

Alkermes plc.  
Form 10-Q  
July 30, 2015  
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 June 30, 2015

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Edgar Filing: Alkermes plc. - Form 10-Q

Ireland  
(State or other jurisdiction of incorporation or organization)

98-1007018  
(I.R.S. Employer Identification No.)

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of the registrant's ordinary shares, \$0.01 par value, outstanding as of July 27, 2015 was 149,398,549 shares.

---

Table of Contents

ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

	Page No.
<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u> <u>Condensed Consolidated Financial Statements (unaudited): Condensed Consolidated Balance Sheets — June 30, 2015 and December 31, 2014</u>	5
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss — For the Three and Six Months Ended June 30, 2015 and 2014</u>	6
<u>Condensed Consolidated Statements of Cash Flows — For the Six Months Ended June 30, 2015 and 2014</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<u>Item 2.</u>	18

	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures about Market Risk Controls and Procedures</u>	
<u>Item 3.</u>		29
<u>Item 4.</u>		29

PART II - OTHER  
INFORMATION

	<u>Legal Proceedings</u>	
<u>Item 1.</u>		30
<u>Item 1A.</u>	<u>Risk Factors</u>	30
	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	
<u>Item 2.</u>		30
	<u>Other Information</u>	
<u>Item 5.</u>		31
<u>Item 6.</u>	<u>Exhibits</u>	32
<u>Signatures</u>		33
<u>Exhibit Index</u>		34

Table of Contents

Cautionary Note Concerning Forward-Looking Statements

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

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
  - our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products, including our development programs;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations and other significant agreements relating to our products, including our development programs;
- our expectations regarding the financial impact related to the sale of our Gainesville, GA facility and the related manufacturing and royalty revenue associated with products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam and the related contingent consideration (herein referred to as the “Gainesville Transaction”);
- our expectations regarding the impact of adoption of new accounting pronouncements;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management’s objectives and strategies with respect to managing such exposures;
  - our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations; and
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

Actual results might differ materially from those expressed or implied by the forward-looking statements contained in this Form 10-Q because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements in this Form 10-Q, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Form 10-Q might not occur. For more information regarding the risks and uncertainties of our business, see “Item 1A—Risk Factors” in Part II of this Form 10-Q, “Part I, Item 1A—Risk Factors” of our Annual Report on Form 10-K for the

Edgar Filing: Alkermes plc. - Form 10-Q

year ended December 31, 2014 (the “Annual Report”) and any subsequent reports filed with the U.S. Securities and Exchange Commission (“SEC”).

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

Table of Contents

Form 10-Q and “Part I, Item 1A—Risk Factors” of our Annual Report. These and other factors could cause our results to differ materially from those expressed in the estimates included in this Form 10-Q.

Note Regarding Company

Alkermes plc (as used in this report, together with our subsidiaries, “Alkermes,” “the Company,” “us,” “we” and “our”) is an integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of commercial drug products and a clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis.

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations (“®”) and registration applications (“TM”), including ARISTADATM, LinkeRx®, NanoCrystal®, SECATM and VIVITROL®. The following are trademarks of the respective companies listed: ABILIFY®—Otsuka Pharmaceutical Co., Ltd.; AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc.; BIDILTM—Arbor Pharmaceuticals, LLC; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC; INVEGA® SUSTENNA®, INVEGA TRINZATM, XEPLION®, and RISPERDAL® CONSTA®—Johnson & Johnson Corp. (or its affiliate); MEGACE®—E.R. Squibb & Sons, LLC; RITALIN LA® and FOCALIN XR®—Novartis AG; TECFIDERA®—Biogen MA Inc.; TRICOR®—Abbvie Inc.; VERELAN®—Recro Technology, LLC; ZOHYDRO® ER—Ferrimill Limited; and ZYPREXA®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.



Table of Contents

## PART I. FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements:

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	June 30, 2015	December 31, 2014
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 196,893	\$ 224,064
Investments — short-term	579,877	407,102
Receivables, net	135,782	151,551
Inventory	38,801	51,357
Prepaid expenses and other current assets	50,424	29,289
Deferred tax assets — current	15,185	13,430
Total current assets	1,016,962	876,793
PROPERTY, PLANT AND EQUIPMENT, NET	239,258	265,740
INTANGIBLE ASSETS—NET	407,599	479,412
GOODWILL	92,873	94,212
CONTINGENT CONSIDERATION	59,100	-
INVESTMENTS—LONG-TERM	55,589	170,480
OTHER ASSETS	43,295	34,635
<b>TOTAL ASSETS</b>	<b>\$ 1,914,676</b>	<b>\$ 1,921,272</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 125,722	\$ 121,258
Long-term debt—short-term	6,750	6,750
Deferred revenue—short-term	1,746	2,574
Total current liabilities	134,218	130,582
LONG-TERM DEBT	348,056	351,220
OTHER LONG-TERM LIABILITIES	12,859	11,914
DEFERRED TAX LIABILITIES, NET—LONG-TERM	12,747	18,918
DEFERRED REVENUE—LONG-TERM	7,805	11,801
Total liabilities	515,685	524,435
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS' EQUITY:		

Edgar Filing: Alkermes plc. - Form 10-Q

Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at June 30, 2015 and December 31, 2014, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 150,581,367 and 148,545,150 shares issued; 149,304,016 and 147,538,519 shares outstanding at June 30, 2015, and December 31, 2014, respectively	1,503	1,482
Treasury shares, at cost (1,277,351 and 1,006,631 shares at June 30, 2015 and December 31, 2014, respectively)	(49,384)	(32,052)
Additional paid-in capital	2,038,700	1,942,878
Accumulated other comprehensive loss	(2,725)	(3,136)
Accumulated deficit	(589,103)	(512,335)
Total shareholders' equity	1,398,991	1,396,837
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 1,914,676</b>	<b>\$ 1,921,272</b>

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

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,	2014	June 30,	2014
	2015		2015	2014
	(In thousands, except per share amounts)			
<b>REVENUES:</b>				
Manufacturing and royalty revenues	\$ 113,162	\$ 130,366	\$ 241,906	\$ 241,646
Product sales, net	37,172	21,595	68,309	38,674
Research and development revenue	1,036	1,463	2,369	3,316
Total revenues	151,370	153,424	312,584	283,636
<b>EXPENSES:</b>				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	30,418	43,290	70,392	82,129
Research and development	87,882	67,207	158,160	119,347
Selling, general and administrative	71,539	50,663	134,589	93,213
Amortization of acquired intangible assets	14,052	15,089	29,272	27,665
Total expenses	203,891	176,249	392,413	322,354
<b>OPERATING LOSS</b>	<b>(52,521)</b>	<b>(22,825)</b>	<b>(79,829)</b>	<b>(38,718)</b>
<b>OTHER INCOME, NET:</b>				
Interest income	795	323	1,455	834
Interest expense	(3,315)	(3,385)	(6,603)	(6,741)
Gain on Gainesville Transaction	9,911	—	9,911	—
Increase in the fair value of contingent consideration	1,500	—	1,500	—
Other income (expense), net	585	518	374	(1,332)
Gain on sale of property, plant and equipment	—	12,285	—	12,285
Gain on sale of investment in Acceleron Pharma Inc.	—	15,296	—	15,296
Total other income, net	9,476	25,037	6,637	20,342
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(43,045)</b>	<b>2,212</b>	<b>(73,192)</b>	<b>(18,376)</b>
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>	<b>3,064</b>	<b>(1,523)</b>	<b>3,574</b>	<b>2,243</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (46,109)</b>	<b>\$ 3,735</b>	<b>\$ (76,766)</b>	<b>\$ (20,619)</b>
<b>(LOSS) EARNINGS PER COMMON SHARE:</b>				
Basic	\$ (0.31)	\$ 0.03	\$ (0.52)	\$ (0.14)
Diluted	\$ (0.31)	\$ 0.02	\$ (0.52)	\$ (0.14)
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				
Basic	148,867	144,913	148,480	144,140
Diluted	148,867	154,300	148,480	144,140
<b>COMPREHENSIVE LOSS:</b>				
Net (loss) income	\$ (46,109)	\$ 3,735	\$ (76,766)	\$ (20,619)

Edgar Filing: Alkermes plc. - Form 10-Q

Holding (losses) gains, net of tax of \$(39), \$6,174, \$170 and \$7,627, respectively	(80)	4,540	409	2,009
Reclassification of unrealized gains to realized gains	—	(15,296)	—	(15,296)
COMPREHENSIVE LOSS	\$ (46,189)	\$ (7,021)	\$ (76,357)	\$ (33,906)

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

6

---

Table of ContentsALKERMES PLC AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended	
	June 30,	2014
	2015	2014
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (76,766)	\$ (20,619)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	43,108	47,486
Share-based compensation expense	39,206	32,758
Deferred income taxes	(21,624)	(10,664)
Excess tax benefit from share-based compensation	(16,506)	(6,984)
Gain on Gainesville Transaction	(9,911)	—
Increase in fair value of contingent consideration	(1,500)	—
Gain on sale of property, plant and equipment	(104)	(12,160)
Gain on sale of investment of Acceleron Pharma Inc.	—	(15,296)
Other non-cash charges	(435)	9,965
Changes in assets and liabilities:		
Receivables	3,249	(5,162)
Inventory, prepaid expenses and other assets	7,012	(19,714)
Accounts payable and accrued expenses	21,138	3,693
Deferred revenue	(788)	(1,304)
Other long-term liabilities	592	3,306
Cash flows (used in) provided by operating activities	(13,329)	5,305
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions of property, plant and equipment	(24,755)	(11,438)
Proceeds from the sale of equipment	40	14,361
Net proceeds from the Gainesville Transaction	50,241	—
Purchases of investments	(269,447)	(433,203)
Sales and maturities of investments	212,143	184,446
Cash flows used in investing activities	(31,778)	(245,834)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of ordinary shares, net	—	248,406
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	21,837	21,821
Excess tax benefit from share-based compensation	16,506	6,984
Employee taxes paid related to net share settlement of equity awards	(17,032)	(12,546)
Principal payments of long-term debt	(3,375)	(3,376)
Cash flows provided by financing activities	17,936	261,289
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(27,171)</b>	<b>20,760</b>

Edgar Filing: Alkermes plc. - Form 10-Q

CASH AND CASH EQUIVALENTS—Beginning of period	224,064	167,562
CASH AND CASH EQUIVALENTS—End of period	\$ 196,893	\$ 188,322
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 4,480	\$ 1,491
Fair value of warrants received as part of Gainesville Transaction	\$ 2,123	\$ —
Fair value of contingent consideration received as part of Gainesville Transaction	\$ 57,600	\$ —

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

Table of Contents

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited)

1. THE COMPANY

Alkermes is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of commercial drug products and a clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes has a research and development (“R&D”) center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and six months ended June 30, 2015 and 2014 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2014. The year-end condensed consolidated balance sheet data, which is presented for comparative purposes, was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (“U.S.”) (commonly referred to as “GAAP”). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to state fairly the results of operations for the reported periods.

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

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly owned subsidiaries as disclosed in Note 2, Summary of Significant Accounting Policies, within the “Notes to Consolidated Financial Statements” accompanying its Annual Report. Intercompany accounts and transactions have been eliminated.

#### Use of Estimates

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

#### Segment Information

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



Table of Contents

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

New Accounting Pronouncements

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

In April 2014, the FASB adopted guidance that amends the requirements for reporting discontinued operations. Under the amendment, only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results will be reported as discontinued operations in the financial statements. Currently, many disposals, some of which may be routine in nature and not a change in an entity's strategy, are reported in discontinued operations. The Company adopted this guidance on January 1, 2015.

In June 2014, the FASB issued guidance that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. Existing GAAP does not contain explicit guidance on how to account for these share-based payments. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Entities have the option of prospectively applying the guidance to awards granted or modified after the effective date or retrospectively applying the guidance to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In January 2015, the FASB issued guidance that simplifies income statement presentation by eliminating the concept of extraordinary items. The guidance becomes effective for the Company in its year ending December 31, 2016 and is not expected to have an impact on the Company's consolidated financial statements.

In April 2015, the FASB issued guidance simplifying the presentation of debt issuance costs. To simplify presentation of debt issuance costs, the amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The guidance becomes effective for the Company in its year ending December 31, 2016, and early

adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in its year ending December 31, 2018, and the Company could early adopt the standard for its year ending December 31, 2017. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

### 3. DIVESTITURE

On March 7, 2015, the Company entered into a definitive agreement to sell the Gainesville, GA facility, the related manufacturing and royalty revenue associated with products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam to Recro Pharma, Inc. ("Recro") and Recro Pharma LLC (together with Recro, the "Purchasers"). The sale was completed on April 10, 2015 and, under the terms of the agreement, Recro paid the Company \$54.0 million in cash and issued warrants to purchase an aggregate of 350,000 shares of Recro common stock at a per share exercise price of \$19.46, which was two times the closing price of Recro's common stock on the day prior

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

to closing. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam.

The gain on the Gainesville Transaction was determined as follows:

	April 10, 2015 (In thousands)
Sales Proceeds:	
Cash	\$ 54,010
Fair value of warrants	2,123
Fair value of contingent consideration	57,600
Total consideration received	\$ 113,733
Less net assets sold	(101,373)
Less transaction costs	(2,449)
Gain on Gainesville Transaction	\$ 9,911

The Company recorded the gain on the Gainesville Transaction within the accompanying condensed consolidated statement of operations and comprehensive loss. The Company determined that the sale of assets in connection with the Gainesville Transaction did not constitute a strategic shift and that it did not and will not have a major effect on its operations and financial results. Accordingly, the operations from the Gainesville Transaction are not reported in discontinued operations.

During the three and six months ended June 30, 2015, the Gainesville, GA facility and associated intellectual property (“IP”) generated income before income taxes of \$2.4 million and \$7.6 million, respectively, and generated income before income taxes of \$7.8 million and \$16.4 million during the three and six months ended June 30, 2014, respectively.

The Company determined the value of the Gainesville Transaction’s contingent consideration using the following valuation approaches:

- The fair value of the two regulatory milestones were estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone events to occur within the next two and three years, respectively, and used a discount rate of 4.2% and 4.9%, respectively, for each of these events.
- To estimate the fair value of future royalties on net sales of the product, the Company assessed the likelihood of the product being approved for sale and expected future sales given approval and IP protection. The Company then discounted these expected payments using a discount rate of 15.9%, which the Company believes captures a market participant's view of the risk associated with the expected payments.
- The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt plus an alpha, which ranged from 11.3% to 12.2%.

At June 30, 2015, the Company determined that the value of the Gainesville Transaction's contingent consideration increased to \$59.1 million due primarily to a shorter time to payment on the milestones and royalties included in the contingent consideration. The \$1.5 million increase was recorded as "Change in the fair value of contingent consideration" in the three months ended June 30, 2015 in the accompanying condensed consolidated statements of operations and comprehensive loss.

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

The warrants the Company received to purchase 350,000 shares of Recro common stock were determined to have a fair value of \$2.1 million on the closing date of the transaction. At June 30, 2015, the Company determined that the value of these warrants had increased to \$3.0 million and are being recorded within other long-term assets in the accompanying condensed consolidated balance sheets. The company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at June 30, 2015:

Closing stock price at June 30, 2015	\$ 12.92
Warrant strike price	\$ 19.46
Expected term (years)	6.78
Risk-free rate	2.07 %
Volatility	80.0 %

The increase in the fair value of the warrants of \$0.9 million during the three months ended June 30, 2015 was recorded within other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss.

## 4. INVESTMENTS

Investments consisted of the following:

Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
		Less than One Year	Greater than One Year	
(In thousands)				

June 30, 2015

Edgar Filing: Alkermes plc. - Form 10-Q

Short-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	\$ 342,084	\$ 394	\$ (12)	\$ —	\$ 342,466
Corporate debt securities	220,406	75	(80)	—	220,401
International government agency debt securities	17,000	11	(1)	—	17,010
Total short-term investments	579,490	480	(93)	—	579,877

Long-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	24,996	—	(32)	—	24,964
Corporate debt securities	19,068	—	(48)	—	19,020
International government agency debt securities	9,995	—	(9)	—	9,986
	54,059	—	(89)	—	53,970

Held-to-maturity securities:

Certificates of deposit	1,619	—	—	—	1,619
Total long-term investments	55,678	—	(89)	—	55,589
Total investments	\$ 635,168	\$ 480	\$ (182)	\$ —	\$ 635,466

December 31, 2014

Short-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	\$ 226,387	\$ 88	\$ (15)	\$ —	\$ 226,460
Corporate debt securities	140,900	26	(66)	—	140,860
International government agency debt securities	39,774	13	(5)	—	39,782
Total short-term investments	407,061	127	(86)	—	407,102

Long-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	100,429	—	(196)	(40)	100,193
Corporate debt securities	61,187	—	(84)	—	61,103
International government agency debt securities	7,568	—	(2)	(1)	7,565
	169,184	—	(282)	(41)	168,861

Held-to-maturity securities:

Certificates of deposit	1,619	—	—	—	1,619
Total long-term investments	170,803	—	(282)	(41)	170,480
Total investments	\$ 577,864	\$ 127	\$ (368)	\$ (41)	\$ 577,582

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

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

(In thousands)	Six Months Ended June 30,	
	2015	2014
Proceeds from the sales and maturities of marketable securities	\$ 212,143	\$ 184,446
Realized gains	\$ 16	\$ 15,304
Realized losses	\$ 1	\$ 10

The Company's available-for-sale and held-to-maturity securities at June 30, 2015 had 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	\$ 342,340	\$ 342,368	\$ 1,619	\$ 1,619
After 1 year through 5 years	291,209	291,479	—	—
Total	\$ 633,549	\$ 633,847	\$ 1,619	\$ 1,619

At June 30, 2015, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of U.S. government and agency debt securities and corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in healthcare, pharmaceutical and life sciences sectors. The Company's commitment represents approximately 7% of the partnership's total funding, and the Company is accounting for its investment in Fountain under the equity method. At June 30, 2015, the Company had made payments of, and its investment is equal to, \$1.5 million (€1.2 million), which is included within "Other assets" in the

accompanying condensed consolidated balance sheets. During the three and six months ended June 30, 2015, the Company recorded a reduction in its investment in Fountain of less than \$0.1 million and \$0.1 million, respectively, which represented the Company's proportional share of Fountain's net losses for these periods.

## 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)	June 30, 2015	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	\$ 367,430	\$ 220,286	\$ 147,144	\$ —
Corporate debt securities	239,421	—	239,421	—
International government agency debt securities	26,995	—	26,995	—
Contingent consideration	59,100	—	—	59,100
Common stock warrants	2,999	—	—	2,999
Total	\$ 695,945	\$ 220,286	\$ 413,560	\$ 62,099



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

	December 31, 2014	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	\$ 326,653	\$ 189,030	\$ 137,623	\$ —
Corporate debt securities	201,963	—	201,963	—
International government agency debt securities	47,347	—	47,347	—
Total	\$ 575,963	\$ 189,030	\$ 386,933	\$ —

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period. There were no transfers of any securities between the fair value hierarchies during the six months ended June 30, 2015.

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

The following table is a rollforward of the fair value of the Company's assets whose fair value was determined using Level 3 inputs at June 30, 2015:

(In thousands)	Fair Value
Balance, January 1, 2015	\$ —
Acquisition of contingent consideration	57,600
Acquisition of common stock warrants	2,123
Increase in fair value of contingent consideration	1,500
Increase in fair value of warrants	876
Balance, June 30, 2015	\$ 62,099

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's condensed consolidated balance sheets consisted of the \$300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% ("Term Loan B-1") and the \$75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor ("Term Loan B-2" and together with Term Loan B-1, the "Term Loan Facility"). The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future, was as follows at June 30, 2015:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 290,167	\$ 291,569
Term Loan B-2	\$ 64,639	\$ 64,567

## 6. INVENTORY

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

(In thousands)	June 30, 2015	December 31, 2014
Raw materials	\$ 16,625	\$ 21,101
Work in process	10,410	14,824
Finished goods	11,766	15,432
Total inventory	\$ 38,801	\$ 51,357

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

## 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Land	\$ 5,866	\$ 8,163
Building and improvements	132,936	149,158
Furniture, fixture and equipment	193,212	225,834
Leasehold improvements	13,067	12,971
Construction in progress	55,402	39,774
Subtotal	400,483	435,900
Less: accumulated depreciation	(161,225)	(170,160)
Total property, plant and equipment, net	\$ 239,258	\$ 265,740

In April 2015, as part of the Gainesville Transaction, the Company sold certain of its land, buildings, equipment and construction in progress that had a carrying value of \$38.3 million.

In April 2014, the Company sold certain of its land, buildings and equipment at its Athlone, Ireland facility that had a carrying value of \$2.2 million in exchange for \$17.5 million. \$3.0 million of the sale proceeds will remain in escrow pending the completion of certain additional services the Company is obligated to perform, and will be recognized as “Gain on sale of property, plant and equipment” in the statements of operations and comprehensive loss as the services are provided.

## 8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Weighted Amortizable Life (Years)	Six Months Ended June 30, 2015		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,873	\$ —	\$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 465,590	\$ (144,721)	\$ 320,869
NanoCrystal technology	13	74,600	(15,758)	58,842
OCR technologies	12	42,560	(14,672)	27,888
Total		\$ 582,750	\$ (175,151)	\$ 407,599

In April 2015, as part of the Gainesville Transaction, the Company reduced the value of its goodwill by \$1.3 million and sold and/or licensed certain of its collaboration agreements with third-party pharmaceutical companies and Oral Controlled Release (“OCR”) technology which had a gross carrying amount of \$34.1 million and \$23.7 million, respectively.

Based on the Company’s most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at June 30, 2015 is expected to be approximately \$60.0 million, \$60.0 million, \$60.0 million, \$60.0 million and \$55.0 million in the years ending December 31, 2015 through 2019, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company’s actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

## 9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Accounts payable	\$ 26,945	\$ 32,335
Accrued compensation	29,113	36,854
Accrued product reserves	18,261	12,607
Accrued other	51,403	39,462
Total accounts payable and accrued expenses	\$ 125,722	\$ 121,258

## 10. RESTRUCTURING

On April 4, 2013, the Company approved a restructuring plan at its Athlone, Ireland manufacturing facility consistent with the evolution of the Company's product portfolio and designed to improve operational performance for the future. The restructuring plan calls for the Company to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from its customers resulting from generic competition. The Company expects to continue to generate revenues from the manufacturing of these products through the year ending December 31, 2015.

As a result of the termination of these services, the Company also implemented a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the twelve months ended March 31, 2013, the Company recorded a restructuring charge of \$12.3 million, which consisted of severance and outplacement services. The Company has paid in cash \$11.8 million and recorded an adjustment of less than \$0.1 million due to changes in foreign currency since inception of this restructuring plan.

Restructuring activity during the six months ended June 30, 2015 was as follows:

Severance and

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Outplacement Services
Balance, January 1, 2015	\$ 1,328
Payments	(743)
Adjustments	(116)
Balance, June 30, 2015	\$ 469

At June 30, 2015 and December 31, 2014, this restructuring accrual was included within “Accounts payable and accrued expenses,” in the accompanying condensed consolidated balance sheets.

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Term Loan B-1, due September 25, 2019	\$ 290,167	\$ 291,476
Term Loan B-2, due September 25, 2016	64,639	66,494
Total	354,806	357,970
Less: current portion	(6,750)	(6,750)
Long-term debt	\$ 348,056	\$ 351,220

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

## 12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Cost of goods manufactured and sold	\$ 478	\$ 1,770	\$ 2,495	\$ 4,079
Research and development	5,466	4,079	9,923	7,482
Selling, general and administrative	15,933	13,489	26,788	21,197
Total share-based compensation expense	\$ 21,877	\$ 19,338	\$ 39,206	\$ 32,758

At June 30, 2015 and December 31, 2014, \$0.7 million and \$0.8 million, respectively, of share-based compensation cost was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

## 13. (LOSS) EARNINGS PER SHARE

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

Three Months Ended	Six Months Ended
June 30,	June 30,

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	2015	2014	2015	2014
Numerator:				
Net (loss) income	\$ (46,109)	\$ 3,735	\$ (76,766)	\$ (20,619)
Denominator:				
Weighted average number of ordinary shares outstanding	148,867	144,913	148,480	144,140
Effect of dilutive securities:				
Stock options	—	8,067	—	—
Restricted stock units	—	1,320	—	—
Dilutive ordinary share equivalents	—	9,387	—	—
Shares used in calculating diluted loss per share	148,867	154,300	148,480	144,140

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

(In thousands)	Three Months		Six Months Ended	
	Ended June 30, 2015	2014	June 30, 2015	2014
Stock options	9,643	1,879	9,175	9,644
Restricted stock units	2,129	695	2,169	1,892
Total	11,772	2,574	11,344	11,536

#### 14. INCOME TAXES

The Company recorded an income tax provision of \$3.1 million and \$3.6 million for the three and six months ended June 30, 2015, respectively, and an income tax benefit and income tax provision of \$1.5 million and \$2.2 million for the three and six months ended June 30, 2014, respectively. In all of these periods, the income tax provision or benefit primarily relates to U.S. Federal and state taxes on income.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At June 30, 2015, the Company maintained a valuation allowance against certain of its U.S. and foreign deferred tax assets. The Company evaluates, at each reporting period, the need for a valuation allowance on its deferred tax assets on a jurisdiction by jurisdiction basis.



Table of Contents

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited) (Continued)

15. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. For example, the Company is currently involved in various Paragraph IV lawsuits in the U.S. and other proceedings outside of the U.S. involving its patents in respect of TRICOR, MEGACE ES and AMPYRA. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition, cash flows and results of operations.

Table of Contents

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

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

Executive Summary

Net loss for the three months ended June 30, 2015 was \$46.1 million, or \$0.31 per ordinary share— basic and diluted, as compared to a net income of \$3.7 million, or \$0.03 per ordinary share— basic and \$0.02 per ordinary share— diluted for the three months ended June 30, 2014. Net loss for the six months ended June 30, 2015 was \$76.8 million, or \$0.52 per ordinary share— basic and diluted, as compared to a net loss of \$20.6 million, or \$0.14 per ordinary share— basic and diluted, for the six months ended June 30, 2014.

The increase in the net loss incurred in the three and six months ended June 30, 2015, as compared to the prior comparable periods, was primarily due to increases in R&D expense, reflecting an increased investment in our CNS development pipeline, and SG&A expense, reflecting our preparation for the anticipated launch of ARISTADA, our proposed name for aripiprazole lauroxil, later in 2015. The increase in R&D and SG&A expense were partially offset by an increase in net sales of VIVITROL in both the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014. These items are discussed in greater detail later in Results of Operations.

Also impacting the increase in the net loss in the three and six months ended June 30, 2015 was the sale of our facility in Gainesville, GA and the related manufacturing and royalty revenue associated with products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL. During the three and six months ended June 30, 2015, the Gainesville, GA facility generated income before income taxes of \$2.4 million and \$7.6 million, respectively, and generated income before income taxes of \$7.8 million and \$16.4 million during the three and six months ended June 30, 2014, respectively.

Products

Marketed Products

Our key marketed products, which are discussed below, are expected to generate significant revenues for us. They possess long patent lives and, we believe, are singular or competitively advantaged products in their class. Refer to the “Patents and Proprietary Rights” section of our Annual Report for information with respect to the intellectual property protection for our marketed products. We expect revenues from our other marketed products, taken together, to decrease in the future due to existing and expected competition from generic manufacturers.

#### RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA

RISPERDAL CONSTA (risperidone long-acting injection), INVEGA SUSTENNA/XEPLION (one-month paliperidone palmitate) and INVEGA TRINZA (three-month paliperidone palmitate) are long-acting atypical antipsychotics that incorporate our proprietary technologies and are commercialized worldwide by Janssen Pharmaceutica Inc. (“Janssen, Inc.”), Janssen Pharmaceutica International, a division of Cilag International AG (“Janssen International”), and Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates, “Janssen”).

RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is exclusively manufactured by us.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and, as of November 2014, for the

Table of Contents

treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union ("EU") and other countries worldwide for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION 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/XEPLION is manufactured by Janssen.

In May 2015, Janssen announced that the U.S. Food and Drug Administration ("FDA") approved INVEGA TRINZA, an atypical antipsychotic injection, for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. INVEGA TRINZA, the first schizophrenia treatment to be taken just four times a year, became commercially available in the U.S. in June 2015. INVEGA TRINZA uses our proprietary technology and is manufactured by Janssen.

AMPYRA/FAMPYRA

AMPYRA/FAMPYRA, to our knowledge, is the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with multiple sclerosis ("MS") who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen International GmbH ("Biogen") outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency ("EMA") conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of July 2014. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

BYDUREON

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. From August 2012 until February 2014, Bristol-Myers Squibb Company ("Bristol-Myers") and AstraZeneca plc ("AstraZeneca") co-developed and marketed BYDUREON through their diabetes collaboration. In February 2014, AstraZeneca assumed sole responsibility for the development and commercialization of BYDUREON. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly injectable medication approved in the U.S. and Russia and certain of the Commonwealth of Independent States (“CIS”) for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently commercialize, VIVITROL in the U.S., and Cilag GmbH International commercializes VIVITROL in Russia and certain countries of the CIS.

#### Key Development Programs

We also have several proprietary product candidates in various stages of development, as discussed below. Refer to the “Patents and Proprietary Rights” section of our Annual Report for information with respect to the intellectual property protection for our development products.

#### ARISTADA

ARISTADA is an injectable atypical antipsychotic with one-month and extended-duration formulations in development for the treatment of schizophrenia. Once in the body, ARISTADA converts into aripiprazole, which is generally available under the name ABILIFY. As a long-acting investigational medication based on our proprietary LinkeRx technology, ARISTADA is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format. In August 2014, we submitted a New Drug Application (“NDA”) to the FDA for ARISTADA

Table of Contents

for the treatment of schizophrenia. The FDA accepted our application for filing in October 2014, and granted us a Prescription Drug User Fee Act ("PDUFA") date of August 22, 2015.

ALKS 5461

ALKS 5461 is a proprietary, oral investigational medicine in development for the treatment of major depressive disorder ("MDD") in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan, formerly referred to as ALKS 33, is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 5461 acts as a balanced neuromodulator in the brain and represents a new approach with a novel mechanism of action for treating MDD. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies.

In January 2015, we announced topline results from FORWARD-1, one of a series of supportive clinical studies in the FORWARD phase 3 pivotal program designed to evaluate the safety and tolerability of two titration schedules of ALKS 5461. Data from FORWARD-1 confirmed the safety and tolerability of ALKS 5461 in both titration schedules evaluated—one-week and two-week dose escalation schedules. These findings were consistent with the safety and tolerability profile seen in the phase 2 study of ALKS 5461 completed in 2013. In addition, the exploratory efficacy analyses showed that ALKS 5461 reduced depressive symptoms from baseline in patients who received either of the two titration schedules. These data support the one-week titration schedule being utilized in the on-going core phase 3 efficacy studies in the FORWARD program.

ALKS 3831

ALKS 3831 is a novel, proprietary investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in the treatment of schizophrenia in patients with alcohol use.

In January 2015, we announced data from the first phase of a randomized, dose ranging, six-month phase 2 study of ALKS 3831 designed to assess the efficacy, safety and tolerability of ALKS 3831 in the treatment of schizophrenia and its attenuation of weight gain, compared to olanzapine. ALKS 3831 met the primary endpoint of the study, demonstrating equivalence to olanzapine in reduction from baseline in Positive and Negative Syndrome Scale

(“PANSS”) total scores at week 12. Results showed that ALKS 3831 also met the secondary endpoint of demonstrating a lower mean percent weight gain compared to olanzapine at week 12 in the full study population, and a lower mean percent weight gain compared to olanzapine at week 12 in a pre-specified subset of patients who gained weight during the one-week olanzapine lead-in.

In April 2015, we announced data from the completed, six-month, randomized, dose-ranging phase 2 study of ALKS 3831. Patients who received ALKS 3831 during the first phase of the study, which lasted for three months, continued to receive the same dose of ALKS 3831, and patients who had received olanzapine during the first phase were switched to ALKS 3831. Data from the completed study supported and extended the initial positive results showing ALKS 3831’s favorable efficacy and mean weight gain profile and demonstrated for the first time that switching patients from olanzapine to ALKS 3831 resulted in a cessation of mean weight gain. Based on the positive results from our phase 2 study, we plan to advance ALKS 3831 into a pivotal development program in the fourth quarter of 2015.

#### ALKS 6428

In July 2015, we announced the initiation of a new phase 3 program called ALKS 6428. ALKS 6428 is a seven-day taper kit, designed to help physicians transition patients from opioid agonists to antagonist therapy in an outpatient setting and successfully initiate treatment with VIVITROL. We will begin the phase 3 study of ALKS 6428 in the third quarter of 2015.

Table of Contents

ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate ("MMF") molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In May 2015, we presented positive results from a phase 1, randomized, double-blind clinical study of ALKS 8700, designed to evaluate the safety, tolerability and single-dose pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups. Data from the study showed that ALKS 8700 was generally well tolerated and provided MMF exposures comparable to TECFIDERA, with less variability and favorable gastrointestinal tolerability. The most common adverse events were flushing and gastrointestinal-related. Based on the positive results from our phase 1 study, we requested a meeting with the FDA and plan to advance ALKS 8700 with twice-daily dosing into a pivotal development program in the fourth quarter of 2015.

RDB 1450

RDB 1450, formerly referred to as RDB 1419, is our selective effector cell activator ("SECA") that is designed to harness a patient's immune system to preferentially activate and increase the number of tumor killing immune cells. SECA proteins selectively target immune cells to avoid expansion of immune regulatory cells which interfere with the anti-tumor response. SECA molecules are engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic product. We filed an Investigational New Drug ("IND") application with the FDA in the second quarter of 2015 and plan to begin phase 1 clinical trials in the fall of 2015.

ALKS 7119

ALKS 7119 is a novel, proprietary investigational medicine that has a multivalent mechanism of action that acts on key receptors in the brain involved in several CNS diseases, including agitation in Alzheimer's disease, MDD and others. Based on correspondence with the FDA, we are conducting one additional preclinical study and now expect to initiate the first clinical study of ALKS 7119 early in the first quarter of 2016.

Other Partnered Product Candidates



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

## Results of Operations

### Manufacturing and Royalty Revenues

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues earned in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014:

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	June 30, 2015	2014		June 30, 2015	2014	
Manufacturing and royalty revenues:						
AMPYRA/FAMPYRA	\$ 26.9	\$ 19.5	\$ 7.4	\$ 63.5	\$ 40.1	\$ 23.4
INVEGA SUSTENNA/XEPLION	37.4	33.1	4.3	61.2	54.1	7.1
RISPERDAL CONSTA	23.4	26.9	(3.5)	46.5	55.5	(9.0)
BYDUREON	11.1	8.8	2.3	20.9	16.5	4.4
RITALIN LA/FOCALIN XR	0.7	10.9	(10.2)	9.3	20.6	(11.3)
Other	13.7	31.2	(17.5)	40.5	54.8	(14.3)
Manufacturing and royalty revenues	\$ 113.2	\$ 130.4	\$ (17.2)	\$ 241.9	\$ 241.6	\$ 0.3

Table of Contents

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was primarily due to revenues earned on AMPYRA. The increase in AMPYRA revenue was primarily due to a 10% increase in the number of units we shipped to Acorda and a \$2.7 million increase in revenue earned from shipments of AMPYRA made to Acorda by a third-party manufacturer. Under our AMPYRA supply agreement with Acorda, we earn manufacturing and royalty revenues when AMPYRA is shipped to Acorda, either by us or a third-party manufacturer.

AMPYRA/FAMPYRA manufacturing and royalty revenues in the six months ended June 30, 2015 consisted of a \$21.2 million increase in revenues from AMPYRA and a \$2.2 million increase in revenues from FAMPYRA, as compared to the six months ended June 30, 2014. The increase in AMPYRA revenue was primarily due to a 29% increase in the number of units we shipped to Acorda and an \$8.6 million increase in revenue earned from shipments of AMPYRA made to Acorda by a third-party manufacturer. The increase in FAMPYRA revenues was primarily due to a 53% increase in the number of units we shipped to Biogen, partially offset by a 4% decrease in our estimate of end-market sales of FAMPYRA by Biogen. Under our FAMPYRA supply and license agreements with Biogen, we earn manufacturing revenue when FAMPYRA is shipped to Biogen and we earn royalties upon end-market sales of FAMPYRA by Biogen.

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three and six months ended June 30, 2015, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$436.0 million and \$847.0 million, respectively, as compared to \$394.0 million and \$767.0 million in the three and six months ended June 30, 2014, respectively. Partially offsetting the increase in INVEGA SUSTENNA/XEPLION end-market sales by Janssen in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was a 9% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which XEPLION is sold. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION of: 5% on calendar-year net sales up to \$250 million; 7% on calendar-year net sales of between \$250 million and \$500 million; and 9% on calendar-year net sales exceeding \$500 million. The royalty rate resets to 5% at the beginning of each calendar year.

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was due to an 18% decrease in royalty revenues and an 11% decrease in manufacturing revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$302.0 million in the three months ended June 30, 2014 to \$247.0 million in the three months ended June 30, 2015. The decrease in manufacturing revenues was primarily due to an 18% decrease in the amount of RISPERDAL CONSTA shipped to Janssen. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was due to an 18% decrease in royalty revenues and a 16% decrease in manufacturing revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$612.0 million in the six months ended June 30, 2014 to \$501.0 million in the six months ended June 30, 2015. The decrease in manufacturing revenues was primarily due to a 15% decrease in the amount of RISPERDAL CONSTA

shipped to Janssen. Contributing to the decrease in RISPERDAL CONSTA end-market sales by Janssen in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was a 10% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which RISPERDAL CONSTA is sold. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen's end-market net sales of RISPERDAL CONSTA.

The increase in BYDUREON royalty revenues in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was due to an increase in end-market sales of BYDUREON by AstraZeneca. During the three and six months ended June 30, 2015, our estimate of AstraZeneca's end-market sales of BYDUREON was \$137.5 million and \$261.0 million, respectively, as compared to \$111.9 million and \$209.2 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the three and six months ended June 30, 2014, respectively.

The decrease in RITALIN LA/FOCALIN XR and other revenues was primarily due to the Gainesville Transaction.

Table of Contents

In the year ending December 31, 2015, we expect that the loss of the RITALIN LA/FOCALIN XR, VERELAN and ZOHYDRO ER product franchises will result in an approximate \$40.0 million decrease in manufacturing and royalty revenue when compared to the year ended December 31, 2014.

## Product Sales, net

Our product sales, net consist of sales of VIVITROL in the U.S. to wholesalers, a specialty distributor and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three and six months ended June 30, 2015 and 2014:

(In millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	% of Sales	2014	% of Sales	2015	% of Sales	2014	% of Sales
Product sales, gross	\$ 53.1	100.0 %	\$ 31.6	100.0 %	\$ 96.9	100.0 %	\$ 57.5	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(4.7)	(8.9) %	(2.8)	(8.9) %	(8.1)	(8.4) %	(4.4)	(7.7) %
Chargebacks	(4.2)	(7.9) %	(2.1)	(6.6) %	(7.7)	(7.9) %	(3.6)	(6.3) %
Product discounts	(3.9)	(7.3) %	(2.2)	(7.0) %	(7.2)	(7.4) %	(4.1)	(7.1) %
Co-pay assistance	(1.8)	(3.4) %	(1.6)	(5.1) %	(3.2)	(3.3) %	(2.9)	(5.0) %
Product returns	(0.6)	(1.1) %	(0.9)	(2.8) %	(1.0)	(1.0) %	(1.4)	(2.4) %
Other	(0.7)	(1.3) %	(0.4)	(1.2) %	(1.4)	(1.4) %	(2.4)	(4.2) %
Total adjustments	(15.9)	(29.9) %	(10.0)	(31.6) %	(28.6)	(29.4) %	(18.8)	(32.7) %
Product sales, net	\$ 37.2	70.1 %	\$ 21.6	68.4 %	\$ 68.3	70.6 %	\$ 38.7	67.3 %

The increase in product sales, gross for the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was due to a 53% increase in the number of units sold and a 10% increase in price dating back to December 2014. The increase in product sales, gross for the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was due to a 50% increase in the number of units sold and a 13% increase in price. The increase in amount of Medicaid rebates, chargebacks and product discounts in both the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to the increase in the

sales volume of VIVITROL.

## Costs and Expenses

### Cost of Goods Manufactured and Sold

(In millions)	Three Months		Change Favorable/ (Unfavorable)	Six Months		Change Favorable/ (Unfavorable)
	Ended June 30, 2015	2014		Ended June 30, 2015	2014	
Cost of goods manufactured and sold	\$ 30.4	\$ 43.3	\$ 12.9	\$ 70.4	\$ 82.1	\$ 11.7

The decrease in cost of goods manufactured and sold during the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to the Gainesville Transaction in April 2015. During the three months ended June 30, 2015, the Gainesville facility had cost of goods manufactured of \$0.8 million, as compared to \$10.8 million during the three months ended June 30, 2014, primarily related to the sale of RITALIN LA/FOCALIN XR, VERELAN and ZOXYDOL ER. In the year ending December 31, 2015, we expect that the loss of these products will result in an approximate \$25.0 million decrease in cost of goods manufactured when compared to the year ended December 31, 2014.

Table of Contents

In addition to the decrease in cost of goods manufactured and sold related to the Gainesville Transaction, the cost of goods manufactured at our Athlone facility decreased by \$3.7 million and \$4.6 million in the three and six months ended June 30, 2015, respectively, as compared to the three and six months ended June 30, 2014. This decrease is primarily due to the April 2013 restructuring plan as discussed in Note 10, Restructuring, in the notes to condensed consolidated statements. These decreases were partially offset by an increase in cost of goods manufactured and sold related to our Ohio manufacturing facility of \$1.2 million and \$2.4 million in the three and six months ended June 30, 2015, respectively, as compared to the corresponding prior periods, due primarily to the increase in sales of VIVITROL in 2015.

## Research and Development Expense

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

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

(In millions)	Three Months		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	Ended June 30, 2015	2014		June 30, 2015	2014	
External R&D Expenses:						
Key development programs:						
ALKS 5461	\$ 30.3	\$ 20.7	\$ (9.6)	\$ 50.4	\$ 31.7	\$ (18.7)
ARISTADA	10.2	5.8	(4.4)	19.3	13.2	(6.1)
ALKS 3831	4.9	6.0	1.1	10.0	11.1	1.1
ALKS 8700	5.0	2.3	(2.7)	6.7	3.8	(2.9)
ALKS 7106	—	2.4	2.4	—	3.6	3.6
Other development programs	7.9	4.2	(3.7)	13.0	6.7	(6.3)
Total external expenses	58.3	41.4	(16.9)	99.4	70.1	(29.3)
Internal R&D expenses:						
Employee-related	22.9	19.4	(3.5)	45.1	36.8	(8.3)

Edgar Filing: Alkermes plc. - Form 10-Q

Occupancy	1.9	1.8	(0.1)	4.1	3.4	(0.7)
Depreciation	1.4	2.0	0.6	3.0	4.1	1.1
Other	3.3	2.6	(0.7)	6.6	4.9	(1.7)
Total internal R&D expenses	29.5	25.8	(3.7)	58.8	49.2	(9.6)
Research and development expenses	\$ 87.8	\$ 67.2	\$ (20.6)	\$ 158.2	\$ 119.3	\$ (38.9)

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

The increase in expenses related to ALKS 5461 was the result of the timing of three core phase 3 efficacy studies, long-term safety studies and other supporting studies related to the program. We initiated the pivotal clinical development program for ALKS 5461 in March 2014 and data from these studies is expected in 2016. The increase in expenses related to the ARISTADA program was primarily due to the initiation of the phase 1 clinical study of extended dosing intervals of ARISTADA in patients with schizophrenia in December 2014. Expenses incurred under the ALKS 6428, RDB 1450 and ALKS 7119 development programs were not material in the three months ended June 30, 2015 and 2014. The increase in employee-related expenses was primarily due to an increase in headcount as our R&D related headcount has increased by 20% since June 30, 2014 and 10% since December 31, 2014.

Table of Contents

## Selling, General and Administrative Expense

(In millions)	Three Months		Change Favorable/ (Unfavorable)	Six Months Ended		Change Favorable/ (Unfavorable)
	Ended June 30, 2015	2014		June 30, 2015	2014	
Selling, general and administrative expense	\$ 71.5	\$ 50.7	\$ (20.9)	\$ 134.6	\$ 93.2	\$ (41.4)

The increase in SG&A expense for the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to a \$14.3 million and \$25.3 million increase in employee related expenses, respectively, when compared to the corresponding prior periods. This increase in employee related expenses was primarily due to us increasing the size of our commercial operations team as we near the PDUFA date for ARISTADA in August 2015 and preparing for the commercial launch of the product shortly thereafter. Our SG&A-related headcount has increased by 97% from June 30, 2014 and 81% from December 31, 2014.

In addition, as part of the pre-launch planning activities for ARISTADA, our marketing expenses increased by \$3.0 million and \$2.7 million in the three and six months ended June 30, 2015, respectively, when compared to the corresponding prior periods and we had a \$7.2 million increase in professional services in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014.

We also had a \$2.3 million and \$3.9 million increase in IT-related expenses in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014. These increases were primarily due to the anticipated commercial launch of ARISTADA as we purchased hardware to support the increase in our headcount and software to enhance the infrastructure of our commercial operations team.

We expect SG&A expenses to continue to increase in 2015 as pre-launch planning activities accelerate for ARISTADA.

## Amortization of Acquired Intangible Assets



(In millions)	Three Months		Change Favorable/ (Unfavorable)	Six Months		Change Favorable/ (Unfavorable)
	Ended June 30, 2015	2014		Ended June 30, 2015	2014	
Amortization of acquired intangible assets	\$ 14.1	\$ 15.1	\$ 1.0	\$ 29.3	\$ 27.7	\$ (1.6)

The intangible assets being amortized in the three and six months ended June 30, 2015 and 2014 were acquired as part of the acquisition of Elan Drug Technologies (“EDT”) in September 2011. In connection with the acquisition of EDT, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which were expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract.

As part of the Gainesville Transaction, we sold certain of the IP we acquired from EDT that had an original cost of \$57.8 million. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at June 30, 2015 is expected to be approximately \$60.0 million, \$60.0 million, \$60.0 million, \$60.0 million and \$55.0 million in the years ending December 31, 2015 through 2019, respectively.

Table of Contents

## Other (Expense) Income, Net

(In millions)	Three Months		Change Favorable/ (Unfavorable)	Six Months		Change Favorable/ (Unfavorable)
	Ended June 30, 2015	2014		Ended June 30, 2015	2014	
Interest income	\$ 0.8	\$ 0.3	\$ 0.5	\$ 1.5	\$ 0.8	\$ 0.7
Interest expense	(3.3)	(3.4)	0.1	(6.6)	(6.7)	0.1
Gain on Gainesville Transaction	9.9	—	9.9	9.9	—	9.9
Increase in the fair value of contingent consideration	1.5	—	1.5	1.5	—	1.5
Gain on sale of property, plant and equipment	—	12.3	(12.3)	—	12.3	(12.3)
Other income (expense), net	0.6	0.5	0.1	0.3	(1.4)	1.7
Gain on sale of investment in Acceleron Pharma Inc.	—	15.3	(15.3)	—	15.3	(15.3)
Total other (expense) income, net	\$ 9.5	\$ 25.0	\$ (15.5)	\$ 6.6	\$ 20.3	\$ (13.7)

In April 2015, we completed the Gainesville Transaction which included the sale of our facility in Gainesville, GA; related manufacturing and royalty revenue associated with products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL; and the IV/IM and parenteral formulations of Meloxicam, a nonsteroidal anti-inflammatory drug, which has completed multiple phase 2 trials for the management of moderate-to-severe acute pain. We acquired these assets in 2011 as part of our business combination with EDT.

The proceeds from the Gainesville Transaction consisted of \$54.0 million in cash, \$2.1 million in warrants to acquire Recro common stock and \$57.6 million in contingent consideration tied to low double digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in Note 3, Divestiture, in the Notes to Condensed Consolidated Statements.

We will, at each reporting date, update our assessment of the fair value of this contingent consideration and reflect any changes to the fair value within "Increase in the fair value of contingent consideration" until the milestones and/or royalties included in the contingent consideration have been settled. During the three months ended June 30, 2015, we determined that the fair value of the contingent consideration increased by \$1.5 million, due primarily to a shorter time to payment on the milestones and royalties included in the contingent consideration.

The decrease in gain on sale of property, plant and equipment in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, is due to the sale of certain of our land, buildings and equipment at our Athlone, Ireland facility. In April 2014, we sold these assets that had a carrying value of \$2.2 million, in exchange for \$17.5 million and recorded a gain of \$12.3 million, as \$3.0 million of the sales proceeds were placed in escrow pending the completion of certain additional services we are obligated to perform. The decrease in the gain on sale of investment in Acceleron Pharma Inc. was due to our selling our investment in Acceleron Pharma Inc., which consisted of equity securities, in June 2014. The Company received \$24.0 million and realized a gain of \$15.3 million from the sale of this investment.

#### Income Tax Provision

	Three Months			Six Months				
	Ended	Change		Ended	Change			
(In millions)	June 30,	2015	2014	Favorable/ (Unfavorable)	June 30,	2015	2014	Favorable/ (Unfavorable)
Provision (benefit) for income taxes	\$ 3.1	\$ (1.5)	\$ (4.6)	\$ 3.6	\$ 2.2	\$ (1.4)		

The income tax provision in the three and six months ended June 30, 2015 and 2014 primarily relates to U.S. federal and state taxes on income earned in the U.S.

Table of Contents

## Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	June 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 196.9	\$ 224.0
Investments—short-term	579.9	407.1
Investments—long-term	55.6	170.5
Total cash and investments	\$ 832.4	\$ 801.6
Outstanding borrowings—current and long-term	\$ 354.8	\$ 358.0

## Sources and Uses of Cash

We expect that our existing cash and investment balance will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments, for at least the next twelve months. In the event business conditions were to deteriorate, we could rely on borrowings under our Term Loan Facility, which has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts, as long as we meet certain conditions, including a specified leverage ratio.

Information about our cash flows, by category, is presented in the Condensed Consolidated Statements of Cash Flows. The following table summarizes our cash flows for the six months ended June 30, 2015 and 2014:

(In millions)	Six Months Ended June 30,	
	2015	2014
Cash and cash equivalents, beginning of period	\$ 224.1	\$ 167.6
Cash (used in) provided by operating activities	(13.3)	5.3
Cash used in investing activities	(31.8)	(245.8)
Cash provided by financing activities	17.9	261.2
Cash and cash equivalents, end of period	\$ 196.9	\$ 188.3

The increase in cash flows used in operating activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to a 37% increase in cash paid to our employees and an 9% increase in cash paid to our suppliers, partially offset by a 14% increase in cash received from our customers. The increase in cash paid to our employees and suppliers are primarily due to the increase in our headcount, increased R&D activity and preparation for the launch of ARISTADA, as previously discussed. The increase in cash received from our customers is primarily due to the increase in revenues during the six months ended June 30, 2015, as compared to the six months ended June 30, 2014.

The decrease in cash flows used in investing activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to a decrease in the net purchase of investments of \$191.5 million. During the three months ended March 31, 2014, we sold approximately 5.9 million ordinary shares, through a registered direct offering to Invesco Perpetual Income Fund and Invesco Perpetual High Income Fund (the "Invesco Funds"), for gross proceeds of \$250.0 million. These proceeds were then used to purchase available-for-sale investments in accordance with our investment objectives. Our investing activity in the six months ended June 30, 2015 was centered on re-investing available-for-sale investments as they mature and investing excess cash generated from operations. We also received \$54.0 million in cash from the Gainesville Transaction, net of transaction fees of \$2.4 million we incurred as part of the sale and \$1.3 million of cash that remained in the business. These items were partially offset by a \$13.3 million increase in cash used to purchase property, plant and equipment which was primarily related to an investment in our Wilmington, Ohio manufacturing facility, where we will manufacture ARISTADA, and R&D investments in our Athlone, Ireland facility.

The decrease in cash flows provided by financing activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to the registered direct offering to the Invesco Funds mentioned above and a \$4.5 million increase in cash used to pay for employee taxes related to the net share settlement of equity

Table of Contents

awards. These items were partially offset by a \$9.5 million increase in excess tax benefit from share-based compensation.

Our investments at June 30, 2015 consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term	\$ 579.5	\$ 0.5	\$ (0.1)	\$ 579.9
Investments—long-term available-for-sale	54.1	—	(0.1)	54.0
Investments—long-term held-to-maturity	1.6	—	—	1.6
Total	\$ 635.2	\$ 0.5	\$ (0.2)	\$ 635.5

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

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At June 30, 2015, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At June 30, 2015 and December 31, 2014, none of our investments were valued using Level 3 inputs. Level 3 inputs are unobservable and are significant to the overall fair value measurement and require a significant degree of judgment.

## Borrowings

At June 30, 2015, our borrowings consisted of \$356.4 million outstanding under our Term Loan Facility. Refer to Note 10, Long-Term Debt, within the "Notes to Consolidated Financial Statements" accompanying our Annual Report, for a discussion of our outstanding term loans.

#### Contractual Obligations

Refer to Part II, Item 7 of our Annual Report in the "Contractual Obligations" section for a discussion of our contractual obligations. Our contractual obligations as of June 30, 2015 have not materially changed from the date of that report.

#### Off-Balance Sheet Arrangements

At June 30, 2015, 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

Table of Contents

"Critical Accounting Estimates" within Part II, Item 7 of our Annual Report for a discussion of our critical accounting estimates.

New Accounting Standards

Refer to "New Accounting Pronouncements" included in Note 2, Summary of Significant Accounting Policies in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for a discussion of new accounting standards.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks since December 31, 2014, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products as well as certain operating costs arising from expenses and payables at our Irish operations that are settled in euro. These foreign currency exchange rate risks are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since December 31, 2014.

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in



Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), on June 30, 2015. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2015 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control Over Financial Reporting

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

The FDA or other regulatory agencies may not approve our product candidates or may impose limitations upon any product approval.

We must obtain government approvals before marketing or selling our product candidates in the U.S. and in jurisdictions outside the U.S. The FDA, DEA, to the extent a product candidate is a controlled substance, and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the U.S. may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications. See “—Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors” in “Part I, Item 1A – Risk Factors” of our Annual Report.

This product development process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or regulatory agencies outside the U.S. can be delayed, limited or not granted at all for many reasons, including:

- the filing by a third party of a Citizen Petition with the FDA relating to our products. On July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. (“Otsuka”) submitted a Citizen Petition to the FDA requesting that the FDA refuse to approve, or delay approval of, our NDA for ARISTADA, which has a PDUFA date of August 22, 2015. On July 24, 2015, we submitted a Comment in Opposition to the Otsuka Citizen Petition to the FDA in response to Otsuka’s Citizen Petition;
- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;
- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;
- data from pre-clinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners’ manufacturing processes or facilities;

Table of Contents

- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;
- the failure of third-party CROs and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines;
- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's GCP, or EU legislation governing GCP, including the failure to pass FDA, EMA or EU Member State inspections of clinical trials;
- the FDA or other regulatory agencies may change their approval policies or adopt new regulations;
- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful; and
- the FDA or other regulatory agencies may not agree with our or our partners' regulatory approval strategies or components of our or our partners' filings, such as clinical trial designs.

In addition, our product development timelines may be impacted by third-party patent litigation. We cannot be sure that regulatory approval will be granted for product candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of additional products will be limited by any failure to obtain these approvals. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product candidate or if the timing of FDA approval is delayed. If the FDA's or any other regulatory agency's response to any application for approval is delayed or not favorable for any of our product candidates, our share price could decline significantly.

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we would need to comply in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products. In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in the temporary or permanent withdrawal by the FDA or other regulatory agencies of our products from commercial marketing, which could seriously harm our business and cause our share price to decline. Further, even if the FDA provides regulatory approval, controlled substances will not become commercially available until after the DEA provides its final schedule designation, which may take longer and may be more restrictive than we expect or change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization.

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the six months ended June 30, 2015. As of June 30, 2015, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million.

During the three months ended June 30, 2015, we acquired, by means of net share settlements, 201,391 shares of Alkermes ordinary shares at an average price of \$61.27 per share related to the vesting of employee equity awards to satisfy withholding tax obligations. In addition, during the three months ended June 30, 2015, we acquired 4,849 shares of Alkermes ordinary shares, at an average price of \$61.84 per share, tendered by employees as payment of the exercise

Table of Contents

price of stock options granted under our equity compensation plans.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2015, Mr. Gordon G. Pugh, an executive officer of the Company, entered into a trading plan 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

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Form 10-Q.

Table of Contents

SIGNATURES

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

ALKERMES plc

(Registrant)

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

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

Date: July 30, 2015

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1 #†	Employment Agreement, dated as of September 30, 2008, by and between Iain M. Brown and Alkermes, Inc.
10.2 #†	Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.
10.3 #*	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica, Inc. (United States) (Assigned to Alkermes, Inc. in July 2006)
10.4#**	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (Assigned to Alkermes, Inc. in July 2006)
10.5#**	Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (Assigned to Alkermes, Inc. in July 2006)
10.6#**	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003. (Assigned to Alkermes, Inc. in July 2006)
10.7#	Fourth Amendment to Lease Agreement between Alkermes, Inc. and Gl TC 850 Winter Street, LLC, dated as of December 30, 2014
10.8 #†	Amendment to Employment Agreement, dated as of July 22, 2015, by and between Rebecca J. Peterson and Alkermes, Inc.
10.9 #†	Amendment to Employment Agreement, dated as of July 28, 2015, by and between Iain M. Brown and Alkermes, Inc.
31.1 #	Rule 13a-14(a)/15d-14(a) Certification.
31.2 #	Rule 13a-14(a)/15d-14(a) Certification.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101 #	The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated



Edgar Filing: Alkermes plc. - Form 10-Q

Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements

# Filed herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

\* Portions of such exhibit have been omitted pursuant to a request for confidential treatment submitted to the Securities and Exchange Commission.

34

---