

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

(State or other jurisdiction of incorporation or organization)

98-1007018

(I.R.S. Employer Identification No.)

Edgar Filing: Alkermes plc. - Form 10-Q

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

	Page No.
<u>PART I - FINANCIAL INFORMATION</u>	
Item 1. <u>Condensed Consolidated Financial Statements (unaudited):</u>	
<u>Condensed Consolidated Balance Sheets — September 30, 2018 and December 31, 2017</u>	5
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss — For the Three and Nine Months Ended September 30, 2018 and 2017</u>	6
<u>Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2018 and 2017</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	29
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	43
Item 4. <u>Controls and Procedures</u>	43
<u>PART II - OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	44
Item	
1A. <u>Risk Factors</u>	44
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	44
Item 5. <u>Other Information</u>	44
Item 6. <u>Exhibits</u>	45
<u>Signatures</u>	46

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

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including the development, regulatory (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 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. 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

Edgar Filing: Alkermes plc. - Form 10-Q

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.

5

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		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.

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:		

Edgar Filing: Alkermes plc. - Form 10-Q

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.

7

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.

8

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:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
	Manufacturing Revenue	Royalty Revenue	Total	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

11

ALKERMES PLC AND SUBSIDIARIES

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

(In thousands)	Three Months Ended September 30, 2017			Nine Months Ended September 30, 2017		
	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

ALKERMES PLC AND SUBSIDIARIES

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

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.

ALKERMES PLC AND SUBSIDIARIES

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:

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
VIVITROL	\$79,893	\$69,177	\$218,778	\$193,704
ARISTADA	36,142	24,504	98,906	65,189
Total product sales, net	\$116,035	\$93,681	\$317,684	\$258,893

ALKERMES PLC AND SUBSIDIARIES

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

Receivables, Net—Receivables, net, include amounts billed and currently unconditionally 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 September 30, 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 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	49,387
Transferred to receivables, net	(45,021)
Contract assets at September 30, 2018	\$13,476

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	5,793
Amounts recognized into revenue	(3,309)
Contract liabilities at September 30, 2018	\$ 11,926

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 shareholders' 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 impacts of the changes are set out below for each of the condensed consolidated balance sheet and the condensed consolidated statement of operations for the current reporting period.

ADJUSTED CONDENSED CONSOLIDATED BALANCE SHEET

	September 30, 2018			Balances Without
				Adoption of Topic
(In thousands)	As Reported	Adjustment	606	
ASSETS				
Contract assets	\$13,476	\$ (13,476)	(1)	\$—
Inventory	88,018	8,772	(2)	96,790
Deferred tax asset	92,279	(120)	(3)	92,159
LIABILITIES				
Contract liabilities—short-term	\$6,916	\$ (6,916)	(4)	\$—
Deferred revenue—short-term	—	5,428	(4)	5,428
Contract liabilities—long-term	5,010	(5,010)	(4)	—
Deferred revenue—long-term	—	4,681	(4)	4,681
SHAREHOLDERS' EQUITY				
Accumulated deficit	\$(1,175,655)	\$ (3,007)	(5)	\$(1,178,662)

The adjustments are a result of the following:

- (1) Adjustment to contract assets 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 to apply the tax impact of the revenue transactions summarized in item (1), above.
- (4) Adjustments to contract liabilities—short-term and contract liabilities—long-term is 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.

ALKERMES PLC AND SUBSIDIARIES

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

ADJUSTED CONDENSED CONSOLIDATED STATEMENTS

OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
	As Reported	Adjustment	Balances Without Adoption of Topic 606	As Reported	Adjustment	Balances Without Adoption of Topic 606
(In thousands, except per share amounts)						
REVENUES:						
Manufacturing and royalty revenues	\$ 116,411	\$ 1,106	(1) \$ 117,517	\$ 359,253	\$ (4,366)	(1) \$ 354,887
Product sales, net	116,035	—	116,035	317,684	—	317,684
Research and development revenue	16,274	(1,100)	(2) 15,174	53,325	48,541	(2) 101,866
License revenue	—	—	—	48,250	(48,250)	(3) —
Total revenues	248,720	6	248,726	778,512	(4,075)	774,437
EXPENSES:						
Cost of goods manufactured and sold	39,410	574	(4) 39,984	127,303	(565)	(4) 126,738
Research and development	101,265	—	101,265	316,434	—	316,434
Selling, general and administrative	128,777	—	128,777	385,181	—	385,181
Amortization of acquired intangible assets	16,426	—	16,426	48,742	—	48,742
Total expenses	285,878	574	286,452	877,660	(565)	877,095
Operating (loss) income	(37,158)	(568)	(37,726)	(99,148)	(3,510)	(102,658)
Other income (expense), net	3,325	—	3,325	(26,128)	—	(26,128)
Loss before income taxes	(33,833)	(568)	(34,401)	(125,276)	(3,510)	(128,786)
Income tax provision (benefit)	611	(104)	507	4,322	11	4,333
Net (loss) income	\$(34,444)	\$(464)	\$(34,908)	\$(129,598)	\$(3,521)	\$(133,119)
Loss per ordinary share — basic and diluted	\$(0.22)	\$(0.00)	\$(0.22)	\$(0.84)	\$(0.04)	\$(0.88)

The adjustments are a result of the following:

- (1) Adjustments to manufacturing and royalty revenues to recognize revenue under Topic 605 in the three and nine months ended September 30, 2018 that was recognized under Topic 606.
- (2) Adjustments to research and development revenue during the three and nine months ended September 30, 2018 to recognize revenue under Topic 605 that was recognized under Topic 606.
- (3) Adjustments to license revenue during the nine months ended September 30, 2018 to recognize revenue under Topic 605 that was recognized under Topic 606.

(4) Adjustments 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 changes in net loss in the condensed consolidated statement of operations, but the overall cash flows used in operating activities did not change.

18

ALKERMES PLC AND SUBSIDIARIES

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

4. INVESTMENTS

Investments consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Losses		Estimated Fair Value	
		Less than One Year Gains	Greater than One Year Losses		
September 30, 2018					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 119,406	\$2	\$(87)	\$(92)	\$ 119,229
Corporate debt securities	95,744	12	(99)	(73)	95,584
International government agency debt securities	36,305	3	(18)	(57)	36,233
Total short-term investments	251,455	17	(204)	(222)	251,046
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	53,225	—	(297)	(110)	52,818
U.S. government and agency debt securities	31,054	—	(140)	—	30,914
International government agency debt securities	24,245	—	(131)	(33)	24,081
	108,524	—	(568)	(143)	107,813
Held-to-maturity securities:					
Fixed term deposit account	1,667	156	—	—	1,823
Certificates of deposit	1,820	—	—	—	1,820
	3,487	156	—	—	3,643
Total long-term investments	112,011	156	(568)	(143)	111,456
Total investments	\$ 363,466	\$ 173	\$(772)	\$(365)	\$ 362,502
December 31, 2017					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 150,673	\$1	\$(130)	\$(233)	\$ 150,311
Corporate debt securities	56,552	3	(48)	(10)	56,497
International government agency debt securities	35,478	1	(54)	(25)	35,400
Total short-term investments	242,703	5	(232)	(268)	242,208
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	83,924	—	(300)	(34)	83,590
U.S. government and agency debt securities	48,948	—	(270)	(71)	48,607
International government agency debt securities	21,453	—	(118)	—	21,335
	154,325	—	(688)	(105)	153,532
Held-to-maturity securities:					

Edgar Filing: Alkermes plc. - Form 10-Q

Fixed term deposit account	1,667	222	—	—	1,889
Certificates of deposit	1,791	—	—	—	1,791
	3,458	222	—	—	3,680
Total long-term investments	157,783	222	(688)	(105)	157,212
Total investments	\$ 400,486	\$ 227	\$ (920)	\$ (373)	\$ 399,420

ALKERMES PLC AND SUBSIDIARIES

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

The proceeds from the sales and maturities of marketable securities, which were identified using the specific identification method, and were primarily reinvested, were as follows:

(In thousands)	Nine Months Ended September 30,	
	2018	2017
Proceeds from the sales and maturities of marketable securities	\$344,624	\$318,492
Realized gains	\$4	\$9
Realized losses	\$268	\$3

The Company's available-for-sale and held-to-maturity securities at September 30, 2018 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized	Estimated	Amortized	Estimated
	Cost	Fair Value	Cost	Fair Value
Within 1 year	\$212,497	\$212,078	\$1,820	\$1,820
After 1 year through 5 years	147,482	146,781	1,667	1,823
Total	\$359,979	\$358,859	\$3,487	\$3,643

At September 30, 2018, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including, but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; the Company's intent not to sell these securities; and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. As of September 30, 2018, the Company's total contribution in Fountain was equal to €4.9 million. The Company's commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method. During the three and nine months ended September 30, 2018, the Company recorded an increase in its investment in Fountain of less than \$0.1 million and a decrease in its investment in Fountain of \$0.4 million, respectively. During the three and nine months ended September 30, 2017, the Company recorded an increase in its investment in Fountain of less than \$0.1 million and a decrease of \$0.6 million, respectively. The changes recorded represent the Company's proportional share of Fountain's net (losses) gains for these periods. The Company's \$4.2 million and \$3.7 million net investment in Fountain at September 30, 2018 and

December 31, 2017, respectively, was included within “Other assets” in the accompanying condensed consolidated balance sheets.

ALKERMES PLC AND SUBSIDIARIES

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

5. FAIR VALUE MEASUREMENTS

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

(In thousands)	September 30,			
	2018	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 71,059	\$71,059	\$—	\$—
U.S. government and agency debt securities	150,143	111,417	38,726	—
Corporate debt securities	148,402	—	147,910	492
International government agency debt securities	60,314	—	60,314	—
Contingent consideration	67,500	—	—	67,500
Common stock warrants	795	—	—	795
Total	\$ 498,213	\$ 182,476	\$ 246,950	\$ 68,787

(In thousands)	December 31,			
	2017	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,889	\$1,889	\$—	\$—
U.S. government and agency debt securities	198,918	124,958	73,960	—
Corporate debt securities	140,087	—	140,087	—
International government agency debt securities	56,735	—	56,735	—
Contingent consideration	84,800	—	—	84,800
Common stock warrants	1,395	—	—	1,395
Total	\$ 483,824	\$ 126,847	\$ 270,782	\$ 86,195

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period.

There were no transfers of any securities between the fair value hierarchies during the nine months ended September 30, 2018. The following table is a rollforward of the fair value of the Company's assets whose fair values were determined using Level 3 inputs at September 30, 2018:

(In thousands)	Fair Value
Balance, January 1, 2018	\$ 86,195
Purchase of corporate debt security	492
Change in the fair value of contingent consideration	(17,300)

Edgar Filing: Alkermes plc. - Form 10-Q

Decrease in the fair value of warrants	(600)
Balance, September 30, 2018	\$ 68,787

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

ALKERMES PLC AND SUBSIDIARIES

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

The Company's contingent consideration relates to the divestiture of its Gainesville, GA facility (the "Gainesville Transaction"), as summarized in Note 15, Divestiture, in the "Notes to Consolidated Financial Statements" of the Company's Annual Report. At September 30, 2018, the Company determined the value of the contingent consideration using the following valuation approaches:

• The Company is entitled to receive \$45.0 million upon regulatory approval of the first NDA for IV/IM and parenteral forms of Meloxicam or any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's IP to which Recro Pharma, Inc. ("Recro") was provided a right of use, through license or transfer (the "Meloxicam Product(s)"). The fair value of the regulatory milestone was estimated based on the likelihood of achieving this regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone event to occur in the first quarter of 2019 and used a discount rate of 3.9%;

• The Company is entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, the Company assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales of such Meloxicam Product assuming approval and IP protection. The Company then discounted these expected payments using a discount rate of 15.0%, which it believes captures a market participant's view of the risk associated with the expected payments; and

- The Company is entitled to receive payments of up to \$80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Products. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved Meloxicam Product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt, which ranged from 3.7% to 5.7%.

At September 30, 2018 and December 31, 2017, the Company determined that the value of the contingent consideration was \$67.5 million and \$84.8 million, respectively. The Company recorded an increase of \$4.2 million and a decrease of \$17.3 million during the three and nine months ended September 30, 2018, respectively, and an increase of \$13.6 million and \$15.9 million during the three and nine months ended September 30, 2017, respectively, within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss.

As part of the Gainesville Transaction, the Company also received warrants to purchase 350,000 shares of Recro common stock at a per share exercise price of \$19.46. The Company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at September 30, 2018:

Closing stock price at September 30, 2018	\$7.11
Warrant strike price	\$19.46
Expected term (years)	3.52
Risk-free rate	2.91 %
Volatility	77.0 %

During the three and nine months ended September 30, 2018, the Company determined that the fair value of the warrants, recorded within "Other assets" in the accompanying condensed consolidated balance sheets, increased by \$0.4 million and decreased by \$0.6 million, respectively, and during the three and nine months ended September 30, 2017, increased by \$0.3 million and \$0.1 million, respectively. The change in the fair value of the warrants was recorded within "Other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, contract assets, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

ALKERMES PLC AND SUBSIDIARIES

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

6. INVENTORY

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

	September 30, December 31,	
(In thousands)	2018	2017
Raw materials	\$ 29,859	\$ 29,883
Work in process	34,872	38,964
Finished goods ⁽¹⁾	23,287	24,428
Total inventory	\$ 88,018	\$ 93,275

(1) At September 30, 2018 and December 31, 2017, the Company had \$16.2 million and \$8.7 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, December 31,	
(In thousands)	2018	2017
Land	\$ 6,293	\$ 6,293
Building and improvements	156,133	155,198
Furniture, fixtures and equipment	307,706	289,455
Leasehold improvements	19,953	19,578
Construction in progress	81,552	54,270
Subtotal	571,637	524,794
Less: accumulated depreciation	(268,550)	(240,058)
Total property, plant and equipment, net	\$ 303,087	\$ 284,736

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	September 30, 2018		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount

Edgar Filing: Alkermes plc. - Form 10-Q

Goodwill		\$92,873	\$ —	\$92,873
Finite-lived intangible assets:				
Collaboration agreements	12	\$465,590	\$ (306,729)	\$158,861
NanoCrystal technology	13	74,600	(37,012)	37,588
OCR technologies	12	42,560	(31,583)	10,977
Total		\$582,750	\$ (375,324)	\$207,426

Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at September 30, 2018 is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

ALKERMES PLC AND SUBSIDIARIES

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

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Accounts payable	\$ 44,114	\$ 55,526
Accrued compensation	60,472	54,568
Accrued sales discounts, allowances and reserves	131,067	111,137
Accrued other	59,376	64,935
Total accounts payable and accrued expenses	\$ 295,029	\$ 286,166

10. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
2023 Term Loans, due March 26, 2023	\$ 279,850	\$ 281,436
Less: current portion	(2,843)	(3,000)
Long-term debt	\$ 277,007	\$ 278,436

In March 2018, the Company amended and refinanced its existing term loan, referred to as Term Loan B-1 (as so amended and refinanced, the “2023 Term Loans”), in order to, among other things, extend the due date of the loan from September 25, 2021 to March 26, 2023, reduce the interest payable from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with no LIBOR floor and increase covenant flexibility (the “Refinancing”).

The Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing was to be accounted for as a debt extinguishment or a debt modification, the Company considered whether creditors remained the same or changed and whether the changes in debt terms were substantial. A change in the debt terms was considered to be substantial if the present value of the remaining cash flows under the new terms of the 2023 Term Loans was at least 10% different from the present value of the remaining cash flows under the former Term Loan B-1 (commonly referred to as the “10% Test”). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. With the exception of one lender, who owned 1% of the total outstanding principal amount of Term Loan B-1 at the date of the Refinancing and was accounted for as a debt extinguishment, the Refinancing was accounted for as a debt modification.

The Refinancing resulted in a \$2.3 million charge in the three months ended March 31, 2018, which was included in “Interest expense” in the accompanying condensed consolidated statement of operations and comprehensive loss.

11. RESTRUCTURING

On January 25, 2018, the Company's management approved a restructuring plan at its Athlone, Ireland manufacturing facility designed to streamline future operational performance. The restructuring plan included a reduction in headcount of 24 employees. In connection with this restructuring plan, during the three months ended March 31, 2018, the Company recorded a restructuring charge of \$3.2 million within cost of goods manufactured and sold and \$0.4 million within R&D expense, which consisted of severance and outplacement services. At June 30, 2018, the Company had made all its severance and outplacement services payments related to this restructuring.

ALKERMES PLC AND SUBSIDIARIES

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

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of goods manufactured and sold	\$2,140	\$1,752	\$6,012	\$5,893
Research and development	7,937	5,497	23,203	16,752
Selling, general and administrative	14,991	12,239	46,828	40,691
Total share-based compensation expense	\$25,068	\$19,488	\$76,043	\$63,336

At September 30, 2018 and December 31, 2017, \$0.5 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

In February 2017, the compensation committee of the Company’s board of directors approved awards of restricted stock units (“RSUs”) to all employees employed by the Company during 2017, in each case subject to vesting on the achievement of the following performance criteria: (i) FDA approval of the NDA for ALKS 5461, (ii) the achievement of the pre-specified primary efficacy endpoints in each of two phase 3 studies of ALKS 3831, and (iii) revenues equal to or greater than a pre-specified amount for the year ending December 31, 2019. These performance criteria are being assessed over a performance period of three years from the date of the grant. At September 30, 2018, there was \$55.7 million of unrecognized compensation cost related to these performance-vesting RSUs, which would be recognized in accordance with the terms of the award when the Company deems it probable that the performance criteria will be met.

13. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the three and nine months ended September 30, 2018 and 2017, as the Company was in a net loss position, the diluted loss per share calculation did not assume conversion or exercise of stock options and awards as they would have had an anti-dilutive effect on loss per share.

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

Three Months Ended September 30,	Nine Months Ended September 30,
--	---------------------------------------

Edgar Filing: Alkermes plc. - Form 10-Q

(In thousands)	2018	2017	2018	2017
Stock options	11,553	9,588	10,274	9,564
Restricted stock units	2,678	2,183	2,621	2,058
Total	14,231	11,771	12,895	11,622

ALKERMES PLC AND SUBSIDIARIES

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

14. COMMITMENTS AND CONTINGENCIES

Lease Commitments

In March 2018, the Company entered into a lease agreement for approximately 220,000 square feet of office and laboratory space located in a building to be built at 900 Winter Street, Waltham, Massachusetts (“900 Winter Street”). The Company plans to occupy the premises in early 2020. The initial term of the lease shall commence on the earlier of: (i) the Delivery Date (defined as (a) the later of January 20, 2020, or (b) the date on which the landlord substantially completes its work in accordance with the terms of the lease), or (ii) the date the Company enters into possession of all or any substantial portion of 900 Winter Street for the conduct of its business (the “Commencement Date”). The initial lease term expires on the last day of the calendar month in which the fifteenth (15th) anniversary of the Commencement Date occurs, with an option to extend for an additional ten (10) years.

Litigation

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company’s best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company’s operating results. At September 30, 2018, there were no potential material losses from claims, asserted or unasserted, or legal proceedings the Company determined were probable of occurring.

INVEGA SUSTENNA ANDA Litigation

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (“Teva”), who filed an abbreviated new drug application (“ANDA”) seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. Requested judicial remedies included recovery of litigation costs and injunctive relief. The Company is not a party to these proceedings.

For information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see “Part I, Item 1A—Risk Factors” of the Company’s Annual Report and specifically the section entitled “—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers.”

AMPYRA ANDA Litigation

Eleven separate Paragraph IV Certification Notices have been received by the Company and/or its partner Acorda from: Accord Healthcare, Inc. (“Accord”); Actavis Laboratories FL, Inc. (“Actavis”); Alkem Laboratories Ltd. (“Alkem”); Apotex Corporation and Apotex, Inc. (collectively, “Apotex”); Aurobindo Pharma Ltd. (“Aurobindo”); MicroLabs Limited (“MicroLabs”); Mylan Pharmaceuticals, Inc. (“Mylan”); Par Pharmaceutical, Inc. (“Par”); Roxane Laboratories, Inc. (“Roxane”); Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, “Sun”); and

Teva (collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, MicroLabs, Mylan, Par, Roxane and Sun, the “ANDA Filers”) advising that each of the ANDA Filers had submitted an ANDA to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. The ANDA Filers challenged the validity of one or more of the Orange Book-listed patents for AMPYRA, and they also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA Filers asserting infringement of one or more of the Orange Book-listed patents for AMPYRA. Requested judicial remedies included recovery of litigation costs and injunctive relief.

ALKERMES PLC AND SUBSIDIARIES

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

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

The Company and/or Acorda entered into a settlement agreement with each of Accord, Actavis, Alkem, Apotex, Aurobindo, MicroLabs, Par and Sun to resolve the patent litigation that the Company and/or Acorda brought against these settling ANDA Filers. The settlements with these settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers, including as described below.

In March 2017, after a bench trial, the U.S. District Court for the District of Delaware (the "Delaware Court") issued an opinion (the "Delaware Court Decision"), which, among other things, invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. The Delaware Court also upheld the validity of the U.S. Patent No. 5,540,938 (the "938 Patent"), which pertains to the formulation of AMPYRA, but that patent expired on July 30, 2018. In May 2017, Acorda filed an appeal with the Federal Circuit of the Delaware Court Decision with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. On July 27, 2018, Acorda and the Company entered into a settlement agreement with Mylan, pursuant to which, among other things, Mylan was permitted to market an authorized generic version of AMPYRA in the U.S. in the event of an affirmance by the Federal Circuit of the Delaware Court Decision. On September 10, 2018, the Federal Circuit affirmed the Delaware Court Decision, which invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. Acorda has until October 24, 2018 to file a petition for rehearing and rehearing en banc of the Federal Circuit's decision.

For information about risks relating to the AMPYRA Paragraph IV litigations and other proceedings see "Part I, Item 1A—Risk Factors" of the Company's Annual Report and specifically the section entitled "—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

VIVITROL IPR Proceeding

On April 20, 2018, Amneal Pharmaceuticals LLC filed an inter partes review ("IPR") petition with the U.S. Patent and Trademark Office challenging U.S. Patent Number 7,919,499 (the "499 Patent"), which is an Orange Book-listed patent for VIVITROL. The Company's Preliminary Patent Owner Response was filed on August 9, 2018. The Patent Trial and Appeal Board will decide whether to institute the IPR by November 9, 2018. If instituted, the Company will vigorously defend the '499 Patent in the IPR proceedings. For information about risks relating to the '499 Patent IPR proceedings see "Part I, Item 1A—Risk Factors" in the Company's Annual Report and specifically the sections entitled "—Patent protection for our products is important and uncertain" and "—Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable."

Government Matters

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

ALKERMES PLC AND SUBSIDIARIES

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

Securities Litigation

On November 22, 2017, a purported stockholder of the Company filed a putative class action against the Company and certain of its officers (collectively, the “Defendants”) in the United States District Court for the Southern District of New York captioned *Gagnon v. Alkermes plc, et al.*, No. 1:17-cv-09178. This complaint has been amended twice since its initial filing. The second amended complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of February 24, 2015 to November 14, 2017 and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on allegedly false or misleading statements and omissions regarding the Company’s marketing practices related to VIVITROL. The lawsuit seeks, among other things, unspecified damages for alleged inflation in the price of securities, and reasonable costs and expenses, including attorneys’ fees. On June 29, 2018, Defendants filed a motion to dismiss the second amended complaint. Oral arguments on this motion are scheduled to be heard on October 23, 2018. For information about risks relating to this action, see “Part I, Item 1A—Risk Factors” of the Company’s Annual Report and specifically the section entitled “—Litigation or arbitration against Alkermes, including securities litigation, or citizen petitions filed with the FDA, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business.”

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

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

Executive Summary

Net loss for the three and nine months ended September 30, 2018 was \$34.4 million and \$129.6 million, or \$0.22 and \$0.84 per ordinary share— basic and diluted, respectively, as compared to a net loss of \$36.3 million and \$148.2 million or \$0.24 and \$0.97 per ordinary share— basic and diluted for the three and nine months ended September 30, 2017, respectively.

The decrease in the net loss in both the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was primarily due to the license and collaboration agreement with Biogen for the development of BIIB098. During the three and nine months ended September 30, 2018, we recognized \$15.7 million and \$99.3 million of revenue related to this agreement, as discussed in the License Revenue and Research and Development Revenue sections below. In addition, revenue from our proprietary product sales, net increased by 24% and 23%, respectively, in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017. The increase in revenue was partially offset by an increase in operating expenses of 12% in both the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, which was primarily due to increased investment in the commercialization of VIVITROL and ARISTADA. These items are discussed in greater detail later in the “Results of Operations” section of this Item 2 of this Form 10-Q.

Products

Marketed Products

Our portfolio of marketed products is designed to address unmet medical needs of patients in major therapeutic areas. See the description of the marketed products below, and refer to “Part I, Item 1A—Risk Factors” of our Annual Report for important factors that could adversely affect our marketed products and to the “Patents and Proprietary Rights” section in “Part I, Item 1— Business” of our Annual Report for information with respect to the IP protection for these marketed products.

Summary information regarding our proprietary products includes:

Product Indication(s)	Licensee	Territory
Initiation or re- initiation of ARISTADA for the treatment of Schizophrenia Schizophrenia	None	Commercialized by Alkermes in the U.S.
Alcohol dependence and Opioid dependence	None	Commercialized by Alkermes in the U.S.
	Cilag GmbH International ("Cilag")	Russia and Commonwealth of Independent States ("CIS")

Edgar Filing: Alkermes plc. - Form 10-Q

Summary information regarding products that use our proprietary technologies includes:

Product	Indication(s)	Licensee	Territory
RISPERDAL CONSTA	Schizophrenia and Bipolar I disorder	Janssen Pharmaceutica Inc. (“Janssen, Inc.”) and Janssen Pharmaceutica International, a division of Cilag International AG (“Janssen International”)	Worldwide
INVEGA SUSTENNA	Schizophrenia and Schizoaffective disorder	Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates “Janssen”)	U.S.
XEPLION	Schizophrenia	Janssen	All countries outside of the U.S. (“ROW”)

INVEGA TRINZA	Schizophrenia	Janssen	U.S.
TREVICTA	Schizophrenia	Janssen	ROW
AMPYRA	Treatment to improve walking in patients with MS, as demonstrated by	Acorda	U.S.
FAMPYRA	an increase in walking speed	Biogen, under sublicense from Acorda	ROW
BYDUREON and BYDUREON BCise	Type 2 diabetes	AstraZeneca plc (“AstraZeneca”)	Worldwide

Proprietary Products

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

ARISTADA INITIO

ARISTADA INITIO (aripiprazole lauroxil), in combination with a single 30 mg dose of oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults. ARISTADA INITIO leverages the company's proprietary NanoCrystal technology and is designed to provide an extended-release formulation using a smaller particle size of aripiprazole lauroxil compared to ARISTADA, thereby enabling faster dissolution and leading to more rapid achievement of relevant levels of aripiprazole. The ARISTADA INITIO regimen, consisting of a single injection of 675 mg ARISTADA INITIO in combination with a single 30 mg dose of oral aripiprazole, can be used to initiate onto any dose of ARISTADA, and provides patients with relevant levels of aripiprazole within four days of treatment initiation. The first ARISTADA dose may be administered on the same day as the ARISTADA INITIO regimen or up to 10 days thereafter. We developed ARISTADA INITIO and exclusively manufacture and commercialize it in the U.S.

In July 2018, U.S. Patent No. 10,016,415 relating to ARISTADA INITIO was granted. This patent has claims to nanoparticulate compositions of aripiprazole lauroxil and expires in 2035.

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA is the first of our products to utilize our proprietary LinkeRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is the first atypical antipsychotic with once-monthly, once-every-six-weeks and once-every-two-months dosing duration options to deliver and maintain therapeutic levels of medication in the body. ARISTADA has four dosing options (441 mg, 662 mg, 882 mg and 1064 mg) and is packaged in a ready-to-use, pre-filled product format. We developed ARISTADA and exclusively manufacture and commercialize it in the U.S.

In September 2018, U.S. Patent No. 10,064,859 relating to ARISTADA was granted. This patent has claims to a process for manufacturing aripiprazole lauroxil and expires in 2035.

VIVITROL

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

Products Using Our Proprietary Technologies

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

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA (paliperidone palmitate)/TREVICTA (paliperidone palmitate 3-monthly injection) and RISPERDAL CONSTA (risperidone long-acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union (“EU”) and other countries outside of the U.S. for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA/XEPLION is manufactured by Janssen. For a discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 14, Commitments and Contingencies in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q, and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see “Part I, Item 1A—Risk Factors” of our Annual Report and specifically the section entitled “—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers.”

INVEGA TRINZA is an atypical antipsychotic injection for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. INVEGA TRINZA is the first schizophrenia treatment to be taken once every three months. This formulation of paliperidone palmitate is marketed in the EU under the trade name TREVICTA. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

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

AMPYRA/FAMPYRA

AMPYRA (dalfampridine)/FAMPYRA (fampridine) is believed to be the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with MS who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen outside the U.S. under the trade name FAMPYRA. FAMPYRA is approved in the EU for the improvement of walking in adults with MS. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA (including the authorized generic version of AMPYRA) and FAMPYRA are manufactured by us.

For a discussion of the legal proceedings related to the patents covering AMPYRA, see Note 14, Commitments and Contingencies in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q, and for information about risks relating to such legal proceedings see “Part I, Item 1A—Risk Factors” of our Annual Report. The legal proceedings related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in April 2025 in the EU.

In September 2018, generic versions of AMPYRA, including the authorized generic version of AMPYRA, entered the U.S. market.

BYDUREON and BYDUREON BCise

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. BYDUREON is also approved in the U.S. as an add-on to basal insulin in adults with type 2 diabetes who have inadequate glycemic control. AstraZeneca is responsible for the development and commercialization of BYDUREON worldwide. BYDUREON, a once-weekly formulation of exenatide, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca. BYDUREON Pen 2 mg, a pre-filled, single-use pen injector that contains the same formulation and dose as the original BYDUREON single-dose tray, is available in the U.S., certain countries in the EU and Japan.

BYDUREON BCise, a new formulation of BYDUREON in an improved once-weekly, single-dose autoinjector device for adults with type 2 diabetes was approved by the FDA in October 2017. In August 2018, BYDUREON BCise

was approved by the European Commission within the marketing authorization for BYDUREON for the treatment of patients with type 2 diabetes.

Key Development Programs

Our R&D is focused on leveraging our formulation expertise and proprietary product platforms to develop novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia, addiction, depression and MS. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key R&D programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed under the heading “Cautionary Note Concerning Forward-Looking Statements” in this Form 10-Q and in “Part I, Item 1A—Risk Factors” of our Annual Report. Refer to the “Patents and Proprietary Rights” section in “Part I, Item 1— Business” of our Annual Report for information with respect to the IP protection for our development products.

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

Preclinical Phase 1 Phase 2 Phase 3 FDA Review

ALKS 5461 Major Depressive Disorder

ALKS 3831 Schizophrenia

BIIB 098 (formerly ALKS 8700) Multiple Sclerosis

ALKS 4230 Cancer immunotherapy

ALKS 5461

ALKS 5461 is a proprietary, investigational, once-daily, oral medicine that acts as an opioid system modulator and represents a novel mechanism of action for the adjunctive treatment of Major Depressive Disorder (“MDD”). ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist. Our NDA for ALKS 5461 was submitted to the FDA in January 2018 and accepted by the FDA for review in April 2018. Acceptance of the NDA for review followed FDA issuance, and then rescission, of a refusal to file letter citing insufficient evidence of effectiveness and the need for additional bridging data, both of which we expect we will need to address in the context of the FDA’s review. The NDA is based on a clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD. The FDA has scheduled an advisory committee meeting for the ALKS 5461 NDA on November 1, 2018 and has issued a target action date for the ALKS 5461 NDA of January 31, 2019 under the Prescription Drug User Fee Act (“PDUFA”).

ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet. ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

The ENLIGHTEN clinical development program for ALKS 3831 includes two key studies: ENLIGHTEN-1, a study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks and ENLIGHTEN-2, a study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over six months. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of ALKS 3831.

Topline results from ENLIGHTEN-2 are expected in the fourth quarter of 2018.

We expect to use safety and efficacy data from the ENLIGHTEN clinical development program, if successful, to serve as the basis of an NDA, which we plan to submit to the FDA in mid-2019.

BIIB098 (formerly ALKS 8700)

BIIB098 (diroximel fumarate), formerly referred to as ALKS 8700, is an oral, novel fumarate candidate in development for the treatment of relapsing forms of MS. BIIB098 is designed to rapidly and efficiently convert to monomethyl fumarate in the body and potentially offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA.

We expect to file a 505(b)(2) NDA for BIIB098 in the fourth quarter of 2018. For more information about 505(b)(2) NDAs, see “Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act” of our Annual Report.

In November 2017, we entered into an exclusive license and collaboration agreement with Biogen relating to BIIB098. For more information about the license and collaboration agreement with Biogen, see “Part 1, Item 1—Business, Collaborative Arrangements” of our Annual Report.

ALKS 4230

ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (“IL-2”) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. Our phase 1 study for ALKS 4230 is designed to evaluate ALKS 4230 as a monotherapy agent and in combination with the anti-PD-1 therapy, pembrolizumab. A dose-escalation stage designed to determine a maximum tolerated dose of ALKS 4230 in a monotherapy setting and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects is ongoing. Upon completion of the dose-escalation stage, we expect to initiate a monotherapy dose-expansion stage of ALKS 4230 in patients with renal cell carcinoma or melanoma. In September 2018, we initiated the combination therapy stage of the phase 1 study, designed to assess the safety profile and anti-tumor activity of ALKS 4230 with pembrolizumab in patients with select advanced solid tumors.

Results of Operations

Manufacturing and Royalty Revenues

Manufacturing revenues for products that incorporate our technologies, 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. Manufacturing revenue from RISPERDAL CONSTA is recognized at the point in time the product has been fully manufactured. Royalties are generally earned on our licensees' net sales of products that incorporate our technologies and are recognized in the period the products are sold by our licensees. The following table compares manufacturing and royalty revenues earned in the three and nine months ended September 30, 2018 and 2017:

(In millions)	Three Months Ended		Change Favorable/ (Unfavorable)	Nine Months Ended		Change Favorable/ (Unfavorable)
	September 30, 2018	September 30, 2017		September 30, 2018	September 30, 2017	
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	\$ 65.6	\$ 57.9	\$ 7.7	\$ 175.0	\$ 153.7	\$ 21.3
AMPYRA/FAMPYRA	20.3	24.5	(4.2)	68.2	79.0	(10.8)
RISPERDAL CONSTA	11.6	21.6	(10.0)	56.2	67.9	(11.7)
BYDUREON	11.9	10.1	1.8	35.2	34.0	1.2
Other	7.0	8.6	(1.6)	24.7	32.0	(7.3)
Manufacturing and royalty revenues	\$ 116.4	\$ 122.7	\$ (6.3)	\$ 359.3	\$ 366.6	\$ (7.3)

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three and nine months ended September 30, 2018, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were \$749.0 million and \$2,165.0 million, respectively, as compared to \$643.0 million and \$1,876.0 million, respectively, during the three and nine months ended September 30, 2017. Under our agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA of: 5% on calendar year net sales up to \$250 million; 7% on calendar year net sales of between \$250 million and \$500 million; and 9% on calendar year net sales exceeding \$500 million. The royalty rate resets to 5% at the beginning of each calendar year. The adoption of Topic 606 had no impact on the method in which we recognize royalty revenue from sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA.

With the adoption of Topic 606, we changed the way we record certain of our manufacturing and royalty revenue for AMPYRA and FAMPYRA. For AMPYRA manufactured under our license and supply agreements with Acorda, we now record manufacturing and royalty revenue as the product is being manufactured, rather than when it is shipped to Acorda. For FAMPYRA, we record manufacturing revenue as the product is being manufactured, rather than when it is shipped to Biogen, but continue to record royalty revenue when the end-market sale of FAMPYRA occurs. See Note 3, Revenue from Contracts with Customers, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, for additional information regarding the adoption of Topic 606.

The decrease in the amount of manufacturing and royalty revenue recognized for AMPYRA and FAMPYRA in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was due to the anticipated entry of generic forms of AMPYRA to the U.S. market following expiration of the '938 Patent in July 2018. Actual entry of generic forms of AMPYRA into the U.S. market occurred in September 2018, following expiration of the '938 Patent and the Federal Circuit's decision affirming the Delaware Court Decision, which had invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. For further discussion of the legal proceedings related to the patents covering AMPYRA, see "Part II, Item 1—Legal Proceedings" and Note 14, Commitments and Contingencies in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, and for information about risks relating to such legal proceedings see "Part I, Item 1A—Risk Factors" of our Annual Report. The legal proceedings related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in April 2025 in the EU.

During the three months ended September 30, 2018, our shipments of AMPYRA to Acorda increased by 14% as compared to the three months ended September 30, 2017, however, revenues from AMPYRA decreased by 27%. In anticipation of the entry of generic forms of AMPYRA to the U.S. market, during the three months ended September 30, 2018, we supplied five batches of AMPYRA for Acorda for which we agreed to defer the receipt of royalties on end-market sales of the product until the product was sold by Acorda, rather than as it was manufactured. Also, during the three months ended September 30, 2018, we produced two batches of the authorized generic version of AMPYRA and, as the price we receive is based on end-market net sales, the revenue recorded for these two batches was at a price substantially lower than what we would have received had the product been resold as branded AMPYRA. During the nine months ended September 30, 2018, revenues from AMPYRA decreased by 20% as compared to the nine months ended September 30, 2017, which was primarily due to a 28% decrease in the amount of product manufactured, as well as the deferral of the royalty payments and production of the authorized generic batches, as described above. We expect that competition from generic forms of AMPYRA will continue to impact our manufacturing and royalty revenues for AMPYRA and we expect our manufacturing and royalty revenues for AMPYRA to continue to decline.

Under Topic 606, we continue to recognize manufacturing revenue for RISPERDAL CONSTA at a point in time, however, we now recognize manufacturing revenue when RISPERDAL CONSTA has been fully manufactured, which is when the product is approved for shipment, rather than when it is shipped. We continue to record royalty revenue when the end-market sale of RISPERDAL CONSTA occurs. The decrease in the amount of revenues from RISPERDAL CONSTA earned in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was primarily due to a 55% and 12% decrease in the amount of RISPERDAL CONSTA shipped to Janssen, respectively, and a 8% and 7% decrease in RISPERDAL CONSTA royalty revenue, respectively. End-market sales of RISPERDAL CONSTA were \$175.0 million and \$559.0 million in the three and nine months ended September 30, 2018, respectively, as compared to \$194.0 million and \$608.0 million in the three and nine months ended September 30, 2017, respectively.

Product Sales, net

Our product sales, net consist of sales of VIVITROL and ARISTADA in the U.S., primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net during the three and nine months ended September 30, 2018 and 2017:

(In millions)	Three Months Ended September 30,				Nine Months Ended September 30,				
	2018	% of Sales	2017	% of Sales	2018	% of Sales	2017	% of Sales	
Product sales, gross	\$ 217.4	100.0	% \$ 168.1	100.0	% \$ 604.1	100.0	% \$ 468.6	100.0	%
Adjustments to product sales, gross:									
Medicaid rebates	(48.2)	(22.2)%	(33.4)	(19.9)%	(144.0)	(23.8)%	(103.5)	(22.1)%	
Chargebacks	(18.2)	(8.4)%	(13.2)	(7.9)%	(48.6)	(8.0)%	(35.1)	(7.5)%	
Product discounts	(17.1)	(7.9)%	(13.0)	(7.7)%	(46.5)	(7.7)%	(36.1)	(7.7)%	
Medicare Part D	(8.1)	(3.7)%	(5.3)	(3.2)%	(20.3)	(3.4)%	(11.1)	(2.4)%	
Other	(9.8)	(4.5)%	(9.5)	(5.6)%	(27.0)	(4.5)%	(23.9)	(5.1)%	
Total adjustments	(101.4)	(46.6)%	(74.4)	(44.3)%	(286.4)	(47.4)%	(209.7)	(44.8)%	
Product sales, net	\$ 116.0	53.4	% \$ 93.7	55.7	% \$ 317.7	52.6	% \$ 258.9	55.2	%

Our product sales, net for VIVITROL and ARISTADA in the three months ended September 30, 2018 were \$79.9 million and \$36.1 million, respectively, as compared to \$69.2 million and \$24.5 million in the three months ended September 30, 2017, respectively. Our product sales, net for VIVITROL and ARISTADA in the nine months ended September 30, 2018 were \$218.8 million and \$98.9 million, respectively, as compared to \$193.7 million and \$65.2 million in the nine months ended September 30, 2017, respectively.

The increase in product sales, gross, in the three and nine months ended September 30, 2018, as compared to the corresponding prior periods, was primarily due to increased unit sales of both VIVITROL and ARISTADA. VIVITROL product sales, gross, increased by 18% in both the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, respectively, which was due to an increase in the number of VIVITROL units sold. ARISTADA product sales, gross, increased by 62% and 65% in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, respectively, which was

primarily due to an increase in the number of ARISTADA units sold of 40% and 47%, respectively. For ARISTADA, we also had a 3% price increase that went into effect in January 2018 and a 4% price increase that went into effect in July 2018. We did not have a price increase for VIVITROL in 2018.

License Revenue

	Three Months			Nine Months		
	Ended	Change		Ended	Change	
(In millions)	September 30,	2017	Favorable/ (Unfavorable)	September 30,	2017	Favorable/ (Unfavorable)
License revenue	\$ —	\$ —	\$ —	\$ 48.3	\$ —	\$ 48.3

During the three months ended June 30, 2018, we 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 our 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. As discussed in Note 3, Revenue from Contracts with Customers, we determined that this \$50.0 million option payment was variable consideration and it 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, which included: (i) the grant of a distinct, right-to-use license to Biogen; (ii) future development services; and (iii) clinical supply. As the license was delivered to Biogen shortly after the agreement was signed during the three months ended December 31, 2017, we recognized the transaction price allocated to the license upon receipt of the \$50.0 million payment. The remaining \$1.7 million of the \$50.0 million payment was allocated to future development services and clinical supply, which will be accounted for as R&D revenue.

Research and Development Revenue

	Three Months			Nine Months		
	Ended	Change		Ended	Change	
(In millions)	September 30,	2017	Favorable/ (Unfavorable)	September 30,	2017	Favorable/ (Unfavorable)
Research and development revenue	\$ 16.3	\$ 1.0	\$ 15.2	\$ 53.3	\$ 2.5	\$ 50.8

The increase in R&D revenue in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was primarily due to the revenue earned under the license and collaboration agreement with Biogen for BIIB098 that we entered into during the three months ended December 31, 2017. Under the agreement, since January 1, 2018, Biogen is responsible for all the BIIB098 development costs we incur, subject to annual budget limitations.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	\$39.4	\$36.1	\$ (3.4)	\$127.3	\$116.2	\$ (11.1)

The increase in cost of goods manufactured and sold in the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was primarily due to increased sales of VIVITROL and ARISTADA, as described above, and the restructuring activity at our Athlone, Ireland manufacturing facility. During the three months ended March 31, 2018, management approved a restructuring plan designed to streamline future operational performance which included a reduction in headcount of 24 employees. Accordingly, we recorded a restructuring charge of \$3.2 million within cost of goods manufactured and sold which consisted of severance and outplacement services. At June 30, 2018, we had made all our severance and outplacement services payments related to this restructuring.

Research and Development Expense

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

The following table sets forth our external R&D expenses for the three and nine months ended September 30, 2018 and 2017 relating to each of our key development programs, all other development programs and our internal R&D expenses by the nature of such expenses:

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
External R&D Expenses:						
Key development programs:						
ALKS 3831	\$9.0	\$19.4	\$ 10.4	\$39.7	\$70.8	\$ 31.1
BIIB098	9.7	11.9	2.2	31.9	37.5	5.6
ALKS 5461	6.3	11.7	5.4	23.1	29.8	6.7
ARISTADA and ARISTADA line extensions	6.2	5.9	(0.3)	17.5	9.9	(7.6)
ALKS 4230	3.1	1.7	(1.4)	12.3	5.1	(7.2)
Other external R&D expenses	13.6	10.5	(3.1)	35.8	28.6	(7.2)
Total external R&D expenses	47.9	61.1	13.2	160.3	181.7	21.4
Internal R&D expenses:						
Employee-related	42.2	33.0	(9.2)	122.8	97.0	(25.8)
Occupancy	2.9	2.4	(0.5)	8.5	7.2	(1.3)
Depreciation	3.0	2.7	(0.3)	8.8	7.7	(1.1)
Other	5.3	5.2	(0.1)	16.0	14.8	(1.2)
Total internal R&D expenses	53.4	43.3	(10.1)	156.1	126.7	(29.4)
Research and development expenses	\$101.3	\$104.4	\$ 3.1	\$316.4	\$308.4	\$ (8.0)

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

The decrease in expenses related to ALKS 3831 was primarily due to the decrease in activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively, partially offset by an increase in activity within a phase 3 study of ALKS 3831 in young adults, which was initiated in June 2017. The decrease in expenses related to BIIB098 was primarily due to the timing of activity within the two-year, multicenter, open-label phase 3 study designed to assess the safety of BIIB098, which was initiated in December 2015. We also initiated an elective, randomized, head-to-head phase 3 study designed to compare the gastrointestinal tolerability of BIIB098 to TECFIDERA in patients with relapsing-remitting MS in March

2017. The decrease in expenses related to ALKS 5461 was primarily due to a decrease in activity within the program as we completed submission of our NDA to the FDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of MDD in January 2018. The increase in expenses related to ARISTADA and ARISTADA line extensions was primarily due to an increase in the activity in a phase 3b clinical study to evaluate the efficacy and safety of ARISTADA and INVEGA SUSTENNA in patients experiencing an acute exacerbation of schizophrenia. The increase in expenses related to ALKS 4230 was primarily related to the timing of the phase 1 study, as described above under the heading “ALKS 4230”.

The increase in employee-related expenses was primarily due to an increase in R&D headcount of 17% from September 30, 2017 to September 30, 2018.

Selling, General and Administrative Expense

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
Selling, general and administrative expense	\$ 128.8	\$ 99.6	\$ (29.1)	\$ 385.2	\$ 310.7	\$ (74.5)

The increase in selling, general and administrative (“SG&A”) expense in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was primarily due to an increase in employee-related expenses of \$14.0 million and \$35.4 million, respectively, and marketing and professional services fees of \$13.1 million and \$34.5 million, respectively. The increase in employee-related expenses was primarily due to an increase in our SG&A-related headcount of 17% from September 30, 2017 to September 30, 2018. The increase in marketing and professional services fees was primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products, and investment in ALKS 5461 as the FDA has issued a PDUFA target action date for the ALKS 5461 NDA of January 31, 2019.

Amortization of Acquired Intangible Assets

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
Amortization of acquired intangible assets	\$ 16.4	\$ 15.5	\$ (0.9)	\$ 48.7	\$ 46.4	\$ (2.3)

We amortize our amortizable intangible assets using the economic-use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at September 30, 2018 is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively.

Other Income (Expense), Net

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
Interest income	\$ 2.6	\$ 1.2	\$ 1.4	\$ 5.9	\$ 3.3	\$ 2.6
Interest expense	(3.4)	(3.1)	(0.3)	(11.9)	(8.8)	(3.1)
	4.2	13.6	(9.4)	(17.3)	15.9	(33.2)

Change in the fair value of contingent consideration						
Other expense, net	(0.1)	(9.1)	9.0	(2.8)	(10.7)	7.9
Total other (expense) income, net	\$ 3.3	\$ 2.6	\$ 0.7	\$ (26.1)	\$ (0.3)	\$ (25.8)

The increase in interest expense in the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was due to the Refinancing in March 2018. The Refinancing, which, among other things, extended the due date of the term loan from September 25, 2021 to March 26, 2023 and lowered the interest rate on our term loan from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with no LIBOR floor, resulted in a charge of \$2.3 million in the three months ended March 31, 2018. The Refinancing is discussed in greater detail in Note 10, Long-Term Debt in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

The decrease in the fair value of contingent consideration during the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, was primarily due to the complete response letter Recro received from the FDA in May 2018 regarding its NDA for IV Meloxicam. As a result of receipt of the complete response letter, we delayed our anticipated date for the FDA’s approval of the IV Meloxicam NDA and reduced the amount of forecasted sales due to this delay in our valuation model. Recro resubmitted the NDA for IV Meloxicam in September 2018 and the FDA assigned a PDUFA goal date of March 24, 2019. The valuation approach used to determine the fair value of the contingent consideration is discussed in greater detail in Note 5, Fair Value Measurements, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Income Tax Provision (Benefit)

(In millions)	Three Months			Nine Months		
	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)	Ended September 30, 2018	2017	Change Favorable/ (Unfavorable)
Income tax provision (benefit)	\$ 0.6	\$ 0.5	\$ (0.1)	\$ 4.3	\$ (5.9)	\$ (10.2)

The 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 unfavorable change in income taxes in the three and nine months ended September 30, 2018, as compared to the corresponding prior periods, was primarily due to an increase in income earned in the U.S.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	September 30, 2018			December 31, 2017		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	\$ 140.9	\$ 75.1	\$ 216.0	\$ 114.7	\$ 76.6	\$ 191.3
Investments—short-term	127.1	123.9	251.0	127.5	114.7	242.2
Investments—long-term	97.7	13.8	111.5	108.9	48.3	157.2
Total cash and investments	\$ 365.7	\$ 212.8	\$ 578.5	\$ 351.1	\$ 239.6	\$ 590.7
Outstanding borrowings—short and long-term	\$ 279.9	\$ —	\$ 279.9	\$ 281.4	\$ —	\$ 281.4

At September 30, 2018, our investments consisted of the following:

(In millions)	Amortized Cost	Gross		Estimated Fair Value
		Unrealized Gains	Unrealized Losses	
Investments—short-term	\$ 251.4	\$ —	\$ (0.4)	\$ 251.0
Investments—long-term available-for-sale	108.5	—	(0.7)	107.8
Investments—long-term held-to-maturity	3.5	0.2	—	3.7
Total	\$ 363.4	\$ 0.2	\$ (1.1)	\$ 362.5

Our investment objectives are to preserve capital, provide sufficient liquidity to satisfy operating requirements and generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily

of short- and long-term U.S. government and agency debt securities, corporate debt securities and debt securities issued by foreign agencies and backed by foreign governments. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. Available-for-sale investments in an unrealized gain position are classified as short-term investments, regardless of maturity date. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2018, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

Sources and Uses of Cash

We expect that our existing cash and investments balance will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments, for at least twelve months following the date on which this Form 10-Q is filed. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, debt refinancings, arrangements relating to assets or other financing methods or structures.

Information about our cash flows, by category, is presented in “Part I, Item 1–Condensed Consolidated Financial Statements of Cash Flows” of this Form 10-Q. The following table summarizes our cash flows for the nine months ended September 30, 2018 and 2017:

(In millions)	Nine Months Ended September 30,	
	2018	2017
Cash and cash equivalents, beginning of period	\$191.3	\$186.4
Cash flows provided by (used in) operating activities	38.7	(16.7)
Cash flows used in investing activities	(14.4)	(4.2)
Cash flows provided by (used in) financing activities	0.4	(0.4)
Cash and cash equivalents, end of period	\$216.0	\$165.1

The change in cash flows provided by operating activities in the nine months ended September 30, 2018, as compared to the cash flows used in operating activities in the nine months ended September 30, 2017, was primarily due to a 24% increase in cash received from our customers, which was driven in large part by the license and collaboration agreement with Biogen for BIIB098, as described above. This was partially offset by a 21% increase in cash paid to our employees, which was primarily due to a 12% increase in our headcount from September 30, 2017 to September 30, 2018.

The increase in cash flows used in investing activities in the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was due to a \$18.4 million increase in additions to our property, plant and equipment, which consisted predominately of construction of facilities and purchase of equipment at our Wilmington, Ohio location for the manufacture of products currently in development and existing proprietary products, partially offset by a \$7.8 million increase in the net sales of investments.

Borrowings

In March 2018, we completed the Refinancing related to the 2023 Term Loans. The 2023 Term Loans mature on March 26, 2023, bear interest for LIBOR Rate Loans (each capitalized term in this sentence as defined in the Amended Credit Agreement) at LIBOR plus 2.25%, with no LIBOR floor and for ABR Loans at ABR plus 1.25%, with an ABR floor of 1.00%.

The 2023 Term Loans amortize in equal quarterly amounts of 0.25% of the original principal amount of the loan, with the balance payable at maturity. The credit agreement, as amended by the March 2018 amendment (the “Amended Credit Agreement”), provides for incremental capacity in an amount of \$175,000,000 plus additional amounts so long

as we meet certain conditions, including a specified leverage ratio. The Amended Credit Agreement includes customary restrictive covenants subject to certain exceptions and baskets. The Amended Credit Agreement also contains customary affirmative covenants and events of default.

At September 30, 2018, the principal balance of our borrowings consisted of \$282.8 million outstanding under our 2023 Term Loans. See Note 10, Long-Term Debt, in the “Notes to condensed Consolidated Financial Statements” in this Form 10-Q, for a further discussion of our 2023 Term Loans.

Contractual Obligations

Refer to the “Contractual Obligations” section within “Part II, Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report and “Part I, Item 2 – Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Quarterly Report on Form 10-Q for the quarter ended March 30, 2018 for a discussion of our contractual obligations. Our contractual obligations have not materially changed from the descriptions in such reports.

Off-Balance Sheet Arrangements

At September 30, 2018, we were not party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different assumptions or conditions. Refer to “Critical Accounting Estimates” within “Part II, Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report for a discussion of our critical accounting estimates. In addition, refer to Note 3, Revenue from Contracts with Customers, in this Form 10-Q for a discussion of how we changed the way we recognize revenue under Topic 606.

New Accounting Standards

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in “Part II, Item 7A – Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are to preserve capital, provide sufficient liquidity to satisfy operating requirements and generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks since December 31, 2017, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products, partially offset by certain operating costs arising from expenses and payables in connection with our Irish operations that are settled predominantly in Euro. These foreign currency exchange rate risks are summarized in “Part II, Item 7A – Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since December 31, 2017.

Item 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of September 30, 2018. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2018 to provide reasonable assurance that the information required to be

43

disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings, refer to Note 14, Commitments and Contingencies in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, which is incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in our Annual Report and subsequent periodic reports. Further discussion of our risk factors appears in "Part I, Item 1A—Risk Factors" of our Annual Report, "Part II, Item 1A—Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and under the heading "Cautionary Note Concerning Forward-Looking Statements" in this Form 10-Q.

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the nine months ended September 30, 2018. As of September 30, 2018, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million.

During the three months ended September 30, 2018, we acquired 1,052 ordinary shares, at an average price of \$41.27 per share, related to the vesting of employee equity awards to satisfy withholding tax obligations.

Item 5. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended September 30, 2018, Mr. James M. Frates, an executive officer of the Company, entered into a trading plan in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for any revision or termination of an established trading plan.

Item 6. Exhibits

The following exhibits are filed or furnished as part of this Form 10-Q:

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1 #†	<u>Form of Incentive Stock Option Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</u>
10.2 #†	<u>Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</u>
10.3 #†	<u>Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</u>
10.4 #†	<u>Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</u>
10.5 #†	<u>Form of Non-Qualified Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</u>
10.6 #†	<u>Form of Incentive Stock Option Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.</u>
10.7 #†	<u>Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.</u>
10.8 #†	<u>Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.</u>
10.9 #†	<u>Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.</u>
10.10 #†	<u>Form of Non-Qualified Stock Option (Non-Employee Director) Award</u>

<u>Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.</u>	
10.11 #*	<u>Sixth Amendment to the Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006), effective as of July 1, 2018.</u>
10.12 #*	<u>First Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of October 3, 2018.</u>
31.1 #	<u>Rule 13a-14(a)/15d-14(a) Certification.</u>
31.2 #	<u>Rule 13a-14(a)/15d-14(a) Certification.</u>
32.1 ‡	<u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101 #+	The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2018, formatted in XBRL ("Extensible Business Reporting Language"): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements.

+XBRL (Extensible Business Reporting Language).

#Filed herewith.

‡Furnished herewith.

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

*Confidential treatment has been granted or requested for certain portions of this exhibit. Such portions have been filed separately with the SEC pursuant to a confidential treatment request.

SIGNATURES

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

ALKERMES plc

(Registrant)

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

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

Date: October 23, 2018