Alkermes plc.
Form 10-Q
July 27, 2017
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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 June 30, 2017

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of July 21, 2017 was 153,656,837 shares.

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ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

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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 These statements discuss future expectations, and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q (“Form 10-Q”) include, without limitation, statements regarding:

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

• our expectations regarding our products, including the development, regulatory (including expectations about regulatory filings, regulatory approvals 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 competition from generic forms of our products, 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;

• our expectations regarding the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents and other proprietary and intellectual property rights and our products; 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 publicly update 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 II, Item 1A – Risk Factors" in this Form 10-Q and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and "Part I, Item 1A—Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2016 (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; studies; surveys and forecasts; and our internal research), on assumptions that we have made, which we believe are reasonable, based on such information, 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. Such information and assumptions are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Part II, Item 1A – Risk Factors" in this Form 10-Q and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and "Part I, Item

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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.

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 ("MS"). Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Form 10-Q include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies, (b) references to the "biopharmaceutical industry" are used interchangeably with references to the "biotechnology" and/or "pharmaceutical industries" and (c) 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® and VIVITROL®.

The following are trademarks of the respective companies listed: AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc. ("Acorda"); BYDUREON® —Amylin Pharmaceuticals, LLC; INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION®, and RISPERDAL CONSTA®—Johnson & Johnson (or its affiliates); TECFIDERA®—Biogen MA Inc. ("Biogen"); 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)

	June 30, 2017	December 31, 2016
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 158,106	$ 186,378
Investments—short-term	317,001	310,856
Receivables, net	199,709	191,102
Inventory	77,352	62,998
Prepaid expenses and other current assets	43,458	39,344
Total current assets	795,626	790,678
INTANGIBLE ASSETS—NET	287,453	318,227
PROPERTY, PLANT AND EQUIPMENT, NET	266,484	264,785
GOODWILL	92,873	92,873
INVESTMENTS—LONG-TERM	85,724	121,931
CONTINGENT CONSIDERATION	65,500	63,200
DEFERRED TAX ASSETS	112,332	47,768
OTHER ASSETS	25,351	26,961
TOTAL ASSETS	$ 1,731,343	$ 1,726,423
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 219,839	$ 207,055
Long-term debt—short-term	3,000	3,000
Deferred revenue—short-term	1,805	1,938
Total current liabilities	224,644	211,993
LONG-TERM DEBT	279,552	280,666
OTHER LONG-TERM LIABILITIES	18,278	17,161
DEFERRED REVENUE—LONG-TERM	6,782	7,122
Total liabilities	529,256	516,942
COMMITMENTS AND CONTINGENCIES (Note 12)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at June 30, 2017 and December 31, 2016, respectively	—	—

Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 155,695,975 and 154,191,281 shares issued; 153,650,197 and 152,430,514 shares outstanding at June 30, 2017, and December 31, 2016, respectively	1,554	1,539
Treasury shares, at cost (2,045,778 and 1,760,767 shares at June 30, 2017 and December 31, 2016, respectively)	(89,221)	(72,639)
Additional paid-in capital	2,291,388	2,231,797
Accumulated other comprehensive loss	(3,335)	(3,274)
Accumulated deficit	(998,299)	(947,942)
Total shareholders' equity	1,202,087	1,209,481
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,731,343	$ 1,726,423

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	$ 129,252	$ 137,034	$ 243,931	$ 243,194
Product sales, net	88,756	57,519	165,212	106,893
Research and development revenue	833	612	1,476	1,853
Total revenues	218,841	195,165	410,619	351,940
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	39,775	33,998	80,187	61,709
Research and development	99,153	97,006	203,988	198,079
Selling, general and administrative	108,950	96,121	211,049	185,840
Amortization of acquired intangible assets	15,472	15,157	30,774	30,313
Total expenses	263,350	242,282	525,998	475,941
OPERATING LOSS	(44,509)	(47,117)	(115,379)	(124,001)
OTHER EXPENSE, NET:				
Interest income	1,171	994	2,114	2,005
Interest expense	(2,923)	(3,323)	(5,687)	(6,618)
Increase in the fair value of contingent consideration	700	2,200	2,300	4,100
Other expense, net	(119)	(467)	(1,618)	(218)
Total other expense, net	(1,171)	(596)	(2,891)	(731)
LOSS BEFORE INCOME TAXES	(45,680)	(47,713)	(118,270)	(124,732)
INCOME TAX BENEFIT	(2,681)	(520)	(6,390)	(116)
NET LOSS	$ (42,999)	$ (47,193)	$ (111,880)	$ (124,616)
LOSS PER COMMON SHARE:				
Basic and diluted	$ (0.28)	$ (0.31)	$ (0.73)	$ (0.82)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic and diluted	153,392	151,301	153,050	151,063
COMPREHENSIVE LOSS:				
Net loss	$ (42,999)	$ (47,193)	$ (111,880)	$ (124,616)
Holding (loss) gain, net of a tax (benefit) provision of $(71), $149, $(49) and $574, respectively	(133)	315	(61)	1,250
COMPREHENSIVE LOSS	$ (43,132)	$ (46,878)	$ (111,941)	$ (123,366)

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)

	Six Months Ended June 30,	
	2017	2016
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (111,880)	$ (124,616)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	48,269	45,786
Share-based compensation expense	43,848	50,887
Deferred income taxes	(6,863)	(8,890)
Excess tax benefit from share-based compensation	—	(4,606)
Increase in the fair value of contingent consideration	(2,300)	(4,100)
Other non-cash charges	3,532	1,143
Changes in assets and liabilities:		
Receivables	(8,606)	(29,522)
Inventory	(14,585)	(13,245)
Prepaid expenses and other assets	(5,574)	(13,408)
Accounts payable and accrued expenses	13,400	12,703
Deferred revenue	(473)	(923)
Other long-term liabilities	5,034	2,699
Cash flows used in operating activities	(36,198)	(86,092)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(20,656)	(22,280)
Proceeds from the sale of equipment	7	81
Investment in Reset Therapeutics, Inc.	—	(15,000)
Purchases of investments	(160,554)	(169,622)
Sales and maturities of investments	190,642	307,953
Cash flows provided by investing activities	9,439	101,132
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	16,404	7,490
Excess tax benefit from share-based compensation	—	4,606
Employee taxes paid related to net share settlement of equity awards	(16,417)	(8,432)
Principal payments of long-term debt	(1,500)	(3,375)
Cash flows (used in) provided by financing activities	(1,513)	289
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(28,272)	15,329
CASH AND CASH EQUIVALENTS—Beginning of period	186,378	181,109
CASH AND CASH EQUIVALENTS—End of period	$ 158,106	$ 196,438
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		

Purchased capital expenditures included in accounts payable and accrued expenses	$ 4,531	$ 2,802

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 MS. 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 six months ended June 30, 2017 and 2016 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2016. 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, judgments, assumptions 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 expense, income taxes including the valuation allowance for deferred tax assets, valuation of contingent consideration, valuation of investments and litigation loss contingencies. 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 in the three and six months ended June 30, 2017 and 2016 relates primarily to U.S. federal and state taxes. The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At June 30, 2017, 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. Numerous updates have been issued subsequent to the initial guidance that provide clarification on a number of specific issues as well as requiring additional disclosures.

This guidance becomes effective for the Company in its year ending December 31, 2018 and the Company will adopt the new standard using the modified retrospective method. The Company is in the process of assessing the impact the new standard will have on its consolidated financial statements, as well as evaluating the disclosure requirements under the new standard. At this time, the Company cannot reasonably estimate the expected impact the adoption of this new standard will have 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; 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 in the process of 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

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ALKERMES PLC AND SUBSIDIARIES

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

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 became effective for the Company on January 1, 2017, and the adoption of this standard did not 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: (i) all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; (ii) excess tax benefits be classified as an operating activity in the statement of cash flows; (iii) 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; (iv) the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and (v) 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 became effective for the Company on January 1, 2017. The amendments related to (i), (iii) and (iv) were adopted by the Company on a modified retrospective basis, which resulted in a cumulative-effect adjustment to reduce accumulated deficit by $61.5 million related to the timing of when excess tax benefits are recognized. The Company elected to continue to record expense only for those awards that are expected to vest. The amendments related to (ii) and (v) were adopted using the prospective transition method.

In June 2016, the FASB issued guidance to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this guidance replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance becomes effective for the Company in its year ending December 31, 2020, with early adoption permitted for the Company in its year ending December 31, 2019. 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, with early adoption permitted. The Company elected to early adopt this standard as of January 1, 2017. The adoption of this standard did not have an impact on the Company's statement of cash flows.

In October 2016, the FASB issued guidance to simplify and improve accounting on transfers of assets between affiliated entities. The updated guidance eliminates the prohibition for all intra-entity asset transfers, except for inventory. 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 January 2017, the FASB issued guidance to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance becomes effective for the Company in its year ending December 31, 2018, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted the provisions of this standard, effective January 1, 2017, and the adoption of this standard had no impact on the Company's consolidated financial statements.

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ALKERMES PLC AND SUBSIDIARIES

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

In January 2017, the FASB issued guidance that simplifies the test for goodwill impairment. This guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. Under the amended guidance, a goodwill impairment charge will now be recognized for the amount by which the carrying value of a reporting unit exceeds its fair value, not to exceed the carrying amount of goodwill. This guidance is effective for the Company in its year ending December 31, 2020, with early adoption permitted for any impairment tests performed after January 1, 2017. The Company adopted the provisions of this standard, effective January 1, 2017, and the adoption of this standard had no impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued guidance that amends the scope of modification accounting for share-based payment arrangements that addresses both diversity in practice and the cost and complexity of accounting for the change to the terms or conditions of a share-based payment award. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance becomes effective for the Company in its year ending December 31, 2018 and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In July 2017, the FASB issued guidance that addresses narrow issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The guidance becomes effective for the Company in its year ending December 31, 2019 and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

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ALKERMES PLC AND SUBSIDIARIES

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

3. INVESTMENTS

Investments consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses(1)	Estimated Fair Value
	(In thousands)			
June 30, 2017				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	$ 198,041	$ 9	$ (252)	$ 197,798
Corporate debt securities	89,765	38	(41)	89,762
International government agency debt securities	29,483	1	(43)	29,441
Total short-term investments	317,289	48	(336)	317,001
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	53,109	—	(237)	52,872
Corporate debt securities	18,433	—	(51)	18,382
International government agency debt securities	10,954	—	(10)	10,944
	82,496	—	(298)	82,198
Held-to-maturity securities:				
Fixed term deposit account	1,667	130	—	1,797
Certificates of deposit	1,729	—	—	1,729
	3,396	130	—	3,526
Total long-term investments	85,892	130	(298)	85,724
Total investments	$ 403,181	$ 178	$ (634)	$ 402,725
December 31, 2016				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	$ 177,203	$ 96	$ (51)	$ 177,248
Corporate debt securities	128,119	47	(53)	128,113
International government agency debt securities	5,511	—	(16)	5,495
Total short-term investments	310,833	143	(120)	310,856
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	81,839	—	(391)	81,448
Corporate debt securities	31,223	—	(89)	31,134

International government agency debt securities	5,992	—	(18)	5,974
	119,054	—	(498)	118,556
Held-to-maturity securities:				
Fixed term deposit account	1,667	—	(7)	1,660
Certificates of deposit	1,715	—	—	1,715
	3,382	—	(7)	3,375
Total long-term investments	122,436	—	(505)	121,931
Total investments	$ 433,269	$ 143	$ (625)	$ 432,787

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

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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:

	Six Months Ended June 30,	
(In thousands)	2017	2016
Proceeds from the sales and maturities of marketable securities	$ 190,642	$ 307,953
Realized gains	$ 9	$ 112
Realized losses	$ 3	$ 28

The Company's available-for-sale and held-to-maturity securities at June 30, 2017 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	$ 281,446	$ 281,180	$ 1,729	$ 1,729
After 1 year through 5 years	118,339	118,019	1,667	1,797
Total	$ 399,785	$ 399,199	$ 3,396	$ 3,526

At June 30, 2017, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of U.S. government and agency debt securities. 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"), a related party. 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 of Reset, its seat on Reset's board of directors and its belief that it can exert significant influence over the operating and financial policies of Reset. During the three and six months ended June 30, 2017, the Company recorded a reduction in its investment in Reset of $1.2 million and $2.8 million, respectively, which represents the Company's proportional share of Reset's net losses for these periods. The Company's $10.5 million investment in Reset at June 30, 2017 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. During the three and six months ended June 30, 2017, the Company recorded a reduction in its investment in Fountain of less than $0.1 million and $0.6 million, respectively, which represents the Company's proportional share of Fountain's net losses for these periods. The Company's $2.1 million (€1.8 million) investment in Fountain at June 30, 2017 is included within "Other assets" in the accompanying condensed consolidated balance sheets.

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

4. FAIR VALUE MEASUREMENTS

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

(In thousands)	June 30, 2017	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 1,797	$ 1,797	$ —	$ —
U.S. government and agency debt securities	250,670	156,305	94,365	—
Corporate debt securities	108,144	—	108,144	—
International government agency debt securities	40,385	—	40,385	—
Contingent consideration	65,500	—	—	65,500
Common stock warrants	1,157	—	—	1,157
Total	$ 467,653	$ 158,102	$ 242,894	$ 66,657

	December 31, 2016	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 1,660	$ 1,660	$ —	$ —
U.S. government and agency debt securities	258,696	156,370	102,326	—
Corporate debt securities	159,247	—	159,247	—
International government agency debt securities	11,469	—	11,469	—
Contingent consideration	63,200	—	—	63,200
Common stock warrants	1,392	—	—	1,392
Total	$ 495,664	$ 158,030	$ 273,042	$ 64,592

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period. There were no transfers of any securities between the fair value hierarchies during the six months ended June 30, 2017.

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 June 30, 2017:

(In thousands)	Fair Value
Balance, January 1, 2017	$ 64,592
Increase in the fair value of contingent consideration	2,300
Decrease in the fair value of warrants	(235)
Balance, June 30, 2017	$ 66,657

In March 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. In connection with the Gainesville Transaction, the Company is eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is

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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 $125.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products, including, at Recro's election, either (i) $10.0 million upon the submission of a New Drug Application ("NDA") filing for the first Meloxicam Product and $30.0 million upon regulatory approval of an NDA for the first Meloxicam Product or (ii) an aggregate of $45.0 million upon regulatory approval of an NDA for the first Meloxicam Product.

At June 30, 2017, 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 for both scenario (i) and scenario (ii), mentioned above, 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 first regulatory milestone event to occur within a few months and used a discount rate of 2.1% for both scenario (i) and scenario (ii). The Company expects the second regulatory milestone event to occur within 2018 and used a discount rate of 2.7% for both scenario (i) and scenario (ii). The Company then assessed the likelihood of Recro opting to pay the Company under each scenario to arrive at a probability-weighted present value for these regulatory milestones;

• 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 intellectual property 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; and

• 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 rate ranging from 9.5% to 11.4%, which included cost of debt plus an alpha.

During the three and six months ended June 30, 2017, the Company determined that the value of the Gainesville Transaction's contingent consideration increased by $0.7 million and $2.3 million, respectively. During the three and

six months ended June 30, 2016, the value of the contingent consideration increased by $2.2 million and $4.1 million, respectively. This increase was recorded as “Increase in the fair value of contingent consideration” in the accompanying condensed consolidated statements of operations and comprehensive loss.

As part of the Gainesville Transaction, the Company also received warrants to purchase 350,000 shares of Recro common stock at a per share exercise price of $19.46. The Company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at June 30, 2017:

Closing stock price at June 30, 2017	$ 7.03	
Warrant strike price	$ 19.46	
Expected term (years)	4.78	
Risk-free rate	1.89	%
Volatility	84.7	%

During the three and six months ended June 30, 2017, the Company determined that the fair value of the warrants, recorded within “Other assets” in the accompanying condensed consolidated balance sheets, decreased by $0.4 million and $0.2 million, respectively. The fair value of the warrants increased by $0.4 million and decreased by $0.4 million during the three and six months ended June 30, 2016, respectively. The change in the fair value of the warrants was

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

recorded within “Other expense, net” in the accompanying condensed consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company’s condensed consolidated balance sheets at June 30, 2017 consisted of a $300.0 million term loan, bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% with a maturity date of September 25, 2021 (“Term Loan B-1”). 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 actual values that could have been or will be realized in the future, was as follows at June 30, 2017:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	$ 282,552	$ 287,179

5. 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)	June 30, 2017	December 31, 2016
Raw materials	$ 29,339	$ 19,413
Work in process	24,724	21,811
Finished goods(1)	23,289	21,774
Total inventory	$ 77,352	$ 62,998

(1) At June 30, 2017 and December 31, 2016, the Company had $12.2 million and $7.1 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Land	$ 6,303	$ 5,913
Building and improvements	155,117	152,871
Furniture, fixture and equipment	276,081	251,437
Leasehold improvements	19,578	19,241
Construction in progress	32,352	41,254
Subtotal	489,431	470,716
Less: accumulated depreciation	(222,947)	(205,931)
Total property, plant and equipment, net	$ 266,484	$ 264,785

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

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

		Six Months Ended June 30, 2017		
(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	$ (243,644)	$ 221,946
NanoCrystal technology	13	74,600	(27,805)	46,795
OCR technologies	12	42,560	(23,848)	18,712
Total		$ 582,750	$ (295,297)	$ 287,453

Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at June 30, 2017 is expected to be approximately $60.0 million, $60.0 million, $55.0 million, $50.0 million and $45.0 million in the years ending December 31, 2017 through 2021, 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.

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016

Accounts payable	$ 54,677	$ 46,275
Accrued compensation	37,281	45,622
Accrued sales discounts, allowances and reserves	73,833	60,973
Accrued other	54,048	54,185
Total accounts payable and accrued expenses	$ 219,839	$ 207,055

9. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Term Loan B-1, due September 25, 2021	$ 282,552	$ 283,666
Less: current portion	(3,000)	(3,000)
Long-term debt	$ 279,552	$ 280,666

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

10. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2017	2016	2017	2016
Cost of goods manufactured and sold	$ 1,908	$ 2,264	$ 4,141	$ 4,542
Research and development	5,661	6,367	11,255	12,798
Selling, general and administrative	15,110	18,000	28,452	33,547
Total share-based compensation expense	$ 22,679	$ 26,631	$ 43,848	$ 50,887

At June 30, 2017 and December 31, 2016, $0.3 million and $1.1 million, respectively, of share-based compensation cost was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

In February 2017, the board of directors awarded restricted stock units (“RSUs”) to all employees of the Company as of the date of the award, subject to vesting on the achievement of two future key milestones in the Company’s clinical-stage pipeline and the achievement of a revenue-related goal; provided that, if any such vesting event occurs during the first year after grant, the vesting of the RSU award will not occur until the one-year anniversary of the grant date. The award will expire if the performance conditions have not been met on or before the three-year anniversary of the grant date. The grant date fair value of the performance-vesting RSUs was equal to the market value of the Company's stock on the date of grant. At June 30, 2017, the Company does not consider it probable that the performance criteria will be met and has not recognized any share-based compensation expense related to these performance-vesting RSUs. At June 30, 2017, there was $59.5 million of unrecognized compensation cost related to these performance-vesting RSUs, which would be recognized in accordance with the terms of the award when the Company deems it probable that the performance criteria will be met.

11. 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 six months ended June 30, 2017 and 2016, 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 June 30,		Six Months Ended June 30,	
(In thousands)	2017	2016	2017	2016
Stock options	9,850	11,168	9,511	10,463
Restricted stock units	2,159	1,370	1,998	1,297
Total	12,009	12,538	11,509	11,760

12. COMMITMENTS AND CONTINGENCIES

Lease Commitments

In March 2017, the Company entered into a lease agreement to lease approximately 65,000 square feet of office space in Waltham, Massachusetts (the “Building”). Beginning March 1, 2017, the Company began leasing approximately 43,290 square feet (“Premises A”) of the Building, and, on January 1, 2018, the Company will gain access to the additional 21,645 square feet (“Premises B”). The lease on both Premises A and Premises B ends on September 30, 2020 and will result in rental expense of approximately $1.2 million in 2017 and $2.2 million from 2018 through 2020.

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Litigation

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 using the latest 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 June 30, 2017, there were no potential material losses from claims, asserted or unasserted, or legal proceedings the Company determined were 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.

On October 15, 2015, Otsuka Pharmaceutical Co., Ltd., Otsuka PD&C, and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") filed an action for declaratory and injunctive relief with the U.S. 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 the 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 the 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 opinion in favor of the Company and the FDA, affirming in all respects the FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka 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 the 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's appellate hearing for this matter occurred on 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" of the 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."

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

AMPYRA

AMPYRA ANDA Litigation

Ten separate Paragraph IV Certification Notices have been received by the Company and/or its partner Acorda from: Accord Healthcare, Inc. ("Accord"); Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd. ("Alkem"); Apotex Corporation and Apotex, Inc. (collectively, "Apotex"); Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc. ("Roxane"); Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc. ("Teva," and collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, Mylan, Par, Roxane and Sun, the "ANDA Filers") advising that each of the ANDA Filers had submitted an abbreviated NDA ("ANDA") to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. The ANDA Filers challenged the validity of the Orange Book-listed patents for AMPYRA, and they 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 No. 5,540,938 (the "'938 Patent"), which the Company owns, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. Requested judicial remedies included recovery of litigation costs and injunctive relief.

All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices from the ANDA Filers. As a result, a 30-month statutory stay of approval period applied to each of the ANDA Filers' ANDAs under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The 30-month stay started on January 22, 2015, and restricted the FDA from approving the ANDA Filers' ANDAs until July 2017 at the earliest, unless a Federal district court issued a decision adverse to all of the asserted Orange Book-listed patents prior to that date. Lawsuits with eight of the ANDA Filers have been consolidated into a single case.

The Company and/or Acorda entered into a settlement agreement with each of Accord, Actavis, Alkem, Apotex, 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 a result of the settlement agreements, the Settling ANDA Filers will be permitted to market generic versions of AMPYRA in the U.S. at a specified date in the future. The parties submitted their respective settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers (the "Non-Settling ANDA Filers"), as described in this Form 10-Q.

On March 31, 2017, after a bench trial, the Delaware Court issued an opinion (the "Delaware Court Decision"), upholding the validity of the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and finding that Apotex, Mylan, Roxane and Teva stipulated that their proposed generic forms of AMPYRA infringed the '938 Patent. The Delaware Court also invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In May 2017, Acorda filed its appeal of the Delaware Court Decision with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, the Non-Settling ANDA Filers filed their cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the '938 Patent.

Mylan challenged the jurisdiction of the Delaware Court with respect to the Delaware action. In January 2015, the Delaware Court denied Mylan's motion to dismiss. Subsequently, in January 2015, the Delaware Court granted Mylan's request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit. In March 2016, the Federal Circuit denied Mylan's appeal, and the case remains in the Delaware Court. Mylan requested the Federal Circuit to reconsider its decision. However, on June 20, 2016, the Federal Circuit denied Mylan's request. Mylan filed an appeal with the U.S. Supreme Court, which was denied. Due to Mylan's motion to dismiss, the Company, along 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 December 2014, the

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

Company, along with Acorda, filed a motion in the Northern District of West Virginia to stay that action in deference to the Delaware action. In February 2015, the District Court for the Northern District of West Virginia granted the motion to stay the proceeding, and, in May 2017, dismissed the proceeding in view of the Delaware Court Decision. The patent infringement case against Mylan, however, was part of the consolidated Delaware action.

In addition to the Paragraph IV Certification Notices received from the ANDA Filers, in April 2017, Acorda received an additional Paragraph IV Certification Notice from Micro Labs, Ltd. ("Micro Labs"), contending that U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 are invalid and not infringed by Micro Labs' proposed generic version of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. On May 24, 2017, Acorda filed a lawsuit against Micro Labs and Micro Labs USA, Inc. in the U.S. District Court for the District of New Jersey asserting infringement of U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. Requested judicial remedies included recovery of litigation costs and injunctive relief. The lawsuit was brought within 45 days from receipt of such Paragraph IV Certification Notice; therefore, the FDA cannot approve Micro Labs' ANDA for 30 months (unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date).

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 II, Item 1A—Risk Factors" in this Form 10-Q and in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and "Part I, Item 1A—Risk Factors" of the Company's Annual Report.

AMPYRA IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed inter partes review ("IPR") petitions with the U.S. Patent and Trademark Office (the "USPTO"), challenging U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda, representing four of the five AMPYRA Orange Book-listed patents. In March 2016, the USPTO's Patent Trials and Appeal Board (the "PTAB") instituted the IPR, and oral argument for the IPR was held on January 19, 2017. On March 9, 2017, the PTAB upheld the challenged claims. This decision does not affect the litigation discussed in the "AMPYRA ANDA Litigation" section above.

BYDUREON, RISPERDAL CONSTA AND VIVITROL

Government Matters

On June 22, 2017, the Company received a subpoena from an Office of the U.S. Attorney for documents related to VIVITROL. The Company is cooperating with the government.

IPR Proceedings

On June 3, 2016, Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Shandong Luye Pharmaceutical Co., Ltd., and Nanjing Luye Pharmaceutical Co., Ltd. (collectively, "Luye") filed two separate IPR petitions challenging U.S. Patent No. 6,667,061 (the "'061 Patent"), which is an Orange Book-listed patent for each of BYDUREON, RISPERDAL CONSTA and VIVITROL. The Company opposed the institution of these IPR petitions. On November 30, 2016, the USPTO's PTAB instituted one of Luye's IPR petitions and denied instituting Luye's other IPR petition. Oral argument for the instituted IPR is currently scheduled for August 28, 2017. A decision on the instituted IPR would be expected, pursuant to the statutory time frame, by November 30, 2017.

The Company will vigorously defend the '061 Patent in the IPR proceedings. 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 June 30, 2017 was $43.0 million, or $0.28 per ordinary share— basic and diluted, as compared to a net loss of $47.2 million, or $0.31 per ordinary share— basic and diluted for the three months ended June 30, 2016. Net loss for the six months ended June 30, 2017 was $111.9 million, or $0.73 per ordinary share— basic and diluted, as compared to a net loss of $124.6 million, or $0.82 per ordinary share— basic and diluted for the six months ended June 30, 2016.

The decrease in the net loss in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to an increase in revenues from our proprietary products, VIVITROL and ARISTADA, which continue to grow in their respective markets. Additionally, during the three months ended June 30, 2017, we launched the ARISTADA two-month dose following its approval by the FDA in June 2017. These items are discussed in greater detail later in the “Results of Operations” section of this Item 2 of this Form 10-Q. The increase in revenues was partially offset by an increase in cost of goods manufactured and sold and in selling, general and administrative (“SG&A”) expense, which was primarily due to costs related to the sale of these products.

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 “Part I, Item 1A—Risk Factors” of our Annual Report for important factors that could adversely affect our marketed products and to the “Patents and Proprietary Rights” section in “Part I, Item 1—Business” of our Annual Report for information with respect to the intellectual property protection for these marketed products.

Summary information regarding our proprietary products includes:

Product	Indication(s)	Licensee	Territory
	Schizophrenia	None	Commercialized by Alkermes in the U.S.
	Alcohol dependence and Opioid dependence	None	Commercialized by Alkermes in the U.S.
			Russia and Commonwealth of Independent States (“CIS”)
		Cilag GmbH International (“Cilag”)	

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Summary information regarding products that use our proprietary technologies includes:

Product	Indication(s)	Licensee	Territory
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	All countries outside of the U.S. (“ROW”)
INVEGA TRINZA	Schizophrenia	Janssen	U.S.
TREVICTA	Schizophrenia	Janssen	ROW
AMPYRA	Treatment to improve walking in patients with MS, as demonstrated by an increase in walking speed	Acorda	U.S.

		Biogen, under sublicense from Acorda	ROW
FAMPYRA			
BYDUREON	Type 2 diabetes	AstraZeneca plc (“AstraZeneca”)	Worldwide

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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 intramuscular 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, once-every-six-weeks and once-every-two-months dosing options to deliver and maintain therapeutic levels of medication in the body. ARISTADA has four dosing options (441 mg, 662 mg, 882 mg and 1064 mg) and is packaged in a ready-to-use, pre-filled product format. ARISTADA 1064mg, our two-month dosing option, was approved by the FDA in June 2017. We developed, manufacture and commercialize ARISTADA in the U.S.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is the only once-monthly, non-narcotic, 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 intramuscular 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 (paliperidone palmitate)/TREVICTA (paliperidone palmitate a 3-monthly injection) 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.

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 is the first schizophrenia treatment to be taken once every three months. TREVICTA is 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.

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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 intramuscular injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us.

AMPYRA/FAMPYRA

AMPYRA (dalfampridine)/FAMPYRA (fampridine) is believed to be 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 (“EMA”) conditionally approved FAMPYRA in the EU, and in May 2017, the EMA granted FAMPYRA a standard marketing authorization in the EU for the improvement of walking in adults with MS. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

We have received notices of ANDA filings for AMPYRA asserting that a generic form of AMPYRA would not infringe AMPYRA’s Orange Book-listed patents and/or those patents are invalid. In response, we and/or Acorda filed lawsuits against certain of the ANDA Filers in the Delaware Court asserting infringement of the ‘938 Patent, which we own, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. On March 31, 2017, the Delaware Court upheld the ‘938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA. In May 2017, Acorda filed its appeal of the Delaware Court Decision with the Federal Circuit with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, the Non-Settling ANDA Filers filed their cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the ‘938 Patent. For further discussion of the legal proceedings related to the patents covering AMPYRA, see “Part II, Item 1—Legal Proceedings” and Note 12, Commitments and Contingencies in the “Notes to Condensed Consolidated Statements” in this Form 10-Q, and for information about risks relating to such legal proceedings see “Part II, Item 1A—Risk Factors” in this Form 10-Q and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and “Part I, Item 1A—Risk Factors” of our Annual Report.

The legal proceedings in the Delaware Court related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in April 2025 in the EU.

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 R&D 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 R&D efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key R&D 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

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Factors" of our Annual Report. Refer to the "Patents and Proprietary Rights" section in "Part I, Item 1— Business" of our Annual Report for information with respect to the intellectual property protection for our development products.

The following graphic summarizes the status of our key development programs:

ALKS 5461

ALKS 5461 is a proprietary, investigational, once-daily, oral sublingual medicine that acts as a balanced neuromodulator in the brain and represents a novel mechanism of action for the adjunctive treatment of major depressive disorder ("MDD"). ALKS 5461 consists of samidorphan, a proprietary oral opioid modulator, and buprenorphine, and is designed to rebalance brain function that is dysregulated in the state of depression. 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 February 2017 and July 2017, we met with the FDA's Division of Psychiatric Products at a Type C meeting and a pre-NDA meeting, respectively, to discuss ALKS 5461. We plan to submit the NDA for ALKS 5461 by the end of 2017.

In June 2017, we initiated Study 217, a phase 3b study of ALKS 5461 in patients suffering from MDD who have had an inadequate response to commonly prescribed drugs for depression. It uses the Montgomery—Åsberg Depression Rating Scale ("MADRS"), and will also include additional scales and endpoints related to social connection, anhedonia and resilience, which are regulated by endogenous opioid modulation and where ALKS 5461 may have particular benefit.

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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 antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

Results from the exploratory phase 1 metabolic study of ALKS 3831, assessing the effects of ALKS 3831 on important metabolic parameters compared to olanzapine, are expected in the second half of 2017.

In June 2017, we announced positive preliminary topline results from ENLIGHTEN-1, the first of two key phase 3 studies from the ENLIGHTEN clinical development program for ALKS 3831. ENLIGHTEN-1 was a multinational, double-blind, randomized, phase 3 study that evaluated the antipsychotic efficacy, safety and tolerability of ALKS 3831 compared to placebo in patients experiencing an acute exacerbation of schizophrenia. ALKS 3831 met the prespecified primary endpoint demonstrating statistically significant reductions from baseline in Positive and Negative Syndrome Scale (“PANSS”) scores compared to placebo. The study also included an olanzapine arm, but was not designed to provide comparative efficacy or safety data between ALKS 3831 and olanzapine. Data from the study showed that olanzapine achieved similar improvements from baseline PANSS scores as compared to placebo.

Results from ENLIGHTEN-2, the second of two key phase 3 studies from the ENLIGHTEN clinical development program for ALKS 3831, are expected in 2018.

In June 2017, we announced the initiation of ENLIGHTEN-Early, a supportive study from the ENLIGHTEN clinical development program for ALKS 3831. ENLIGHTEN-Early is a phase 3 study designed to evaluate the weight gain profile of ALKS 3831 compared to olanzapine in young adult patients with schizophrenia, schizophreniform or bipolar I disorder who are early in their illness.

We expect to use safety and efficacy data from the ENLIGHTEN clinical development program, if successful, to serve as the basis for an NDA to be submitted to the FDA.

In April 2017, we announced data from the phase 2 study of ALKS 3831 in patients with schizophrenia and co-occurring alcohol use disorder. The pre-specified endpoint was a novel composite measure of disease exacerbation as measured by a series of potential events ranging from hospitalization to arrest. The study did not show a difference on this endpoint, as the ALKS 3831 and olanzapine treatment groups performed similarly well. While both groups

experienced an improvement in PANSS total scores, which was an exploratory endpoint in the study, a greater improvement was observed in subjects on ALKS 3831 at the end of the study period. Analysis of the full dataset is ongoing and we will present data at a future medical meeting.

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. In March 2017, in order to assess the differentiated gastrointestinal tolerability profile of ALKS 8700, we initiated an elective randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA in patients with relapsing-remitting MS.

The pivotal clinical program for ALKS 8700 consists of pharmacokinetic bridging 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. We expect to complete these clinical registration requirements for ALKS 8700 by year-end 2017, and to complete the required non-clinical studies and file a 505(b)(2) NDA in 2018.

For more information about 505(b)(2) NDAs, see "Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act" of our Annual Report.

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ALKS 6428

ALKS 6428 is designed to help healthcare providers transition patients from physical dependence on opioids to initiation with VIVITROL. ALKS 6428 is an investigational regimen of ascending doses of oral naltrexone administered in conjunction with ancillary medications, including buprenorphine, during a seven-day treatment period, prior to first VIVITROL injection. In February 2017, we announced that ALKS 6428 did not meet its primary endpoint in a phase 3 study, and no statistically significant difference between treatment groups was observed. Patients in each of the three treatment arms (ALKS 6428 plus tapering doses of buprenorphine, ALKS 6428 plus placebo, and placebo, in each case in conjunction with ancillary medications) performed equally well, with a similar percentage of patients successfully transitioning to initiation with VIVITROL. A second phase 3 study of ALKS 6428 is ongoing in patients who want to transition from buprenorphine maintenance therapy to initiation with VIVITROL for the treatment of opioid dependence.

ALKS 4230

ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (“IL-2”) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects while overcoming limitations of existing IL-2 therapy, which activates both immunosuppressive and tumor-killing immune cells. 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 is being 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 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 data from the first stage of the phase 1 study are expected in 2017.

Results of Operations

Manufacturing and Royalty Revenues

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our

collaborators. The following table compares manufacturing and royalty revenues earned in the three and six months ended June 30, 2017 and 2016:

(In millions)	Three Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)	Six Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 56.6	$ 50.2	$ 6.4	$ 95.8	$ 81.6	$ 14.2
AMPYRA/FAMPYRA	25.3	40.8	(15.5)	54.5	69.0	(14.5)
RISPERDAL CONSTA	25.5	19.4	6.1	46.3	42.7	3.6
BYDUREON	11.6	12.3	(0.7)	23.9	22.8	1.1
Other	10.3	14.3	(4.0)	23.4	27.1	(3.7)
Manufacturing and royalty revenues	$ 129.3	$ 137.0	$ (7.7)	$ 243.9	$ 243.2	$ 0.7

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three and six months ended June 30, 2017, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $629.0 million and $1,233.0 million, respectively, as compared to $560.0 million and $1,073.0 million in the three and six months ended June 30, 2016, respectively. Under our agreement with

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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.

The decrease in AMPYRA/FAMPYRA manufacturing and royalty revenues in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was due to a decline in both manufacturing and royalty revenue. Manufacturing revenue decreased by 35% and 19% in the three and six months ended June 30, 2017, respectively, as compared to the three and six months ended June 30, 2016. The decrease in manufacturing revenue was primarily due to a 43% and 27% decrease in the number of AMPYRA units shipped to Acorda in the three and six months ended June 30, 2017, respectively, partially offset by a 19% and 14% increase in the amount of FAMPYRA shipped to Biogen in the three and six months ended June 30, 2017, respectively. Royalty revenue decreased by 41% and 23% in the three and six months ended June 30, 2017, respectively, as compared to the three and six months ended June 30, 2016. The decrease in royalty revenue was primarily due to the decrease in shipments of AMPYRA to Acorda, as 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. We earn manufacturing revenue when FAMPYRA is shipped to Biogen and we earn royalty revenues on end-market sales of FAMPYRA in the period sold.

On March 31, 2017, the Delaware Court upheld the ‘938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA. If the Federal Circuit upholds the Delaware Court’s findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and the validity of the ‘938 Patent, we can expect competition from generic forms of AMPYRA as early as July 2018 when the ‘938 Patent expires. If the Federal Circuit upholds the Delaware Court’s findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and overturns the Delaware Court’s upholding of the validity of the ‘938 Patent, competition from generic forms of AMPYRA may occur before the July 2018 expiry of the ‘938 Patent. We can expect that competition from generic forms of AMPYRA would impact our manufacturing and royalty revenues. We expect our manufacturing and royalty revenues to decline in advance of generic entry in anticipation of reduced demand for AMPYRA.

For further discussion of the legal proceedings related to the patents covering AMPYRA, see “Part II, Item 1—Legal Proceedings” and Note 12, Commitments and Contingencies in the “Notes to Condensed Consolidated Statements” in this Form 10-Q, and for information about risks relating to such legal proceedings see “Part II, Item 1A—Risk Factors” in this Form 10-Q and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and “Part I, Item 1A—Risk Factors” of our Annual Report. The legal proceedings related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in April 2025 in the EU.

The increase in RISPERDAL CONSTA manufacturing and royalty revenues in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to a 49% and 15% increase in manufacturing revenue in the three and six months ended June 30, 2017, respectively, as compared to the three and six months ended June 30, 2016. This was partially offset by a 10% decrease in royalty revenues in both the

three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016. The increase in manufacturing revenues was primarily due to an increase of 8% and 9% in the number of units of RISPERDAL CONSTA shipped to Janssen during the three and six months ended June 30, 2017, respectively, as compared to the corresponding prior periods. The decrease in royalty revenues was due to a decline in Janssen's end-market sales of RISPERDAL CONSTA, which were $230.0 million and $461.0 million in the three and six months ended June 30, 2016, respectively, as compared to $207.0 million and $414.0 million in the three and six months ended June 30, 2017, respectively.

The change in BYDUREON royalty revenues in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was due to the end-market sales of BYDUREON by AstraZeneca. During the three and six months ended June 30, 2017, AstraZeneca's end-market sales of BYDUREON were $146.0 million and $298.8 million, respectively, as compared to $154.0 million and $289.4 million, respectively, in the three and six months ended June 30, 2016.

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Product Sales, net

Our product sales, net consist of sales of VIVITROL and 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 six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,						Six Months Ended June 30,					
(In millions)	2017	% of Sales		2016	% of Sales		2017	% of Sales		2016	% o	
Product sales, gross	$ 167.9	100.0	%	$ 105.2	100.0	%	$ 300.5	100.0	%	$ 185.7	100	
Adjustments to product sales, gross:												
Medicaid rebates	(42.5)	(25.3)	%	(25.6)	(24.3)	%	(70.1)	(23.3)	%	(39.8)	(21	
Product discounts	(12.9)	(7.7)	%	(8.2)	(7.8)	%	(23.1)	(7.7)	%	(14.4)	(7.7	
Chargebacks	(12.2)	(7.3)	%	(7.2)	(6.8)	%	(21.9)	(7.3)	%	(13.3)	(7.2	
Co-pay assistance	(2.4)	(1.4)	%	(2.4)	(2.3)	%	(4.3)	(1.4)	%	(4.2)	(2.3	
Other	(9.1)	(5.4)	%	(4.3)	(4.1)	%	(15.9)	(5.3)	%	(7.1)	(3.8	
Total adjustments	(79.1)	(47.1)	%	(47.7)	(45.3)	%	(135.3)	(45.0)	%	(78.8)	(42	
Product sales, net	$ 88.8	52.9	%	$ 57.5	54.7	%	$ 165.2	55.0	%	$ 106.9	57.(	

Our product sales, net for VIVITROL and ARISTADA in the three months ended June 30, 2017 were $66.1 million and $22.7 million, respectively, as compared to $47.3 million and $10.2 million in the three months ended June 30, 2016, respectively. Our product sales, net for VIVITROL and ARISTADA in the six months ended June 30, 2017 were $124.5 million and $40.7 million, respectively, as compared to $91.1 million and $15.8 million in the six months ended June 30, 2016, respectively.

The increase in product sales, gross, in the three and six months ended June 30, 2017, as compared to the prior corresponding periods, was due to increased sales of both VIVITROL and ARISTADA. VIVITROL product sales, gross, increased by 42% and 43% in the three and six months ended June 30, 2017, respectively, as compared to the three and six months ended June 30, 2016, which was due to an increase in the number of VIVITROL units sold. ARISTADA product sales, gross, increased by 170% and 205%, in the three and six months ended June 30, 2017, respectively, as compared to the three and six months ended June 30, 2016, which was primarily due to an increase in

the number of ARISTADA units sold. ARISTADA 441 mg, 662 mg and 882 mg launched in the U.S. in October 2015, and ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA and launched in June 2017.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)	Six Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	$ 39.8	$ 34.0	$ (5.8)	$ 80.2	$ 61.7	$ (18.5)

The increase in the cost of goods manufactured and sold in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to increased sales of VIVITROL, ARISTADA and RISPERDAL CONSTA. Cost of goods sold for VIVITROL increased by $2.6 million and $7.6 million in the three and six months ended June 30, 2017, as compared to the prior corresponding periods. Cost of goods sold for ARISTADA increased by $2.0 million and $3.9 million in the three and six months ended June 30, 2017, respectively, as compared to the prior corresponding periods. Cost of goods manufactured for RISPERDAL CONSTA increased by $1.0 million and $3.3 million in the three and six months ended June 30, 2017, respectively, as compared to the prior corresponding periods.

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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:

(In millions)	Three Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)	Six Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)
External R&D Expenses:						
Key development programs:						
ALKS 3831	$ 25.6	$ 17.7	$ (7.9)	$ 51.4	$ 31.9	$ (19.5)
ALKS 8700	10.9	5.7	(5.2)	25.6	9.4	(16.2)
ALKS 5461	8.9	14.5	5.6	18.1	27.2	9.1
ALKS 6428	3.1	5.5	2.4	6.0	10.5	4.5
ARISTADA and ARISTADA line extensions	2.1	9.2	7.1	4.0	23.6	19.6
ALKS 4230	1.5	1.4	(0.1)	3.4	2.5	(0.9)
Other external R&D expenses	5.1	7.6	2.5	12.1	22.5	10.4
Total external R&D expenses	57.2	61.6	4.4	120.6	127.6	7.0
Internal R&D expenses:						
Employee-related	32.3	27.1	(5.2)	64.0	54.1	(9.9)
Occupancy	2.4	2.2	(0.2)	4.8	4.7	(0.1)
Depreciation	2.6	1.8	(0.8)	5.0	3.5	(1.5)
Other	4.7	4.3	(0.4)	9.6	8.2	(1.4)
Total internal R&D expenses	42.0	35.4	(6.6)	83.4	70.5	(12.9)
Research and development expenses	$ 99.2	$ 97.0	$ (2.2)	$ 204.0	$ 198.1	$ (5.9)

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

The increase in the expenses related to ALKS 3831 in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to the timing of activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively. The increase in expenses related to ALKS 8700 in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to further progression of the two-year, multicenter, open-label phase 3 study designed to assess the safety of ALKS 8700, which was initiated in December 2015 and is actively enrolling. We also initiated a phase 3 gastrointestinal tolerability study in March 2017. The decrease in expenses related to ALKS 5461 in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to the completion of the three core phase 3 studies related to the program. We announced topline results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. The decrease in expenses related to ALKS 6428 in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to the completion of a phase 3 clinical study in which topline results were announced in February 2017. The decrease in expenses related to ARISTADA and ARISTADA line extensions in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia.

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The increase in employee-related expenses in both the three and six months ended June 30, 2017, as compared to the three and six months ended June 30, 2016, was primarily due to an increase in R&D headcount of 9% from June 30, 2016 to June 30, 2017.

Selling, General and Administrative Expense

(In millions)	Three Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)	Six Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)
Selling, general and administrative expense	$ 108.9	$ 96.1	$ (12.8)	$ 211.0	$ 185.8	$ (25.2)

The increase in SG&A expense in the three months ended June 30, 2017, as compared to the three months ended June 30, 2016, was primarily due to an increase in marketing and professional service fees of $10.2 million and employee-related expenses of $2.1 million. The increase in SG&A expense in the six months ended June 30, 2017, as compared to the six months ended June 30, 2016, was primarily due to an increase in marketing and professional service fees of $17.3 million and employee-related expenses of $6.2 million. The increase in marketing and professional services fees was primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products. The increase in employee-related expenses was primarily due to an increase in our SG&A-related headcount of 20% from June 30, 2016 to June 30, 2017.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)	Six Months Ended June 30, 2017	2016	Change Favorable/ (Unfavorable)
Amortization of acquired intangible assets	$ 15.5	$ 15.2	$ (0.3)	$ 30.8	$ 30.3	$ (0.5)

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 June 30, 2017 is expected to be approximately $60.0 million, $60.0 million, $55.0 million, $50.0 million and $45.0 million in the years ending December 31, 2017 through 2021, respectively.

Income Tax Benefit

	Three Months Ended June 30,		Change Favorable/	Six Months Ended June 30,		Change Favorable/
(In millions)	2017	2016	(Unfavorable)	2017	2016	(Unfavorable)
Income tax benefit	$ (2.7)	$ (0.5)	$ 2.2	$ (6.4)	$ (0.1)	$ 6.3

The income tax benefit in the three and six months ended June 30, 2017 and 2016 primarily relates to U.S. federal and state taxes. The favorable change in income taxes in the three and six month periods ended June 30, 2017, as compared to the corresponding prior periods, was primarily due to the recognition of excess tax benefits related to share-based compensation.

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 including the requirement that all future excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement. On January 1, 2017, we adopted this standard on a modified retrospective basis, which resulted in a favorable cumulative-effect adjustment of $61.5 million to accumulated deficit due to the change in the accounting treatment of excess tax benefits and tax deficiencies.

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Liquidity and Financial Condition

Our financial condition is summarized as follows:

	June 30, 2017			December 31, 2016		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 58.6	$ 99.5	$ 158.1	$ 81.2	$ 105.2	$ 186.4
Investments—short-term	184.6	132.4	317.0	184.4	126.5	310.9
Investments—long-term	56.1	29.6	85.7	60.1	61.8	121.9
Total cash and investments	$ 299.3	$ 261.5	$ 560.8	$ 325.7	$ 293.5	$ 619.2
Outstanding borrowings—short and long-term	$ 282.6	$ —	$ 282.6	$ 283.7	$ —	$ 283.7

At June 30, 2017, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Losses	Estimated Fair Value
Investments—short-term	$ 317.3	$ —	$ (0.3)	$ 317.0
Investments—long-term available-for-sale	82.5	—	(0.3)	82.2
Investments—long-term held-to-maturity	3.4	0.1	—	3.5
Total	$ 403.2	$ 0.1	$ (0.6)	$ 402.7

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 June 30, 2017, 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 investments 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 twelve months following the date from which this Form 10-Q was filed. 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, debt refinancings, arrangements relating to assets or other financing methods or structures.

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Information about our cash flows, by category, is presented in the “Condensed Consolidated Statements of Cash Flows”. The following table summarizes our cash flows for the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
(In millions)	2017	2016
Cash and cash equivalents, beginning of period	$ 186.4	$ 181.1
Cash used in operating activities	(36.2)	(86.1)
Cash provided by investing activities	9.4	101.1
Cash (used in) provided by financing activities	(1.5)	0.3
Cash and cash equivalents, end of period	$ 158.1	$ 196.4

The decrease in cash flows used in operating activities was primarily due to a 25% increase in cash received from our customers, partially offset by a 24% increase in cash paid to our employees and a 3% increase in cash paid to our suppliers. The increase in cash received from our customers was primarily due to the increase in revenue, as previously discussed. The increase in cash paid to employees was primarily due to a 19% increase in our headcount from June 30, 2016 to June 30, 2017. The increase in cash paid to our suppliers was primarily related to the timing and an increase in the volume of payments.

The decrease in cash flows provided by investing activities in the six months ended June 30, 2017, as compared to the six months ended June 30, 2016, was primarily due to a $108.2 million decrease in the net sales of investments. This was partially offset by a $1.6 million decrease in cash paid for property, plant and equipment and the $15.0 million investment we made in Reset in February 2016.

The increase in cash flows used in financing activities in the six months ended June 30, 2017, as compared to the six months ended June 30, 2016, was primarily due to the decrease in principal payments on our long-term debt. In September 2016, one of our two outstanding term loans matured and we repaid the outstanding principal balance in its entirety.

Borrowings

At June 30, 2017, the principal balance of our borrowings consisted of $285.8 million outstanding under our Term Loan B-1. Refer to Note 10, Long-Term Debt, within the “Notes to Consolidated Financial Statements” of our Annual Report, for a discussion of our outstanding term loans.

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.

In March 2017, we entered into a lease agreement to lease approximately 65,000 square feet of office space in Waltham, Massachusetts (the "Building"). Beginning March 1, 2017, we began leasing approximately 43,290 square feet ("Premises A") of the Building, and, on January 1, 2018, we will gain access to the additional 21,645 square feet ("Premises B"). The lease on both Premises A and Premises B ends on September 30, 2020 and will result in rental expense of approximately $1.2 million in 2017 and $2.2 million from 2018 through 2020.

Off-Balance Sheet Arrangements

At June 30, 2017, 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.

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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, 2016, 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, 2016.

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), on June 30, 2017. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2017 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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, refer to Note 12, Commitments and Contingencies in the "Notes to Condensed Consolidated Statements" in this Form 10-Q, which is incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

We face claims against our intellectual property rights and competition from generic drug manufacturers, which, for AMPYRA, could result in entry of generic competition in July 2018 or, in certain circumstances, earlier.

In the U.S., generic manufacturers of innovator drug products may file abbreviated New Drug Applications ("ANDAs") and, in doing so, certify that their products do not infringe the innovator's patents and/or that the innovator's patents are invalid or unenforceable. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known as "Paragraph IV" litigation in the U.S.

We have received notices of ANDA filings for AMPYRA asserting that generic forms of AMPYRA would not infringe AMPYRA's Orange Book-listed patents and/or those patents are invalid. In response, we and/or our partner, Acorda Therapeutics, Inc. ("Acorda"), filed lawsuits against the ANDA filers in Federal district court, including in the U.S. District Court for the District of Delaware (the "Delaware Court"), asserting infringement of U.S. Patent No. 5,540,938 (the "'938 Patent"), which we own, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. On March 31, 2017, the Delaware Court issued an opinion upholding the validity of the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidating U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA. In May 2017, Acorda filed its appeal of the opinion issued by the Delaware Court with respect to its findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In addition, three of the ANDA filers who have not entered into settlement agreements with us and/or Acorda (the "Non-Settling ANDA Filers") appealed the opinion issued by the Delaware Court with respect to its findings on the validity of the '938 Patent with the objective of commercializing their generic forms of AMPYRA before the '938 Patent's July 2018 expiration date. If the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") upholds the Delaware Court's findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and the validity of the '938 Patent, we can expect competition from generic forms of AMPYRA as early as July 2018 when the '938 Patent expires. If the Federal Circuit upholds the Delaware Court's findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and overturns the Delaware Court's upholding of the validity of the '938 Patent, competition from generic forms of AMPYRA may occur before the July 2018 expiry of the '938 Patent. Continued litigation based on such appeals may be costly and time consuming. For further discussion of the legal proceedings related to the patents covering AMPYRA, see "Part II, Item 1—Legal

Proceedings" and Note 12, Commitments and Contingencies in the "Notes to Condensed Consolidated Statements" in this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017.

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover generic forms of our products. If an ANDA filer were to receive U.S. Food and Drug Administration approval to sell a generic version of our products and/or prevail in any patent litigation, our products would become subject to increased competition and demand for and sales of our products would likely decline significantly, resulting in decreased revenue. Our results of operations may be adversely affected by such decreased revenue.

There have been no other material changes from the risk factors disclosed in our Annual Report. For a further discussion of our Risk Factors, refer to "Part I, Item 1A – Risk Factors" of our Annual Report and our Quarterly Report on Form 10-Q for the period ending March 31, 2017.

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the six months ended June 30, 2017. As of June 30, 2017, we had purchased a total of 8,866,342 shares at a cost of $114.0 million.

During the three months ended June 30, 2017, we acquired 56,665 Alkermes ordinary shares, at an average price of $57.70 per share related to the vesting of employee equity awards to satisfy withholding tax obligations. During the three months ended June 30, 2017, we acquired 2,115 Alkermes ordinary shares, at an average price of $58.90 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2017, Messrs. Shane Cooke, James M. Frates, Michael J. Landine, Richard F. Pops and Mark Stejbach, each an executive officer of the Company, each 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: July 27, 2017

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EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1†	Alkermes plc 2011 Stock Option and Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on May 24, 2017).
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 six months ended June 30, 2017, formatted in XBRL (“Extensible Business Reporting Language”): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (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.