

Alkermes plc.
Form 10-Q
November 03, 2011

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2011

OR

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

Commission File Number 001-35299

ALKERMES PLC

(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.)

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

(Address of principal executive offices)

011-353-1-709-4000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting
company

*(Do not check if a smaller
reporting company)*

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

The number of shares of the issuer's Common Stock, \$0.01 par value, outstanding as of November 1, 2011, was 129,585,141 shares.

**ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011**

	Page No.
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Consolidated Financial Statements (Unaudited):</u>	3
<u>Condensed Consolidated Balance Sheets September 30, 2011 and March 31, 2011</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss For the Three and Six Months Ended September 30, 2011 and 2010</u>	4
<u>Condensed Consolidated Statement of Shareholders Equity For the Six Months Ended September 30, 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows For the Six Months Ended September 30, 2011 and 2010</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	33
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	34
<u>Item 1A. Risk Factors</u>	34
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	34
<u>Item 5. Other Information</u>	34
<u>Item 6. Exhibits</u>	34
<u>Signatures</u>	35
<u>Exhibit Index</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	
<u>EX-101 DEFINITION LINKBASE DOCUMENT</u>	

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements:**

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2011	March 31, 2011
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 89,237	\$ 38,394
Investments short-term	126,327	162,928
Receivables	79,644	22,969
Inventory	47,118	20,425
Prepaid expenses and other current assets	13,382	8,244
Total current assets	355,708	252,960
PROPERTY, PLANT AND EQUIPMENT NET	304,611	95,020
INTANGIBLE ASSETS NET	687,983	
GOODWILL	104,989	
INVESTMENTS LONG-TERM	24,990	93,408
OTHER ASSETS	25,822	11,060
TOTAL ASSETS	\$ 1,504,103	\$ 452,448
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 83,750	\$ 44,934
Deferred revenue current	4,249	3,123
Long-term debt current	2,325	
Total current liabilities	90,324	48,057
LONG-TERM DEBT	441,859	
DEFERRED REVENUE LONG-TERM	4,359	4,837
DEFERRED TAX LIABILITIES LONG-TERM	49,829	
OTHER LONG-TERM LIABILITIES	8,052	7,536
Total liabilities	594,423	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 September 30, 2011 and March 31, 2011, respectively		
Common stock, par value, \$0.01 per share; 450,000,000 and 160,000,000 shares authorized; 129,584,585 and 105,771,507 shares issued; 129,584,585 and 95,702,299 shares outstanding at September 30, 2011 and March 31, 2011, respectively	1,294	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 September 30, 2011 and March 31, 2011, respectively		4
Treasury stock, at cost (none and 10,069,208 shares at September 30, 2011 and March 31, 2011, respectively)		(131,095)
Additional paid-in capital	1,358,023	936,295
Accumulated other comprehensive loss	(2,916)	(3,013)
Accumulated deficit	(446,721)	(411,228)
Total shareholders equity	909,680	392,018
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 1,504,103	\$ 452,448

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		Six Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	\$ 54,039	\$ 42,623	\$ 102,979	\$ 78,431
Product sales, net	9,887	6,469	19,573	12,673
Research and development revenue	8,052	155	11,309	423
Total revenues	71,978	49,247	133,861	91,527
EXPENSES:				
Cost of goods manufactured and sold	17,530	13,911	33,749	26,576
Research and development	28,160	23,932	56,210	46,909
Selling, general and administrative	36,234	18,436	67,731	38,162
Amortization of acquired intangible assets	1,817		1,817	
Total expenses	83,741	56,279	159,507	111,647
OPERATING LOSS	(11,763)	(7,032)	(25,646)	(20,120)
OTHER (EXPENSE), NET:				
Interest income	383	673	885	1,525
Interest expense	(7,561)	(2,168)	(7,561)	(3,298)
Other income (expense), net	336	(82)	425	(183)
Total other (expense), net	(6,842)	(1,577)	(6,251)	(1,956)
LOSS BEFORE INCOME TAXES	(18,605)	(8,609)	(31,897)	(22,076)
INCOME TAX PROVISION (BENEFIT)	3,650	(943)	3,596	(1,001)
NET LOSS	\$ (22,255)	\$ (7,666)	\$ (35,493)	\$ (21,075)
LOSS PER COMMON SHARE:				
Basic and diluted	\$ (0.22)	\$ (0.08)	\$ (0.36)	\$ (0.22)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic and diluted	102,474	95,511	99,578	95,419
COMPREHENSIVE LOSS:				
Net loss	\$ (22,255)	\$ (7,666)	\$ (35,493)	\$ (21,075)
Unrealized (losses) gains on marketable securities:				

Edgar Filing: Alkermes plc. - Form 10-Q

Holding (losses) gains, net of tax	(188)	453	341	947
Unrealized (losses) gains on marketable securities	(188)	453	341	947
Unrealized losses on derivative contracts, net of tax	(244)		(244)	
COMPREHENSIVE LOSS	\$ (22,687)	\$ (7,213)	\$ (35,396)	\$ (20,128)

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

4

Table of Contents

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
(unaudited)

	Common Stock		Non-voting Common Stock		Accumulated Additional Paid-In Comprehensive Income (Loss)			Treasury Stock		Total
	Shares	Amount	Shares	Amount	Capital	Deficit	Shares	Amount		
(In thousands, except share data)										
BALANCE										
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	433,436	3			1,351					1,354
Receipt of Alkermes stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards								(96,528)	(1,098)	(1,098)
Share-based compensation expense					9,347					9,347
Unrealized gains on marketable securities, net of tax of \$559							947			947
Net loss							(21,075)			(21,075)
BALANCE										
September 30, 2010	105,248,764	\$ 1,050	382,632	\$ 4	\$ 921,024	\$ (2,445)	\$ (386,763)	(10,041,793)	\$ (130,779)	\$ 402,091
BALANCE										
March 31,	105,771,507	\$ 1,055	382,632	\$ 4	\$ 936,295	\$ (3,013)	\$ (411,228)	(10,069,208)	\$ (131,095)	\$ 392,018

2011						
Issuance of common stock to Elan Corporation, plc in connection with the purchase of Elan Drug Technologies, refer to Note 1						
<i>The Company</i>	31,900,000	319		524,755		525,074
Issuance of common stock under employee stock plans	1,770,477	18		12,203		12,221
Receipt of Alkermes stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards				3,105	(170,823)	(3,105)
Share-based compensation expense				12,636		12,636
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 \$202					341	341
Unrealized loss on cash					(244)	(244)

flow hedge, net of tax of \$145								
Net loss					(35,493)			(35,493)

BALANCE								
September 30, 2011	129,584,585	\$ 1,294	\$	\$ 1,358,023	\$ (2,916)	\$ (446,721)	\$	\$ 909,680

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)

	Six Months Ended	
	September 30,	
	2011	2010
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (35,493)	\$ (21,075)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	6,377	4,062
Share-based compensation expense	12,712	9,404
Deferred income taxes	(9,664)	
Other non-cash charges	719	1,899
Changes in assets and liabilities, excluding the effect of acquisitions:		
Receivables	733	(10,454)
Inventory, prepaid expenses and other assets	(11,921)	1,791
Accounts payable and accrued expenses	20,794	(7,710)
Deferred revenue	189	1,692
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	(15,554)	(27,077)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(3,654)	(6,719)
Sales of property, plant and equipment	3	206
Acquisition of Elan Drug Technologies, net of cash acquired	(494,962)	
Investment in Acceleron Pharmaceuticals, Inc.		(501)
Purchases of investments	(134,801)	(240,371)
Sales and maturities of investments	240,363	276,437
Cash flows (used in) provided by investing activities	(393,051)	29,052
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock for share-based compensation arrangements	12,221	1,354
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	459,448	(44,043)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	50,843	(42,068)
CASH AND CASH EQUIVALENTS Beginning of period	38,394	79,324
CASH AND CASH EQUIVALENTS End of period	\$ 89,237	\$ 37,256

SUPPLEMENTAL CASH FLOW DISCLOSURE:

Non-cash investing and financing activities:

Purchased capital expenditures included in accounts payable and accrued expenses	\$	131	\$	578
--	----	-----	----	-----

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

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

6

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)****1. THE COMPANY**

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

Except where specifically noted or the context otherwise requires, the use of the terms such as Alkermes and Company and we and our and us in these *Notes to Condensed Consolidated Financial Statements* refers to Alkermes and Alkermes, Inc., interchangeably.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES*Basis of Presentation*

The accompanying condensed consolidated financial statements of Alkermes for the three and six months ended September 30, 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 (the Annual Report), and the audited financial statements and notes thereto, which has been filed with the U.S. Securities and Exchange Commission (SEC). The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full fiscal year.

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 US Holdings, Inc., Alkermes, Inc., Eagle Holdings USA, Inc., Alkermes Gainesville LLC, Alkermes Controlled Therapeutics, Inc., and

Alkermes Europe, Ltd. Intercompany accounts and transactions have been eliminated.

Use of Estimates

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

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)***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 assets, liabilities, and transactions being hedged.

During the three months ended September 30, 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 and 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 three months ended September 30, 2011, the Company entered into an interest rate cap contract that was not designated as a hedging instrument. The interest rate cap is recorded at fair value with associated gains or losses recognized in current earnings 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 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 30, 2011. The adoption of this standard did not impact the Company's financial position or results of operations.

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

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 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 from agreements with Amylin Pharmaceuticals, Inc. (Amylin), and Cilag GmbH

International (Cilag). Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty whether any

9

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

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 six months ended September 30, 2011, the Company recognized into revenue \$3.0 million received from Cilag upon the achievement of developmental milestones during this period. During the six months ended September 30, 2011, the Company recognized a \$7.0 million milestone payment it received from Amylin as there were no remaining performance obligations under this agreement.

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 September 30, 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 six months ended September 30, 2011, the Company incurred approximately \$22.3 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 six months ended

Edgar Filing: Alkermes plc. - Form 10-Q

September 30, 2011, the Company's results of operations included revenues of \$9.1 million and net income of \$0.7 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	\$ 5,038
Receivables	57,408
Inventory	29,670
Prepaid expenses and other current assets	2,134
Property plant and equipment	210,800
Acquired identifiable intangible assets	689,800
Goodwill	104,989
Other assets	4,360
Accounts payable and accrued expenses	(19,048)
Deferred tax liabilities	(59,493)
Other long-term liabilities	(584)
Total	\$ 1,025,074

Asset categories acquired in the EDT acquisition included working capital, 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.

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

Collaboration agreements	\$ 500,300
NanoCrystal technology	74,600
OCR technology	66,300
In-process research and development	46,000
Trademark	2,600
Total	\$ 689,800

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 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.

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

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 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 and six months ended September 30, 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.

(In thousands, except per share data)	Three Months Ended		Six Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Revenues	\$ 121,090	\$ 112,359	\$ 244,049	\$ 210,688
Net loss	\$ (4,881)	\$ (10,008)	\$ (7,817)	\$ (23,733)
Basic and diluted loss per common share	\$ (0.04)	\$ (0.08)	\$ (0.06)	\$ (0.19)

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	
September 30, 2011					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 78,030	\$ 91	\$	\$	\$ 78,121
International government agency debt securities	31,727	115	(2)		31,840
Corporate debt securities	15,119	46			15,165
	124,876	252	(2)		125,126
Money market funds	1,201				1,201
Total short-term investments	126,077	252	(2)		126,327
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	11,000		(1)		10,999
Corporate debt securities	8,011			(425)	7,586
Strategic investments	644		(96)		548
	19,655		(97)	(425)	19,133
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	25,512		(97)	(425)	24,990
Total investments	\$ 151,589	\$ 252	\$ (99)	\$ (425)	\$ 151,317

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
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.

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)	Six Months Ended September 30,	
	2011	2010
Proceeds from the sales and maturities of marketable securities	\$ 240,363	\$ 276,437
Realized gains	\$ 37	\$ 63
Realized losses	\$ 11	\$ 20

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

The Company's available-for-sale and held-to-maturity securities at September 30, 2011 have contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized	Estimated	Amortized	Estimated
	Cost	Fair Value	Cost	Fair Value
Within 1 year	\$ 72,733	\$ 72,897	\$ 5,857	\$ 5,857
After 1 year through 5 years	71,154	70,814		
Total	\$ 143,887	\$ 143,711	\$ 5,857	\$ 5,857

At September 30, 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 has an \$8.5 million investment in a collaborative partner, Acceleron Pharma, Inc. (Acceleron), which is recorded within Other assets in the accompanying condensed consolidated balance sheets at September 30, 2011 and March 31, 2011. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company will continue to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

The Company's investment in Civitas Therapeutics, Inc. (Civitas) was \$0.9 million and \$1.3 million at September 30, 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 six months ended September 30, 2011, the Company reduced its investment in Civitas by \$0.4 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)	September 30, 2011	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	89,120	89,120		
International government agency debt securities	31,840	31,840		
Corporate debt securities	22,751		21,045	1,706
Strategic equity investments	548	548		
Interest rate cap contract	12		12	
Total	\$ 145,472	\$ 122,709	\$ 21,057	\$ 1,706
Liabilities:				
Interest rate swap contract	\$ 388		388	
Total	\$ 388	\$	\$ 388	\$
	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 six months ended September 30, 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	728
Total unrealized losses included in comprehensive loss	(69)
Balance, September 30, 2011	\$ 1,706

During the six months ended September 30, 2011, there was one investment in corporate debt securities transferred into Level 3 from Level 2 as trading in this security ceased during the period.

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

The Company's Level 3 investments at September 30, 2011 consist of two investments in corporate debt securities. The Company used a discounted cash flow model to determine the estimated fair value of these securities. The assumptions used in the discounted

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

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	\$ 306,951	\$ 302,250
Second Lien Term Loan	\$ 137,233	\$ 137,200

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)	September 30, 2011	March 31, 2011
Raw materials	\$ 13,886	\$ 3,100
Work in process	12,131	5,843
Finished goods (1)	20,719	11,127
Consigned-out inventory (2)	382	355
Total inventory	\$ 47,118	\$ 20,425

(1) At September 30, 2011 and March 31, 2011, the Company had \$1.8 million and \$2.0 million, respectively, of finished goods inventory located at its third party warehouse and shipping service provider.

(2) At September 30, 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

Property, plant and equipment consist of the following:

(In thousands)	September 30, 2011	March 31, 2011
Land	\$ 4,572	\$ 301
Building and improvements	144,606	36,792
Furniture, fixture and equipment	168,771	62,660
Leasehold improvements	45,179	44,779
Construction in progress	37,749	42,194
Subtotal	400,877	186,726
Less: accumulated depreciation	(96,266)	(91,706)

Total property, plant and equipment	\$	304,611	\$	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	September 30, 2011	
			Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 500,300	\$ (1,273)	\$ 499,027
NanoCrystal technology	13	74,600	(131)	74,469
OCR technology	12	66,300	(227)	66,073
Trademark	1	2,600	(186)	2,414
Total finite-lived intangible assets		643,800	(1,817)	641,983
Indefinite-lived intangible assets:				
IPR&D		46,000		46,000
Total		\$ 689,800	\$ (1,817)	\$ 687,983

The Company recorded goodwill of \$105.0 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 three months ended September 30, 2011. The Company recorded \$1.8 million of amortization expense related to its intangible assets during the six months ended September 30, 2011. Based upon the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheet as of September 30, 2011, is expected to be in the range of approximately \$42.0 million to \$76.0 million annually through fiscal year 2017.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	September 30, 2011	March 31, 2011
Accounts payable	\$ 15,396	\$ 9,269
Accrued compensation	17,421	17,481
Accrued other	50,933	18,184
Total accounts payable and accrued expenses	\$ 83,750	\$ 44,934

10. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	September 30, 2011	March 31, 2011
First Lien Term Loan, due September 16, 2017	\$ 306,951	\$
Second Lien Term Loan, due September 16, 2018	137,233	

Total	444,184
Less: current portion	(2,325)
Long-term debt	\$ 441,859 \$

On September 16, 2011, the Company entered into the Term Loans with certain of its subsidiaries, as guarantors, 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. 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):

Fiscal Year:

2012	\$ 775
2013	3,100
2014	3,100
2015	3,100
2016	3,100
Thereafter	436,825
Total	 \$ 450,000

The initial applicable margin for borrowings under the First Lien Term Loan will be 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 will be 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 with completion of the Company's first fiscal quarter ending after the Merger, 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. 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 September 30, 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 cap and an interest rate swap agreement, 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 six months ended September 30, 2011, the Company had amortization expense of \$0.3 million related to the offering costs and original issue discount.

11. DERIVATIVE INSTRUMENTS

During the three months ended September 30, 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 operations and comprehensive loss due to the decline in value of this contract during the three and six months ended September 30, 2011.

During the three months ended September 30, 2011, the Company entered into an interest rate swap agreement with Morgan Stanley Capital Services LLC (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

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

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 March 31, 2011
<i>Interest rate swap</i>		
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$ 388
<i>Interest rate cap</i>		
Asset derivative not designated as a hedging instrument	Other long-term assets	\$ 11

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)
September 30, 2011	\$ (245)	\$	\$

The cash flow hedge was deemed to be perfectly effective at September 30, 2011. Accordingly, the Company included the loss incurred during the three and six months ended September 30, 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 September 30, 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 September 30,		Six Months Ended September 30,	
	2011	2010	2011	2010
Cost of goods manufactured and sold	\$ 529	\$ 525	\$ 1,085	\$ 886

Edgar Filing: Alkermes plc. - Form 10-Q

Research and development	2,309	1,637	4,244	3,152
Selling, general and administrative	4,214	2,786	7,383	5,366
Total share-based compensation expense	\$ 7,052	\$ 4,948	\$ 12,712	\$ 9,404

At September 30, 2011 and March 31, 2011, \$0.5 million and \$0.6 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

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.

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

The potential common equivalent shares consisted of the following:

(In thousands)	Three Months Ended		Six Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Stock options	8,084	13,898	8,076	13,736
Restricted stock units	1,457	909	1,555	850
Total	9,541	14,807	9,631	14,586

14. INCOME TAXES

The Company recorded an income tax provision of \$3.7 million and \$3.6 million for the three and six months ended September 30, 2011, respectively, and an income tax benefit of \$0.9 million and \$1.0 million for the three and six months ended September 30, 2010, respectively. During the three months ended September 30, 2011, the Company 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 \$9.5 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 September 30, 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

The Company and/or the Company's product partners are involved in various so-called Paragraph IV litigation proceedings in the U.S. In the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by the Company) may file Abbreviated New Drug Applications (ANDAs) and, in doing so, they are not required to include preclinical and clinical data to establish safety and effectiveness of their drug. Instead, they would rely on such data provided by the New Drug Application (NDA) held with respect to the innovator drug. However, to benefit from this less costly abbreviated procedure, the ANDA applicant must demonstrate that its drug is generic or bioequivalent to the innovator drug, and, to the extent that patents protecting the innovator drug are listed in the Orange Book, the ANDA applicant must write to the holder of the NDA for the innovator drug and the patent holder (to the extent that the Orange Book-listed patents are not owned by the holder of the NDA for the innovator drug) certifying that their product either does not infringe the innovator's and patent holder's patents and/or that the relevant patents are invalid. The innovator and the patent holder may sue the ANDA applicant within 45 days of receiving the certification and, if they do so, the U.S. Food and Drug Administration may not approve the ANDA for 30 months from the date of certification unless, at some point before the expiry of those 30 months, a court makes a final decision in the ANDA applicant's favor.

The Company is involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of five different products: TriCor, Focalin XR, Avinza, Luvox CR, and Megace ES either as plaintiff or as an interested party (where the suit is being brought in the name of one of our collaborators).

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

Alkermes plc (as used in this section, together with our subsidiaries, us, we, our, Alkermes or the Company) is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. We have 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, we have a research and development center and corporate offices in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio.

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

Except where specifically noted or the context otherwise requires, the use of terms such as Alkermes and Company and we and our and us in this *Management's Discussion and Analysis of Financial Condition and Results of Operations* refers to Alkermes, to Alkermes, Inc., and to EDT, interchangeably.

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. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, would expect, anticipate, continue or other similar words. These statements discuss future expectations; contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward looking information. Forward-looking statements in this Quarterly Report on Form 10-Q include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

- our expectations regarding the commercialization of our products, 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 for our products;

- our efforts and ability to evaluate and license product candidates and build our pipeline;

- our expectations regarding our product candidates, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial potential of such product candidates 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 and product candidates, 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;

our beliefs regarding Adjusted EBITDA

our ability to protect our intellectual property rights;

our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with respect to managing such exposures;

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; and

our future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including the risks and uncertainties described or discussed in this Quarterly Report on Form 10-Q and in our Registration Statement.

Table of Contents

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

Executive Summary

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business (EDT) of Elan Corporation, plc (Elan) were combined (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.

Prior to the acquisition, EDT 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 NanoCry[®] technology. We acquired EDT to create a larger, faster-growing biopharmaceutical company that is immediately, and that we anticipate will be sustainably, profitable on a cash earnings basis with the goal of diversifying our commercialized product portfolio and pipeline candidates, enhancing our financial resources in order to invest in our proprietary drug candidates, pursuing additional growth opportunities and reducing our cost of capital. 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 U.S. GAAP, which means that the operating results of Alkermes, Inc. are included for all periods being presented, where as 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 reflect the full quarter of operations of Alkermes, Inc., and 14 days of operations of the former EDT business, together with the consolidated balance sheet as of September 30, 2011. Net loss for the three months ended September 30, 2011, was \$22.3 million, or \$0.22 per common share basic and diluted, as compared to a net loss of \$7.7 million, or \$0.08 per common share basic and diluted, for the three months ended September 30, 2010. Net loss for the six months ended September 30, 2011, was \$35.5 million, or \$0.36 per common share basic and diluted, as compared to a net loss of \$21.1 million, or \$0.22 per common share basic and diluted, for the six months ended September 30, 2010.

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 six months ended September 30, 2011, we had Adjusted EBITDA of \$13.3 million and \$16.9 million, respectively as compared to Adjusted EBITDA of \$0.5 million and \$(5.4) million for the three and six months ended September 30, 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***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, which we refer to as Janssen, and is the first and only long-acting, atypical antipsychotic approved by the United States (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. Alkermes earns 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 is commercialized in the EU under the trade name XEPLION. We earn royalties on worldwide sales of INVEGA SUSTENNA and XEPLION.

AMPYRA®/FAMPYRA®

AMPYRA (dalfampridine) is a product of Acorda Therapeutics and is a potassium channel blocker approved by the FDA in January 2010 as a treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed. AMPYRA is the first and only product approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Acorda commercially launched AMPYRA in the U.S. in March 2010.

Table of Contents

In June 2009, Acorda entered into an agreement with Biogen Idec for commercialization of dalfampridine outside the U.S. In January 2010, Biogen Idec announced that it submitted a centralized Marketing Authorization Application to the European Medicines Agency (EMA) and a New Drug Submission (NDS) to Health Canada for dalfampridine. Following a recommendation for conditional marketing authorization from the EMA s Committee for Medicinal Products for Human Use in May 2011, Biogen Idec received conditional approval in July 2011 from the European Commission for dalfampridine for the improvement of walking in adult patients with MS with walking disability. Biogen Idec commercializes dalfampridine in countries outside the U.S. in which the product is approved, under the trade name FAMPYRA. Biogen Idec received a Notice of Deficiency from Health Canada regarding its application for approval of FAMPYRA in Canada, and it responded to the Notice of Deficiency in April 2011. Health Canada has approximately a year to reply to that response. In May 2011, FAMPYRA was approved for use in Australia by the Australian Therapeutic Goods Administration. Alkermes earns manufacturing revenues and royalties on worldwide sales of AMPYRA and 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 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.

BYDUREON

We entered into an agreement with Amylin Pharmaceuticals, Inc. (Amylin) in May 2000 for the development of a once weekly formulation of exenatide, BYDUREON, for the treatment of type 2 diabetes. BYDUREON is a long-acting injectable formulation of Amylin s BYETTA® (exenatide). An NDA for BYDUREON was submitted to the FDA in May 2009. The FDA issued complete response letters on the BYDUREON NDA to Amylin in March 2010 and in October 2010. In the October 2010 complete response letter, the FDA requested a thorough QT (tQT) study with exposures of exenatide at higher than typical therapeutic levels of BYDUREON, such as those that might be achieved in patients with impaired renal function, and the submission of the results of the DURATION-5 clinical study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of BYDUREON. In 2011, Amylin conducted a tQT study in response to the complete response letter, and in July 2011, we, Eli Lilly and Company (Lilly) and Amylin announced results of the study and submitted a reply to the complete response letter for the BYDUREON NDA, which included the results of the tQT study. The FDA assigned a Prescription Drug User Fee Act action date of January 28, 2012 for BYDUREON.

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. Amylin licensed the rights to commercialize BYDUREON outside the U.S. to Lilly. 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 quarter ended September 30, 2011. We are entitled to receive an additional \$7.0 million milestone payment upon first commercial launch of BYDUREON in the U.S., if approved by the FDA. We earn royalties on sales of BYDUREON in territories in which it is commercially sold.

Table of Contents**ESTABLISHED LICENSED-PRODUCT PORTFOLIO**

We have a portfolio of additional, established products marketed by our licensees. These additional licensed products were part of EDT and we earn manufacturing and/or royalty revenues for these products. The majority of these products leverage our proprietary drug delivery technologies. These products include:

Collaborator	Product	Indication	Territory
Abbott Laboratories	<i>TriCor[®] 145, Lipanthyl</i>	Cholesterol reduction	U.S. and Certain European territories
Acorda Therapeutics, Inc.	<i>Zanaflex[®] Capsules</i>	Muscle spasticity	U.S.
Jazz Pharmaceuticals Inc.	<i>Luvox CR[®]</i>	Obsessive-Compulsive Disorder	U.S.
Pfizer Inc.	<i>Avinza[®]</i>	Chronic pain	U.S.
Merck & Co., Inc.	<i>Emend[®]</i>	Nausea associated with chemotherapy	All major territories worldwide
Novartis AG	<i>Focalin XR[®] Ritalin LA[®]</i>	Attention Deficit Hyperactivity Disorder	U.S. and Switzerland All major territories worldwide
Par Pharmaceutical Companies, Inc. (Strativa)	<i>Megace[®] ES</i>	Cachexia associated with AIDS	U.S.
Pfizer Inc.	<i>Rapamune[®]</i>	Renal transplant rejection	All major territories worldwide
Shionogi Inc. Sunovion Pharmaceuticals Canada, Inc.	<i>Naprelan[®]</i>	Pain	U.S. Canada
UCB, Inc.	<i>Verelan[®], Verelan[®] PM</i>	Hypertension	U.S.

KEY DEVELOPMENT PROGRAMS

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

ALKS 37 is an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced constipation, or 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.

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 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 plan to advance ALKS 9070 into pivotal development by the end of calendar year 2011.

ALKS 5461 is a combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for treatment-resistant depression (TRD) and cocaine addiction. We initiated a multicenter, randomized, double-blind,

Table of Contents

placebo-controlled phase 1b study of ALKS 5461 for the treatment of TRD in June 2011, and we expect to announce the results of this study in early calendar year 2012.

We filed an Investigational New Drug application (IND) for ALKS 5461 for the treatment of cocaine addiction in June 2011 and started enrollment of a phase 1/2 study. This study is expected to be 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 addiction.

ALKS 33 is an oral opioid modulator that we are developing for the potential treatment of addiction and other CNS disorders. In July 2011, we announced topline results from a phase 2 clinical study of ALKS 33 in the treatment of binge eating disorder. While ALKS 33 demonstrated a significant reduction from baseline in the efficacy endpoint of self-reported weekly binge eating episodes, the reduction was not significantly different from that observed with placebo. Based on these results, we have determined that future studies in the binge eating indication are less attractive than other potential alternatives and we will not pursue further development of ALKS 33 in this area. ALKS 33 remains in development for other CNS indications based on the compound's favorable characteristics of once-daily dosing, 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.

ZOXYDRO (hydrocodone bitartrate) extended-release capsules 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.

Meloxicam IV is a once-daily, rapid-onset, intravenous non-steroidal anti-inflammatory drug that we are developing for the management of moderate to moderately severe pain. Phase 2b studies of Meloxicam IV were completed in 2011, achieving all primary and secondary endpoints. We are continuing clinical development of Meloxicam IV evaluating the efficacy, safety and tolerability in post-operative patients.

A marketing authorization previously filed in the U.K. for MORPHELAN®, a morphine product candidate, has been withdrawn.

Results of Operations*Manufacturing and Royalty Revenues*

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Manufacturing and royalty revenues:						
RISPERDAL CONSTA	\$ 44.3	\$ 42.1	\$ 2.2	\$ 92.8	\$ 77.3	\$ 15.5
TRICOR 145	1.8		1.8	1.8		1.8
Other	7.9	0.5	7.4	8.4	1.1	7.3
Manufacturing and royalty revenues	\$ 54.0	\$ 42.6	\$ 11.4	\$ 103.0	\$ 78.4	\$ 24.6

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. Royalty fees 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 September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to a 6% increase in the unit net sales price earned on manufacturing revenues and a 3% increase in royalty fees, partially offset by a 2% decrease in the quantity shipped to Janssen. The increase in royalty fees is due to an increase in Janssen's end market sales of RISPERDAL CONSTA from \$377.7 million during the three months ended September 30, 2010 to \$390.0 million during the three months ended September 30, 2011. The increase in RISPERDAL CONSTA manufacturing revenues for the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to a 19% increase in the quantity shipped to Janssen, an 8% increase in royalty fees and a 5% increase in the unit net sales price earned on manufacturing revenues. The increase in

Table of Contents

royalty fees is due to an increase in Janssen's end market sales of RISPERDAL CONSTA from \$733.4 million during the six months ended September 30, 2010 to \$793.6 million during the three months ended September 30, 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 six months ended September 30, 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 record royalty revenues equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in the period that the product is sold by Janssen. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

TRICOR 145 and the other manufacturing and royalty revenues were primarily due to the addition of EDT's portfolio of commercialized products from September 16, 2011, the closing date of the Business Combination, through September 30, 2011.

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 six months ended September 30, 2011 and 2010:

(In millions)	2011	Three Months Ended September 30,		% of Sales	2011	Six Months Ended September 30,		% of Sales
		% of Sales	2010			% of Sales	2010	
Product sales, gross	\$ 13.3	100.0%	\$ 10.8	100.0%	\$ 27.4	100.0%	\$ 18.2	100.0%
Adjustments to product sales, gross:								
Medicaid rebates	(1.0)	(7.5)%	(0.3)	(2.8)%	(2.2)	(8.0)%	(0.8)	(4.4)%
Chargebacks	(1.0)	(7.5)%	(0.5)	(4.6)%	(2.1)	(7.7)%	(0.9)	(4.9)%
Reserve for inventory in the channel (1)		%	(2.1)	(19.4)%	(0.7)	(2.6)%	(1.7)	(9.3)%
Other	(1.4)	(10.6)%	(1.4)	(13.0)%	(2.8)	(10.2)%	(2.1)	(11.6)%
Total adjustments	(3.4)	(25.6)%	(4.3)	(39.8)%	(7.8)	(28.5)%	(5.5)	(30.2)%
Product sales, net	\$ 9.9	74.4%	\$ 6.5	60.2%	\$ 19.6	71.5%	\$ 12.7	69.8%

(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 September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to a 19% increase in price and a 3% increase in the number of

units sold. The increase in product sales, gross for the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to a 26% increase in the number of units sold and a 19% increase in price. The increase in Medicaid rebates during the three and six months ended September 30, 2011, as compared to the three and six months ended September 30, 2010, is 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 three and six months ended September 30, 2011, as compared to the three and six months ended September 30, 2010, is primarily due to the increase in the price of VIVITROL and increased Public Health Service pricing discounts. The decrease in the reserve for inventory in the channel during the three and six months ended September 30, 2011, as compared to the three and six months ended September 30, 2010, is primarily due to a decrease in the amount of VIVITROL shipped in the month of September 2011 as compared to the month of September 2010.

Table of Contents*Research and development revenue*

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Research and development revenue	\$ 8.1	\$ 0.2	\$ 7.9	\$ 11.3	\$ 0.4	\$ 10.9

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 September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to the recognition of a \$7.0 million milestone payment we earned upon the first sale of BYDUREON in the E.U. in July 2011. The increase in R&D revenue for the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to the \$7.0 million BYDUREON milestone payment 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.

Costs and Expenses*Cost of Goods Manufactured and Sold*

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Cost of goods manufactured and sold	\$ 17.5	\$ 13.9	\$ (3.6)	\$ 33.7	\$ 26.6	\$ (7.1)

The increase in cost of goods manufactured and sold in the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to \$4.9 million of cost of goods manufactured from the addition of EDT's portfolio of commercialized products from the completion of the Business Combination on September 16, 2011 through September 30, 2011, partially offset by a \$1.8 million decrease in RISPERDAL CONSTA cost of goods manufactured due to a decrease in the number of units shipped to Janssen. The increase in cost of goods manufactured and sold in the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to the additional \$4.9 million of cost of goods manufactured from EDT, an \$1.1 million increase in VIVITROL cost of goods manufactured and sold due to an increase in the number of units sold and a \$0.9 million increase in RISPERDAL CONSTA cost of goods manufactured related to an increase in the number of units shipped to Janssen.

Research and Development Expense

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Research and development	\$ 28.2	\$ 23.9	\$ (4.3)	\$ 56.2	\$ 46.9	\$ (9.3)

The increase in R&D expenses in the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to a \$4.4 million increase in costs incurred in connection with our ALKS 37 and ALKS 9070 development programs and a \$1.9 million increase in employee-related expense due to an increase in headcount within the legacy Alkermes, Inc. business, partially offset by a \$1.4 million decrease in

laboratory expenses and a \$0.7 million decrease in license and collaboration fees under our collaboration agreement with Acceleron.

The increase in R&D expenses in the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to a \$5.6 million increase in professional services, a \$4.0 million increase in employee related expense and a \$2.8 million increase in preclinical and clinical study expense, partially offset by a \$2.1 million decrease in license and collaboration fees.

The increase in professional services and preclinical and 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 legacy Alkermes, Inc. business and share-based compensation expense as recent equity grants have been 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.

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 research and development activities are tracked by project and may be reimbursed to us by our

Table of Contents

partners. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

Selling, General and Administrative Expense

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Selling, general and administrative	\$ 36.2	\$ 18.4	\$ (17.8)	\$ 67.7	\$ 38.2	\$ (29.5)

The increase in selling general and administrative (SG&A) costs for the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to a \$12.7 million increase in professional services, a \$2.4 million increase in employee related expenses and the addition of \$1.0 million in SG&A costs related to the EDT business. The increase in professional services was primarily due to costs incurred in connection with the Business Combination. 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 six months ended September 30, 2011, as compared to the six months ended September 30, 2010, was primarily due to a \$21.5 million increase in professional services, a \$4.0 million increase in employee-related expenses and the addition of \$1.0 million in SG&A costs related to the EDT business. The increase in professional services was primarily due to costs incurred in connection with the Business Combination. 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.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Amortization of acquired intangible assets	\$ 1.8	\$	\$ (1.8)	\$ 1.8	\$	\$ (1.8)

In connection with the Business Combination, we acquired certain amortizable intangible assets with a fair value of \$643.8 million, which are expected to be amortized over 12 to 13 years. We also acquired \$46.0 million of intangible assets related to various preclinical product candidates, or in-process research, and \$105.0 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		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2011	September 30, 2010		September 30, 2011	September 30, 2010	
Total other (expense), net	\$ (6.8)	\$ (1.6)	\$ (5.2)	\$ (6.3)	\$ (2.0)	\$ (4.3)

The increase in other (expense), net for the three and six months ended September 30, 2011, as compared to the three and six months ended September 30, 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 pays interest at three-month LIBOR plus 5.25% and the \$140.0 million second lien term loan facility (the Second Lien Term Loan and together the Term Loans) has a principal amount of \$140.0 million and pays interest at three-month LIBOR plus 8.00%. Under both loan agreements, three-month LIBOR is subject to an interest rate floor of 1.50%.

Income Tax Provision (Benefit)

(In millions)	Three Months Ended September 30,		Change Favorable/ (Unfavorable)	Six Months Ended September 30,		Change Favorable/ (Unfavorable)
	2011	2010		2011	2010	
Income tax provision (benefit)	\$ 3.7	\$ (0.9)	\$ (4.6)	\$ 3.6	\$ (1.0)	\$ 4.6

The increase in the income tax provision in the three and six months ended September 30, 2011, as compared to the three and six months ended September 30, 2010, is primarily due to the \$13.2 million current tax expense related to the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland and a deferred tax benefit of \$9.5 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 recorded during the three months ended September 30, 2011.

Table of Contents*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) interest expense, (ii) income taxes, (iii) depreciation and amortization, (iv) non-cash expenses relating to share based 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 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:

it does not reflect non-cash costs of our share based 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 income to our Adjusted EBITDA on a historical basis for each of the periods indicated:

(In millions)	Three Months Ended		Six Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Net loss, GAAP	\$ (22.3)	\$ (7.7)	\$ (35.5)	\$ (21.1)
Depreciation expense included in cost of goods manufactured and sold	1.5	1.0	2.4	2.0
Depreciation expense included in R&D	0.8	0.7	1.6	1.2
Depreciation expense included in SG&A	0.4	0.3	0.6	0.7
Share-based compensation included in cost of goods manufactured and sold	0.5	0.5	1.0	0.9
Share-based compensation included in R&D	2.3	1.6	4.2	3.2
Share-based compensation included in SG&A	4.2	2.8	7.4	5.4
Amortization of acquired intangible assets	1.8		1.8	
Interest expense	7.6	2.2	7.6	3.3
Income tax expense	3.7	(0.9)	3.6	(1.0)
Professional fees related to the Business Combination included in SG&A	12.8		22.2	
Adjusted EBITDA	\$ 13.3	\$ 0.5	\$ 16.9	\$ (5.4)

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2011	March 31, 2011
Cash and cash equivalents	\$ 89.2	\$ 38.4
Investments short-term	126.3	162.9
Investments long-term	25.0	93.4
 Total cash, cash equivalents and investments	 \$ 240.5	 \$ 294.7
 Working capital	 \$ 265.4	 \$ 204.9
Long-term debt	\$ 444.2	\$

Table of Contents

Our cash flows for the six months ended September 30, 2011 and 2010 were as follows:

(In millions)	Six Months Ended September 30,	
	2011	2010
Cash and cash equivalents, beginning of period	\$ 38.4	\$ 79.3
Cash (used in) operating activities	(15.6)	(27.1)
Cash (used in) provided by investing activities	(393.0)	29.1
Cash provided by (used in) financing activities	459.4	(44.0)
Cash and cash equivalents, end of period	\$ 89.2	\$ 37.3

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 decrease in cash used in operating activities during the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, is primarily due to a decrease in cash used for working capital and a decrease in cash principal payments on our 7% Notes that was allocated to operating activities to account for the original issue discount on our non-recourse RISPERDAL CONSTA secured 7% Notes (the 7% Notes). The change in cash flows (used in)/provided by investing activities during the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, is primarily due to the acquisition of EDT. The increase in cash flows provided by financing activities during the six months ended September 30, 2011, as compared to the six months ended September 30, 2010, is primarily due to the issuance of the Term Loans used to finance the acquisition of EDT. We redeemed the balance of the 7% Notes in full on July 1, 2010.

Our investments at September 30, 2011 consist of the following:

(In millions)	Amortized	Gross Unrealized		Estimated
	Cost	Gains	Losses	Fair Value
Investments short-term	\$ 126.1	\$ 0.3	\$ (0.1)	\$ 126.3
Investments long-term available-for-sale	19.6		(0.5)	19.1
Investments long-term held-to-maturity	5.9			5.9
Total	\$ 151.6	\$ 0.3	\$ (0.6)	\$ 151.3

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

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2011, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

Borrowings

At September 30, 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.

Table of Contents**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:

		Less Than One Year (Fiscal 2012)	One to Three Years (Fiscal 2013- 2014)	Three to Five Years (Fiscal 2015- 2016)	More than Five Years (After Fiscal 2017)
Contractual Cash Obligations (in thousands)	Total				
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	866	102	382	382	
Purchase obligations	6,454	6,454			
Capital expansion programs	10,641	10,641			
Total contractual cash obligations	\$ 686,900	\$ 34,134	\$ 75,633	\$ 74,876	\$ 502,257

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.

Off-Balance Sheet Arrangements

At September 30, 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.

Table of Contents

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 \$105.0 million which 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 fiscal year 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. We will perform our required annual goodwill impairment assessment during the third quarter of fiscal year 2012.

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 six 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 entered into the \$310.0 million First Lien Term Loan and the \$140.0 million Second Lien Term Loan with certain of our subsidiaries, as guarantors, 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 Loan Facilities 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 Merger, 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 an interest rate cap and an interest rate swap agreement to mitigate the interest rate risk on \$65.0 million principal amount of our term loans. The interest rate cap protects us if three-month LIBOR were to reach 1.78% from the date of issuance through December 3, 2012 and 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 0.35% at September 30, 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 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.

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 fiscal year 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 \$4.5 million.

Table of Contents

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 six months ended September 30, 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 \$5.4 million and \$1.4 million, respectively.

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 September 30, 2011. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 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 EDT are included in the results of operations of Alkermes plc beginning on September 17, 2011.

Other than changes to our processes as a result of the Business Combination, 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**

The Company and/or the Company's product partners are involved in various so-called Paragraph IV litigation proceedings in the U.S. In the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by the Company) may file Abbreviated New Drug Applications (ANDAs) and, in doing so, they are not required to include preclinical and clinical data to establish safety and effectiveness of their drug. Instead, they would rely on such data provided by the New Drug Application (NDA) held with respect to the innovator drug. However, to benefit from this less costly abbreviated procedure, the ANDA applicant must demonstrate that its drug is generic or bioequivalent to the innovator drug, and, to the extent that patents protecting the innovator drug are listed in the Orange Book, the ANDA applicant must write to the holder of the NDA for the innovator drug and the patent holder (to the extent that the Orange Book-listed patents are not owned by the holder of the NDA for the innovator drug) certifying that their product either does not infringe the innovator's and patent holder's patents and/or that the relevant patents are invalid. The innovator and the patent holder may sue the ANDA applicant within 45 days of receiving the certification and, if they do so, the U.S. Food and Drug Administration may not approve the ANDA for 30 months from the date of certification unless, at some point before the expiry of those 30 months, a court makes a final decision in the ANDA applicant's favor.

We are involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of five different products: TriCor, Focalin XR, Avinza, Luvox CR, and Megace ES either as plaintiff or as an interested party (where the suit is being brought in the name of one of our collaborators).

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 September 30, 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 November 21, 2007, our board of directors authorized a program to repurchase up to \$175.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. On June 16, 2008, the board of directors authorized the expansion of this program to \$215.0 million. We did not purchase any shares under this program during the quarter ended September 30, 2011. As of September 30, 2011, we have purchased a total of 8,866,342 shares under this program at a cost of \$114.0 million.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended September 30, 2011, Mr. Richard F. Pops, a director and executive officer of the Company, and Ms. Kathryn L. Biberstein, Mr. James M. Frates and Mr. Michael J. Landine, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

Item 6. Exhibits

(a) List of Exhibits:

Exhibit

No.

- 2.1 Business Combination Agreement and Plan of Merger, dated as of May 9, 2011, by and among Elan, Alkermes, Inc., Alkermes plc and certain other parties (Incorporated by reference to Annex A to the proxy statement/prospectus forming a part of the Registration Statement on Form S-4, as amended (Registration No. 333-175078), which was declared effective by the Securities and Exchange Commission on August 4, 2011).
- 3.1 Amended and Restated Memorandum and Articles of Association of Alkermes plc (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on September 16, 2011.)
- 4.1 Shareholder s Agreement by and among Elan, Elan Science Three Limited and Alkermes plc (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on September 16, 2011.)
- 10.1 First Lien Term Loan Credit Agreement, dated as of September 16, 2011, among Alkermes, Inc., the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 16, 2011.)
- 10.2 Second Lien Term Loan Credit Agreement, dated as of September 16, 2011, among Alkermes, Inc., the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 16, 2011.)
- 10.3 Intellectual Property Transfer Agreement, dated as of September 15, 2011 between Alkermes, Inc., Alkermes Controlled Therapeutics, Inc. and Alkermes Pharma Holdings Limited (Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on September 16, 2011.)
- 10.4 Form of Deed of Indemnification for Alkermes plc Officers (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.5 Form of Deed of Indemnification for Alkermes plc Directors/Secretary (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.6 Form of Deed of Indemnification for Alkermes Inc. and Subsidiaries Directors/Secretary (Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.7 Fiscal 2012 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.8 Shane Cooke Offer Letter, dated as of September 15, 2011 (Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on September 20, 2011.)+

Edgar Filing: Alkermes plc. - Form 10-Q

- 10.9 Employment Agreement by and between Alkermes Pharma Ireland Limited and Shane Cooke, dated as of September 16, 2011 (Incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.10 James L. Botkin Offer Letter, dated as of September 15, 2011 (Incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 10.11 Employment Agreement by and between Alkermes Gainesville LLC and James L. Botkin, dated as of September 16, 2011 (Incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K filed on September 20, 2011.)+
- 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 September 30, 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: November 3, 2011