UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-1007018**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Connaught House
1 Burlington Road
Dublin 4, Ireland
(Address of principal executive offices)

+ 353-1-772-8000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
Emerging growth company ☐	

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

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of April 22, 2019 was 156,904,489 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2019

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," "intend," 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 those expectations related to product development, regulatory filings, regulatory approvals and regulatory timelines, therapeutic and commercial scope and potential, and the costs and expenses related to such activities;
- 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 or competitive products and competitive development programs;
- 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 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; and
- other factors discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, assumptions and uncertainties, the forward-looking events discussed in this Form 10-Q might not occur. For

more information regarding the risks, assumptions and uncertainties of our business, see "Part I, Item 1A—Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018 (the "Annual Report").

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 "Part I, 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 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 commercial drug products and a clinical pipeline of product candidates focused on central nervous system ("CNS") disorders such as schizophrenia, depression, addiction and multiple sclerosis ("MS"), and oncology. 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" in this Form 10-Q are intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references in this Form 10-Q 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®, VIVITROL® and VUMERITY™.

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

	March 31, 2019	December 31, 2018
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$225,234	$266,762
Investments—short-term	356,894	272,533
Receivables, net	222,811	292,223
Contract assets	8,447	8,230
Inventory	92,861	90,196
Prepaid expenses and other current assets	56,492	53,308
Total current assets	962,739	983,252
PROPERTY, PLANT AND EQUIPMENT, NET	320,004	309,987
INTANGIBLE ASSETS, NET	181,049	191,001
INVESTMENTS—LONG-TERM	43,005	80,744
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	37,600	65,200
RIGHT-OF-USE ASSETS	18,010	—
DEFERRED TAX ASSETS	87,605	85,807
OTHER ASSETS	13,651	16,143
TOTAL ASSETS	$1,756,536	$1,825,007
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$313,969	$333,762
Contract liabilities—short-term	2,078	3,169
Operating lease liabilities—short-term	8,795	—
Long-term debt—short-term	2,843	2,843
Total current liabilities	327,685	339,774
LONG-TERM DEBT	275,923	276,465
OTHER LONG-TERM LIABILITIES	28,425	27,958
OPERATING LEASE LIABILITIES—LONG-TERM	11,020	—
CONTRACT LIABILITIES—LONG-TERM	11,342	9,525
Total liabilities	654,395	653,722
COMMITMENTS AND CONTINGENT LIABILITIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 159,577,874 and 158,180,833 shares issued; 156,885,028 and 155,757,344 shares outstanding at March 31, 2019 and December 31, 2018, respectively	1,593	1,579
Treasury shares, at cost (2,692,846 and 2,423,489 shares at March 31, 2019 and December 31, 2018, respectively)	(117,949)	(108,969)
Additional paid-in capital	2,502,773	2,467,323
Accumulated other comprehensive loss	(2,510)	(3,280)
Accumulated deficit	(1,281,766)	(1,185,368)
Total shareholders' equity	1,102,141	1,171,285
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,756,536	$1,825,007

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

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended March 31,	
	2019	2018
	(In thousands, except per share amounts)	
REVENUES:		
Manufacturing and royalty revenues	$ 108,915	$ 114,601
Product sales, net	99,481	91,842
Research and development revenue	14,706	18,707
Total revenues	223,102	225,150
EXPENSES:		
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	45,361	44,476
Research and development	102,570	108,346
Selling, general and administrative	141,220	118,147
Amortization of acquired intangible assets	9,952	16,069
Total expenses	299,103	287,038
OPERATING LOSS	(76,001)	(61,888)
OTHER EXPENSE, NET:		
Interest income	3,570	1,485
Interest expense	(3,500)	(5,487)
Change in the fair value of contingent consideration	(22,600)	(1,900)
Other (expense) income, net	(1,721)	792
Total other expense, net	(24,251)	(5,110)
LOSS BEFORE INCOME TAXES	(100,252)	(66,998)
INCOME TAX BENEFIT	(3,854)	(4,493)
NET LOSS	$ (96,398)	$ (62,505)
LOSS PER ORDINARY SHARE:		
Basic and diluted	$ (0.62)	$ (0.40)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic and diluted	156,336	154,424
COMPREHENSIVE LOSS:		
Net loss	$ (96,398)	$ (62,505)
Holding gain (loss), net of a tax provision (benefit) of $229 and $(100), respectively	770	(336)
COMPREHENSIVE LOSS	$ (95,628)	$ (62,841)

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)

	Three Months Ended March 31,	
	2019	2018
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (96,398)	$ (62,505)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	19,642	25,722
Share-based compensation expense	24,616	20,042
Deferred income taxes	(3,225)	(4,101)
Change in the fair value of contingent consideration	22,600	1,900
Loss on debt refinancing	—	2,298
Payment made for debt refinancing	—	(1,840)
Other non-cash charges	1,116	(75)
Changes in assets and liabilities:		
Receivables	69,411	19,430
Contract assets	(217)	(16,959)
Inventory	(1,700)	(431)
Prepaid expenses and other assets	(69)	890
Right-of-use assets	2,131	—
Accounts payable and accrued expenses	(15,888)	(14,123)
Contract liabilities	725	245
Operating lease liabilities	(2,297)	—
Other long-term liabilities	1,765	2,669
Cash flows provided by (used in) operating activities	22,212	(26,838)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(23,639)	(18,485)
Proceeds from the sale of equipment	85	324
Proceeds from contingent consideration	5,000	—
Purchases of investments	(102,127)	(35,995)
Sales and maturities of investments	55,978	79,500
Cash flows (used in) provided by investing activities	(64,703)	25,344
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	10,554	13,164
Employee taxes paid related to net share settlement of equity awards	(8,880)	(15,724)
Principal payments of long-term debt	(711)	—
Payment made for debt refinancing	—	(737)
Cash flows provided by (used in) financing activities	963	(3,297)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(41,528)	(4,791)
CASH AND CASH EQUIVALENTS—Beginning of period	266,762	191,296
CASH AND CASH EQUIVALENTS—End of period	$ 225,234	$ 186,505
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 7,850	$ 7,516

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

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(unaudited)

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
				(In thousands, except share data)				
BALANCE — December 31, 2018	158,180,833	$ 1,579	$ 2,467,323	$ (3,280)	$ (1,185,368)	(2,423,489)	$ (108,969)	$ 1,171,285
Issuance of ordinary shares under employee stock plans	656,352	7	10,547	—	—	—	—	10,554
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	740,689	7	93	—	—	(269,357)	(8,980)	(8,880)
Share-based compensation expense	—	—	24,810	—	—	—	—	24,810
Unrealized gain on marketable securities, net of tax provision of $229	—	—	—	770	—	—	—	770
Net loss	—	—	—	—	(96,398)	—	—	(96,398)
BALANCE — March 31, 2019	159,577,874	$ 1,593	$ 2,502,773	$ (2,510)	$ (1,281,766)	(2,692,846)	$ (117,949)	$ 1,102,141

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
				(In thousands, except share data)				
BALANCE — December 31, 2017	156,057,632	$ 1,557	$ 2,338,755	$ (3,792)	$ (1,044,365)	(2,048,176)	$ (89,347)	$ 1,202,808
Issuance of ordinary shares under employee stock plans	539,563	6	13,159	—	—	—	—	13,165
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	716,123	7	(7)	—	—	(261,159)	(15,724)	(15,724)
Share-based compensation expense	—	—	20,176	—	—	—	—	20,176
Unrealized loss on marketable securities, net of tax benefit of $(100)	—	—	—	(337)	—	—	—	(337)
Cumulative effect adjustment related to the adoption of new accounting standards	—	—	—	—	(1,692)	—	—	(1,692)
Net loss	—	—	—	—	(62,505)	—	—	(62,505)
BALANCE — March 31, 2018	157,313,318	$ 1,570	$ 2,372,083	$ (4,129)	$ (1,108,562)	(2,309,335)	$ (105,071)	$ 1,155,891

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

1. THE COMPANY

Alkermes plc (the "Company") 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 commercial drug products and a clinical pipeline of product candidates focused on central nervous system ("CNS") disorders such as schizophrenia, depression, addiction and multiple sclerosis ("MS"), and oncology. Headquartered in Dublin, Ireland, the Company has a research and development ("R&D") center in Waltham, Massachusetts; R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three months ended March 31, 2019 and 2018 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2018. 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 United States ("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.

Income Taxes

The Company's income tax benefit in the three months ended March 31, 2019 and 2018 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 March 31, 2019, the Company maintained a valuation allowance against certain of its U.S. and foreign deferred tax assets. The Company evaluates, at each reporting period, the need for a valuation allowance on its deferred tax assets on a jurisdiction-by-jurisdiction basis.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued guidance that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Effective January 1, 2019, the Company adopted the requirements under Accounting Standards Update ("ASU") 2016-02, *Leases* ("Topic 842") using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. Topic 842 was issued in order to increase transparency and comparability among organizations by recognizing right-of-use lease assets and operating lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The main difference between previous GAAP ("Topic 840") and Topic 842 is the recognition of right-of-use lease assets and lease liabilities by lessees for those leases classified as operating leases under Topic 840. At January 1, 2019, the Company recorded a right-of-use asset of $20.1 million and an operating lease liability of $22.1 million. For additional information regarding how the Company is accounting for leases under Topic 842, refer to Note 9, *Leases*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, 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 ASU 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 ASU 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 ASU will have on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which 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. This ASU became effective for and was adopted by the Company in the year ending December 31, 2019 and the adoption of the ASU did not have an impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-14, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which aims to improve the effectiveness of fair value measurement disclosures. The amendments in this ASU 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. This ASU 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 ASU will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which 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). This ASU 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. This ASU 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 ASU will have on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction Between Topic 808 and Topic 606*, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB's revenue standard, Topic 606. This ASU 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 ASU 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).

Manufacturing and Royalty Revenue

During the three months ended March 31, 2019 and 2018, the Company recorded manufacturing and royalty revenues as follows:

	Three Months Ended March 31, 2019		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 53,298	$ 53,298
RISPERDAL CONSTA	17,921	4,385	22,306
AMPYRA/FAMPYRA	5,680	6,506	12,186
Other	7,346	13,779	21,125
	$ 30,947	$ 77,968	$ 108,915

	Three Months Ended March 31, 2018		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 46,086	$ 46,086
AMPYRA/FAMPYRA	13,563	14,696	28,259
RISPERDAL CONSTA	17,792	4,912	22,704
Other	6,236	11,316	17,552
	$ 37,591	$ 77,010	$ 114,601

Product Sales, Net

The Company's product sales, net consist of sales of VIVITROL and ARISTADA (together with ARISTADA INITIO) 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.

During the three months ended March 31, 2019 and 2018, the Company recorded product sales, net, as follows:

	Three Months Ended March 31,	
(In thousands)	**2019**	**2018**
VIVITROL	$ 69,183	$ 62,682
ARISTADA	30,298	29,160
Total product sales, net	$ 99,481	$ 91,842

Research and Development Revenue

The Company recorded research and development ("R&D") revenue of $13.9 million and $17.5 million during the three months ended March 31, 2019 and 2018, respectively, related to its license and collaboration agreement with Biogen for Diroximel fumarate ("BIIB098"). The Company expects to earn an additional $77.6 million in R&D revenue under this agreement with Biogen through 2021.

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. Contract assets are classified as current.

Contract assets consisted of the following:

(In thousands)	**Contract Assets**
Contract assets at January 1, 2019	$ 8,230
Additions	7,346
Transferred to receivables, net	(7,129)
Contract assets at March 31, 2019	$ 8,447

Contract Liabilities—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, 2019	$ 12,694
Additions	1,516
Amounts recognized into revenue	(790)
Contract liabilities at March 31, 2019	$ 13,420

4. INVESTMENTS

Investments consisted of the following (in thousands):

March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses Less than One Year	Gross Unrealized Losses Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 156,443	$ 349	$ (11)	$ (149)	$ 156,632
U.S. government and agency debt securities	108,113	257	(4)	(45)	108,321
International government agency debt securities	91,818	193	—	(70)	91,941
Total short-term investments	356,374	799	(15)	(264)	356,894
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	28,570	—	(84)	(45)	28,441
U.S. government and agency debt securities	10,984	—	(4)	(5)	10,975
	39,554	—	(88)	(50)	$ 39,416
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	102	—	—	1,769
	3,487	102	—	—	3,589
Total long-term investments	43,041	102	(88)	(50)	43,005
Total investments	399,415	901	(103)	(314)	399,899
December 31, 2018					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 120,197	$ 57	$ (62)	$ (274)	$ 119,918
U.S. government and agency debt securities	80,055	115	(11)	(87)	80,072
International government agency debt securities	72,091	85	(8)	(117)	72,051
	272,343	257	(81)	(478)	272,041
Held-to-maturity securities:					
Corporate debt securities	492	—	—	—	492
Total short-term investments	272,835	257	(81)	(478)	272,533
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	53,505	—	(185)	(93)	$ 53,227
U.S. government and agency debt securities	18,474	—	(21)	(12)	18,441
International government agency debt securities	5,457	—	(4)	—	5,453
	77,436	—	(210)	(105)	77,121
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	136	—	—	1,803
	3,487	136	—	—	3,623
Total long-term investments	80,923	136	(210)	(105)	80,744
Total investments	$ 353,758	$ 393	$ (291)	$ (583)	$ 353,277

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)	Three Months Ended March 31, 2019	2018
Proceeds from the sales and maturities of marketable securities	$ 55,978	$ 79,500
Realized gains	$ —	$ 1
Realized losses	$ 492	$ 4

The Company's available-for-sale and held-to-maturity securities at March 31, 2019 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$ 213,318	$ 213,172	$ 1,820	$ 1,820
After 1 year through 5 years	182,610	183,138	1,667	1,769
Total	$ 395,928	$ 396,310	$ 3,487	$ 3,589

At March 31, 2019, 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 March 31, 2019, the Company's total contribution in Fountain was equal to €5.5 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 months ended March 31, 2019 and 2018, the Company recorded a decrease in its investment in Fountain of less than $0.1 million. The changes recorded represent the Company's proportional share of Fountain's net losses for these periods. The Company's $5.6 million and $5.5 million net investment in Fountain at March 31, 2019 and December 31, 2018, respectively, was included within "Other assets" in the accompanying condensed consolidated balance sheets.

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)	March 31, 2019	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 62,556	$ 62,556	$ —	$ —
U.S. government and agency debt securities	119,296	68,704	50,592	—
Corporate debt securities	185,073	—	185,073	—
International government agency debt securities	91,941	—	91,941	—
Contingent consideration	37,600	—	—	37,600
Common stock warrants	772	—	—	772
Total	$ 497,238	$ 131,260	$ 327,606	$ 38,372

	December 31, 2018	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 54,590	$ 54,590	$ —	$ —
U.S. government and agency debt securities	98,513	60,107	38,406	—
Corporate debt securities	173,637	—	173,145	492
International government agency debt securities	77,504	—	77,504	—
Contingent consideration	65,200	—	—	65,200
Common stock warrants	1,205	—	—	1,205
Total	$ 470,649	$ 114,697	$ 289,055	$ 66,897

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 three months ended March 31, 2019. 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 March 31, 2019:

(In thousands)	Fair Value
Balance, January 1, 2019	$ 66,897
Change in the fair value of contingent consideration	(22,600)
Payment received for contingent consideration	(5,000)
Impairment of corporate debt security	(492)
Decrease in the fair value of warrants	(433)
Balance, March 31, 2019	$ 38,372

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

The Company's contingent consideration relates to the divestiture of its Gainesville, GA facility in March 2015 (the "Gainesville Transaction"). On December 20, 2018, the Company entered into a Second Amendment to the Purchase and Sale Agreement ("Purchase and Sale Agreement Amendment") with Recro Pharma, Inc. ("Recro"), pursuant to which the Company received one $5.0 million payment in the first quarter of 2019 and will receive another $5.0 million payment in the second quarter of 2019; the Company is eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other Meloxicam Product(s); and is eligible to receive up to $130.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

In accordance with the accounting standard for fair value measurements, the Company's contingent consideration has been classified as a Level 3 asset as its fair value is based on significant inputs not observable in the market. The fair value of the contingent consideration at March 31, 2019 was determined as follows:

- The Company received $5.0 million in the first quarter of 2019 and expects to receive another $5.0 million in the second quarter of 2019; the Company is entitled to receive $5.0 million upon regulatory approval of a New Drug Application ("NDA") for the first Meloxicam Product; and $45.0 million in seven equal, annual installments beginning on the first anniversary of such approval. The fair value of the regulatory milestone was estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone event to occur in the first quarter of 2020 and used a discount rate of 16.0%;

- 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 given approval and IP protection. These expected payments were then discounted using a discount rate of 16.0%, which the Company 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 of 15.0%.

Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration recorded in any given period.

In March 2019, Recro received a second complete response letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding its NDA for IV Meloxicam. As a result of Recro's receipt of this second CRL, the Company delayed its anticipated date for the FDA's approval of the IV Meloxicam NDA and reduced the probability of success and amount of forecasted sales due to this delay in our valuation model. At March 31, 2019 and December 31, 2018, the Company determined that the value of the contingent consideration was $37.6 million and $65.2 million, respectively. The Company recorded a decrease of $22.6 million and $1.9 million during the three months ended March 31, 2019 and 2018, respectively, within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss.

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

6. INVENTORY

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

(In thousands)	March 31, 2019	December 31, 2018
Raw materials	$ 33,526	$ 31,824
Work in process	41,548	38,019
Finished goods(1)	17,787	20,353
Total inventory	$ 92,861	$ 90,196

(1) At March 31, 2019 and December 31, 2018, the Company had $11.7 million and $11.0 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Land	$ 6,560	$ 6,486
Building and improvements	170,289	157,053
Furniture, fixtures and equipment	320,882	314,831
Leasehold improvements	20,105	20,105
Construction in progress	89,245	88,983
Subtotal	607,081	587,458
Less: accumulated depreciation	(287,077)	(277,471)
Total property, plant and equipment, net	$ 320,004	$ 309,987

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	March 31, 2019 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	$ 465,590	$ (326,532)	$ 139,058
NanoCrystal technology	13	74,600	(40,873)	33,727
OCR technologies	12	42,560	(34,296)	8,264
Total		$ 582,750	$ (401,701)	$ 181,049

Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at March 31, 2019 is expected to be approximately $40.0 million, $40.0 million, $40.0 million, $35.0 million and $35.0 million in the years ending December 31, 2019 through 2023, 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.

9. LEASES

The Company adopted Topic 842 on January 1, 2019. Topic 842 allows the Company to elect a package of practical expedients, which include: (i) an entity need not reassess whether any expired or existing contracts are or contain leases; (ii) an entity need not reassess the lease classification for any expired or existing leases; and (iii) an entity need not reassess any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize this package of practical expedients and has not elected the hindsight methodology in its implementation of Topic 842.

The Company elected to adopt this standard using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. With the adoption of Topic 842, the Company's condensed consolidated balance sheet now contains the following line items: Right-of-use assets, Operating lease liabilities—short-term and Operating lease liabilities—long-term.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2019:

- An operating lease for 175,000 square feet of office and laboratory space in Waltham, Massachusetts that expires in 2021, with an option to extend the term for up to two five-year periods;
- An operating lease for 67,000 square feet of office space in Waltham, Massachusetts that expires in 2020, with an option to extend the term for up to two one-year periods;
- An operating lease for 14,600 square feet of office space in Dublin, Ireland that expires in 2022, with an option to extend the term for an additional five-year period; and
- An operating lease for 7,000 square feet of corporate office and administrative space in Washington, D.C. that expires in 2029 and includes an option to extend the term for an additional five-year period.

The Company also has two additional operating leases that are included in its lease accounting but are not considered significant.

The Company has elected to not recognize right-of-use assets and lease liabilities arising from short-term leases, which are leases that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

As all the existing leases subject to the new lease standard were previously classified as operating leases by the Company, they were similarly classified as operating leases under the new standard. The Company has determined that the identified operating leases did not contain non-lease components and require no further allocation of the total lease cost. Additionally, the agreements in place did not contain information to determine the rate implicit in the leases. As such, the Company calculated the incremental borrowing rate based on the assumed remaining lease term for each lease in order to calculate the present value of the remaining lease payments. At March 31, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 4.46% and 4.1 years, respectively.

As of March 31, 2019, right-of-use assets and liabilities arising from operating leases were $18.0 million and $19.8 million, respectively. During the three months ended March 31, 2019, cash paid for amounts included for the measurement of lease liabilities was $2.3 million and the Company recorded operating lease expense of $2.1 million.

Future lease payments under non-cancelable leases as of March 31, 2019 and December 31, 2018:

(In thousands)	March 31, 2019	December 31, 2018
2019	$ 6,806	$ 9,394
2020	8,652	10,717
2021	2,520	4,706
2022	500	2,455
2023	509	2,389
Thereafter	3,100	23,940
Total lease payments	$ 22,087	$ 53,601
Less: imputed interest	(2,272)	—
Total operating lease liabilities	$ 19,815	$ 53,601

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 that is being 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.

As the Company (a) does not have the right to obtain or control the leased premises during the construction period; (b) does not have the right of payment for the partially constructed assets and, thus, could be potentially leased to another tenant; and (c) does not legally own or control the land on which the property improvements are being constructed, it was not included as a right-of-use asset at March 31, 2019. Additionally, the future lease payments, outlined above, included the 900 Winter Street payments as of December 31, 2018; these payments are not included in the table under Topic 842.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Accounts payable	$ 48,956	$ 39,767
Accrued compensation	48,653	67,613
Accrued sales discounts, allowances and reserves	140,736	152,911
Accrued other	75,624	73,471
Total accounts payable and accrued expenses	$ 313,969	$ 333,762

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
2023 Term Loans, due March 26, 2023	$ 278,766	$ 279,308
Less: current portion	(2,843)	(2,843)
Long-term debt	$ 275,923	$ 276,465

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 a 0% 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.

The estimated fair value of the 2023 Term Loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy, as described in Note 5, *Fair Value Measurements*, above) and which may not be representative of actual values that could have been, or will be, realized in the future, was $277.5 million and $274.7 million at March 31, 2019 and December 31, 2018, respectively.

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	March 31, 2019	March 31, 2018
Cost of goods manufactured and sold	$ 1,978	$ 1,418
Research and development	7,746	6,714
Selling, general and administrative	14,892	11,910
Total share-based compensation expense	$ 24,616	$ 20,042

At March 31, 2019 and December 31, 2018, $2.9 million and $2.7 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.

In December 2018, the Company achieved the pre-specified primary efficacy endpoints on its second of the two phase 3 studies of ALKS 3831, resulting in the vesting of a portion of the performance-based RSUs and the recognition

of $17.1 million in share-based compensation expense related to these awards. The Company recognized $2.1 million, $6.7 million and $8.3 million of this expense in cost of goods manufactured and sold; R&D expense; and SG&A expense, respectively.

At March 31, 2019, there was $33.2 million of unrecognized compensation cost related to the remaining unvested portion of the performance-based RSUs, which would be recognized in accordance with the terms of the award if and when the Company deems it probable that the performance criteria will be met. The unvested portion of the awards will expire if the performance conditions have not been met on or before the three-year anniversary of the grant date.

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 months ended March 31, 2019 and 2018, 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 March 31,	
(In thousands)	2019	2018
Stock options	12,522	10,217
Restricted stock units	2,232	2,808
Total	14,754	13,025

14. COMMITMENTS AND CONTINGENT LIABILITIES

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, utilizing all 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 March 31, 2019, 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 U.S. 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, including the section entitled "—We or our licensees may face claims against intellectual property 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.

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 were 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 which pertained 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. On October 24, 2018, Acorda filed a petition for rehearing and rehearing en banc of the Federal Circuit's decision. On January 4, 2019, the Federal Circuit denied Acorda's petition. On April 4, 2019, Acorda filed a petition for writ of certiorari to the Supreme Court of the United States.

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, including the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

VIVITROL IPR Proceeding

On April 20, 2018, Amneal Pharmaceuticals LLC filed a petition with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office seeking an inter partes review ("IPR") of U.S. Patent Number 7,919,499 (the " '499 Patent"), which is an Orange Book-listed patent for VIVITROL, seeking cancellation of claims 1-13 of the '499 Patent. On November 7, 2018, the PTAB issued an order instituting an IPR of all challenged claims. On February 7, 2019, the Company filed its patent owner's response. Amneal's reply is due on May 7, 2019. A decision on the matter is expected by November 7, 2019. 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, including 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, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business."

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co Ltd, Pharmathen SA, Teva Pharmaceutical Industries Ltd and Dehns Ltd (a law firm representing an unidentified opponent) filed notices of opposition with the European Patent Office (the "EPO") in respect of EP 2 269 577 B (the "EP '577" Patent), which is a patent directed to certain risperidone microsphere compositions, including RISPERDAL CONSTA. Following a hearing on the matter on January 23, 2019, on April 8, 2019, the EPO issued a written decision revoking the EP'577 Patent. The Company has approximately two months from the date of the decision to appeal the decision to the EPO's Technical Boards of Appeal. The Company will continue to vigorously defend the EP '577 Patent. For information about risks relating to the EP '577 Patent opposition proceedings see "Part I, Item 1A—Risk Factors" of the Company's Annual Report, including 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, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business."

Government Matters

On June 22, 2017 and January 17, 2019, the Company received a subpoena and a civil investigative demand, respectively, each from an Office of the U.S. Attorney for documents related to VIVITROL. The Company is cooperating with the government.

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, "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 was 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 through November 14, 2017 and alleged 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 sought, 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. On March 28, 2019, the United States District Court for the Southern District of New York issued an order granting Defendants' motion to dismiss and dismissing the case in its entirety and with prejudice. On April 11, 2019, the lead plaintiff filed a motion for reconsideration. Briefing on the motion for reconsideration will be completed on May 2, 2019. For information about risks relating to this action, see "Part I, Item 1A—Risk Factors" of the Company's Annual Report, including 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."

On December 27, 2018, a purported stockholder of the Company filed a putative class action against the Company and certain of its officers in the United States District Court for the Eastern District of New York captioned Karimian v. Alkermes plc, et al., No. 1:18-cv-07410. On January 31, 2019, a purported stockholder of the Company filed a similar putative class action against the Company and the same officers in the United States District Court for the Eastern District of New York captioned McDermott v. Alkermes plc, et al., No. 1:19-cv-00624. These complaints were filed on behalf of putative classes of purchasers of Alkermes securities during the period of February 17, 2017 through November 1, 2018 and allege 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 regulatory submission for ALKS 5461 and the FDA's review and consideration of that submission. The lawsuits seek, among other things, unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. On March 12, 2019, the United States District Court for the Eastern District of New York consolidated the two cases and appointed a lead plaintiff. For information about risks relating to these actions, see "Part I, Item 1A—Risk Factors" of the Company's Annual Report, including 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 was filed with the U.S. Securities and Exchange Commission (the "SEC") on February 15, 2019.

Executive Summary

Net loss for the three months ended March 31, 2019 was $96.4 million or $0.62 per ordinary share— basic and diluted, as compared to a net loss of $62.5 million or $0.40 per ordinary share— basic and diluted for the three months ended March 31, 2018.

The increase in the net loss in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, was primarily due to a $22.6 million reduction in the fair value of contingent consideration related to the CRL that Recro received regarding its NDA for IV Meloxicam in March 2019 and an increase in selling, general and administrative ("SG&A") expenses of 20% in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. 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)	Party Responsible for Commercialization	Territory
	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	Alkermes	U.S.
	Schizophrenia	Alkermes	U.S.
	Alcohol dependence and Opioid dependence	Alkermes Cilag GmbH International (“Cilag”)	U.S. Russia and Commonwealth of Independent States (“CIS”)

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

Proprietary Products

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

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA is the first of our products to utilize our proprietary LinkeRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is available in four dose strengths with once-monthly dosing (441 mg, 662 mg, 882 mg), a six-week dosing option (882 mg) and a two-month dosing option (1064 mg). ARISTADA is packaged in a ready-to-use, pre-filled product format. We developed ARISTADA and manufacture and commercialize it in the U.S.

In April 2019, we announced positive topline results from ALPINE ("**A**ripiprazole **L**auroxil and **P**aliperidone palmitate: **IN**itiation **E**ffectiveness"), a six-month study evaluating the efficacy, safety and tolerability of ARISTADA

and INVEGA SUSTENNA when used to initiate patients experiencing an acute exacerbation of schizophrenia in the hospital and maintain treatment in an outpatient setting. Data were presented at the 2019 Congress of the Schizophrenia International Research Society ("SIRS").

In March 2019, U.S. Patent Nos. 10,226,458 and 10,238,651 relating to ARISTADA were granted. These patents have claims to methods of treating schizophrenia and expire in 2032 and 2035, respectively.

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 our proprietary NanoCrystal technology and provides an extended-release formulation of aripiprazole lauroxil in a smaller particle size compared to ARISTADA. This smaller particle size enables faster dissolution and leads 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, when used to initiate onto any dose of ARISTADA, 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.

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.

For a discussion of legal proceedings related to the patents covering VIVITROL, see Note 14, *Commitments and Contingent Liabilities* 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" in our Annual Report, including the sections entitled "— Patent protection for our products is important and uncertain," "— Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business" and "— Litigation, arbitration or regulatory action (such as citizens petitions) filed against regulatory agencies related to our product or Alkermes, including securities litigation, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

Products Using Our Proprietary Technologies

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

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate 3-month 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 legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 14, *Commitments and Contingent Liabilities* 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" in our Annual Report, including the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

INVEGA TRINZA is approved in the U.S. for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA is the first schizophrenia treatment to be taken once every three months. 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. For a discussion of legal proceedings related to one of the patents covering RISPERDAL CONSTA, see Note 14, *Commitments and Contingent Liabilities* 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" in our Annual Report, including the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

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, and in oncology. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key R&D programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in "Part I, Item 1A—Risk 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 key development candidates.

Diroximel fumarate (BIIB098)

Diroximel fumarate ("BIIB098"), formerly referred to as ALKS 8700, is a novel, oral fumarate in development for the treatment of relapsing forms of MS. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and may have the potential to offer differentiated gastrointestinal tolerability due to its chemical structure as compared to the currently marketed dimethyl fumarate, TECFIDERA.

The pivotal clinical program for diroximel fumarate consists of pharmacokinetic bridging studies comparing diroximel fumarate and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of diroximel fumarate, which we initiated in December 2015. We submitted a 505(b)(2) NDA for diroximel fumarate in December 2018, which was accepted for review by the FDA in February 2019. The NDA was assigned a Prescription Drug User Fee Act ("PDUFA") target action date in the fourth quarter of 2019. For more information about 505(b)(2) NDAs, see "Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act" of our Annual Report. In addition, EVOLVE-MS-2, an elective, randomized, head-to-head phase 3 study of the gastrointestinal tolerability of diroximel fumarate versus TECFIDERA is ongoing, with topline results expected in mid-2019.

In November 2017, we entered into an exclusive license and collaboration agreement with Biogen relating to diroximel fumarate. For more information about the license and collaboration agreement with Biogen, see "Part 1, Item

1—Business, Collaborative Arrangements" of our Annual Report. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY, which has been conditionally accepted by the FDA and will be confirmed upon approval.

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 robust antipsychotic efficacy of olanzapine while mitigating olanzapine-associated weight gain.

The ENLIGHTEN clinical development program for ALKS 3831 includes two key phase 3 studies: ENLIGHTEN-1, a four-week study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo, and ENLIGHTEN-2, a six-month study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of ALKS 3831.

In November 2018, we announced positive topline results from ENLIGHTEN-2. ALKS 3831 met the prespecified co-primary endpoints, demonstrating both a lower mean percent weight gain from baseline at six months compared to the olanzapine group, and a lower proportion of patients who gained 10% or more of their baseline body weight at six months compared to the olanzapine group. The most common adverse events reported in the ALKS 3831 treatment group were weight gain, somnolence and dry mouth. In April 2019, we presented additional data from the ENLIGHTEN-2 study and interim results from an ongoing ENLIGHTEN-2 52-week open-label, safety extension study at SIRS.

We plan to conduct a pre-NDA meeting with the FDA in the second quarter of 2019 to discuss the FDA's key requirements including the efficacy, safety, weight and metabolic profile of ALKS 3831, and plan to submit an NDA for ALKS 3831 in mid-2019.

ALKS 4230

ALKS 4230 is a novel, engineered fusion protein designed to selectively activate tumor-killing immune cells while avoiding the expansion of immunosuppressive cells by preferentially binding to the intermediate affinity interleukin-2 ("IL-2") receptor complex. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects of existing IL-2 therapy, while mitigating certain limitations. 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.

ARTISTRY-1, a phase 1 study for ALKS 4230 in which ALKS 4230 is administered as an intravenous infusion, is designed to evaluate the safety profile and anti-tumor activity of ALKS 4230 as a monotherapy agent and in combination with the anti-PD-1 therapy, pembrolizumab. A dose-escalation stage designed to determine the 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 ARTISTRY-1 in patients with renal cell carcinoma or melanoma. Initial data from the dose-escalation stage of ARTISTRY-1, demonstrating dose-dependent pharmacodynamic effects on circulating CD8+ T cells and natural killer cells with minimal and non-dose dependent effect on immunosuppressive regulatory T cells, were presented at the 2018 Society for Immunotherapy of Cancer meeting. The combination therapy stage of ARTISTRY-1 is also ongoing, assessing ALKS 4230 in combination with pembrolizumab in patients with select advanced solid tumors.

In February 2019, we announced the initiation of ARTISTRY-2, a new phase 1/2 study of ALKS 4230 administered subcutaneously as monotherapy and in combination with pembrolizumab in patients with advanced solid tumors. ARTISTRY-2 will be conducted in two stages: dose-escalation followed by dose-expansion. The dose-escalation stage is designed to evaluate the safety and tolerability of ascending doses of ALKS 4230 administered subcutaneously once-weekly and once-every-three-weeks as both lead-in monotherapy and in combination with pembrolizumab. Following identification of the optimal dose and recommended dosing schedule, the dose-expansion stage of the study will evaluate ALKS 4230 administered subcutaneously in combination with pembrolizumab in patients with advanced solid tumors.

The dose-expansion stage will evaluate overall response rate, duration of response, non-progression rate at specific time points and overall survival.

ALKS 5461 Update

ALKS 5461 is a proprietary, once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of major depressive disorder ("MDD") in patients with an inadequate response to standard antidepressant therapies. ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist.

The clinical development program for ALKS 5461 included three core phase 3 efficacy studies (FORWARD-3, FORWARD-4 and FORWARD-5), one core phase 2 efficacy study (Study 202), and additional supportive studies to evaluate the long-term safety, dosing, pharmacokinetic profile and human abuse potential of ALKS 5461. Our NDA for ALKS 5461, submitted to the FDA in January 2018, and accepted for review by the FDA in April 2018 after the issuance, and then rescission, of a refusal to file letter, was based on a comprehensive clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD.

In February 2019, we announced receipt of a CRL from the FDA for the ALKS 5461 NDA. The CRL states that the FDA is unable to approve the ALKS 5461 NDA in its present form and requests additional clinical data to provide substantial evidence of effectiveness of ALKS 5461 for the adjunctive treatment of MDD. We are evaluating next steps for ALKS 5461.

Results of Operations

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned in the three months ended March 31, 2019 and 2018:

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 53.3	$ 46.1	7.2
RISPERDAL CONSTA	22.3	22.7	$ (0.4)
AMPYRA/FAMPYRA	12.2	28.3	$ (16.1)
Other	21.1	17.5	3.6
Manufacturing and royalty revenues	$ 108.9	$ 114.6	$ (5.7)

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three months ended March 31, 2019, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $790.0 million, as compared to $696.0 million during the three months ended March 31, 2018. 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 decrease in revenues from RISPERDAL CONSTA was primarily due to an 11% decrease in RISPERDAL CONSTA royalty revenue. End-market sales of RISPERDAL CONSTA were $179.0 million in the three months ended March 31, 2019 as compared to $196.0 million in the three months ended March 31, 2018. We recognize manufacturing revenue, equal to 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA, at the point in time when RISPERDAL CONSTA has been fully manufactured, which is when the product is approved for shipment. We record royalty revenue, equal to 2.5% of end-market net sales, when the end-market sale of RISPERDAL CONSTA occurs.

The decrease in the amount of manufacturing and royalty revenue recognized for AMPYRA and FAMPYRA was primarily due to the entry of generic forms of AMPYRA to the U.S. market in September 2018. AMPYRA revenues

decreased by 80% in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. We do not anticipate manufacturing any AMPYRA for Acorda during the remainder of 2019. This decrease related to AMPYRA was partially offset by a 30% increase in FAMPYRA revenues. The increase in FAMPYRA revenues was due to a 43% increase in manufacturing revenue due to an increase in the amount of FAMPYRA we manufactured and a 10% increase in royalty revenue due to higher estimated net sales of FAMPYRA. We recognize manufacturing revenues for AMPYRA and FAMPYRA and royalty revenue from AMPYRA over time as the products move through the manufacturing process, using an input method based on costs as a measure of progress. Royalty revenue from FAMPYRA is recognized in the period FAMPYRA is sold by Biogen.

Product Sales, net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO 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 months ended March 31, 2019 and 2018:

	March 31,			
(In millions)	**2019**	**% of Sales**	**2018**	**% of Sales**
Product sales, gross	$ 196.1	100.0 %	$ 177.6	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(47.2)	(24.1) %	(41.6)	(23.4) %
Chargebacks	(16.8)	(8.6) %	(14.7)	(8.3) %
Product discounts	(15.1)	(7.7) %	(14.1)	(7.9) %
Medicare Part D	(7.5)	(3.8) %	(5.4)	(3.0) %
Other	(10.0)	(5.1) %	(10.0)	(5.7) %
Total adjustments	(96.6)	(49.3) %	(85.8)	(48.3) %
Product sales, net	$ 99.5	50.7 %	$ 91.8	51.7 %

Our product sales, net, for VIVITROL and ARISTADA/ARISTADA INITIO in the three months ended March 31, 2019 were $69.2 million and $30.3 million, respectively, as compared to $62.7 million and $29.1 million in the three months ended March 31, 2018, respectively.

The increase in product sales, gross was primarily due to increased unit sales of both VIVITROL and ARISTADA. VIVITROL product sales, gross, increased by 8%, which was due to an increase in the number of VIVITROL units sold. We did not have a price increase for VIVITROL in 2018 or in the three months ended March 31, 2019. ARISTADA and ARISTADA INITIO collective product sales, gross, increased by 15%, which was due to a 4% increase in the number of ARISTADA and ARISTADA INITIO collective units sold and a 4% and a 6% price increase that went into effect in July 2018 and February 2019, respectively. This was partially offset by a 41% increase in Medicaid rebates and a 34% increase in Medicare Part D claims related to ARISTADA and ARISTADA INITIO.

Research and Development Revenue

	Three Months Ended March 31,		Change Favorable/
(In millions)	**2019**	**2018**	**(Unfavorable)**
Research and development revenue	$ 14.7	$ 18.7	$ (4.0)

The decrease in R&D revenue was primarily due to the revenue earned under the license and collaboration agreement with Biogen for BIIB098. Our R&D revenues earned under our license and collaboration agreement with Biogen for BIIB098 were $13.9 million and $17.5 million in the three months ended March 31, 2019 and 2018, respectively, and the decrease is due to the timing of activity within the program. As previously discussed, we submitted a 505(b)(2) NDA for BIIB098 in December 2018, which was accepted by the FDA for review in February 2019.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	$ 45.4	$ 44.5	$ (0.9)

The increase in cost of goods manufactured and sold was primarily due to a 19% increase in cost of goods sold related to VIVITROL due to an increase in sales of VIVITROL. This increase was partially offset by a restructuring charge of $3.2 million within cost of goods manufactured and sold recorded during the three months ended March 31, 2018 due to management's approval of a restructuring plan at our Athlone, Ireland manufacturing facility designed to streamline future operational performance. The restructuring plan consisted of severance and outplacement services for a reduction in headcount of 24 employees.

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 months ended March 31, 2019 and 2018 relating to each of our development programs and our internal R&D expenses by the nature of such expenses:

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
External R&D Expenses:			
Development programs:			
BIIB098	$ 9.3	$ 11.5	$ 2.2
ALKS 3831	7.7	15.1	7.4
ALKS 5461	6.4	8.3	1.9
ALKS 4230	5.2	7.1	1.9
ARISTADA and ARISTADA line extensions	3.0	4.6	1.6
Other external R&D expenses	12.5	11.2	(1.3)
Total external R&D expenses	44.1	57.8	13.7
Internal R&D expenses:			
Employee-related	46.3	39.6	(6.7)
Depreciation	3.3	2.7	(0.6)
Occupancy	3.0	2.9	(0.1)
Other	5.9	5.3	(0.6)
Total internal R&D expenses	58.5	50.5	(8.0)
Research and development expenses	$ 102.6	$ 108.3	$ 5.7

These amounts are not necessarily predictive of future R&D expenses. In an effort to allocate our spending most effectively, we continually evaluate our 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 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 and TECFIDERA in patients with relapsing-remitting MS in March 2017. 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 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 decrease in expenses related to ARISTADA and ARISTADA line extensions was primarily due to the timing of the ALPINE study, as described under the heading "Key Development Programs" above. The decrease in expenses related to ALKS 4230 was primarily related to the timing of the ARTISTRY development program for ALKS 4230, as described under the heading "Key Development Programs" above.

The increase in employee-related expenses was primarily due to an increase in R&D headcount of 14% from March 31, 2018 to March 31, 2019.

Selling, General and Administrative Expense

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
Selling, general and administrative expense	$ 141.2	$ 118.1	$ (23.1)

The increase in SG&A expense was primarily due to an increase in employee-related expenses of $17.0 million and marketing and professional services fees of $5.5 million. The increase in employee-related expenses was primarily due to an increase in our SG&A-related headcount of 22% from March 31, 2018 to March 31, 2019. The increase in marketing and professional services fees was primarily due to additional brand investments in VIVITROL, ARISTADA and ARISTADA INITIO, as well as an increase in patient access support services, such as reimbursement and transition assistance, for all of these products.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
Amortization of acquired intangible assets	$ 10.0	$ 16.1	$ 6.1

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 March 31, 2019 is expected to be approximately $40.0 million, $40.0 million, $40.0 million, $35.0 million and $35.0 million in the years ending December 31, 2019 through 2023, respectively.

Other Expense, net

(In millions)	Three Months Ended March 31, 2019	2018	Change Favorable/ (Unfavorable)
Interest income	$ 3.6	$ 1.5	$ 2.1
Interest expense	(3.5)	(5.5)	2.0
Change in the fair value of contingent consideration	(22.6)	(1.9)	(20.7)
Other (expense) income, net	(1.7)	0.8	(2.5)
Total other expense, net	$ (24.2)	$ (5.1)	$ (19.1)

The decrease in the fair value of contingent consideration was primarily due to Recro's receipt of a second CRL from the FDA in March 2019 regarding its NDA for IV Meloxicam. As a result of this second CRL, we delayed our anticipated date for the FDA's approval of the IV Meloxicam NDA and reduced the probability of success and amount of forecasted sales due to this delay in our valuation model. 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 Benefit

(In millions)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018	Change Favorable/ (Unfavorable)
Income tax benefit	$ (3.9)	$ (4.5)	$ (0.6)

The income tax benefit in the three months ended March 31, 2019 primarily relates to a $7.9 million discrete tax benefit to take account of proposed foreign derived intangible income regulations issued by the Department of the Treasury and the U.S. Internal Revenue Service in March 2019. The benefit is partially offset by a $4.9 million discrete tax expense for employee equity activity during the quarter. The income tax benefit in the three months ended March 31, 2018 primarily relates to U.S. federal and state taxes on employee equity activity during the period.

We will continue to evaluate the impact of tax legislation and will update our disclosures as additional information and interpretive guidance becomes available.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	March 31, 2019 U.S.	March 31, 2019 Ireland	March 31, 2019 Total	December 31, 2018 U.S.	December 31, 2018 Ireland	December 31, 2018 Total
Cash and cash equivalents	$ 140.4	$ 84.8	$ 225.2	$ 139.3	$ 127.5	$ 266.8
Investments—short-term	285.3	71.6	356.9	203.3	69.2	272.5
Investments—long-term	17.8	25.2	43.0	51.5	29.2	80.7
Total cash and investments	$ 443.5	$ 181.6	$ 625.1	$ 394.1	$ 225.9	$ 620.0
Outstanding borrowings—short and long-term	$ 278.8	$ —	$ 278.8	$ 279.3	$ —	$ 279.3

At March 31, 2019, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 356.4	$ 0.8	$ (0.3)	$ 356.9
Investments—long-term available-for-sale	39.5	—	(0.1)	39.4
Investments—long-term held-to-maturity	3.5	0.1	—	3.6
Total	$ 399.4	$ 0.9	$ (0.4)	$ 399.9

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 March 31, 2019, 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 three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
(In millions)	**2019**	**2018**
Cash and cash equivalents, beginning of period	$ 266.8	$ 191.3
Cash flows provided by (used in) operating activities	22.2	(26.8)
Cash flows (used in) provided by investing activities	(64.7)	25.3
Cash flows provided by (used in) financing activities	0.9	(3.3)
Cash and cash equivalents, end of period	$ 225.2	$ 186.5

The change in cash flows from operating activities in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, was primarily due to a 33% 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 24% increase in cash paid to our employees, which was primarily due to a 12% increase in our headcount from March 31, 2018 to March 31, 2019.

The increase in cash flows from investing activities in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, was primarily due to an $89.7 million increase in the net purchases of investments, partially offset by a $5.0 million payment we received from Recro in connection with the contingent consideration from the Gainesville Transaction.

The change in cash flows from financing activities in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, was primarily due to a $4.2 million increase in cash received from our employees upon the exercise of stock options, net of employee taxes.

Borrowings

At March 31, 2019, the principal balance of our borrowings consisted of $281.4 million outstanding under our 2023 Term Loans. See Note 11, *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 for a discussion of our contractual obligations. Our contractual obligations have not materially changed from the date of our Annual Report.

Off-Balance Sheet Arrangements

At March 31, 2019, 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.

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. In addition, refer to Note 9, *Leases*, in this Form 10-Q for a discussion of how we changed the way we account for leases under Topic 842.

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, 2018, 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, 2018.

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 March 31, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2019 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

For information regarding legal proceedings, refer to Note 14, *Commitments and Contingent Liabilities* 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***

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the three months ended March 31, 2019. As of March 31, 2019, we had purchased a total of 8,866,342 shares under this program at a cost of $114.0 million.

During the three months ended March 31, 2019, we acquired 266,319 of our ordinary shares, at an average price of $33.35 per share, related to the vesting of employee equity awards to satisfy withholding tax obligations. During the three months ended March 31, 2019, we acquired 3,038 of our ordinary shares, at an average price of $32.92 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

Item 5. ***Other Information***

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended March 31, 2019, Messrs. James M. Frates, David J. Gaffin, Craig C. Hopkinson, Michael J. Landine and Richard F. Pops, each an executive officer of the Company, entered into a trading plan in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for 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 #	Second Amendment, effective as of January 31, 2019, to License and Collaboration Agreement by and between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH dated November 27, 2017.
31.1 #	Rule 13a-14(a)/15d-14(a) Certification.
31.2 #	Rule 13a-14(a)/15d-14(a) Certification.
32.1 ‡	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH #	XBRL Taxonomy Extension Schema Document.
101.CAL #	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF #	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB #	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE #	XBRL Taxonomy Extension Presentation Linkbase Document.

Filed herewith.

‡ Furnished herewith.

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: April 25, 2019

Alkermes Pharma Ireland Limited
Monksland, Athlone, Co Westmeath, Ireland, N37 EA09
T +353 90 649 5000 **F** +353 90 649 5402
www.alkermes.com

Biogen Swiss Manufacturing GmbH
Neuhofstrasse 30
6340 Baar
Switzerland

31 January 2019

Re: Amendment to License and Collaboration Agreement

Dear Sirs

We refer to the License and Collaboration Agreement dated 27 November 2017 between Alkermes Pharma Ireland Limited ("**Alkermes**") and Biogen Swiss Manufacturing GmBH ("**Biogen**") (the "**License**"). This letter is supplemental to the License and amends Section 5.1.2 thereto as set out below.

Capitalised terms used in this letter shall have the same meaning as set out in the License.

1. Alkermes and Biogen hereby agree that, with effect from the date this letter is signed by Biogen, the six (6) month period within which Alkermes and Biogen are to negotiate the terms of a commercial supply agreement for the Manufacture of Commercial Supplies shall be extended by a further period of two (2) months and Section 5.1.2 of the License is hereby amended accordingly.

2. Notwithstanding Section 14.3 of the License, this letter, the License and the Exhibits referred to therein represent the entire agreement between the Parties regarding their subject matter.

3. This letter shall be governed by and construed in accordance with the laws of the State of New York (other than its choice of law principles).

To indicate Biogen's agreement to the above terms, please arrange for this letter to be executed by a duly authorised officer of Biogen where indicated below and return to us.

Yours faithfully

/s/ Kevin Brady
Alkermes Pharma Ireland Limited

Agreed and Accepted

BIOGEN SWISS MANUFACTURING GMBH

By: /s/ Fabrice Etienne
(Signature)

Name: FABRICE ETIENNE

Title: Head of External Manufacturing

Date: 31 Jan 2019

Exhibit 31.1

CERTIFICATIONS

I, Richard F. Pops, certify that:

1 I have reviewed this quarterly report on Form 10-Q of Alkermes plc;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: April 25, 2019

Exhibit 31.2

CERTIFICATIONS

I, James M. Frates, certify that:

1 I have reviewed this quarterly report on Form 10-Q of Alkermes plc;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: April 25, 2019

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Alkermes plc (the "Company") for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Richard F. Pops, Chairman and Chief Executive Officer of the Company, and James M. Frates, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

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

Date: April 25, 2019