Alkermes plc.
Form 10-Q
October 23, 2018

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 every Interactive Data File required to be submitted 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 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	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 October 19, 2018 was 155,382,787 shares.

ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

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; we and our licensees may not be able to continue to successfully commercialize our and their products; there may be a reduction in payment rate or reimbursement for our products or an increase in our financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding our products; our 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 our 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 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 ("™"), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, LinkeRx®, NanoCrystal® and VIVITROL®.

The following are trademarks of the respective companies listed: AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc. ("Acorda"); BYDUREON® and BCise®—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 ™ 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.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2018	December 31, 2017
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$216,041	$ 191,296
Investments—short-term	251,046	242,208
Receivables, net	250,913	233,590
Contract assets	13,476	—
Inventory	88,018	93,275
Prepaid expenses and other current assets	50,265	48,475
Total current assets	869,759	808,844
PROPERTY, PLANT AND EQUIPMENT, NET	303,087	284,736
INTANGIBLE ASSETS, NET	207,426	256,168
INVESTMENTS—LONG-TERM	111,456	157,212
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	67,500	84,800
DEFERRED TAX ASSETS	92,279	98,560
OTHER ASSETS	16,330	14,034
TOTAL ASSETS	$1,760,710	$ 1,797,227
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$295,029	$ 286,166
Contract liabilities—short-term	6,916	1,956
Long-term debt—short-term	2,843	3,000
Total current liabilities	304,788	291,122
LONG-TERM DEBT	277,007	278,436
OTHER LONG-TERM LIABILITIES	23,190	19,204
CONTRACT LIABILITIES—LONG-TERM	5,010	5,657
Total liabilities	609,995	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 September 30, 2018 and December 31, 2017, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 157,674,736 and 156,057,632 shares issued; 155,363,980 and 154,009,456 shares outstanding at September 30, 2018 and December 31, 2017, respectively	1,574	1,557

Treasury shares, at cost (2,310,756 and 2,048,176 shares at September 30, 2018 and December 31, 2017, respectively)	(105,132)	(89,347)
Additional paid-in capital	2,433,594	2,338,755
Accumulated other comprehensive loss	(3,666)	(3,792)
Accumulated deficit	(1,175,655)	(1,044,365)
Total shareholders' equity	1,150,715	1,202,808
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,760,710	$ 1,797,227

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

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing and royalty revenues	$116,411	$122,677	$359,253	$366,608
Product sales, net	116,035	93,681	317,684	258,893
Research and development revenue	16,274	1,027	53,325	2,503
License revenue	—	—	48,250	—
Total revenues	248,720	217,385	778,512	628,004
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	39,410	36,054	127,303	116,241
Research and development	101,265	104,411	316,434	308,399
Selling, general and administrative	128,777	99,633	385,181	310,682
Amortization of acquired intangible assets	16,426	15,643	48,742	46,417
Total expenses	285,878	255,741	877,660	781,739
OPERATING LOSS	(37,158)	(38,356)	(99,148)	(153,735)
OTHER (EXPENSE) INCOME, NET:				
Interest income	2,561	1,173	5,946	3,287
Interest expense	(3,346)	(3,129)	(11,959)	(8,816)
Change in the fair value of contingent consideration	4,200	13,600	(17,300)	15,900
Other expense, net	(90)	(9,078)	(2,815)	(10,696)
Total other (expense) income, net	3,325	2,566	(26,128)	(325)
LOSS BEFORE INCOME TAXES	(33,833)	(35,790)	(125,276)	(154,060)
INCOME TAX PROVISION (BENEFIT)	611	486	4,322	(5,904)
NET LOSS	$(34,444)	$(36,276)	$(129,598)	$(148,156)
LOSS PER ORDINARY SHARE:				
Basic and diluted	$(0.22)	$(0.24)	$(0.84)	$(0.97)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic and diluted	155,328	153,684	154,979	153,263
COMPREHENSIVE LOSS:				
Net loss	$(34,444)	$(36,276)	$(129,598)	$(148,156)
Holding gain, net of a tax provision (benefit) of $95, $35, $42 and $(14), respectively	314	83	126	22
COMPREHENSIVE LOSS	$(34,130)	$(36,193)	$(129,472)	$(148,134)

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

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ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2018	2017
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(129,598)	$(148,156)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	77,758	73,305
Share-based compensation expense	76,043	63,336
Deferred income taxes	3,879	(11,919)
Change in the fair value of contingent consideration	17,300	(15,900)
Impairment of investment in Reset Therapeutics, Inc.	—	10,471
Loss on debt refinancing	2,298	—
Payment made for debt refinancing	(2,251)	—
Other non-cash charges	1,209	3,357
Changes in assets and liabilities:		
Receivables	(17,322)	(16,434)
Contract assets	(4,366)	—
Inventory	(2,596)	(21,843)
Prepaid expenses and other assets	(3,291)	(1,944)
Accounts payable and accrued expenses	12,899	43,430
Contract liabilities	2,485	(1,102)
Other long-term liabilities	4,321	6,680
Cash flows provided by (used in) operating activities	38,768	(16,719)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(51,841)	(33,482)
Proceeds from the sale of equipment	428	50
Purchases of investments	(307,603)	(289,226)
Sales and maturities of investments	344,624	318,492
Cash flows used in investing activities	(14,392)	(4,166)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	18,318	18,298
Employee taxes paid related to net share settlement of equity awards	(15,785)	(16,418)
Payment made for debt refinancing	(743)	—
Principal payments of long-term debt	(1,421)	(2,250)
Cash flows provided by (used in) financing activities	369	(370)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	24,745	(21,255)
CASH AND CASH EQUIVALENTS—Beginning of period	191,296	186,378
CASH AND CASH EQUIVALENTS—End of period	$216,041	$165,123
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		

Purchased capital expenditures included in accounts payable and accrued expenses	$7,117	$5,321

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

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 and nine months ended September 30, 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 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.

ALKERMES PLC AND SUBSIDIARIES

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

Income Taxes

The Company's income tax provision (benefit) in the three and nine months ended September 30, 2018 and 2017 primarily related 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 September 30, 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.

As of September 30, 2018, the Company has not modified its position with respect to provisional amounts recorded to its financial statements as a result of the Tax Cuts and Jobs Act ("Tax Reform") that was enacted in December 2017. The Company will continue to analyze the impact of Tax Reform. For additional information, please refer to Note 2, Summary of Significant Accounting Policies, in the "Notes to Consolidated Financial Statements" accompanying the Annual Report.

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
	$ —

ALKERMES PLC AND SUBSIDIARIES

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

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.

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 is effective for the Company in this 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. Numerous updates have been issued subsequent to the initial guidance that provide clarification on a number of specific issues. 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 continues to assess the impact that this guidance will have on its consolidated financial statements. At this time, the Company cannot conclude as to the total expected impact the adoption of this new guidance will have on its consolidated financial statements, but does believe that the adoption will have a material impact on the Company's balance sheet as it currently has, among other operating leases, two operating leases for 67,000 and 175,000 square feet of office and laboratory space in two separate locations in Waltham, Massachusetts that expire in 2020 and 2021, respectively, and an operating lease for 14,600 square feet of corporate office space in Dublin, Ireland that expires in 2022. In addition, during the three months ended March 31, 2018, the Company entered into a lease for approximately 220,000 square feet of office and laboratory space to be constructed in Waltham, Massachusetts with a delivery date of January 2020.

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.

ALKERMES PLC AND SUBSIDIARIES

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

In June 2018, the FASB issued guidance that addresses the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation – Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance becomes effective for the Company in the year ending December 31, 2019 and early adoption is permitted. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued amendments that aim to improve the effectiveness of fair value measurement disclosures. The amendments in this guidance modify the disclosure requirements on fair value measurements based on the concepts in FASB Concepts Statement, Conceptual Framework for Financial Reporting - Chapter 8: Notes to Financial Statements, including the consideration of costs and benefits. The amendments become effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

In August 2018, the FASB issued guidance that aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The guidance also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. The guidance becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

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 obligation(s) in the contract(s) (iii) determine the transaction price (iv) allocate the transaction price to the performance obligation(s) in the contract(s) and (v) recognize revenues when (or as) the Company satisfies the performance obligation(s).

Collaboration Arrangements

The Company has entered into collaboration and/or license 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 (Diroximel Fumarate, formerly ALKS 8700). Substantially all of the products developed under these 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 and nine months ended September 30, 2018 and 2017, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

(In thousands)	Three Months Ended September 30, 2018 Manufacturing Revenue	Royalty Revenue	Total	Nine Months Ended September 30, 2018 Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$—	$65,620	$65,620	$—	$174,956	$174,956
AMPYRA/FAMPYRA	12,894	7,445	20,339	38,000	30,276	68,276
RISPERDAL CONSTA	7,267	4,316	11,583	42,296	13,922	56,218
BYDUREON	—	11,944	11,944	—	35,202	35,202
Other	5,036	1,889	6,925	19,420	5,181	24,601
	$25,197	$91,214	$116,411	$99,716	$259,537	$359,253

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

	Three Months Ended September 30, 2017			Nine Months Ended September 30, 2017		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$—	$57,912	$57,912	$—	$153,736	$153,736
AMPYRA/FAMPYRA	11,527	12,951	24,478	37,596	41,357	78,953
RISPERDAL CONSTA	16,838	4,693	21,531	52,858	15,021	67,879
BYDUREON	—	10,095	10,095	—	33,996	33,996
Other	6,384	2,277	8,661	23,581	8,463	32,044
	$34,749	$87,928	$122,677	$114,035	$252,573	$366,608

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 control of the 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 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.

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 uncertain 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 as set forth below, 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 manufactured under our license and supply agreements with Acorda are incorporated into the standard cost-based model described in the manufacturing revenues section, above, as the terms of such agreements entitle the Company to royalty revenue as the product is being manufactured, which represents a faithful depiction of the transfer of goods, and not based on the actual 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.

ALKERMES PLC AND SUBSIDIARIES

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

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 performance obligations under the arrangement may be derived using a "best estimate of selling price" if the Company does not sell the goods or services separately.

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.

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 the agreement in November 2017, the Company received an up-front cash payment of $28.0 million. In June 2018, the Company received an additional cash payment of $50.0 million following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098. The Company is also eligible to receive an additional payment of $150.0 million 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. The Company will also receive royalties on net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to low double-digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all such products and the minimum annual payments for BIIB098 are subject to reductions as set forth in 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 of intellectual property to Biogen; (ii) future development services; (iii) clinical supply; and (iv) participation on a joint steering committee with Biogen. The Company's participation on the joint steering committee was considered to be perfunctory and thus not recognized as a performance obligation. The performance obligations, 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 Company allocated the arrangement consideration to each performance obligation 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 standalone selling price of the license in order to allocate the consideration to the performance obligations. To estimate the standalone selling price 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.

As 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 development services and $0.1 million to clinical supply. The amounts allocated to the development services and clinical supply will be recognized over the course of the development 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 the $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 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 in the transaction price as it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The royalties are subject to the sales-based exception and will be recorded when the subsequent sale occurs.

In June 2018, the Company recognized $48.3 million in license revenue related to the license and collaboration agreement with Biogen for BIIB098, which was triggered by Biogen's decision to pay the $50.0 million option payment following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098, including certain data from the long-term safety clinical trial and part A of the elective, randomized, head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and dimethyl fumarate. The Company previously determined that this $50.0 million milestone payment was variable consideration, as described above, and was not included in the initial transaction price as it was not probable that a significant reversal in the amount of cumulative revenue recognized would not occur. Upon receipt of the $50.0 million payment, the constraint preventing revenue recognition from previously occurring was removed and the payment was included in the transaction price and allocated to the performance obligations, as previously described. The Company recognized the transaction price allocated to the license upon receipt of the $50.0 million payment as the license had already been delivered to Biogen. The remaining $1.7 million of the $50.0 million payment was allocated to future development services and clinical supply, and, as of September 30, 2018, an additional $0.9 million of the $1.7 million was recognized and accounted for as R&D revenue.

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 and nine months ended September 30, 2018 primarily related to revenue earned under the Company's license and collaboration agreement with Biogen for BIIB098.

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

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 payers. 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 control of the Company's product. The Company estimates this liability using the most likely amount method based on its 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 and nine months ended September 30, 2018 and 2017, the Company recorded product sales, net, as follows:

	Three Months Ended September 30,