Alkermes plc.
Form 10-Q
April 26, 2018
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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 March 31, 2018

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 April 20, 2018 was 155,037,850 shares.

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ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

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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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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" other similar words. These statements discuss future expectations, and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q ("Form 10-Q") include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including the development, regulatory (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 new legislation and related regulations, including the Tax Cuts and Jobs Act of 2017, and the 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, other proprietary and intellectual property ("IP") rights, and our products, including the commercialization of such 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. These risks, assumptions and uncertainties include, among others: the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of our products, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the United States ("U.S.") Food and Drug Administration ("FDA") in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and, for ALKS 5461, evidence of efficacy and adequacy of bridging to buprenorphine; clinical development activities may not be completed on time or at all; the results of our clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks, assumptions and uncertainties described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 (the "Annual Report") and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are

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available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

This Form 10-Q includes data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Form 10-Q also includes data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source, and, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 1A—Risk Factors" in our Annual Report and in subsequent reports filed with the SEC. These and other factors could cause our results to differ materially from those expressed in the estimates included in this Form 10-Q.

Note Regarding Company 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 product candidates 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 intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references to "licensees" are used interchangeably with references to "partners."

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations ("®") and other trademarks ("TM"), including ALKERMES®, 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. (together with its affiliates, “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)

	March 31, 2018	December 31, 2017
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 186,505	$ 191,296
Investments—short-term	218,057	242,208
Receivables, net	214,160	233,590
Contract assets	26,069	—
Inventory	84,884	93,275
Prepaid expenses and other current assets	46,463	48,475
Total current assets	776,138	808,844
PROPERTY, PLANT AND EQUIPMENT, NET	289,621	284,736
INTANGIBLE ASSETS, NET	240,099	256,168
INVESTMENTS—LONG-TERM	137,473	157,212
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	82,900	84,800
DEFERRED TAX ASSETS	100,504	98,560
OTHER ASSETS	16,950	14,034
TOTAL ASSETS	$ 1,736,558	$ 1,797,227
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 268,166	$ 286,166
Long-term debt—short-term	2,843	3,000
Contract liabilities—short-term	3,521	1,956
Total current liabilities	274,530	291,122
LONG-TERM DEBT	278,088	278,436
OTHER LONG-TERM LIABILITIES	21,883	19,204
CONTRACT LIABILITIES—LONG-TERM	6,166	5,657
Total liabilities	580,667	594,419
COMMITMENTS AND CONTINGENCIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at March 31, 2018 and December 31, 2017,	—	—

respectively		
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 157,313,318 and 156,057,632 shares issued; 155,003,983 and 154,009,456 shares outstanding at March 31, 2018 and December 31, 2017, respectively	1,570	1,557
Treasury shares, at cost (2,309,335 and 2,048,176 shares at March 31, 2018 and December 31, 2017, respectively)	(105,071)	(89,347)
Additional paid-in capital	2,372,083	2,338,755
Accumulated other comprehensive loss	(4,129)	(3,792)
Accumulated deficit	(1,108,562)	(1,044,365)
Total shareholders' equity	1,155,891	1,202,808
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,736,558	$ 1,797,227

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 March 31,	
	2018	2017
	(In thousands, except per share amounts)	
REVENUES:		
Manufacturing and royalty revenues	$ 114,601	$ 114,679
Product sales, net	91,842	76,456
Research and development revenue	18,707	643
Total revenues	225,150	191,778
EXPENSES:		
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	44,476	40,412
Research and development	108,346	104,835
Selling, general and administrative	118,147	102,099
Amortization of acquired intangible assets	16,069	15,302
Total expenses	287,038	262,648
OPERATING LOSS	(61,888)	(70,870)
OTHER EXPENSE, NET:		
Interest income	1,485	943
Interest expense	(5,487)	(2,764)
Change in the fair value of contingent consideration	(1,900)	1,600
Other income (expense), net	792	(1,499)
Total other expense, net	(5,110)	(1,720)
LOSS BEFORE INCOME TAXES	(66,998)	(72,590)
INCOME TAX BENEFIT	(4,493)	(3,709)
NET LOSS	$ (62,505)	$ (68,881)
LOSS PER ORDINARY SHARE:		
Basic and diluted	$ (0.40)	$ (0.45)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic and diluted	154,424	152,704
COMPREHENSIVE LOSS:		
Net loss	$ (62,505)	$ (68,881)
Holding (loss) gain, net of a tax (benefit) provision of $(100) and $23, respectively	(336)	72
COMPREHENSIVE LOSS	$ (62,841)	$ (68,809)

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)

	Three Months Ended March 31,	
	2018	2017
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (62,505)	$ (68,881)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	25,722	23,763
Share-based compensation expense	20,042	21,169
Deferred income taxes	(4,101)	(1,215)
Change in the fair value of contingent consideration	1,900	(1,600)
Loss on debt refinancing	2,298	—
Payment made for debt refinancing	(1,840)	—
Other non-cash charges	(75)	1,623
Changes in assets and liabilities:		
Receivables	19,430	14,615
Contract assets	(16,959)	—
Inventory	(431)	(733)
Prepaid expenses and other assets	890	(2,901)
Accounts payable and accrued expenses	(14,123)	(1,730)
Contract liabilities	245	(105)
Other long-term liabilities	2,669	2,248
Cash flows used in operating activities	(26,838)	(13,747)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(18,485)	(9,382)
Proceeds from the sale of equipment	324	3
Purchases of investments	(35,995)	(30,161)
Sales and maturities of investments	79,500	55,000
Cash flows provided by investing activities	25,344	15,460
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	13,164	7,114
Employee taxes paid related to net share settlement of equity awards	(15,724)	(13,148)
Payment made for debt refinancing	(737)	—
Principal payments of long-term debt	—	(750)
Cash flows used in financing activities	(3,297)	(6,784)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(4,791)	(5,071)
CASH AND CASH EQUIVALENTS—Beginning of period	191,296	186,378
CASH AND CASH EQUIVALENTS—End of period	$ 186,505	$ 181,307
SUPPLEMENTAL CASH FLOW DISCLOSURE:		

Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 7,516	$ 4,978

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 FINANCIAL 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. The Company has a diversified portfolio of marketed drug products and a clinical pipeline of product candidates 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 months ended March 31, 2018 and 2017 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2017. 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 the Company, 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, in the “Notes to Consolidated Financial Statements” accompanying the Company’s 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 and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments, contingent consideration and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines. The Company’s chief decision maker, the Chairman of the Board and Chief Executive Officer, reviews the Company’s operating results on an aggregate basis and manages the Company’s operations as a single operating unit.

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ALKERMES PLC AND SUBSIDIARIES

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

Income Taxes

The Company's income tax benefit in the three months ended March 31, 2018 and 2017 primarily relates 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 March 31, 2018, 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 guidance 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 ("Topic 606") 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 and require additional disclosures. The two permitted transition methods under the new guidance are the full retrospective method, in which case the guidance would be applied to each prior reporting period presented and the cumulative effect of applying the guidance would be recognized at the earliest period shown, or the modified retrospective method, in which case the cumulative effect of applying the guidance would be recognized at the date of initial application. In July 2015, the FASB approved the deferral of the new guidance's effective date by one year. The new guidance became effective for annual reporting periods beginning after December 15, 2017.

Effective January 1, 2018, the Company adopted the requirements of Topic 606 using the modified retrospective method. As part of the adoption, the Company reviewed all contracts that were not yet completed as of the date of initial application in determining the cumulative-effect impact related to the adoption of Topic 606. The cumulative-effect impact recorded to retained earnings resulted in an adjustment of approximately $0.8 million, which was primarily due to the acceleration of manufacturing revenue, offset by an adjustment to deferred revenue for license and milestone payments that will now be recognized over time. The following balance sheet accounts were impacted:

	Topic 606 Adjustment
(In thousands)	
Contract assets	$ 9,110
Inventory	(8,209)
Deferred tax asset	109
Contract liabilities—short-term	(1,104)
Contract liabilities—long-term	(724)
Accumulated deficit	818
	$ —

For additional information regarding how the Company is accounting for revenue under the updated guidance, refer to Note 3, Revenue from Contracts with Customers, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

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ALKERMES PLC AND SUBSIDIARIES

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

In January 2016, the FASB issued guidance that enhances the reporting model for financial instruments by addressing certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amendments in this guidance 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 the year ending December 31, 2018, and the Company has determined that the adoption of this guidance will not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The main difference between previous GAAP and this guidance is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. This guidance becomes effective for the Company in the year ending December 31, 2019, and the Company is currently assessing the impact that this guidance will have on its consolidated financial statements. At this time, the Company cannot reasonably estimate the expected impact the adoption of this new guidance will have on its consolidated financial statements.

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 the year ending December 31, 2020, with early adoption permitted for the Company in the year ending December 31, 2019. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

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. Effective January 1, 2018, the Company adopted this guidance and recorded a cumulative-effect adjustment of $0.9 million to retained earnings.

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 the year ending December 31, 2019 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

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ALKERMES PLC AND SUBSIDIARIES

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

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Under Topic 606, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenues following the five step model prescribed under Topic 606: (i) identify contract(s) with a customer (ii) identify the performance obligations in the contract (iii) determine the transaction price (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenues when (or as) the Company satisfies the performance obligation.

Collaborative Arrangements

The Company has entered into collaboration agreements with pharmaceutical companies including Janssen for INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA as well as RISPERDAL CONSTA; Acorda for AMPYRA/FAMPYRA; AstraZeneca for BYDUREON; and Biogen for BIIB098 (formerly ALKS 8700). Substantially all of the products developed under the Company's collaborative arrangements, except for BIIB098, are currently being marketed as approved products, for which the Company receives payments for manufacturing services and/or royalties on net product sales.

During the three months ended March 31, 2018 and 2017, the Company recorded manufacturing and royalty revenues from its collaborative arrangements as follows:

	Three Months Ended March 31, 2018		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 46,086	$ 46,086
AMPYRA/FAMPYRA	13,563	14,696	28,259
RISPERDAL CONSTA	17,792	4,912	22,704
BYDUREON	—	9,749	9,749
Other	6,236	1,567	7,803
	$ 37,591	$ 77,010	$ 114,601

	Three Months Ended March 31, 2017		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 39,182	$ 39,182
AMPYRA/FAMPYRA	13,836	15,383	29,219

RISPERDAL CONSTA	15,640	5,181	20,821
BYDUREON	—	12,266	12,266
Other	9,376	3,815	13,191
	$ 38,852	$ 75,827	$ 114,679

Manufacturing revenues— The Company recognizes manufacturing revenues from the sale of products it manufactures, which is its one performance obligation under such arrangements, for resale by its licensees. Manufacturing revenues for the Company's partnered products, with the exception of those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using a standard cost-based model as a measure of progress, which represents a faithful depiction of the transfer of goods. The Company recognizes manufacturing revenue from these products over-time as it determined, in each instance, that it has a right to payment for performance completed to date if its customer were to terminate the manufacturing agreement for reasons other than the Company's non-performance and the products have no alternative future use. The Company invoices its licensees upon shipment with payment terms between 30 to 90 days. Prior to the adoption of Topic 606, the Company recorded manufacturing revenue from the sale of products it manufactures for resale by its partners after the Company had shipped such products and risk of loss had passed to the Company's partner, assuming persuasive evidence of an arrangement existed, the sales price was fixed or determinable and collectability was reasonably assured.

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ALKERMES PLC AND SUBSIDIARIES

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

The Company is the exclusive manufacturer of RISPERDAL CONSTA for commercial sale under its manufacturing and supply agreement with Janssen. The Company determined that it is appropriate to record revenue under this agreement at the point in time when control of the product passes to Janssen, which is determined to be when the product has been fully manufactured, since Janssen does not control the product during the manufacturing process and, in the event Janssen terminates the manufacturing and supply agreement, it is unclear whether, and at what amount, the Company would be reimbursed for performance completed to date for product not yet fully manufactured. The manufacturing process is considered fully complete once the finished goods have been approved for shipment by both the Company and Janssen.

The sales price for certain of the Company’s manufacturing revenues is based on the end-market sales price earned by its licensees. As end-market sales generally occur after the Company has recorded manufacturing revenue, the Company estimates the sales price for such products based on information supplied to it by the Company’s licensees, its historical transaction experience and other third-party data. Differences between actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The difference between the Company’s actual and estimated manufacturing revenues has not been material.

Royalty revenues—The Company recognizes royalty revenues related to the sale of products by its licensees that incorporate the Company's technologies. Royalties, with the exception of those earned on sales of AMPYRA, qualify for the sales-and-usage exemption under Topic 606 as (i) royalties are based strictly on the sales-and-usage by the licensee; and (ii) a license of IP is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned under the terms of a license agreement in the period the products are sold by the Company's partner and the Company has a present right to payment. Royalties on AMPYRA are incorporated into the standard cost-based model described in the manufacturing revenues section, above, as the terms of the agreement are such that the Company is entitled to the royalty revenue as the product is being manufactured, which represents a faithful depiction of the transfer of goods, and not based on the end-market sales of the licensee. Certain of the Company's royalty revenues are recognized by the Company based on information supplied to the Company by its partners and require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The difference between the Company’s actual and estimated royalty revenues has not been material.

Multiple Element Arrangements

When entering into multiple element arrangements, the Company identifies whether its performance obligations under the arrangement represent a distinct good or service or a series of distinct goods or services. A series of distinct goods or services is required to be accounted for as a single performance obligation provided that (i) each distinct good or service in the series promised would meet the criteria to be a performance obligation satisfied over-time; and (ii) the same method would be used to measure the Company’s progress toward complete satisfaction of the performance obligation to transfer each distinct good or service in the series to the customer. If a contract is separated into more than one performance obligation, the Company allocates the total transaction price to each performance obligation in an amount based on the estimated relative standalone selling prices of the promised goods or services underlying each performance obligation. The fair value of deliverables under the arrangement may be derived using a “best estimate of selling price” if vendor-specific objective evidence and third-party evidence is not available.

The Company recognizes revenue when or as it satisfies a performance obligation by transferring an asset to a customer. An asset is transferred when or as the customer obtains control of that asset. Significant management judgment is required in determining the consideration to be earned under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

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In November 2017, the Company granted Biogen, under a license and collaboration agreement, a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize BIIB098 and other products covered by patents licensed to Biogen under the agreement. Upon entering into this agreement in November 2017, the Company received an up-front cash payment of $28.0 million. The Company is also eligible to receive additional payments upon achievement of milestones, as follows: (i) a $50.0 million option payment upon Biogen's decision to continue the collaboration after having reviewed certain data from the Company's long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and TECFIDERA; and (ii) a $150.0 million payment upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) new drug application ("NDA") (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. The Company is also eligible to receive additional payments upon achievement of developmental milestones with respect to the first two products, other than BIIB098, covered by patents licensed to Biogen under the agreement. In addition, the Company will receive a mid-teens percentage royalty on worldwide net sales of BIIB098, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of BIIB098, and worldwide net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement. Biogen paid a portion of the BIIB098 development costs the Company incurred in 2017 and, since January 1, 2018, Biogen is responsible for all BIIB098 development costs the Company incurs, subject to annual budget limitations. The Company has retained the right to manufacture clinical supplies and commercial supplies of BIIB098 and all other products covered by patents licensed to Biogen under the agreement, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements.

The Company evaluated the agreement under Topic 606 and determined that it had four initial performance obligations: (i) the grant of a distinct, right-to-use license to Biogen; (ii) future development services; (iii) assuming the Company enters into a supply agreement with Biogen, clinical supply; and (iv) participation on a joint steering committee with Biogen. The participation on the joint steering committee was considered to be perfunctory and thus not recognized as a separate unit of accounting. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate performance obligations as the license is separately identifiable from the development services and clinical supply, and the development services are not expected to significantly modify or customize the IP.

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions. The Company allocated the non-contingent consideration to each unit of accounting using the relative selling price method based on its best estimate of selling price for the license and other deliverables. The Company used a discounted cash flow model to estimate the fair value of the license in order to allocate the consideration to the performance obligations. To estimate the fair value of the license, the Company assessed the likelihood of the FDA's approval of BIIB098 and estimated the expected future cash flows assuming FDA approval and the maintenance of the IP protecting BIIB098. The Company then discounted these cash flows using a discount rate of 8.0%, which it believes captures a market participant's view of the risk associated with the expected cash flows. The best estimate of selling price of the development services and clinical supply were determined through third-party evidence. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

At the date the license was delivered to Biogen, under Topic 606, the Company allocated $27.0 million to the delivery of the license, $0.9 million to future R&D work and $0.1 million to clinical supply. The amounts allocated to the R&D services and clinical supply will be recognized over the course of the R&D work and as clinical supply is delivered to Biogen, which is expected to continue through 2019.

The Company determined that the future milestones it is entitled to receive, including an option payment of $50.0 million upon Biogen's decision to continue the collaboration after having reviewed certain data from the Company's long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and TECFIDERA, and a $150.0 million payment upon approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098, and sales-based royalties, are variable consideration. The Company is using the most likely amount method for estimating the variable consideration to be

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ALKERMES PLC AND SUBSIDIARIES

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

received related to the milestones under this arrangement. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty as to whether these milestones would be achieved at the time the license and collaboration agreement was entered into. Accordingly, the Company has not included these milestones or royalties in the transaction price as it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

Research and development revenue—R&D revenue consists of funding that compensates the Company for formulation, pre clinical and clinical testing under R&D arrangements with its partners. The Company generally bills its partners under R&D arrangements using a full time equivalent ("FTE") or hourly rate, plus direct external costs, if any. Revenue is recognized as the obligations under the R&D arrangements are performed. The research and development revenue recorded during the three months ended March 31, 2018 primarily related to revenue earned under the Company's license and collaboration agreement with Biogen for BIIB098.

Product Sales, Net

The Company's product sales, net consist of sales of VIVITROL and ARISTADA in the U.S. primarily to wholesalers, specialty distributors and pharmacies. Product sales, net are recognized when the customer obtains control of the product, which is when the product has been received by the customer.

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers, health care providers or payors. The Company's process for estimating reserves established for these variable consideration components does not differ materially from historical practices. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. The following are the Company's significant categories of sales discounts and allowances:

Medicaid Rebates—the Company records accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel using the most likely amount method. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on the Company's average manufacturer prices. The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjusts its rebate based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from the Company's estimates;

Chargebacks—discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase a product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the contracted price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is made using the most likely amount method and is based on actual and expected utilization of these programs.

Chargebacks could exceed historical experience and the Company's estimates of future participation in these programs. To date, actual chargebacks have not differed materially from the Company's estimates;

Product Discounts—cash consideration, including sales incentives, given by the Company under agreements with a number of wholesaler, distributor, pharmacy, and treatment provider customers that provide them with a discount on the purchase price of products. The reserve is made using the most likely amount method and to date, actual product discounts have not differed materially from the Company's estimates; and

Product Returns—the Company records an estimate for product returns at the time its customers take title to the Company's product. The Company estimates this liability using the most likely amount method based on its

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

historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at product sales, net. Once product is returned, it is destroyed.

During the three months ended March 31, 2018 and 2017, the Company recorded product sales, net, as follows:

	Three Months Ended March 31,	
(In thousands)	2018	2017
VIVITROL	$ 62,682	$ 58,456
ARISTADA	29,160	18,000
Total product sales, net	$ 91,842	$ 76,456

Receivables, Net—Receivables, net, include amounts billed and currently due from customers. The amounts due are stated at their net estimated realizable value. The Company maintains an allowance for doubtful accounts to provide for the estimated amount of receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and collateral to the extent applicable. The Company's allowance for doubtful accounts was $0.2 million at March 31, 2018 and December 31, 2017.

Contract Assets—Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over-time. The products included in the contract assets table below complete the manufacturing process in ten days to eight weeks. As such, the Company availed itself of the practical expedient to not disclose the transaction price allocated to the remaining performance obligations as the only performance obligation is completing the manufacturing of such products, and the time remaining to manufacture the products is less generally less than eight weeks. Contract assets are classified as current.

Contract assets consisted of the following:

(In thousands)	Contract Assets
Contract assets at January 1, 2018	$ 9,110
Additions	23,882
Transferred to receivables, net	(6,923)
Contract assets at March 31, 2018	$ 26,069

Contract Liabilities—The Company's contract liabilities consist of contractual obligations related to deferred revenue.

Contract liabilities consisted of the following:

(In thousands)	Contract Liabilities
Contract liabilities at January 1, 2018	$ 9,442
Additions	909
Amounts recognized into revenue	(664)
Contract liabilities at March 31, 2018	$ 9,687

In order to determine revenue recognized in the period from contract liabilities, we first allocate revenue to the individual contract liability balance outstanding at the beginning of the period until the revenue exceeds that balance. If additional advances are received on those contracts in subsequent periods, we assume all revenue recognized in the reporting period first applies to the beginning contract liability as opposed to a portion applying to the new advances for the period.

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ALKERMES PLC AND SUBSIDIARIES

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

The Company adopted Topic 606 using the modified retrospective method. As such, the Company recognized the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under the old revenue recognition guidance ("Topic 605"). The quantitative impact of the changes are set out below for each the condensed consolidated balance sheet and the condensed consolidated statement of operations for the current reporting period.

ADJUSTED CONDENSED CONSOLIDATED BALANCE SHEET

	March 31, 2018			
	As Reported	Adjustment		Balances Without Adoption of Topic 606
	(In thousands)			
ASSETS				
Contract assets	$ 26,069	$ (26,069)	(1)	$ —
Inventory	84,884	12,058	(2)	96,942
Deferred tax asset	100,504	1,148	(3)	101,652
LIABILITIES				
Contract liabilities—short-term	$ 3,521	$ (3,521)	(4)	$ —
Deferred revenue—short-term	—	2,532	(4)	2,532
Contract liabilities—long-term	6,166	(6,166)	(4)	—
Deferred revenue—long-term	—	5,505	(4)	5,505
SHAREHOLDERS' EQUITY				
Accumulated deficit	$ (1,108,562)	$ (11,213)	(5)	$ (1,119,775)

The adjustments are a result of the following:

(1) Adjustment to contract assets is to reverse revenue recognized over time under Topic 606.
(2) Adjustment to inventory to add back the cost of goods manufactured related to the revenue transactions summarized in item (1), above.
(3) Adjustment to deferred tax asset is to apply the tax impact of the revenue transactions summarized in item (1), above.
(4)

Adjustment to contract liabilities—short-term and contract liabilities—long-term to reclassify amounts previously classified as deferred revenue—short-term and deferred revenue—long-term under Topic 605.

(5) Adjustment to accumulated deficit for the net impact of the transactions noted in items (1) through (4), above.

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ALKERMES PLC AND SUBSIDIARIES

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

ADJUSTED CONDENSED CONSOLIDATED STATEMENTS

OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended March 31, 2018			
	As Reported	Adjustment		Balances Without Adoption of Topic 606
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	$ 114,601	$ (16,959)	(1)	$ 97,642
Product sales, net	91,842	—		91,842
Research and development revenue	18,707	(178)		18,529
Total revenues	225,150	(17,137)		208,013
EXPENSES:				
Cost of goods manufactured and sold	44,476	(3,849)	(2)	40,627
Research and development	108,346	—		108,346
Selling, general and administrative	118,147	—		118,147
Amortization of acquired intangible assets	16,069	—		16,069
Total expenses	287,038	(3,849)		283,189
Operating loss	(61,888)	(13,288)		(75,176)
Other expense, net	(5,110)	—		(5,110)
Loss before income taxes	(66,998)	(13,288)		(80,286)
Income tax benefit	(4,493)	(1,257)		(5,750)
Net loss	$ (62,505)	$ (12,031)		$ (74,536)
Loss per ordinary share — basic and diluted	$ (0.40)	$ (0.08)		$ (0.48)

The adjustments are a result of the following:

(1) Adjustment to manufacturing and royalty revenues to recognize revenue under Topic 605 in the three months ended March 31, 2018 that was recognized under Topic 606.
(2) Adjustment to cost of goods manufactured and sold to recognize the cost from the transactions noted in item (1), above.

The Company’s changes in assets and liabilities within its condensed consolidated statement of cash flows changed as a result of the differences in the condensed consolidated balance sheet and change in net income in the condensed

consolidated statement of operations but the overall cash flows used in operating activities did not change.

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ALKERMES PLC AND SUBSIDIARIES

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

4. INVESTMENTS

Investments consisted of the following (in thousands):

March 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses Less than One Year	Gross Unrealized Losses Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	$ 125,234	$ —			