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)

x 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

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

Commission File Number 001-35299

# **ALKERMES PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

Ireland

98-1007018

(State or other jurisdiction of incorporation or organization)

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

#### 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 x No o

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

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

Large accelerated filer o

Accelerated filer o

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

Smaller reporting company o

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

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

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

		Page No.
T. 4	PART I - FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements:	3
	Condensed Consolidated Balance Sheets December 31, 2011 and March 31, 2011	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss For the	
	Three and Nine Months Ended December 31, 2011 and 2010	4
	Condensed Consolidated Statement of Shareholders Equity For the Nine Months Ended	
	<u>December 31, 2011</u>	5
	Condensed Consolidated Statements of Cash Flows For the Nine Months Ended	
	<u>December 31, 2011 and 2010</u>	6
	Notes to Condensed Consolidated Financial Statements	7
<u>Item 2.</u>	Management s Discussion and Analysis of Financial Condition and Results of Operations	21
<u>Item 3.</u>	Quantitative and Qualitative Discloures about Market Risk	35
Item 4.	Controls and Procedures	36
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 5.	Other Information	37
Item 6.	Exhibits	37
Signatures		38
Exhibit Inde	ex	
	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	
	Z. 101 1 to community Zamouse Document	

#### PART I. FINANCIAL INFORMATION

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

## ALKERMES PLC AND SUBSIDIARIES

# CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	Б	December 31, 2011 (In thousands, exc share ar	•	
ASSETS				
CURRENT ASSETS:				
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
TOTAL ASSETS	\$	1,505,827	\$	452,448
LIABILITIES AND SHAREHOLDERS EQUITY				
CURRENT LIABILITIES:				
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
COMMITMENTS AND CONTINGENCIES (Note 15)				
SHAREHOLDERS EQUITY:				
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 Non-voting common stock, par value, \$0.01 per share; none and 450,000 shares		1,296		1,055
authorized; none and 382,632 shares issued and outstanding at December 31, 2011 and March 31, 2011, respectively				4

Treasury stock, at cost (27,033 and 10,069,208 shares at December 31, 2011 and

11 custify stock, at cost (27,055 and 10,005,200 shares at December 51, 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
TOTAL LIABILITIES AND SHAREHOLDERS EOUITY	\$ 1,505,827	\$ 452,448

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

#### ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

#### (unaudited)

	Three Mon Decem			Nine Months Ended December 31,			
	2011		2010		2011		2010
		(In t	thousands, excep	t per s	hare amounts)		
REVENUES:							
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
EXPENSES:							
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)
OTHER (EXPENSE) INCOME, NET:							
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)
LOSS PER COMMON SHARE:							
Basic and diluted	\$ (0.11)	\$	(0.12)	\$	(0.46)	\$	(0.34)
WEIGHTED AVERAGE NUMBER OF COMMON							
SHARES OUTSTANDING:							
Basic and diluted	129,670		95,667		109,645		95,502
COMPREHENSIVE LOSS:							
Net loss	\$ (14,828)	\$	(11,383)	\$	(50,321)	\$	(32,458)
Unrealized gains (losses) on marketable securities:							
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.

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

## (unaudited)

Accumulated

						A	dditional	(	Other				
		Stock Non-	_					_			Treasury		
	Shares	Amount	Shares	Amo	ount		•		s) Income xcept share		Shares	Amount	Total
BALANCE						(1	ii tiiousana	.s, c.	acept share	uata)			
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							1.204				(101.550)	(1.204)	
stock based awards							1,384				(121,550)	(1,384)	
Share-based													
compensation							15 121						15 121
expense							15,131						15,131
Unrealized gains on marketable securities,													
net of tax of \$255									431				431
Net loss									731	(32,458)			(32,458)
BALANCE										(32, 130)			(32, 130)
December 31, 2010	105,395,641	\$ 1,051	382,632	\$	4	\$	927,435	\$	(2,961) \$	(398,146)	(10,066,815)	\$ (131,065) \$	396,318
	, ,	,	ĺ				,		( ) , , .				,
BALANCE													
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	21 000 000	210					504.755						505.074
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	1,900,547	20					13,031						13,031
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

Share-based compensation expense									
Excess tax benefit									
from share-based									
compensation					3,127				3,127
Conversion of					5,127				5,12,
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						(50,3	321)		(50,321)
BALANCE									
December 31, 2011	129,774,455	\$ 1,296		\$ \$	1,368,444	\$ (2,921) \$ (461,5	549) (27,033)	\$ (417) 5	\$ 904,853

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

#### ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

#### (unaudited)

	Nine Months Ended December 31, 2011			2010
		In thou	sands)	2010
CASH FLOWS FROM OPERATING ACTIVITIES:	,		,	
Net loss	\$ (50,3	21)	\$	(32,458)
Adjustments to reconcile net loss to cash flows from operating activities:				
Depreciation and amortization	27,2	251		6,210
Share-based compensation expense	21,7	43		15,196
Deferred income taxes	(11,2	239)		
Other non-cash charges	2,6	664		2,273
Changes in assets and liabilities, excluding the effect of acquisitions:				
Receivables	(22,0	(50)		1,147
Inventory, prepaid expenses and other assets	(8,0	(52)		4,059
Accounts payable and accrued expenses	20,8	344		(4,928)
Deferred revenue	1,3	98		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	(17,7	(62)		(14,180)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property, plant and equipment	(8,8	359)		(8,029)
Sales of property, plant and equipment		3		260
Acquisition of Elan Drug Technologies, net of cash acquired	(494,7	74)		
Investment in Acceleron Pharmaceuticals, Inc.	(2	231)		(501)
Purchases of investments	(159,3	(22)		(324,143)
Sales and maturities of investments	267,6	604		349,546
Cash flows (used in) provided by investing activities	(395,5	79)		17,133
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from the issuance of common stock for share-based compensation arrangements	13,0	51		1,982
Excess tax benefit from share-based compensation	3,1	27		
Proceeds from the issuance of long-term debt	444,1	.00		
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal				(45,397)
Cash flows provided by (used in) financing activities	460,2	278		(43,415)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	46,9	37		(40,462)
CASH AND CASH EQUIVALENTS Beginning of period	38,3	94		79,324
CASH AND CASH EQUIVALENTS End of period	\$ 85,3	31	\$	38,862
SUPPLEMENTAL CASH FLOW DISCLOSURE:				
Non-cash investing and financing activities:				
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 2,1	39	\$	550
Investment in Civitas Therapeutics, Inc.	\$ 1,5	47	\$	1,320

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

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 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

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.

7

#### **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

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

8

**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

#### 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.

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

10

#### 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

11

#### 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.

	ree Months Ended ecember 31,	Nine Mont Decemb	ed	
(In thousands, except per share data)	2010	2011		2010
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)

#### ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. INVESTMENTS

Investments consist of the following:

	Gross Unrealized Losses									
	A	mortized Cost		Gains	(	Less than One Year (thousands)	G	reater than One Year		Estimated Fair Value
<u>December 31, 2011</u>						ŕ				
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
March 31, 2011										
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.

# 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:

	Nine Months Ended December 31,							
(In thousands)	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:

		Available		Held-to-maturity				
<b>7</b>	A	mortized		Estimated		Amortized		Estimated
(In thousands)		Cost	F	air Value		Cost	F	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.

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.

# 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:

	December 31,			
(In thousands)	2011	Level 1	Level 2	Level 3
Assets:				
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	
Total	\$ 142,878	\$ 119,080	\$ 11,217	\$ 12,581
Liabilities:				
Interest rate swap contract	\$ (421)	\$	\$ (421)	\$
Total	\$ (421)	\$	\$ (421)	\$

	March 31,			
	2011	Level 1	Level 2	Level 3
Assets:				
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		
Total	\$ 250,581	\$ 214,780	\$ 34,754	\$ 1,047

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:

	Fair
(In thousands)	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

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.

# 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				