Alkermes plc.
Form 10-Q
November 02, 2016
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	98-1007018
(State or other jurisdiction of incorporation or organization)	(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 (Do not check if a smaller reporting company)	Smaller reporting company

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of October 24, 2016 was 151,970,482 shares.

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ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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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 sta 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 (including expectations about regulatory filing, regulatory approval and regulatory timelines), 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, and our industry generally;

• 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, licensing arrangements and other significant agreements with third parties relating to our products, including our development programs;

• 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;

• our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements; and

• other factors discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward looking statements 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. All subsequent written and oral forward looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward looking statements, whether as a result of new information, future events or otherwise. In light of these risks, assumptions and uncertainties, 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 "Part I, Item 1A—Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015 (the "Annual Report") and any subsequent reports filed with the United States ("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 sources (including, without limitation, industry publications, medical and clinical journals and studies, surveys and forecasts and our internal research), on assumptions that we have made, which we believe are reasonable, based on those data and other similar sources and on our knowledge of the markets for our 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 "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 this Form 10-Q.

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Note Regarding Company and Product References

Alkermes plc (as used in this report, together with our subsidiaries, “Alkermes,” the “Company,” “us,” “we” and “our”) is a ful integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of marketed drug products and a clinical pipeline of products that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis. Except as otherwise suggested by the context, references to “products” or “our products” in this Form 10-Q include our marketed products, marketed products using our proprietary technologies, our product candidates and product candidates using our proprietary technologies, and references to “licensees” are used interchangeably with references to “collaborative partners” and “partners.”

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations (“®”) and other trademarks (“TM”), including ARISTADA®, LinkeRx®, NanoCrystal®, SECATM and VIVITROL®. The following are trademarks of the respective companies listed: AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc.; BYDUREON® —Amylin Pharmaceuticals, LLC; INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION®, and RISPERDAL CONSTA®—Johnson & Johnson (or its affiliate); RITALIN LA® and FOCALIN XR®—Novartis AG; TECFIDERA®—Biogen MA Inc.; 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.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2016	December 31, 2015
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 202,239	$ 181,109
Investments—short-term	347,218	353,669
Receivables, net	177,446	155,487
Inventory	54,155	38,411
Prepaid expenses and other current assets	26,204	26,286
Total current assets	807,262	754,962
PROPERTY, PLANT AND EQUIPMENT, NET	262,181	254,819
INTANGIBLE ASSETS—NET	333,550	379,186
INVESTMENTS—LONG-TERM	75,147	264,071
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	58,400	55,300
DEFERRED TAX ASSETS	50,296	40,856
OTHER ASSETS	27,667	13,677
TOTAL ASSETS	$ 1,707,376	$ 1,855,744
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 185,716	$ 168,735
Long-term debt—short-term	3,000	65,737
Deferred revenue—short-term	1,524	1,735
Total current liabilities	190,240	236,207
LONG-TERM DEBT	282,576	284,207
OTHER LONG-TERM LIABILITIES	17,206	13,080
DEFERRED REVENUE—LONG-TERM	7,660	7,975
Total liabilities	497,682	541,469
COMMITMENTS AND CONTINGENCIES (Note 13)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 153,451,571 and 152,128,941 shares issued; 151,805,300 and	1,531	1,518

150,700,989 shares outstanding at September 30, 2016, and December 31, 2015, respectively		
Treasury shares, at cost (1,646,271 and 1,427,952 shares at September 30, 2016 and December 31, 2015, respectively)	(67,255)	(58,661)
Additional paid-in capital	2,205,028	2,114,711
Accumulated other comprehensive loss	(2,808)	(3,795)
Accumulated deficit	(926,802)	(739,498)
Total shareholders' equity	1,209,694	1,314,275
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,707,376	$ 1,855,744

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

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ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	$ 110,250	$ 114,072	$ 353,444	$ 355,978
Product sales, net	69,802	37,903	176,695	106,212
Research and development revenue	189	678	2,042	3,047
Total revenues	180,241	152,653	532,181	465,237
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	35,456	33,806	97,165	104,198
Research and development	99,444	92,558	297,523	250,718
Selling, general and administrative	91,145	89,497	276,985	224,086
Amortization of acquired intangible assets	15,323	14,207	45,636	43,479
Total expenses	241,368	230,068	717,309	622,481
OPERATING LOSS	(61,127)	(77,415)	(185,128)	(157,244)
OTHER (EXPENSE) INCOME, NET:				
Interest income	912	865	2,917	2,320
Interest expense	(3,375)	(3,325)	(9,993)	(9,928)
Change in the fair value of contingent consideration	(1,000)	1,200	3,100	2,700
Gain on the Gainesville Transaction	—	26	—	9,937
Other (expense) income, net	(752)	629	(970)	1,003
Total other (expense) income, net	(4,215)	(605)	(4,946)	6,032
LOSS BEFORE INCOME TAXES	(65,342)	(78,020)	(190,074)	(151,212)
(BENEFIT) PROVISION FOR INCOME TAXES	(2,655)	2,995	(2,771)	6,569
NET LOSS	$ (62,687)	$ (81,015)	$ (187,303)	$ (157,781)
LOSS PER COMMON SHARE:				
Basic and diluted	$ (0.41)	$ (0.54)	$ (1.24)	$ (1.06)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic and diluted	151,652	149,512	151,261	148,828
COMPREHENSIVE LOSS:				
Net loss	$ (62,687)	$ (81,015)	$ (187,303)	$ (157,781)
Holding (loss) gains, net of a tax (benefit) provision of $(129), $(5), $445 and $165, respectively	(261)	14	988	424
COMPREHENSIVE LOSS	$ (62,948)	$ (81,001)	$ (186,315)	$ (157,357)

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

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ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2016	2015
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (187,303)	$ (157,781)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	69,605	63,815
Share-based compensation expense	74,613	74,473
Deferred income taxes	(12,545)	(35,073)
Excess tax benefit from share-based compensation	(5,118)	(32,817)
Gain on the Gainesville Transaction	—	(9,937)
Change in the fair value of contingent consideration	(3,100)	(2,700)
Other non-cash charges	1,901	(520)
Changes in assets and liabilities:		
Receivables	(21,960)	(1,955)
Inventory, prepaid expenses and other assets	(18,266)	13,542
Accounts payable and accrued expenses	26,833	46,291
Deferred revenue	(526)	(1,172)
Other long-term liabilities	4,506	1,059
Cash flows used in operating activities	(71,360)	(42,775)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(33,787)	(36,729)
Proceeds from the sale of equipment	100	181
Investment in Reset Therapeutics, Inc.	(15,000)	—
Net proceeds from the Gainesville Transaction	—	50,267
Purchases of investments	(296,712)	(350,157)
Sales and maturities of investments	493,520	335,169
Cash flows provided by (used in) investing activities	148,121	(1,269)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	12,746	31,633
Excess tax benefit from share-based compensation	5,118	32,817
Employee taxes paid related to net share settlement of equity awards	(8,432)	(17,065)
Principal payments of long-term debt	(65,063)	(5,064)
Cash flows (used in) provided by financing activities	(55,631)	42,321
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	21,130	(1,723)
CASH AND CASH EQUIVALENTS—Beginning of period	181,109	224,064
CASH AND CASH EQUIVALENTS—End of period	$ 202,239	$ 222,341
SUPPLEMENTAL CASH FLOW DISCLOSURE:		

Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 3,642	$ 2,409
Fair value of warrants received as part of the Gainesville Transaction	$ —	$ 2,123
Fair value of contingent consideration received as part of the Gainesville Transaction	$ —	$ 57,600

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

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS — (Unaudited)

1. THE COMPANY

Alkermes plc 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 its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. Alkermes has a diversified portfolio of marketed drug products and a clinical pipeline of products that address 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; an R&D 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 nine months ended September 30, 2016 and 2015 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2015. 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 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 that 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 and litigation. 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. The Company's chief decision maker, the Chairman of the Board 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.

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ALKERMES PLC AND SUBSIDIARIES

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

Income Taxes

The Company's income tax (benefit) provision in the three and nine months ended September 30, 2016 and 2015 relates primarily 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 September 30, 2016, 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.

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 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. This 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.

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 Company adopted this guidance on January 1, 2016, and this guidance does not have an impact 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 Company adopted this guidance on January 1, 2016, and this guidance does not have an impact on its consolidated financial statements.

In January 2016, the FASB issued guidance that enhances the reporting model for financial instruments through addressing certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amendments in this update include: requiring equity securities to be measured at fair value with changes in fair value recognized through the income statement; simplifying the impairment assessment of equity instruments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminating the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities; eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments;

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ALKERMES PLC AND SUBSIDIARIES

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

requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset; and clarifying that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. This guidance becomes effective for the Company in its year ending December 31, 2018, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The main difference between previous GAAP and this guidance is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. This guidance becomes effective for the Company in its year ending December 31, 2019, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In March 2016, the FASB issued guidance as part of its simplification initiative to eliminate the requirement to retroactively adopt the equity method of accounting when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence. This guidance becomes effective for the Company in its year ending December 31, 2017, and the Company does not currently expect this guidance to have an impact on its consolidated financial statements.

In March 2016, the FASB issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions. The amendments in this update established that: all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; excess tax benefits be classified as an operating activity in the statement of cash flows; the entity make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, which is current GAAP, or account for forfeitures as they occur; the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and cash paid by an employer when directly withholding shares for tax-withholding purposes be classified as a financing activity in the statement of cash flows. This guidance becomes effective for the Company in its year ending December 31, 2017, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In August 2016, the FASB issued guidance to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This guidance becomes effective for the Company in its year ending December 31, 2018, and 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 its Gainesville, GA facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and other parenteral forms of Meloxicam and certain intellectual property related to IV/IM and parenteral forms of Meloxicam (the "Gainesville Transaction") 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 to the Company 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 to closing. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (together, the "Meloxicam Products") and up to $120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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

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	(2,724)
Gain on the Gainesville Transaction	$ 9,636

During the three and nine months ended September 30, 2015, the Gainesville, GA facility and associated intellectual property ("IP") generated income before income taxes of none and $4.5 million, respectively. The Company recorded the initial gain on the Gainesville Transaction in the three months ended June 30, 2015 and made adjustments in the third and fourth quarters of 2015 to record additional transaction costs. 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.

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 was 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 one and two years, respectively, and used a discount rate of 3.2% and 4.1%, respectively, for each of these events.

• To estimate the fair value of future royalties on net sales of the Meloxicam Products, the Company assessed the likelihood of the Meloxicam Products being approved for sale and estimated the expected future sales given approval and IP protection. The Company then discounted these expected payments using a discount rate of 17.0%, 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 Meloxicam Products, 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 10.8% to 12.2%.

During the nine months ended September 30, 2016, the Company determined that the value of the Gainesville Transaction's contingent consideration increased due primarily to a shorter time to payment on the milestones and royalties included in the contingent consideration, although the value did decrease during the three months ended September 30, 2016 due to a change in the planned timing of the New Drug Application ("NDA") submission for Meloxicam. These changes were recorded as "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss.

The warrants the Company received to purchase 350,000 shares of Recro common stock have a fair value of $1.5 million at September 30, 2016 and are being recorded within "Other 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 September 30, 2016:

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ALKERMES PLC AND SUBSIDIARIES

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

Closing stock price at September 30, 2016	$ 8.84
Warrant strike price	$ 19.46
Expected term (years)	5.52
Risk-free rate	1.26 %
Volatility	77.4 %

An increase in the fair value of the warrants of $0.2 million and a decrease in the fair value of the warrants of $0.3 million during the three and nine months ended September 30, 2016, respectively, was recorded within “Other (expense) income, net” in the accompanying condensed consolidated statements of operations and comprehensive loss. The fair value of the warrants decreased by $0.3 million in the three months ended September 30, 2015 and increased by $0.6 million in the nine months ended September 30, 2015.

4. INVESTMENTS

Investments consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Losses(1)	Estimated Fair Value
	(In thousands)			
September 30, 2016				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	$ 193,228	$ 219	$ (1)	$ 193,446
Corporate debt securities	142,692	108	(41)	142,759
International government agency debt securities	10,998	16	(1)	11,013
Total short-term investments	346,918	343	(43)	347,218
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	57,578	—	(81)	57,497
Corporate debt securities	8,774	—	(13)	8,761
International government agency debt securities	5,515	—	(8)	5,507
	71,867	—	(102)	71,765
Held-to-maturity securities:				

Fixed term deposit account	1,667	—	—	1,667
Certificates of deposit	1,715	—	—	1,715
	3,382	—	—	3,382
Total long-term investments	75,249	—	(102)	75,147
Total investments	$ 422,167	$ 343	$ (145)	$ 422,365
December 31, 2015				
Short-term investments:				
Available-for-sale securities:				
Corporate debt securities	$ 175,098	$ 20	$ (179)	$ 174,939
U.S. government and agency debt securities	141,789	51	(104)	141,736
International government agency debt securities	37,070	—	(76)	36,994
Total short-term investments	353,957	71	(359)	353,669
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	211,216	—	(764)	210,452
Corporate debt securities	38,381	—	(111)	38,270
International government agency debt securities	12,039	—	(71)	11,968
	261,636	—	(946)	260,690
Held-to-maturity securities:				
Fixed term deposit account	1,666	—	—	1,666
Certificates of deposit	1,715	—	—	1,715
	3,381	—	—	3,381
Total long-term investments	265,017	—	(946)	264,071
Total investments	$ 618,974	$ 71	$ (1,305)	$ 617,740

(1) Losses represent marketable securities that were in loss positions for less than one year.

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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:

	Nine Months Ended September 30,	
(In thousands)	2016	2015
Proceeds from the sales and maturities of marketable securities	$ 493,520	$ 335,169
Realized gains	$ 124	$ 109
Realized losses	$ 28	$ 3

The Company's available-for-sale and held-to-maturity securities at September 30, 2016 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$ 253,081	$ 253,156	$ 1,715	$ 1,715
After 1 year through 5 years	165,704	165,827	1,667	1,667
Total	$ 418,785	$ 418,983	$ 3,382	$ 3,382

At September 30, 2016, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including, but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

In February 2016, the Company entered into a collaboration and license option agreement with Reset Therapeutics, Inc. ("Reset"). The Company made an upfront, non-refundable payment of $10.0 million in partial consideration of the

grant to the Company of the rights and licenses included in such agreement, which was included in R&D expense in the three months ended March 31, 2016, and simultaneously made a $15.0 million investment in exchange for shares of Reset's Series B Preferred Stock. The Company is accounting for its investment in Reset under the equity method based on its percentage of ownership, its seat on the board of directors and its belief that it can exert significant influence over the operating and financial policies of Reset. During the three and nine months ended September 30, 2016, the Company recorded a reduction in its investment in Reset of $0.7 million and $1.0 million, respectively, which represents the company's proportional share of Reset's net loss for the period. The Company's $14.0 million investment at September 30, 2016 is included within "Other assets" in the accompanying condensed consolidated balance sheets.

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 the 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 September 30, 2016, the Company had made payments of, and its investment is equal to, $2.3 million (€1.8 million), which is included within "Other assets" in the accompanying condensed consolidated balance sheets. During the three and nine months ended September 30, 2016, the Company recorded a reduction in its investment in Fountain of $0.3 million and $0.4 million, respectively, which represents the Company's proportional share of Fountain's net loss for the period.

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ALKERMES PLC AND SUBSIDIARIES

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

5. FAIR VALUE MEASUREMENTS

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

(In thousands)	September 30, 2016	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 1,667	$ 1,667	$ —	$ —
U.S. government and agency debt securities	250,943	140,276	110,667	—
Corporate debt securities	151,520	—	151,520	—
International government agency debt securities	16,520	—	16,520	—
Contingent consideration	58,400	—	—	58,400
Common stock warrants	1,545	—	—	1,545
Total	$ 480,595	$ 141,943	$ 278,707	$ 59,945

	December 31, 2015	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 1,666	$ 1,666	$ —	$ —
U.S. government and agency debt securities	352,188	214,456	137,732	—
Corporate debt securities	213,209	—	213,209	—
International government agency debt securities	48,962	—	48,962	—
Contingent consideration	55,300	—	—	55,300
Common stock warrants	1,821	—	—	1,821
Total	$ 673,146	$ 216,122	$ 399,903	$ 57,121

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 nine months ended September 30, 2016.

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 values were determined using Level 3 inputs at September 30, 2016:

(In thousands)	Fair Value
Balance, January 1, 2016	$ 57,121
Change in the fair value of contingent consideration	3,100
Decrease in the fair value of warrants	(276)
Balance, September 30, 2016	$ 59,945

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 approximated 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"). In September 2016, Term Loan B-2 matured and the Company repaid the outstanding principal balance in its

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ALKERMES PLC AND SUBSIDIARIES

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

entirety. The estimated fair value of Term-Loan B-1, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of the actual value that could have been or will be realized in the future, was as follows at September 30, 2016:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	$ 285,576	$ 287,761

6. INVENTORY

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

(In thousands)	September 30, 2016	December 31, 2015
Raw materials	$ 18,159	$ 16,445
Work in process	16,634	12,423
Finished goods(1)	19,362	9,543
Total inventory	$ 54,155	$ 38,411

(1) At September 30, 2016 and December 31, 2015, the Company had $8.0 million and $3.0 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2016	December 31, 2015
Land	$ 5,913	$ 5,913
Building and improvements	152,686	136,797
Furniture, fixture and equipment	244,740	218,718
Leasehold improvements	19,171	16,597
Construction in progress	37,968	51,542
Subtotal	460,478	429,567
Less: accumulated depreciation	(198,297)	(174,748)
Total property, plant and equipment, net	$ 262,181	$ 254,819

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

		Nine Months Ended September 30, 2016		
(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	$ 465,590	$ (205,725)	$ 259,865
NanoCrystal technology	13	74,600	(22,853)	51,747
OCR technologies	12	42,560	(20,622)	21,938
Total		$ 582,750	$ (249,200)	$ 333,550

Based on the Company’s most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at September 30, 2016 is expected to be approximately $60.0 million, $60.0 million, $60.0

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ALKERMES PLC AND SUBSIDIARIES

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

million, $55.0 million and $50.0 million in the years ending December 31, 2016 through 2020, 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.

On January 21, 2016, following the Company's press release regarding its ALKS 5461 development program, the Company's stock price declined by 44% from the previous day's closing price, which the Company considered to be an impairment triggering event. To determine if its goodwill was impaired, the Company assessed qualitative factors to determine whether it was necessary to perform the two-step impairment test. Based on the weight of all available evidence, the Company determined that the fair value of its reporting unit more-likely-than-not exceeded its carrying value.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2016	December 31, 2015
Accounts payable	$ 43,824	$ 37,401
Accrued compensation	38,490	40,371
Accrued sales discounts, allowances and reserves	51,845	28,449
Accrued taxes	766	1,195
Accrued other	50,791	61,319
Total accounts payable and accrued expenses	$ 185,716	$ 168,735

10. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2016	December 31, 2015
Term Loan B-1, due September 25, 2019	$ 285,576	$ 287,207
Term Loan B-2, due September 25, 2016	—	62,737
Total	285,576	349,944
Less: current portion	(3,000)	(65,737)
Long-term debt	$ 282,576	$ 284,207

In September 2016, Term Loan B-2 matured and the Company repaid the outstanding principal balance of $60.9 million in its entirety.

In October 2016, the Company amended Term Loan B-1, pursuant to which, among other things, the due date of Term Loan B-1 was extended from September 25, 2019 to September 25, 2021 (the “Refinancing”). The Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing is to be accounted for as a debt extinguishment or a debt modification, the Company will consider whether creditors remained the same or changed and whether the changes in debt terms are substantial. A change in the debt terms is considered to be substantial if the present value of the remaining cash flows under the new terms of Term Loan B-1 are at least 10% different from the present value of the remaining cash flows under the original terms of Term Loan B-1 (commonly referred to as the “10% Test”). The Company will perform a separate 10% Test for each individual creditor participating in the loan syndication. The loans of any creditors no longer participating in the loan syndication will be accounted for as a debt extinguishment.

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ALKERMES PLC AND SUBSIDIARIES

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

11. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2016	2015	2016	2015
Cost of goods manufactured and sold	$ 2,151	$ 4,311	$ 6,693	$ 6,806
Research and development	6,032	9,028	18,830	18,951
Selling, general and administrative	15,543	21,928	49,090	48,716
Total share-based compensation expense	$ 23,726	$ 35,267	$ 74,613	$ 74,473

At September 30, 2016 and December 31, 2015, $1.3 million and $1.1 million, respectively, of share-based compensation cost was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

12. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the three and nine months ended September 30, 2016 and 2015, as the Company was in a net loss position, the diluted loss per share does not assume conversion or exercise of stock options and awards as they would have an anti-dilutive effect on loss per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2016	2015	2016	2015
Stock options	9,203	9,539	10,507	9,110
Restricted stock units	1,298	1,482	1,247	1,838
Total	10,501	11,021	11,754	10,948

13. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At September 30, 2016, there are no potential losses from claims, asserted or unasserted, or legal proceedings the Company feels are probable of occurring.

ARISTADA

On July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. ("Otsuka PD&C") filed a Citizen Petition with the U.S. Food and Drug Administration ("FDA") which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition.

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ALKERMES PLC AND SUBSIDIARIES

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

On October 15, 2015, Otsuka Pharm. Co., Otsuka PD&C, and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") filed an action for declaratory and injunctive relief with the United States District Court for the District of Columbia (the "DC Court") against Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Stephen Ostroff, Acting Commissioner, FDA; and the FDA, requesting that the DC Court (a) expedite the legal proceedings; (b) declare that the FDA's denial of Otsuka's claimed exclusivity rights and approval of the ARISTADA NDA were arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (c) vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) declare that Otsuka's claimed exclusivity rights preclude FDA from granting approval of the Alkermes NDA until the expiration of such exclusivity rights in December 2017; and (e) grant any and all other, further, and additional relief, including all necessary and appropriate protective preliminary, interim, or permanent relief, as the nature of the cause may require, including all necessary and appropriate declarations of rights and injunctive relief. The Company successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an unambiguous opinion in favor of Alkermes and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the U.S. Court of Appeals for the District of Columbia Circuit ("DC Circuit") asking the DC Circuit to reverse the DC Court's decision, vacate FDA's approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka's lost exclusivity. The DC Circuit has scheduled this appellate hearing for December 12, 2016. The Company believes Otsuka's action is without merit and will continue to vigorously defend ARISTADA against such action. For information about risks relating to this action, see "Part I, Item 1A—Risk Factors" in the Company's Annual Report and specifically the section entitled "Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business."

AMPYRA

AMPYRA ANDA Litigation

Ten separate Paragraph IV Certification Notices have been submitted to us and/or the Company's licensee Acorda Therapeutics, Inc. ("Acorda") from Accord Healthcare, Inc. ("Accord"); Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd. ("Alkem"); Apotex, Inc.; Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc.; Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc., advising that each of these

companies had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of the Orange Book-listed patents for AMPYRA, and they have also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent Nos. 5,540,938 (which the Company owns), 8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). Requested judicial remedies include recovery of litigation costs and injunctive relief. Lawsuits with eight of the ANDA filers have been consolidated into a single case. The Delaware Court held a bench trial that concluded on September 23, 2016. Mylan is challenging the jurisdiction of the Delaware Court with respect to the Delaware action. Due to Mylan's motion to dismiss, the Company, together with Acorda, also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. patents and requesting the same judicial relief as in the Delaware action. In March 2016, the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") upheld the Delaware Court's ruling that the litigation against Mylan can continue in the Delaware Court. In June 2016, the Federal Circuit denied Mylan's request for a rehearing to reconsider its previous ruling. Mylan has appealed the Federal Circuit's decision to the Supreme Court of the U.S. All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30-month statutory stay of approval period applies to each of the ANDAs under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The 30-month stay starts from January 22, 2015, which is the end of the new

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ALKERMES PLC AND SUBSIDIARIES

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

chemical entity exclusivity period for AMPYRA. This stay restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date. Such FDA approval would permit the ANDA filers to market generic versions of AMPYRA (dalfampridine) Extended Release Tablets, 10 mg.

The Company and/or Acorda has entered into a settlement agreement with each of Accord, Actavis, Alkem, Aurobindo, Par and Sun (collectively, the "Settling ANDA Filers") to resolve the patent litigation that the Company and/or Acorda brought against the Settling ANDA Filers in the Delaware Court as described above. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market a generic version of AMPYRA in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have submitted their respective settlement agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers do not resolve pending patent litigation that the Company and Acorda brought against the other ANDA filers, as described above.

The Company intends to vigorously enforce its intellectual property rights. For information about risks relating to the AMPYRA Paragraph IV litigations and other proceedings see "Part I, Item 1A—Risk Factors" in the Company's Annual Report and specifically the section entitled "We face claims against our intellectual property rights and competition from generic drug manufacturers."

AMPYRA IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has filed inter partes review ("IPR") petitions with the U.S. Patent and Trademark Office (the "USPTO"), challenging U.S. Patent Nos. 8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). In March 2016, the USPTO's Patent Trials and Appeal Board instituted the IPR. A ruling on the IPR petitions is expected within one year of the IPR's institution. The challenged patents are four of the five AMPYRA Orange-Book listed patents. The 30-month statutory stay period based on patent infringement suits filed by us and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

BYDUREON, RISPERDAL CONSTA AND VIVITROL IPR Proceedings

On June 3, 2016, the USPTO accepted two separate IPR petitions filed by Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Shandong Luye Pharmaceutical Co., Ltd., and Nanjing Luye Pharmaceutical Co., Ltd. (collectively, "Luye") challenging U.S. Patent Number 6,667,061 (the "'061 Patent"), which is an Orange Book-listed patent for each of BYDUREON, RISPERDAL CONSTA and VIVITROL. On September 1, 2016, the Company filed a response to Luye's IPR petitions with the USPTO, following which the USPTO has a further three-month period to decide whether or not to institute a review of the challenged claims of the '061 Patent. If such review is instituted, a decision on the matter would be expected, pursuant to the statutory time frame, within one year of the USPTO's decision to institute such review.

The Company opposed Luye's requests to institute the IPRs against the '061 Patent. If the USPTO institutes such challenge, the Company will vigorously defend the '061 Patent. For information about risks relating to the '061 Patent IPR proceedings see "Part I, Item 1A—Risk Factors" in the Company's Annual Report and specifically the sections entitled "Patent protection for our products is important and uncertain" and "Uncertainty over intellectual property in the pharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable".

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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 September 30, 2016 was $62.7 million, or $0.41 per ordinary share— basic and diluted, as compared to a net loss of $81.0 million, or $0.54 per ordinary share— basic and diluted for the three months ended September 30, 2015. Net loss for the nine months ended September 30, 2016 was $187.3 million, or $1.24 per ordinary share— basic and diluted, as compared to a net loss of $157.8 million, or $1.06 per ordinary share— basic and diluted for the nine months ended September 30, 2015. Included in the net loss during the nine months ended September 30, 2015 was $4.5 million of net income related to our Gainesville, GA manufacturing facility, which we sold as part of the Gainesville Transaction in April 2015.

The decrease in the net loss incurred in the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, was primarily due to a 47% increase in net sales of VIVITROL and the addition of sales related to ARISTADA, which was first commercialized beginning in October 2015. The increase in net loss incurred in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to increases in R&D expense, reflecting an increased investment in our CNS development pipeline, and selling, general and administrative (“SG&A”) expense, reflecting the commercialization of ARISTADA beginning in October 2015. The increase in R&D and SG&A expenses was partially offset by an increase in net sales of VIVITROL and ARISTADA. Additionally, in the nine months ended September 30, 2016, this increase in expenses was partially offset by a decrease in cost of goods manufactured and sold primarily due to the Gainesville Transaction. These items are discussed in greater detail later in the “Results of Operations” section of this Form 10-Q.

Products

Marketed Products

The key marketed products discussed below are expected to generate significant revenues for us. See the description of the marketed products below and refer to the “Patents and Proprietary Rights” section of our Annual Report for information with respect to the intellectual property protection for these marketed products.

Product	Indication(s)	Licensee	Territory
Proprietary Products			
ARISTADA	Schizophrenia	None	Commercialized by Alkermes in the U.S.
VIVITROL	Alcohol dependence and Opioid dependence	None	Commercialized by Alkermes in the U.S.
		Cilag GmbH International (“Cilag”)	Russia and Commonwealth of Independent States (“CIS”)
Products Using Our Proprietary Technologies			
RISPERDAL CONSTA	Schizophrenia and Bipolar I disorder	Janssen Pharmaceutica Inc. ("Janssen, Inc.") and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
INVEGA SUSTENNA	Schizophrenia and Schizoaffective disorder	Janssen Pharmaceutica N.V. (together with Janssen, Inc. Janssen International and their affiliates "Janssen")	U.S.
XEPLION	Schizophrenia	Janssen	Rest of World (“ROW”)
INVEGA TRINZA / TREVICTA	Schizophrenia	Janssen	Worldwide

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AMPYRA / FAMPYRA	Treatment to improve walking in patients with multiple sclerosis (“MS”), as demonstrated by an increase in walking speed	Acorda	U.S.
		Biogen International GmbH (“Biogen”), under sublicense from Acorda	ROW
BYDUREON	Type 2 diabetes	AstraZeneca plc (“AstraZeneca”)	Worldwide

Proprietary Products

We develop and commercialize products designed to address the unmet needs of patients suffering from addiction and schizophrenia.

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA is the first of our products to utilize our proprietary LinkeRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is the first atypical antipsychotic with once-monthly and six-week dosing options for delivering and maintaining therapeutic levels of medication in the body through an intramuscular injection. ARISTADA has three dosing options (441 mg, 662 mg and 882 mg) and is packaged in a ready-to-use, pre-filled product format. We developed, manufacture and commercialize ARISTADA in the U.S.

On September 27, 2016, U.S. Patent No. 9,452,131 relating to ARISTADA was granted. This patent was added to the patents listed in the Orange Book for ARISTADA, has claims that cover methods of treatment for schizophrenia, and expires in 2035.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is the only once monthly, non-addictive, injectable medication approved in the U.S., Russia and certain countries of the 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 one injection every four weeks. We developed and exclusively manufacture VIVITROL.

We commercialize VIVITROL in the U.S., and Cilag commercializes VIVITROL in Russia and certain countries of the CIS.

Products Using Our Proprietary Technologies

We have granted licenses under our proprietary technologies to enable third parties to develop, commercialize and, in some cases, manufacture products for which we receive royalties and/or manufacturing revenues. Such arrangements include the following:

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and RISPERDAL CONSTA (risperidone long acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the 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 outside of the U.S. 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.

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INVEGA TRINZA is 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 once every three months, became commercially available in the U.S. in June 2015. In May 2016, TREVICTA (paliperidone palmitate a 3-monthly injection), was approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by 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 microspheres are exclusively manufactured by us.

AMPYRA/FAMPYRA

AMPYRA (dalfampridine)/FAMPYRA (fampridine), 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 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 outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of August 2015. 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. AstraZeneca is responsible for the development and commercialization of BYDUREON worldwide. BYDUREON, a once-weekly formulation of exenatide, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca.

BYDUREON Pen 2 mg, a pre filled, single use pen injector that contains the same formulation and dose as the original BYDUREON single dose tray, is available in the U.S., certain countries in the EU and Japan.

Key Development Programs

Our research and development is focused on leveraging our formulation expertise and proprietary product platforms to develop novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia, addiction, depression and MS. As part of our ongoing research and development efforts, we have devoted, and will continue to devote, significant resources to conducting clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our key current research and development programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in “Part I, Item 1A—Risk Factors” of our Annual Report. Refer to the “Patents and Proprietary Rights” section of our Annual Report for information with respect to the intellectual property protection for our product candidates.

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Product Candidate	Target Indication(s)	Status
Aripiprazole Lauroxil Two-Month Dose	Schizophrenia	sNDA Submitted
ALKS 5461	Major Depressive Disorder	Phase 3
ALKS 3831	Schizophrenia	Phase 3
ALKS 8700	MS	Phase 3
ALKS 6428	Transition from Physical Dependence on Opioids to VIVITROL	Phase 3
ALKS 4230 (formerly referred to as RDB 1450)	Cancer Immunotherapy	Phase 1

Aripiprazole Lauroxil Two-Month Dose

Aripiprazole lauroxil is an injectable atypical antipsychotic, currently commercially available as ARISTADA with once-monthly and six-week dosing options for the treatment of schizophrenia. Aripiprazole lauroxil is also in development with a two-month dosing interval. In February 2016, we announced positive topline results from a randomized, open-label, pharmacokinetic study evaluating a two-month dosing interval of aripiprazole lauroxil extended-release injectable suspension for the treatment of schizophrenia. Based on these phase 1 results, we submitted a supplemental NDA ("sNDA") to the FDA in August 2016 and the sNDA was accepted by the FDA in October 2016.

ALKS 5461

ALKS 5461 is a once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of major depressive disorder ("MDD") in patients with 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. 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 October 2016, we announced positive topline results from FORWARD-5, a phase 3 randomized, double-blind, multicenter, placebo-controlled, sequential parallel comparison design study of ALKS 5461 in MDD from the FORWARD (Focused on Results With a Rethinking of Depression) pivotal program. ALKS 5461 2mg/2mg met the prespecified primary endpoint of significantly reducing depression scores compared to placebo, as measured by the 6-item Montgomery—Åsberg Depression Rating Scale ("MADRS-6"). ALKS 5461 2mg/2mg also demonstrated statistically significant reductions in the 10-item Montgomery—Åsberg Depression Rating Scale ("MADRS-10") scores compared to placebo. The 1mg/1mg dose of ALKS 5461 showed improvement in depressive symptoms in the study, but did not separate significantly from placebo. The most commonly reported adverse events for ALKS 5461 in the

FORWARD-5 study were nausea, dizziness and fatigue. FORWARD-5 was conducted in two sequential stages: Stage 1 was 5 weeks in duration, Stage 2 was 6 weeks. In Stage 1, the average change from baseline depression scores was calculated for weeks 3 through 5. For Stage 2, the average change was calculated for weeks 3 through 6. The results of Stages 1 and 2 were then averaged. Depression scores were assessed using MADRS-6 and MADRS-10. MADRS-6, a subscale of the MADRS-10 assessment tool for depression, focuses on the core symptoms of depression.

In January 2016, we announced the topline results of FORWARD-3 and FORWARD-4. Neither study met the prespecified primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline in MADRS-10 total scores. FORWARD-4 tested two dose levels of ALKS 5461 (2mg/2mg and 0.5mg/0.5mg) compared to placebo. There was a clear trend toward efficacy with the 2mg/2mg dose of ALKS 5461 on the primary endpoint, and post hoc analyses achieved statistical significance for the entire 2mg/2mg dose group on the MADRS-10 endpoint. Based on these analyses, we believe that FORWARD-4 provides supportive evidence of the efficacy of ALKS 5461 in the treatment of MDD. The most commonly reported adverse events in FORWARD-4 were nausea, headache and dizziness. FORWARD-3 tested ALKS 5461 (2mg/2mg) compared to placebo. Placebo response was greater than that observed in FORWARD-4 and no treatment effect of ALKS 5461 was observed.

Based on the results of FORWARD-5, along with the substantial data collected to date on the efficacy and safety of ALKS 5461 for the treatment of MDD from the previously completed successful, randomized, placebo-controlled phase

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2 study, together with supportive evidence from FORWARD-4, we plan to request a meeting with the FDA's Division of Psychiatric Products to discuss the filing strategy for ALKS 5461.

ALKS 3831

ALKS 3831 is a novel, proprietary, oral 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 provide the strong efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties and to have utility in the treatment of schizophrenia in patients with co-occurring alcohol use disorder.

In December 2015 and February 2016, we announced the initiation of ENLIGHTEN-1 and ENLIGHTEN-2, respectively, the two phase 3 studies from the ENLIGHTEN pivotal program for ALKS 3831. The ENLIGHTEN pivotal program will also include supportive studies to evaluate the pharmacokinetic, metabolic and long-term safety profile of ALKS 3831. We expect to use safety and efficacy data from the ENLIGHTEN pivotal program to serve as the basis for an NDA to be submitted to the FDA, pending study results.

In October 2016, we announced the initiation of a phase 1 metabolic study of ALKS 3831 to assess the effects of ALKS 3831 on whole body insulin sensitivity, lipid metabolism and other important metabolic parameters compared to olanzapine. Subjects will be randomized to receive ALKS 3831, olanzapine or placebo for 21 days. Results from the study are expected in the first half of 2017.

ALKS 8700

ALKS 8700 is a novel, proprietary, oral investigational 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.

We plan to file a 505(b)(2) NDA using pharmacokinetic bridging data from studies comparing ALKS 8700 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of ALKS 8700, which we initiated in December 2015. Additionally, we plan to initiate a randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA next year. We will need to conduct additional preclinical studies and pharmacokinetic studies to further support pharmacokinetic and pharmacodynamic comparability to TECFIDERA. We expect to complete ALKS 8700 registration studies and file the NDA in 2018.

ALKS 6428

ALKS 6428 is designed to help physicians transition patients from physical dependence on opioids to VIVITROL for the treatment of opioid dependence. This transition process includes the administration of doses of oral naltrexone in conjunction with buprenorphine during a seven-day treatment period. In September 2015, we initiated a phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence. Enrollment for this study was completed in October 2016 and results from this study are expected in the first half of 2017.

ALKS 4230

ALKS 4230, formerly referred to as RDB 1450, 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 application with the FDA in the first quarter of 2016 and initiated a phase 1 clinical trial in May 2016. This phase 1 study will be conducted in two stages: a dose-escalation stage followed by a dose-expansion stage. The first stage of the study is designed to determine a maximum tolerated dose, and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects. Following the identification of the optimal dose range of ALKS

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4230 in the first stage of the study, the dose-expansion stage of the study will evaluate ALKS 4230 in patients with selected solid tumor types. Initial results from the first stage of the phase 1 study are expected in 2017.

ALKS 7119

ALKS 7119 is a novel, proprietary, oral 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. In January 2016, we announced the initiation of a phase 1, double-blind, placebo-controlled study designed to evaluate the safety and tolerability of single ascending doses of ALKS 7119 in healthy subjects. In April 2016, we announced that early results of the single-ascending-dose study demonstrated a favorable tolerability profile and pharmacokinetic properties consistent with potential once-daily dosing.

Based on these early results, we initiated the multiple-ascending-dose study in healthy volunteers in July 2016. In October 2016, due to tolerability issues observed in a small number of subjects in the study, we ceased further development of ALKS 7119. The effects observed were not observed in the single-ascending dose study or anticipated based on pre-clinical models.

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 nine months ended September 30, 2016 and 2015:

(In millions)	Three Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)
Manufacturing and royalty revenues:						
Continuing products:						
	$ 50.0	$ 41.4	$ 8.6	$ 131.6	$ 102.5	$ 29.1

INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA						
AMPYRA/FAMPYRA	12.9	22.1	(9.2)	81.9	85.6	(3.7)
RISPERDAL CONSTA	23.2	26.3	(3.1)	65.9	72.8	(6.9)
BYDUREON	11.6	13.0	(1.4)	34.4	33.9	0.5
Other	12.5	11.3	1.2	39.6	42.4	(2.8)
	110.2	114.1	(3.9)	353.4	337.2	16.2
Divested products:						
RITALIN LA & FOCALIN XR	—	—	—	—	9.3	(9.3)
Other	—	—	—	—	9.5	(9.5)
	—	—	—	—	18.8	(18.8)
Manufacturing and royalty revenues	$ 110.2	$ 114.1	$ (3.9)	$ 353.4	$ 356.0	$ (2.6)

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three and nine months ended September 30, 2016, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $556.0 million and $1,629.0 million, as compared to $459.0 million and $1,306.0 million in the three and nine months ended September 30, 2015, respectively. Under our agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA 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.

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The decrease in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, was primarily due to a 36% decrease in the amount of AMPYRA we shipped to Acorda and a decrease in the amount of revenue we earned on product shipped to Acorda by a third-party manufacturer. The decrease in AMPYRA/FAMPYRA manufacturing and royalty revenues in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to a decrease in the amount of revenue we earned on product shipped to Acorda by a third-party manufacturer. Under our supply and license agreements with Acorda, we earn manufacturing and royalty revenues when AMPYRA is shipped to Acorda, either by us or a third-party manufacturer. During the three and nine months ended September 30, 2016, we earned none and $8.8 million of revenue from product shipped to Acorda by a third-party manufacturer, respectively, as compared to $5.4 million and $17.8 million in the three and nine months ended September 30, 2015, respectively.

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, was primarily due to a decrease in Janssen's end market sales of RISPERDAL CONSTA and a decrease in the price we earned on shipments of RISPERDAL CONSTA to Janssen. During the three and nine months ended September 30, 2016, Janssen's end market sales of RISPERDAL CONSTA were $222.0 million and $683.0 million, respectively, as compared to $235.0 million and $736.0 million in the three and nine months ended September 30, 2015, respectively. Manufacturing revenues decreased by 13% and 10% in the three and nine months ended September 30, 2016, respectively, as compared to the corresponding prior periods, which was primarily due to an 11% and 14% decrease in price during these respective periods.

The difference in BYDUREON royalty revenues in the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, was due to end-market sales of BYDUREON by AstraZeneca. During the three and nine months ended September 30, 2016, AstraZeneca's end-market sales of BYDUREON were $144.7 million and $434.1 million, respectively, as compared to $161.3 million and $424.0 million in the three and nine months ended September 30, 2015, respectively.

The divested products relate to products sold as part of the Gainesville Transaction.

Product Sales, net

Our product sales, net consist of sales of VIVITROL and, following its approval by the FDA in October 2015, ARISTADA in the U.S., primarily to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net for sales during the three and nine months ended September 30, 2016 and 2015:

(In millions)	Three Months Ended September 30, 2016	% of Sales		2015	% of Sales		Nine Months Ended September 30, 2016	% of Sales		2015	% of Sa
Product sales, gross	$ 122.8	100.0	%	$ 59.6	100.0	%	$ 308.5	100.0	%	$ 156.5	100.0
Adjustments to product sales, gross:											
Medicaid rebates	(25.1)	(20.4)	%	(9.2)	(15.4)	%	(64.9)	(21.0)	%	(17.3)	(11.1)
Product discounts	(9.9)	(8.1)	%	(4.5)	(7.6)	%	(24.3)	(7.9)	%	(11.7)	(7.5)
Chargebacks	(10.0)	(8.2)	%	(4.9)	(8.2)	%	(23.3)	(7.5)	%	(12.6)	(8.0)
Co-pay assistance	(2.2)	(1.8)	%	(1.9)	(3.2)	%	(6.4)	(2.1)	%	(5.1)	(3.2)
Other	(5.8)	(4.7)	%	(1.2)	(2.0)	%	(12.9)	(4.2)	%	(3.6)	(2.3)
Total adjustments	(53.0)	(43.2)	%	(21.7)	(36.4)	%	(131.8)	(42.7)	%	(50.3)	(32.1)
Product sales, net	$ 69.8	56.8	%	$ 37.9	63.6	%	$ 176.7	57.3	%	$ 106.2	67.9

The increase in product sales, gross for the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, was primarily due to a 66% and 65% increase in the number of VIVITROL units sold, respectively, and the addition of gross sales from ARISTADA, which was first commercialized in October 2015. The increase in the amount of Medicaid rebates as a percentage of sales in the three and nine months ended September 30, 2016, as compared to the corresponding prior periods, was primarily due to an increase in the amount of VIVITROL sold under the Medicaid Drug Rebate Program.

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Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	$ 35.5	$ 33.8	$ (1.7)	$ 97.2	$ 104.2	$ 7.0

The increase in the cost of goods manufactured and sold during the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, was primarily due to an increase in sales of VIVITROL and the addition of ARISTADA sales, partially offset by a decrease in costs of goods manufactured for AMPYRA/FAMPYRA. The decrease in cost of goods manufactured and sold during the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to the Gainesville Transaction. During the nine months ended September 30, 2015, the Gainesville facility had cost of goods manufactured of $10.2 million. This decrease was partially offset by an increase in cost of goods sold for VIVITROL and ARISTADA.

Research and Development Expense

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

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

			Change			Change

(In millions)	Three Months Ended September 30, 2016	2015	Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Favorable/ (Unfavorable)
External R&D Expenses:						
Key development programs:						
ALKS 3831	$ 21.1	$ 5.0	$ (16.1)	$ 53.0	$ 15.0	$ (38.0)
ALKS 5461	10.0	35.3	25.3	37.2	85.6	48.4
ARISTADA and ARISTADA line extensions	9.6	7.2	(2.4)	33.2	26.4	(6.8)
ALKS 6428	4.9	2.4	(2.5)	15.4	4.6	(10.8)
ALKS 8700	8.6	3.3	(5.3)	18.0	10.0	(8.0)
Non-refundable upfront payment to Reset	—	—	—	10.0	—	(10.0)
Other development programs	7.9	4.3	(3.6)	22.8	15.3	(7.5)
Total external R&D expenses	62.1	57.5	(4.6)	189.6	156.9	(32.7)
Internal R&D expenses:						
Employee-related	27.9	27.0	(0.9)	82.0	72.1	(9.9)
Occupancy	2.2	2.1	(0.1)	6.9	6.2	(0.7)
Depreciation	2.1	1.5	(0.6)	5.6	4.5	(1.1)
Other	5.1	4.5	(0.6)	13.4	11.0	(2.4)
Total internal R&D expenses	37.3	35.1	(2.2)	107.9	93.8	(14.1)
Research and development expenses	$ 99.4	$ 92.6	$ (6.8)	$ 297.5	$ 250.7	$ (46.8)

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 3831 was primarily due to the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively. The decrease in expenses related

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to ALKS 5461, in both the three and nine months ended September 30, 2016, as compared to the corresponding prior periods, was primarily due to the timing of the three core phase 3 studies related to the program. We announced the results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. The increase in expenses related to ARISTADA and ARISTADA line extension programs during the three and nine months ended September 30, 2016, as compared to the corresponding prior periods, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. Based on the results of this study, we submitted a sNDA to the FDA in August 2016. The increase in expenses related to ALKS 6428, in both the three and nine months ended September 30, 2016, as compared to the corresponding prior periods, was primarily due to the initiation of the phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence in September 2015. The increase in expenses related to ALKS 8700 during the three and nine months ended September 30, 2016, as compared to the three and nine months ended September 30, 2015, was primarily due to the timing of the two-year, multicenter, open-label study designed to assess the safety of ALKS 8700, which was initiated in December 2015. The $10.0 million non-refundable, upfront payment made to Reset was partial consideration of a grant to us of rights and licenses pursuant to a collaboration and license option agreement with Reset. Expenses incurred under the ALKS 7119 and ALKS 4230 development programs in the three and nine months ended September 30, 2016 and 2015 were not material.

The increase in employee-related expenses was primarily due to an increase in R&D headcount of 22% from September 30, 2015 to September 30, 2016.

Selling, General and Administrative Expense

	Three Months Ended September 30,		Change Favorable/	Nine Months Ended September 30,		Change Favorable/
(In millions)	2016	2015	(Unfavorable)	2016	2015	(Unfavorable)
Selling, general and administrative expense	$ 91.1	$ 89.5	$ (1.6)	$ 277.0	$ 224.1	$ (52.9)

The increase in SG&A expense for the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, primarily relates to an increase in employee-related expenses of $29.1 million and marketing and professional service fees of $21.2 million. The increase in employee-related expenses was due to an increase in headcount, as we increased the size of our commercial operations team in anticipation of the launch of ARISTADA in October 2015. During the nine months ended September 30, 2015, our SG&A headcount increased by 88%, with the most significant increases occurring during the second quarter of 2015. In addition, our SG&A headcount has increased by an additional 10% from September 30, 2015 to September 30, 2016. The increase in marketing and professional service fees was primarily due to the commercialization of ARISTADA commencing in October 2015.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)
Amortization of acquired intangible assets	$ 15.3	$ 14.2	$ (1.1)	$ 45.6	$ 43.5	$ (2.1)

The intangible assets being amortized in the three and nine months ended September 30, 2016 and 2015 were acquired as part of the acquisition of Elan Drug Technologies ("EDT") in September 2011. In connection with the acquisition of EDT, we acquired certain amortizable intangible assets with a fair value of $643.2 million, which were expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract.

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at September 30, 2016 is expected to be approximately $60.0 million, $60.0 million, $60.0 million, $55.0 million and $50.0 million in the years ending December 31, 2016 through 2020, respectively.

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Other (Expense) Income, Net

(In millions)	Three Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)
Interest income	$ 0.9	$ 0.9	$ —	$ 2.9	$ 2.3	$ 0.6
Interest expense	(3.3)	(3.3)	—	(9.9)	(9.9)	—
Change in the fair value of contingent consideration	(1.0)	1.2	(2.2)	3.1	2.7	0.4
Gain on Gainesville Transaction	—	—	—	—	9.9	(9.9)
Other (expense) income, net	(0.8)	0.6	(1.4)	(1.0)	1.0	(2.0)
Total other (expense) income, net	$ (4.2)	$ (0.6)	$ (3.6)	$ (4.9)	$ 6.0	$ (10.9)

The proceeds from the Gainesville Transaction included contingent consideration tied to low double digit royalties on net sales of the Meloxicam Products and up to $120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products. 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" in this Form 10-Q. We update our assessment of the fair value of this contingent consideration at each reporting date and reflect any changes to the fair value within "Change in the fair value of contingent consideration" in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss until the milestones and/or royalties included in the contingent consideration have been settled. The decrease in the fair value of the contingent consideration in the three months ended September 30, 2016 was primarily due to a delay in the timing of future clinical events, partially offset by a shorter time to payment on the milestones and royalties included in the contingent consideration. The increase in the fair value of the contingent consideration in the nine months ended September 30, 2016 was primarily due to a shorter time to payment on the milestones and royalties included in the contingent consideration, partially offset by a delay in the timing of future clinical events.

Income Tax (Benefit) Provision

(In millions)	Three Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2016	2015	Change Favorable/ (Unfavorable)
(Benefit) provision for income taxes	$ (2.7)	$ 3.0	$ 5.7	$ (2.8)	$ 6.6	$ 9.4

The income tax (benefit) provision in the three and nine months ended September 30, 2016 and 2015 primarily relates to U.S. federal and state taxes. The favorable change in income taxes in the three and nine months ended September

30, 2016, as compared to the corresponding prior periods, was due to a reduction in income earned in the U.S.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

	September 30, 2016			December 31, 2015		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 115.9	$ 86.3	$ 202.2	$ 70.8	$ 110.3	$ 181.1
Investments—short-term	211.0	136.2	347.2	202.4	151.2	353.6
Investments—long-term	23.0	52.1	75.1	129.1	135.0	264.1
Total cash and investments	$ 349.9	$ 274.6	$ 624.5	$ 402.3	$ 396.5	$ 798.8
Outstanding borrowings—current and long-term	$ 285.6	$ —	$ 285.6	$ 349.9	$ —	$ 349.9

At September 30, 2016, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Losses	Estimated Fair Value
Investments—short-term	$ 346.9	$ 0.3	$ —	$ 347.2
Investments—long-term available-for-sale	71.9	—	(0.1)	71.8
Investments—long-term held-to-maturity	3.4	—	—	3.4
Total	$ 422.2	$ 0.3	$ (0.1)	$ 422.4

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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. Available-for-sale investments in an unrealized gain position are classified as short-term investments, regardless of maturity date. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2016, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

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. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures.

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 nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
(In millions)	2016	2015
Cash and cash equivalents, beginning of period	$ 181.1	$ 224.1
Cash used in operating activities	(71.4)	(42.8)
Cash provided by (used in) investing activities	148.1	(1.3)
Cash (used in) provided by financing activities	(55.6)	42.3
Cash and cash equivalents, end of period	$ 202.2	$ 222.3

The increase in cash flows used in operating activities in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to a 17% increase in cash paid to our suppliers and a 28% increase in cash paid to our employees, partially offset by a 10% increase in cash received from our customers. The increase in cash paid to our suppliers and employees was primarily due to the increase in our R&D activity, the commercialization of ARISTADA and an increase in our R&D and SG&A headcount, as previously discussed.

The increase in cash flows provided by investing activities in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to a $211.8 million increase in the net sales of investments. This was partially offset by a $15.0 million investment we made in Reset in February 2016 and the proceeds from the Gainesville Transaction of $50.3 million in April 2015.

The decrease in cash flows provided by financing activities in the nine months ended September 30, 2016, as compared to the nine months ended September 30, 2015, was primarily due to the $60.9 million principal payment we made for Term Loan B-2, which matured on September 25, 2016. In addition, there was a decrease of $10.3 million in cash received from our employees from the exercise of stock options, net of amounts withheld for taxes, and a $28.2 million decrease in excess tax benefit from share-based compensation.

Borrowings

At September 30, 2016, our borrowings consisted of $288.0 million outstanding under our Term Loan Facility.

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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. Term Loan B-2 was due on September 25, 2016 and we paid the outstanding principal balance of $60.9 million in its entirety.

In October 2016, we entered into the Refinancing whereby the due date of Term Loan B-1 was extended from September 25, 2019 to September 25, 2021. Refer to Note 10, Long-Term Debt, within the “Notes to Condensed Consolidated Statements” in this Form 10-Q, for a discussion of the Refinancing.

Contractual Obligations

Refer to the “Contractual Obligations” section within “Part II, Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report for a discussion of our contractual obligations. Our contractual obligations have not materially changed from the date of that Annual Report.

Off-Balance Sheet Arrangements

At September 30, 2016, 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 "Critical Accounting Estimates" within “Part II, Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations” 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 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, 2015, 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 partially offset by certain operating costs arising from expenses and payables at our Irish operations that are settled predominantly 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, 2015.

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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 September 30, 2016. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2016 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.

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. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see “Part I, Item 1A – Risk Factors” of our Annual Report.

ARISTADA

On July 13, 2015, Otsuka PD&C filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition.

On October 15, 2015, Otsuka filed an action for declaratory and injunctive relief with the DC Court against Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Stephen Ostroff, Acting Commissioner, FDA; and the FDA, requesting that the DC Court (a) expedite the legal proceedings; (b) declare that the FDA's denial of Otsuka's claimed exclusivity rights and approval of the ARISTADA NDA were arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (c) vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) declare that Otsuka's claimed exclusivity rights preclude FDA from granting approval of the Alkermes NDA until the expiration of such exclusivity rights in December 2017; and (e) grant any and all other, further, and additional relief, including all necessary and appropriate protective preliminary, interim, or permanent relief, as the nature of the cause may require, including all necessary and appropriate declarations of rights and injunctive relief. The Company successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an unambiguous opinion in favor of Alkermes and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the DC Circuit asking the DC Circuit to reverse the DC Court's decision, vacate FDA's approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka's lost exclusivity. The DC Circuit has scheduled this appellate hearing for December 12, 2016. The Company believes Otsuka's action is without

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merit and will continue to vigorously defend ARISTADA against such action. For information about risks relating to this action, see “Part I, Item 1A—Risk Factors” in the Company’s Annual Report and specifically the section entitled “Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business.”

AMPYRA

AMPYRA ANDA Litigation

Ten separate Paragraph IV Certification Notices have been submitted to us and/or the Company’s licensee Acorda from Accord; Actavis; Alkem; Apotex, Inc.; Aurobindo; Mylan; Par; Roxane Laboratories, Inc.; Sun; and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of the Orange Book-listed patents for AMPYRA, and they have also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA filers in the Delaware Court asserting infringement of U.S. Patent Nos. 5,540,938 (which the Company owns), 8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). Requested judicial remedies include recovery of litigation costs and injunctive relief. Lawsuits with eight of the ANDA filers have been consolidated into a single case. The Delaware Court held a bench trial that concluded on September 23, 2016. Mylan is challenging the jurisdiction of the Delaware Court with respect to the Delaware action. Due to Mylan’s motion to dismiss, the Company, together with Acorda, also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. patents and requesting the same judicial relief as in the Delaware action. In March 2016, the Federal Circuit upheld the Delaware Court’s ruling that the litigation against Mylan can continue in the Delaware Court. In June 2016, the Federal Circuit denied Mylan’s request for a rehearing to reconsider its previous ruling. Mylan has appealed the Federal Circuit’s decision to the Supreme Court of the United States. All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30-month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30-month stay starts from January 22, 2015, which is the end of the new chemical entity exclusivity period for AMPYRA. This stay restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date. Such FDA approval would permit the ANDA filers to market generic versions of AMPYRA (dalfampridine) Extended Release Tablets, 10 mg.

The Company and/or Acorda has entered into a settlement agreement with each of the Settling ANDA Filers to resolve the patent litigation that the Company and/or Acorda brought against the Settling ANDA Filers in the Delaware Court as described above. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market a generic version of AMPYRA in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have submitted their respective settlement agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers do not resolve pending patent litigation that the Company and Acorda brought against the other ANDA filers, as described above.

The Company intends to vigorously enforce its intellectual property rights. For information about risks relating to the AMPYRA Paragraph IV litigations and other proceedings see “Part I, Item 1A—Risk Factors” in the Company’s Annual Report and specifically the section entitled “We face claims against our intellectual property rights and competition from generic drug manufacturers.”

AMPYRA IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has filed IPR petitions with the USPTO, challenging U.S. Patent Nos. 8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). In March 2016, the USPTO’s Patent Trials and Appeal Board instituted the IPR. A ruling on the IPR petitions is expected within one year of the IPR’s institution. The challenged patents are four of the five AMPYRA Orange-Book listed patents. The 30-month statutory stay period based on patent infringement suits filed by us and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

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BYDUREON, RISPERDAL CONSTA AND VIVITROL IPR Proceedings

On June 3, 2016 the USPTO accepted two separate IPR petitions filed by Luye challenging the ‘061 Patent, which is an Orange Book-listed patent for each of BYDUREON, RISPERDAL CONSTA and VIVITROL. On September 1, 2016, the Company filed a response to Luye’s IPR petitions with the USPTO, following which the USPTO has a further three-month period to decide whether or not to institute a review of the challenged claims of the ‘061 Patent. If such review is instituted, a decision on the matter would be expected, pursuant to the statutory time frame, within one year of the USPTO’s decision to institute such review.

The Company opposed Luye’s requests to institute the IPRs against the ‘061 Patent. If the USPTO institutes such challenge, the Company will vigorously defend the ‘061 Patent. For information about risks relating to the ‘061 Patent IPR proceedings see “Part I, Item 1A—Risk Factors” in the Company’s Annual Report and specifically the sections entitled “Patent protection for our products is important and uncertain” and “Uncertainty over intellectual property in the pharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable”.

Item 1A. Risk Factors

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the nine months ended September 30, 2016. As of September 30, 2016, we had purchased a total of 8,866,342 shares at a cost of $114.0 million.

During the three months ended September 30, 2016, we acquired 161,921 Alkermes ordinary shares, at an average price of $45.27 per share, in connection with the vesting of employee equity awards to satisfy withholding tax obligations.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended September 30, 2016, Mr. Paul J Mitchell, a director of the Company, Dr. Elliot W. Ehrich, Messrs. Iain M. Brown, James M. Frates, David J. Gaffin, Gordon G. Pugh, and Ms. Kathryn L. Biberstein, each 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.

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SIGNATURES

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

ALKERMES plc

(Registrant)

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

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

Date: November 2, 2016

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EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1#†	Form of Employment Agreement by and between Alkermes, Inc. and each of Iain M. Brown and David J. Gaffin
10.2#	Amendment No. 4, dated as of October 12, 2016, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by Amendment No. 2 on February 14, 2013 and as amended by Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto and Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent.
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.
101#+	The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2016, formatted in XBRL (“Extensible Business Reporting Language”): (i) the Condensed Consolidated 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 Statements.

+ XBRL (Extensible Business Reporting Language).

Filed herewith.

‡ Furnished herewith.

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