels supporting once-daily dosing. The second phase 1 study was a randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the subjective and objective effects of a potent opioid agonist, remifentanyl, a commercially available analgesic. Data showed that the onset of action of ALKS 33 was rapid and observed as early as 15 minutes following oral administration. A full blockade of the opioid agonist was observed and sustained for more than 24 hours following a single administration of ALKS 33. ALKS 33 was generally well tolerated in both studies.

The phase 2 study of ALKS 33 was designed to assess the safety, tolerability, pharmacokinetics and efficacy of daily oral administration of three different dose levels of ALKS 33 compared to placebo in 400 alcohol dependent patients. The phase 2 study showed that ALKS 33 was generally well tolerated and characterized by its potential for daily dosing, non-hepatic metabolism, extended pharmacologic benefit in the event of missed doses and pharmacologic activity in reducing heavy drinking behavior.

### *ZOXYDRO*

ZOXYDRO (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. ZOXYDRO utilizes our oral controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. In August 2011, Zogenix announced positive top-line results from its pivotal phase 3 efficacy study of ZOXYDRO for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. Zogenix expects to submit an NDA for ZOXYDRO to the FDA in early 2012. We will earn manufacturing revenues in the U.S. for ZOXYDRO and are entitled to receive a royalty on U.S. sales of ZOXYDRO, if approved. We have maintained all rights to the product in territories outside the U.S. and will seek to develop and license the product through commercial partnerships in those territories.

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

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Manufacturing and royalty revenues:						
RISPERDAL CONSTA	\$ 38.3	\$ 35.2	\$ 3.1	\$ 131.1	\$ 112.5	\$ 18.6
INVEGA SUSTENNA/XEPLION	9.3		9.3	10.0		10.0
TRICOR 145	15.7		15.7	17.5		17.5
RITALIN LA/FOCALIN XR	11.6		11.6	13.1		13.1
AMPYRA/FAMPYRA	10.2		10.2	10.8		10.8
VERELAN	6.6		6.6	8.1		8.1
Other	21.1	0.7	20.4	25.2	1.9	23.3
Manufacturing and royalty revenues	\$ 112.8	\$ 35.9	\$ 76.9	\$ 215.8	\$ 114.4	\$ 101.4

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 increase in RISPERDAL CONSTA manufacturing and royalty revenues for the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was primarily due to a 5% increase in the unit net sales price earned on manufacturing revenues and a 3% increase in the quantity shipped to Janssen. Janssen's end-market sales of RISPERDAL CONSTA were \$385.4 million and \$387.8 million during the three months ended December 31, 2011 and 2010, respectively. The increase in RISPERDAL CONSTA manufacturing and royalty revenues for the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to a 14% increase in the quantity shipped to Janssen, a 5% increase in the unit net sales price earned on manufacturing revenues and a 5% increase in royalties. The increase in royalties is due to an increase in Janssen's end-market sales of RISPERDAL CONSTA from \$1,121.3 million during the nine months ended December 31, 2010 to \$1,179.0 million during the nine months ended December 31, 2011.

Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues when product is shipped to Janssen, based on a percentage of Janssen's estimated unit net sales price. Revenues include a quarterly adjustment from Janssen's estimated unit net sales price to Janssen's actual unit net sales price for product shipped. In the three and nine months ended December 31, 2011 and 2010, our RISPERDAL CONSTA manufacturing revenues were based on an average of 7.5% of Janssen's unit net sales price. We anticipate that we will continue to earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA for product shipped in the fiscal year ending March 31, 2012 and beyond. Under our license agreements with Janssen, we receive royalty payments equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to us. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) the expiration of the last patent claiming the product in such country, or (ii) fifteen years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to our revenues.

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA, our long acting atypical antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA is launched around the world. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with RISPERDAL CONSTA and INVEGA SUSTENNA. Increased competition may lead to reduced unit sales of RISPERDAL CONSTA and INVEGA SUSTENNA, as well as increasing pricing pressure. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S., and INVEGA SUSTENNA is covered by a patent until 2018 in the EU and 2019 in the U.S., and as such, we do not anticipate any generic competition in the short-term.

The increase in TRICOR 145, RITALIN LA/FOCALIN XR, AMPYRA/FAMPYRA, INVEGA SUSTENNA/XEPLION, VERELAN and the other manufacturing and royalty revenues were primarily due to the addition of the portfolio of commercialized products from the former EDT business on September 16, 2011, which was the closing date of the Business Combination.

We expect the sales of a number of our mature products, including TRICOR 145, RITALIN LA/FOCALIN XR, and VERELAN to decline over the near-term as generic competition enters the market. We expect AMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market and Biogen Idec continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the

Table of Contents

U.S. and FAMPYRA is covered by a patent until 2025 in the EU, and as such, we do not anticipate any generic versions of this product in the near-term.

*Product Sales, net*

Our product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three and nine months ended December 31, 2011 and 2010:

(In millions)	Three Months Ended December 31,				Nine Months Ended December 31,			
	2011	% of Sales	2010	% of Sales	2011	% of Sales	2010	% of Sales
Product sales, gross	\$ 15.2	100.0%	\$ 9.8	100.0%	\$ 42.6	100.0%	\$ 28.0	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(1.3)	(8.6)%	(1.1)	(11.2)%	(3.6)	(8.5)%	(1.9)	(6.8)%
Chargebacks	(0.9)	(5.9)%	(0.7)	(7.1)%	(3.0)	(7.0)%	(1.6)	(5.7)%
Reserve for inventory in the channel (1)	(0.8)	(5.3)%	0.6	6.1%	(1.5)	(3.5)%	(1.1)	(3.9)%
Other	(1.6)	(10.5)%	(0.9)	(9.2)%	(4.3)	(10.1)%	(3.0)	(10.7)%
Total adjustments	(4.6)	(30.3)%	(2.1)	(21.4)%	(12.4)	(29.1)%	(7.6)	(27.1)%
Product sales, net	\$ 10.6	69.7%	\$ 7.7	78.6%	\$ 30.2	70.9%	\$ 20.4	72.9%

- (1) Our reserve for inventory in the channel is an estimate that reflects the deferral of the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel as we do not yet have the history to reasonably estimate returns related to these shipments. We estimate the product shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by our customers as well as prescription information.

The increase in product sales, gross for the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was due to a 55% increase in the number of units sold. The increase in product sales, gross for the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to a 35% increase in the number of units sold and a 13% increase in price. The increase in Medicaid rebates during the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to higher rebates resulting from a price increase in October 2010 and the impact of increased Medicaid rebates and the extension of Medicaid rebates to Medicaid managed care organizations. The increase in chargebacks during the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the increase in the price of VIVITROL and increased Public Health Service pricing discounts.

We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S. In addition, we anticipate that Janssen will increase sales of VIVITROL in Russia and the CIS and there exists the potential to launch the product in other countries around the world. A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid addiction that may compete with VIVITROL, which may negatively impact future sales of VIVITROL. Increased competition may lead

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

to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent not expected to expire until 2029 in the U.S., and as such, we do not anticipate any generic versions of this product in the near-term.

### *Research and Development Revenue*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Research and development revenue	\$ 2.3	\$ 0.3	\$ 2.0	\$ 13.6	\$ 0.7	\$ 12.9

Research and development ( R&D ) revenue is generally earned for services performed and milestones achieved under arrangements with our collaborators. The increase in R&D revenue for the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was primarily due to the addition of on-going R&D projects from the former EDT business. The increase in R&D revenue for the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the \$7.0 million BYDUREON milestone payment we earned upon the launch of the product in the EU as well as a \$3.0 million milestone payment we earned upon the receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication in April 2011.

Table of Contents**Costs and Expenses***Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Cost of goods manufactured and sold	\$ 42.8	\$ 12.9	\$ (29.9)	\$ 76.5	\$ 39.4	\$ (37.1)

The increase in cost of goods manufactured and sold in the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was primarily due to \$30.2 million of cost of goods manufactured from the addition of EDT's portfolio of commercialized products. The increase in cost of goods manufactured and sold in the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the additional \$35.1 million of cost of goods manufactured for the former EDT business. The changes in the cost of goods manufactured and sold by the Alkermes, Inc. business, including RISPERSDAL CONSTA, VIVITROL and polymer were not significant in the three or nine months ended December 31, 2011 as compared to the three and nine months ended December 31, 2010.

We expect an increase in cost of goods manufactured and sold in fiscal year 2013 as compared to fiscal year 2012 as a result of the inclusion of a full year of operations from the former EDT business as well as from an increase in production volumes to support higher sales of AMPYRA/FAMPYRA and VIVITROL, as well as various other contract manufacturing activities.

*Research and Development Expense*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Research and development	\$ 40.5	\$ 22.5	\$ (18.0)	\$ 96.7	\$ 69.4	\$ (27.3)

The increase in R&D expense in the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was primarily due to the addition of \$8.6 million of R&D expense for the former EDT business, as well as an increase of \$5.4 million in clinical study expense and \$2.8 million in employee-related expense from the Alkermes, Inc. business. The increase in clinical study expense was primarily due to activity related to our ALKS 37 and ALKS 9070 development programs, and the increase in employee-related expense is primarily due to an increase in headcount within the Alkermes, Inc. business and share-based compensation expense as recent equity grants were awarded with a higher grant-date fair value than older grants.

The increase in R&D expense in the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the addition of \$9.5 million of R&D expense for the former EDT business, and an increase in the following expenses from the Alkermes, Inc. business: \$8.2 million in clinical study expense; \$6.3 million in professional service expense; and \$6.8 million in employee-related expense, partially offset by a \$2.4 million decrease in license and collaboration fees. The increase in clinical study expense and professional service expense was primarily due to activity related to our ALKS 37 and ALKS 9070 development programs, and the increase in

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

employee-related expense is primarily due to an increase in headcount within the Alkermes, Inc. business and share-based compensation expense as recent equity grants were awarded with a higher grant-date fair value than older grants. The decrease in license and collaboration expense was primarily due to a decrease in expense under our collaboration agreement with Acceleron.

We expect a modest increase in R&D spend in the year ended March 31, 2013 as a result of including a full year of operations from the former EDT business. In addition, we expect increased R&D investment as certain key development programs, notably ALKS 9070, ALKS 37 and ALKS 5461, continue to advance through the pipeline.

A significant portion of our R&D expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative R&D activities are tracked by project and may be reimbursed to us by our partners. We account for our R&D expenses on a departmental and functional basis in accordance with our budget and management practices.

Table of Contents*Selling, General and Administrative Expense*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Selling, general and administrative	\$ 35.5	\$ 20.5	\$ (15.0)	\$ 103.2	\$ 58.7	\$ (44.5)

The increase in selling general and administrative ( SG&A ) expense for the three months ended December 31, 2011, as compared to the three months ended December 31, 2010, was primarily due to the addition of \$7.0 million of SG&A expense for the former EDT business, as well as an increase of \$3.7 million in professional service expense, \$1.4 million in marketing expense and \$1.4 million in employee-related expenses from the Alkermes, Inc. business. The increase in professional services was primarily due to costs incurred in connection with the Business Combination. The increase in marketing expenses is due to an analysis we are performing to determine the marketability of our existing products and product candidates, and the increase in employee-related expenses was primarily due to an increase in headcount and share-based compensation expense as recent equity grants have been awarded with a higher grant-date fair value than older grants.

The increase in SG&A costs for the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the addition of \$7.9 million of SG&A expense for the former EDT business, as well as an increase of \$25.3 million in professional service expense, \$5.5 million in employee-related expenses, \$2.8 million in marketing expense and \$1.6 million in travel-related expenses from the Alkermes, Inc. business. The increase in professional service and travel-related expense was primarily due to costs incurred in connection with the Business Combination. The increase in employee-related expense was primarily due to an increase in headcount and share-based compensation expense as recent equity grants were awarded with a higher grant-date fair value than older grants and the increase in marketing expenses was due to an analysis we are performing to determine the marketability of our existing products and product candidates.

We expect an increase in SG&A spend in the year ended March 31, 2013 as a result of including a full year of operations from the former EDT business.

*Amortization of Acquired Intangible Assets*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Amortization of acquired intangible assets	\$ 11.9	\$	\$ (11.9)	\$ 13.7	\$	\$ (13.7)

In connection with the Business Combination, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which are 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 upon our most recent analysis, amortization of intangible assets included within our consolidated balance sheet as of December 31, 2011 is expected to be in the range of approximately \$42.0 million to \$76.0 million annually through fiscal year 2017.



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

We also acquired \$45.8 million of intangible assets related to various preclinical product candidates, or in-process research, and \$105.7 million of goodwill, both of which are considered indefinite-lived assets and not amortized, but are subject to an annual review for impairment or when circumstances indicate the fair value may be below its carrying value.

### *Other Income (Expense), Net*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Total other (expense), net	\$ (9.8)	\$ 0.6	\$ (10.4)	\$ (16.0)	\$ (1.4)	\$ (14.6)

The increase in other (expense), net for the three and nine months ended December 31, 2011, as compared to the three and nine months ended December 31, 2010, was primarily due to our entry into \$450.0 million of term loan financing during the three months ended September 30, 2011. The \$310.0 million first lien term loan facility (the *First Lien Term Loan*) has a principal amount of \$310.0 million and an interest rate of three-month LIBOR plus 5.25% and the \$140.0 million second lien term loan facility (the *Second Lien Term Loan* and, together with the *First Lien Term Loan*, the *Term Loans*) has a principal amount of \$140.0 million and an interest rate of three-month LIBOR plus 8.00%. Under both loan agreements, three-month LIBOR is subject to an interest rate floor of 1.50%. Interest expense on the term loans was \$10.5 million and \$18.0 million in the three and nine months ended December 31, 2011, respectively.

Table of Contents

We expect interest expense to increase in fiscal year 2013, as fiscal year 2013 will include a full year of interest expense on the \$450.0 million principal balance of the Term Loans. Beyond fiscal year 2013, we anticipate that interest expense will decrease as the Term Loans are paid down.

*Income Tax Provision (Benefit)*

(In millions)	Three Months Ended December 31,		Change Favorable/ (Unfavorable)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Income tax provision (benefit)	\$ 0.1	\$ 0.0	\$ (0.1)	\$ 3.7	\$ (1.0)	\$ 4.7

We recorded an income tax provision of \$0.1 million and an income tax provision of \$3.7 million for the three and nine months ended December 31, 2011, respectively, and an income tax provision of less than \$0.1 million and an income tax benefit of \$1.0 million for the three and nine months ended December 31, 2010, respectively. During the nine months ended December 31, 2011, we recorded a \$13.2 million current tax expense for the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland and a deferred tax benefit of \$10.2 million in connection with the Business Combination, as we recorded a U.S. deferred tax liability in purchase accounting allowing for the partial release of an existing valuation allowance.

*Non-GAAP Financial Measures*

We use Adjusted EBITDA as a supplemental measure of our performance and liquidity that is not required by, or presented in accordance with, GAAP. We define Adjusted EBITDA as net income (loss) before (i) net interest expense, (ii) income taxes, (iii) depreciation and amortization, (iv) non-cash expenses relating to share-based compensation arrangements with our employees, and (v) professional fees related to the Business Combination. In evaluating our business, we consider Adjusted EBITDA as a key indicator of financial operating performance and as a measure of our ability to generate cash for operations and future capital expenditures.

Adjusted EBITDA is not a GAAP measure of performance. We use this non-GAAP measure primarily as a measure of the financial performance of our assets without regard to financing methods, capital structures, taxes or historical cost basis; our liquidity and operating performance over time and in relation to other companies that own similar assets and that we believe calculate EBITDA in a manner similar to us; and the ability of our assets to generate cash sufficient for us to pay potential interest expenses. We believe that this measure may also be useful to investors for the same purpose and for an indication of our ability to generate cash flow at a level that can sustain or support our operations. Investors should not consider this measure in isolation or as a substitute for operating income or loss, cash flow from operations determined under GAAP, or any other measure for determining our operating performance that is calculated in accordance with GAAP. In addition, because Adjusted EBITDA is not a GAAP measure, it may not necessarily be comparable to similarly titled measures employed by other companies.

In evaluating Adjusted EBITDA, you should be aware that it excludes expenses that we will incur in the future on a recurring basis. Adjusted EBITDA has limitations as an analytical tool, and you should not consider it in isolation. Some of its limitations are:

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

- it does not reflect non-cash costs of our share-based compensation arrangements, which are an ongoing component of our employee compensation program; and
- although depreciation and amortization are non-cash charges, the assets being depreciated and amortized will often have to be replaced in the future, and Adjusted EBITDA does not reflect the cost or cash requirements for such replacements.

We compensate for these limitations by relying primarily on our GAAP results and using Adjusted EBITDA only supplementally. The following table presents a reconciliation of our net loss to our Adjusted EBITDA on a historical basis for each of the periods indicated:

Table of Contents

(In millions)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2011	2010	2011	2010
Net loss	\$ (14.8)	\$ (11.4)	\$ (50.3)	\$ (32.5)
Depreciation expense included in cost of goods manufactured and sold	6.9	1.0	9.3	3.1
Depreciation expense included in R&D	1.7	0.8	3.3	2.1
Depreciation expense included in SG&A	0.4	0.3	1.0	1.0
Share-based compensation included in cost of goods manufactured and sold	0.8	0.4	1.9	1.3
Share-based compensation included in R&D	2.5	1.6	6.7	4.7
Share-based compensation included in SG&A	5.7	3.8	13.1	9.2
Amortization of acquired intangible assets	11.9		13.7	
Net interest expense (income)	10.1	(0.7)	16.8	1.1
Income tax provision (benefit)	0.1	0.1	3.7	(0.9)
Non-recurring costs related to the EDT merger	4.4		26.7	
Costs related to the redemption of the non-recourse 7% Notes				2.2
Adjusted EBITDA	\$ 29.7	\$ (4.1)	\$ 45.9	\$ (8.7)

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

(In millions)	December 31, 2011	March 31, 2011
Cash and cash equivalents	\$ 85.4	\$ 38.4
Investments short-term	128.1	162.9
Investments long-term	20.5	93.4
Total cash, cash equivalents and investments	\$ 234.0	\$ 294.7
Working capital	\$ 277.9	\$ 204.9
Long-term debt	\$ 444.8	\$

Our cash flows for the nine months ended December 31, 2011 and 2010 were as follows:

(In millions)	Nine Months Ended December 31,	
	2011	2010
Cash and cash equivalents, beginning of period	\$ 38.4	\$ 79.3
Cash (used in) operating activities	(17.8)	(14.1)
Cash (used in) provided by investing activities	(395.6)	17.1
Cash provided by (used in) financing activities	460.3	(43.4)
Cash and cash equivalents, end of period	\$ 85.3	\$ 38.9

Our primary sources of liquidity are cash provided by past operating activities, payments we have received under R&D arrangements and other arrangements with collaborators, term loan financing and private placements of debt securities. The increase in cash used in operating activities

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

during the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to an increase in cash used for working capital and a decrease in cash principal payments on our non-recourse RISPERDAL CONSTA secured 7% Notes (the 7% Notes ) that was allocated to operating activities to account for the original issue discount on our 7% Notes. The change in cash flows (used in)/provided by investing activities during the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the acquisition of EDT. The increase in cash flows provided by financing activities during the nine months ended December 31, 2011, as compared to the nine months ended December 31, 2010, was primarily due to the issuance of the Term Loans used to finance the acquisition of EDT, partially offset by the cash used for the redemption of the 7% Notes in full on July 1, 2010.

Our investments at December 31, 2011 consist of the following:

Table of Contents

(In millions)		Amortized Cost		Gross Unrealized			Estimated Fair Value		
				Gains	Losses				
Investments	short-term	\$	123.3	\$	0.2	\$	(0.1)	\$	123.4
Investments	long-term available-for-sale		19.7				(0.4)		19.3
Investments	long-term held-to-maturity		5.9						5.9
Total		\$	148.9	\$	0.2	\$	(0.5)	\$	148.6

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 December 31, 2011, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At December 31, 2011 and March 31, 2011, 8% and less than 1%, respectively, of our investments are valued using unobservable, or Level 3 inputs, to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. During the nine months ended December 31, 2011, there were two investments in corporate debt securities transferred into Level 3 from Level 2 as trading in these securities ceased during the period. Also, during the nine months ended December 31, 2011, there was one investment in an international government agency debt security transferred into Level 3 from Level 1 as trading in this security ceased during the period. The illiquidity of our Level 3 investments does not have a material impact on our overall liquidity, operations, financial flexibility or stability. We believe that our current cash and cash equivalents and short and long-term investments, combined with anticipated revenues will generate sufficient cash flows to meet our current anticipated liquidity and capital requirements for the foreseeable future.

*Borrowings*

At December 31, 2011, our borrowings consisted of \$450.0 million of term loan financing under the Term Loans. Please refer to Note 10 *Long-Term Debt* in the accompanying Notes to Condensed Consolidated Financial Statements for a discussion of our outstanding term loans.

*Contractual Obligations*

During quarter ended September 30, 2011, we entered into the Term Loans and assumed certain operating lease and purchase obligations related to the Business Combination. The following table summarizes the additions to our contractual obligations table that appeared within Part II of Alkermes, Inc.'s Annual Report:

Edgar Filing: Alkermes plc. - Form 10-Q

<b>Contractual Cash Obligations</b>	<b>Total</b>	<b>Less Than One Year (Fiscal 2012)</b>	<b>One to Three Years (Fiscal 2013- 2014)</b>	<b>Three to Five Years (Fiscal 2015- 2016)</b>	<b>More than Five Years (After Fiscal 2017)</b>
Term Loans - Principal	\$ 450,000	\$ 775	\$ 6,200	\$ 6,200	\$ 436,825
Term Loans - Interest	218,939	16,162	69,051	68,294	65,432
Operating lease obligations	38,801	6,731	10,173	7,974	13,923
Purchase obligations	6,454	6,454			
Capital expansion programs	10,641	10,641			
Total contractual cash obligations	\$ 724,835	\$ 40,763	\$ 85,424	\$ 82,468	\$ 516,180

We pay interest under our Term Loans at three-month LIBOR plus 5.25% with respect to our First Lien Term Loan and at three-month LIBOR plus 8.00% with respect to our Second Lien Term Loan. Under each term loan agreement, LIBOR is subject to an interest rate floor of 1.50%. For the purposes of the contractual obligation table, interest has been calculated at the interest rate floor of 1.50% plus 5.25% and 8.00% for the First and Second lien term loans, respectively. Beginning in fiscal year 2013, we are required to make principal payments on the First Lien Term Loan for amounts up to 50% of excess cash flows as defined in the First Lien Term Loan credit agreement.

Table of Contents

*Off-Balance Sheet Arrangements*

At December 31, 2011, 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 Part II, Item 7 of Alkermes, Inc.'s Annual Report in the *Critical Accounting Estimates* section for a discussion of our critical accounting estimates.

On April 1, 2011, we prospectively adopted the accounting guidance related to the milestone method of revenue recognition for research and development arrangements. 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 the impact the adoption of this standard had on us.

In connection with the acquisition of EDT on September 16, 2011, we added to our listing of our most significant critical accounting estimates the valuation of acquired intangible assets, including in-process research and development (IPR&D). These intangible assets consist primarily of collaboration agreements, technology associated with human therapeutic products and IPR&D product candidates. When significant identifiable intangible assets are acquired, we engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

- estimating the timing of and expected costs to complete, the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.



We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates.

If these projects are not successfully developed, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. We believe that the foregoing assumptions used in the IPR&D analysis were reasonable at the time of the respective acquisition. No assurance can be given, however, that the underlying assumptions used to estimate expected project sales, development costs or profitability, or the events associated with such projects, will transpire as estimated.

In connection with the acquisition of EDT, we recorded goodwill of \$105.7 million which represented the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition.

The Company's goodwill balance solely relates to the EDT acquisition in the fiscal year ending March 31, 2012. We assess our goodwill balance within our single reporting unit annually and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. In performing our annual goodwill impairment assessment, we first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If we believe, as a result of our qualitative assessment, that it is more-likely-than-not that the fair value of the reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. If, based on our qualitative assessment, we are required to proceed to the quantitative assessment; we first compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to our reporting unit exceeds the fair value of our reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of our reporting unit's goodwill. If the carrying value of our reporting unit's goodwill exceeds its implied fair value, then the company records an impairment loss equal to the difference. As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of the Company's goodwill was not recorded.

Table of Contents

*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 Alkermes, Inc.'s 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 in the first nine months of fiscal year 2012, 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.

In September 2011, we and certain of our subsidiaries, as guarantors, entered into the First Lien Term Loan and the Second Lien Term Loan, with Morgan Stanley Senior Funding, Inc., (MSSF) as administrative agent and as collateral agent, MSSF and HSBC Securities (USA) Inc., (HSBC) as co-syndication agents, joint lead arrangers and joint bookrunners, and various other financial institutions, as lenders. Borrowings under the Term Loans bear interest at a rate per annum equal to an applicable margin plus, at our option, either (1) LIBOR determined by reference to the costs of funds for eurodollar deposits for the interest period relevant to such borrowing adjusted for certain additional costs or (2) a base rate determined by reference to the highest of (a) the rate *The Wall Street Journal* publishes as the U.S. Prime Rate, (b) the federal funds effective rate plus one-half of 1.00% and (c) LIBOR described in subclause (1) plus 1.00%. LIBOR is subject to an interest rate floor of 1.50% and the base rate is subject to an interest rate floor of 2.50%.

The initial applicable margin for borrowings under the First Lien Term Loan is 5.25% with respect to LIBOR borrowings and 4.25% with respect to base rate borrowings. Commencing with completion of our first fiscal quarter ending after the Business Combination, the applicable margin under the First Lien Term Loan is subject to adjustment each fiscal quarter, based upon meeting a certain consolidated leverage ratio during the preceding quarter. The initial applicable margin for borrowings under the Second Lien Term Loan is 8.00% with respect to LIBOR borrowings and 7.00% with respect to base rate borrowings and is not subject to adjustment.

In accordance with the terms of the Term Loans, we entered into two interest rate cap agreements and an interest rate swap agreement to mitigate the interest rate risk on \$225.0 million principal amount of the Term Loans. One interest rate cap, with a notional amount of \$65.0 million protects us if three-month LIBOR were to reach 1.78% from the date of issuance through December 3, 2012. The second interest rate cap, with a notional amount of \$160.0 million protects us if three-month LIBOR were to reach 3% from the date of issuance through December 13, 2013. The interest rate swap protects us if three-month LIBOR were to reach 2.057% from December 3, 2012 through September 3, 2014. As the three-month LIBOR rate was 0.56% at December 31, 2011, the LIBOR floor under the agreement is 1.50% and as our interest rate cap fixes our interest rate at 1.78% for \$65.0 million principal amount and 3.0% for \$160.0 million principal amount of our term loans, we do not expect changes in the three-month LIBOR to have a material effect on our financial statements through March 31, 2012.

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

We do not use derivative financial instruments for speculative trading purposes. The counterparties to our interest rate cap and interest rate swap contracts are multinational commercial banks. We believe the risk of counterparty nonperformance is remote.

As a result of the Business Combination, we incur substantial operating costs in Ireland. We face exposure to changes in the exchange ratio of the U.S. dollar and the Euro arising from expenses and payables at our Ireland operations that are settled in Euros. The impact of changes in the exchange ratio of the U.S. dollar and the Euro on our U.S. dollar denominated manufacturing and royalty revenues earned in foreign countries is partially offset by the opposite impact of changes in the exchange ratio of the U.S. dollar and the Euro on operating expenses and payables incurred at our Ireland operations that are settled in Euros. For the remainder of the fiscal year ended March 31, 2012, an average 10% weakening in the U.S. dollar relative to the Euro would result in an increase to our budgeted expenses denominated in the Euro of \$2.2 million.

As summarized in Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* of Alkermes, Inc.'s Annual Report, we are exposed to foreign currency fluctuations related to manufacturing and royalty revenues we receive on RISPERDAL CONSTA as a majority of these sales are made in foreign countries and are denominated in currencies in which the product is sold, which is predominately the Euro. For the nine months ended December 31, 2011, an average 10% strengthening of the U.S. dollar relative to the currencies in which RISPERDAL CONSTA is sold would have resulted in our RISPERDAL CONSTA manufacturing and royalty revenues being reduced by approximately \$7.4 million and \$1.4 million, respectively.

Table of Contents

**Item 4. Controls and Procedures**

*a) Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, (the Exchange Act ) at December 31, 2011. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2011 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*

As discussed above, on September 16, 2011, the business of Alkermes, Inc. and EDT were combined under Alkermes plc in a transaction accounted for as a reverse acquisition. For purposes of the Business Combination, Alkermes, Inc. was treated as the accounting acquirer under the purchase method of accounting, even though Alkermes plc is the issuer of ordinary shares in the transaction. As Alkermes, Inc. was determined to be the acquirer for accounting purposes, the historical financial statements of Alkermes plc reflect the financial position, results of operations and cash flows of Alkermes, Inc. only. Following the Merger, the financial statements of the current period reflect the financial position, results of operations and cash flows of Alkermes plc. The results of operations of the former EDT business are included in the results of operations of Alkermes plc beginning on September 17, 2011.

Other than continuing changes to our processes as a result of the Business Combination during the quarter ended December 31, 2011, there have been no material changes to 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 other legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of certain of our products. 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 and financial condition.

**Item 1A. Risk Factors**

The following information updates should be read in conjunction with the information disclosed in Part 1, Item 1A, Risk Factors, of the Alkermes, Inc. Annual Report. You should also read the following information together with those risk factors set forth under the caption Risk Factors in our Registration Statement, which risk factors are incorporated herein by reference. There have been no material changes from the Risk Factors set forth, or incorporated by reference, in such Registration Statement except for the addition of the following Risk Factor.

*Our investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by the volatility in the United States credit markets.*

As of December 31, 2011, a significant amount of our investments were invested in U.S. government treasury and agency securities. Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. In addition, general credit, liquidity, market and interest risks associated with our investment portfolio may have an adverse effect on our financial condition.

**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 December 31, 2011. As of December 31, 2011, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million.

**Item 5. Other Information**

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

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 December 31, 2011, Mr. Floyd E. Bloom and Robert A. Breyer, each a director of the Company, and 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.	
-------------	--

10.1	Alkermes plc 2011 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on December 8, 2011 (File No. 001-35299)).+
10.2	Amendment to Amended and Restated Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan (Incorporated by reference to our Current Report on Form 8-K filed on October 7, 2011 (File No. 001-35299)). +
31.1	Rule 13a-14(a)/15d-14(a) Certification (filed herewith).
31.2	Rule 13a-14(a)/15d-14(a) Certification (filed herewith).
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 December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive loss (iii) Condensed Consolidated Statement of Shareholder' Equity (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements (furnished herewith).]
+	Indicates a management contract or any compensatory plan, contract or arrangement.

Table of Contents

**SIGNATURES**

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

ALKERMES plc

(Registrant)

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

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

Date: February 2, 2012