UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 D04 C5Y6
(Address of principal executive offices)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, $0.01 par value	ALKS	Nasdaq Global Select Market

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

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

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

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

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

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of October 18, 2019 was 157,522,247 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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, 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, rules, 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" of our Annual Report on Form 10-K for the year ended December 31, 2018 (the "Annual Report") and "Part II, Item 1A—Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (the "Q2 Quarterly Report").

This Form 10-Q may include 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 and we have not independently verified such data. This Form 10-Q includes data based on our own internal estimates and research, which have not been verified by any independent source. Any such internal estimates and research and third-party data 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" of our Annual Report and "Part II, Item 1A—Risk Factors" of our Q2 Quarterly Report. These and other factors could cause our results to differ materially from those expressed in this Form 10-Q.

Note Regarding Company and Product References

Alkermes plc (as used in this report, together with our subsidiaries, "Alkermes," the "Company," "us," "we" and "our") is a 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, and product candidates 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 United States ("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); TECFIDERA®—Biogen MA Inc. (together with its affiliates, "Biogen"); and ZYPREXA®—Eli Lilly & Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I. FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2019	December 31, 2018
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$261,426	$266,762
Investments—short-term	325,756	272,533
Receivables, net	250,234	292,223
Contract assets	5,022	8,230
Inventory	100,987	90,196
Prepaid expenses and other current assets	54,493	53,308
Total current assets	997,918	983,252
PROPERTY, PLANT AND EQUIPMENT, NET	341,406	309,987
INTANGIBLE ASSETS, NET	160,814	191,001
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	87,615	85,807
CONTINGENT CONSIDERATION	27,400	65,200
INVESTMENTS—LONG-TERM	21,352	80,744
RIGHT-OF-USE ASSETS	13,835	—
OTHER ASSETS	14,782	16,143
TOTAL ASSETS	$1,757,995	$1,825,007
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$357,126	$333,762
Operating lease liabilities—short-term	8,627	—
Long-term debt—short-term	2,843	2,843
Contract liabilities—short-term	1,798	3,169
Total current liabilities	370,394	339,774
LONG-TERM DEBT	274,838	276,465
CONTRACT LIABILITIES—LONG-TERM	11,188	9,525
OPERATING LEASE LIABILITIES—LONG-TERM	6,657	—
OTHER LONG-TERM LIABILITIES	26,734	27,958
Total liabilities	689,811	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 September 30, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 160,203,448 and 158,180,833 shares issued; 157,496,990 and 155,757,344 shares outstanding at September 30, 2019 and December 31, 2018, respectively	1,599	1,579
Treasury shares, at cost (2,706,458 and 2,423,489 shares at September 30, 2019 and December 31, 2018, respectively)	(118,300)	(108,969)
Additional paid-in capital	2,563,157	2,467,323
Accumulated other comprehensive loss	(1,638)	(3,280)
Accumulated deficit	(1,376,634)	(1,185,368)
Total shareholders' equity	1,068,184	1,171,285
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,757,995	$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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	$ 138,774	$ 116,035	$ 374,890	$ 317,684
Manufacturing and royalty revenues	103,783	116,411	340,595	359,253
Research and development revenue	12,686	16,274	41,732	53,325
License revenue	—	—	1,000	48,250
Total revenues	255,243	248,720	758,217	778,512
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	42,319	39,410	133,903	127,303
Research and development	107,671	101,265	314,676	316,434
Selling, general and administrative	148,701	128,777	444,996	385,181
Amortization of acquired intangible assets	10,173	16,426	30,187	48,742
Total expenses	308,864	285,878	923,762	877,660
OPERATING LOSS	(53,621)	(37,158)	(165,545)	(99,148)
OTHER (EXPENSE) INCOME, NET:				
Interest income	3,509	2,561	10,785	5,946
Interest expense	(3,385)	(3,346)	(10,405)	(11,959)
Change in the fair value of contingent consideration	1,300	4,200	(27,800)	(17,300)
Other expense, net	(1,664)	(90)	(1,534)	(2,815)
Total other (expense) income, net	(240)	3,325	(28,954)	(26,128)
LOSS BEFORE INCOME TAXES	(53,861)	(33,833)	(194,499)	(125,276)
INCOME TAX (BENEFIT) PROVISION	(983)	611	(3,233)	4,322
NET LOSS	$ (52,878)	$ (34,444)	$ (191,266)	$ (129,598)
LOSS PER ORDINARY SHARE:				
Basic and diluted	$ (0.34)	$ (0.22)	$ (1.22)	$ (0.84)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic and diluted	157,199	155,328	156,845	154,979
COMPREHENSIVE LOSS:				
Net loss	$ (52,878)	$ (34,444)	$ (191,266)	$ (129,598)
Holding gain (loss), net of a tax provision (benefit) of $(15), $95, $479 and $42, respectively	(24)	314	1,642	126
COMPREHENSIVE LOSS	$ (52,902)	$ (34,130)	$ (189,624)	$ (129,472)

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

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,	
	2019	2018
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (191,266)	$ (129,598)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	59,901	77,758
Share-based compensation expense	79,590	76,043
Deferred income taxes	(3,025)	3,879
Change in the fair value of contingent consideration	27,800	17,300
Loss on debt refinancing	—	2,298
Payment made for debt refinancing	—	(2,251)
Other non-cash charges	90	1,209
Changes in assets and liabilities:		
Receivables	41,988	(17,322)
Contract assets	3,207	(4,366)
Inventory	(10,324)	(2,596)
Prepaid expenses and other assets	2,120	(3,291)
Right-of-use assets	6,306	—
Accounts payable and accrued expenses	20,542	12,899
Contract liabilities	292	2,485
Operating lease liabilities	(6,845)	—
Other long-term liabilities	(369)	4,321
Cash flows provided by operating activities	30,007	38,768
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(58,972)	(51,841)
Proceeds from the sale of equipment	900	428
Proceeds from contingent consideration	10,000	—
Purchases of investments	(141,749)	(307,603)
Sales and maturities of investments	149,459	344,624
Cash flows used in investing activities	(40,362)	(14,392)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	16,381	18,318
Employee taxes paid related to net share settlement of equity awards	(9,230)	(15,785)
Principal payments of long-term debt	(2,132)	(1,421)
Payment made for debt refinancing	—	(743)
Cash flows provided by financing activities	5,019	369
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(5,336)	24,745
CASH AND CASH EQUIVALENTS—Beginning of period	266,762	191,296
CASH AND CASH EQUIVALENTS—End of period	$ 261,426	$ 216,041
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 14,664	$ 7,117

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
Issuance of ordinary shares under employee stock plans	197,953	2	2,052	—	—	—	—	2,054
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	20,289	—	—	—	—	(6,397)	(194)	(194)
Share-based compensation expense	—	—	28,261	—	—	—	—	28,261
Unrealized gain on marketable securities, net of tax provision of $265	—	—	—	896	—	—	—	896
Net loss	—	—	—	—	(41,990)	—	—	(41,990)
BALANCE — June 30, 2019	159,796,116	$ 1,595	$ 2,533,086	$ (1,614)	$ (1,323,756)	(2,699,243)	$ (118,143)	$ 1,091,168
Issuance of ordinary shares under employee stock plans	383,957	3	3,770	—	—	—	—	3,773
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	23,375	1	—	—	—	(7,215)	(157)	(156)
Share-based compensation expense	—	—	26,301	—	—	—	—	26,301
Unrealized loss on marketable securities, net of tax benefit of $(15)	—	—	—	(24)	—	—	—	(24)
Net loss	—	—	—	—	(52,878)	—	—	(52,878)
BALANCE — September 30, 2019	160,203,448	$ 1,599	$ 2,563,157	$ (1,638)	$ (1,376,634)	(2,706,458)	$ (118,300)	$ 1,068,184

	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
Issuance of ordinary shares under employee stock plans	297,889	2	3,833	—	—	—	—	3,835
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	1,250	1	(2)	—	—	(369)	(17)	(18)
Share-based compensation expense	—	—	30,947	—	—	—	—	30,947
Unrealized loss on marketable securities, net of tax provision of $47	—	—	—	149	—	—	—	149
Cumulative effect adjustment related to the adoption of new accounting standards	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	(32,649)	—	—	(32,649)
BALANCE — June 30, 2018	157,612,457	$ 1,573	$ 2,406,861	$ (3,980)	$ (1,141,211)	(2,309,704)	$ (105,088)	$ 1,158,155
Issuance of ordinary shares under employee stock plans	56,945	1	1,317	—	—	—	—	1,318
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	5,334	—	1	—	—	(1,052)	(44)	(43)
Share-based compensation expense	—	—	25,415	—	—	—	—	25,415
Unrealized loss on marketable securities, net of tax provision of $95	—	—	—	314	—	—	—	314
Cumulative effect adjustment related to the adoption of new accounting standards	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	(34,444)	—	—	(34,444)
BALANCE — September 30, 2018	157,674,736	$ 1,574	$ 2,433,594	$ (3,666)	$ (1,175,655)	(2,310,756)	$ (105,132)	$ 1,150,715

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

1. THE COMPANY

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. The Company has a diversified portfolio of commercial drug products and a clinical pipeline of product candidates focused on CNS disorders such as schizophrenia, depression, addiction and MS, and oncology. Headquartered in Dublin, Ireland, the Company has an R&D center in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and nine months ended September 30, 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 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 Annual Report. 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 any 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 from contracts with its customers and related allowances, 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) provision primarily relates to U.S. federal and state taxes. The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At September 30, 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 has not yet adopted this ASU and 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 has not yet adopted this ASU and 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 has not yet adopted this ASU and 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 has not yet adopted this ASU and 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).

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 and nine months ended September 30, 2019 and 2018, the Company recorded product sales, net, as follows:

(In thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
VIVITROL	$ 85,164	$ 79,893	$ 242,546	$ 218,778
ARISTADA	53,610	36,142	132,344	98,906
Total product sales, net	$ 138,774	$ 116,035	$ 374,890	$ 317,684

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2019 and 2018, the Company recorded manufacturing and royalty revenues as follows:

(In thousands)	Three Months Ended September 30, 2019			Nine Months Ended September 30, 2019		
	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 68,382	$ 68,382	$ —	$ 188,968	$ 188,968
RISPERDAL CONSTA	4,520	3,813	8,333	42,948	12,266	55,214
AMPYRA/FAMPYRA	5,134	2,582	7,716	17,287	12,405	29,692
Other	6,428	12,924	19,352	25,173	41,548	66,721
	$ 16,082	$ 87,701	$ 103,783	$ 85,408	$ 255,187	$ 340,595

(In thousands)	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 65,620	$ 65,620	$ —	$ 174,956	$ 174,956
RISPERDAL CONSTA	7,267	4,316	11,583	42,296	13,922	56,218
AMPYRA/FAMPYRA	12,894	7,445	20,339	38,000	30,276	68,276
Other	5,036	13,833	18,869	19,420	40,383	59,803
	$ 25,197	$ 91,214	$ 116,411	$ 99,716	$ 259,537	$ 359,253

Research and Development Revenue

The Company recorded research and development ("R&D") revenue of $12.1 million and $39.5 million during the three and nine months ended September 30, 2019, respectively, and $15.7 million and $51.0 million during the three and nine months ended September 30, 2018, respectively, related to its license and collaboration agreement with Biogen for diroximel fumarate ("BIIB098"). The Company expects to earn an additional $26.9 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	24,506
Transferred to receivables, net	(27,714)
Contract assets at September 30, 2019	$ 5,022

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	2,182
Amounts recognized into revenue	(1,890)
Contract liabilities at September 30, 2019	$ 12,986

4. INVESTMENTS

Investments consisted of the following (in thousands):

September 30, 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	$ 159,490	$ 775	$ (5)	$ (7)	$ 160,253
U.S. government and agency debt securities	99,582	490	(1)	—	100,071
International government agency debt securities	65,133	306	—	(7)	65,432
Total short-term investments	324,205	1,571	(6)	(14)	325,756
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	11,017	—	(8)	(30)	10,979
U.S. government and agency debt securities	3,497	—	(2)	—	3,495
International government agency debt securities	3,351	—	(8)	—	3,343
	17,865	—	(18)	(30)	$ 17,817
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	48	—	—	1,715
	3,487	48	—	—	3,535
Total long-term investments	21,352	48	(18)	(30)	21,352
Total investments	$ 345,557	$ 1,619	$ (24)	$ (44)	$ 347,108
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)	Nine Months Ended September 30, 2019	2018
Proceeds from the sales and maturities of marketable securities	$ 149,459	$ 344,624
Realized gains	$ —	$ 4
Realized losses	$ 497	$ 268

The Company's available-for-sale and held-to-maturity securities at September 30, 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	$ 232,284	$ 232,939	$ 1,820	$ 1,820
After 1 year through 5 years	109,786	110,634	1,667	1,715
Total	$ 342,070	$ 343,573	$ 3,487	$ 3,535

At September 30, 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 September 30, 2019, the Company's total contribution in Fountain was equal to €5.6 million. The Company's commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method. During the three and nine months ended September 30, 2019, the Company recorded a decrease in its investment in Fountain of $0.3 million and $0.4 million, respectively. During the three and nine months ended September 30, 2018, the Company recorded an increase in its investment in Fountain of less than $0.1 million and a decrease in its investment in Fountain of $0.4 million, respectively. The changes recorded represent the Company's proportional share of Fountain's net losses for these periods. The Company's $5.3 million and $5.5 million net investment in Fountain at September 30, 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)	September 30, 2019	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 25,155	$ 25,155	$ —	$ —
U.S. government and agency debt securities	103,566	66,573	36,993	—
Corporate debt securities	171,232	—	169,279	1,953
International government agency debt securities	68,775	—	68,775	—
Contingent consideration	27,400	—	—	27,400
Common stock warrants	2,111	—	—	2,111
Total	$ 398,239	$ 91,728	$ 275,047	$ 31,464

	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 nine months ended September 30, 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 September 30, 2019:

(In thousands)	Fair Value
Balance, January 1, 2019	$ 66,897
Purchase of corporate debt security	1,953
Change in the fair value of contingent consideration	(27,800)
Payments received from contingent consideration	(10,000)
Impairment of corporate debt security	(492)
Increase in the fair value of warrants	906
Balance, September 30, 2019	$ 31,464

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 a $5.0 million payment in the first quarter of 2019 and 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 product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's IP to which Recro was provided a right of use, through license or transfer (the "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 September 30, 2019 was determined as follows:

- The Company received a $5.0 million payment in the first quarter of 2019 and another $5.0 million payment 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 will occur to the balance sheet date. The Company expects the regulatory milestone event to occur in the third quarter of 2020 and used a discount rate of 16.7%;

- 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 17.0%, 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 16.7%.

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 September 30, 2019 and December 31, 2018, the Company determined that the value of the contingent consideration was $27.4 million and $65.2 million, respectively. The Company recorded an increase of $1.3 million and a decrease of $27.8 million during the three and nine months ended September 30, 2019, respectively, and an increase of $4.2 million and a decrease of $17.3 million during the three and nine months ended September 30, 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)	September 30, 2019	December 31, 2018
Raw materials	$ 34,336	$ 31,824
Work in process	48,315	38,019
Finished goods(1)	18,336	20,353
Total inventory	$ 100,987	$ 90,196

(1) At September 30, 2019 and December 31, 2018, the Company had $11.5 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)	September 30, 2019	December 31, 2018
Land	$ 6,560	$ 6,486
Building and improvements	173,220	157,053
Furniture, fixtures and equipment	332,886	314,831
Leasehold improvements	20,737	20,105
Construction in progress	114,905	88,983
Subtotal	648,308	587,458
Less: accumulated depreciation	(306,902)	(277,471)
Total property, plant and equipment, net	$ 341,406	$ 309,987

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	September 30, 2019 Gross Carrying Amount	September 30, 2019 Accumulated Amortization	September 30, 2019 Net Carrying Amount	December 31, 2018 Gross Carrying Amount	December 31, 2018 Accumulated Amortization	December 31, 2018 Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873	$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:							
Collaboration agreements	12	$ 465,590	$ (341,214)	$ 124,376	$ 465,590	$ (319,311)	$ 146,279
NanoCrystal technology	13	74,600	(44,800)	29,800	74,600	(38,942)	35,658
OCR(1) technologies	12	42,560	(35,922)	6,638	42,560	(33,496)	9,064
Total		$ 582,750	$ (421,936)	$ 160,814	$ 582,750	$ (391,749)	$ 191,001

(1) OCR refers to the Company's oral control released technologies.

Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at September 30, 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. Upon adoption, the Company elected the package of transition practical expedients, which allowed it to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within its condensed consolidated balance sheets and to instead recognize those lease payments on a straight-line basis in its condensed consolidated statements of operations over the lease term.

The Company elected to adopt this standard using the optional modified retrospective transition method with no restatement of its prior periods or cumulative adjustment to retained earnings. 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.

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 September 30, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 4.71% and 4.1 years, respectively.

As of September 30, 2019, right-of-use assets and liabilities arising from operating leases were $13.8 million and $15.3 million, respectively. During the three and nine months ended September 30, 2019, cash paid for amounts included for the measurement of lease liabilities was $2.2 million and $6.8 million, respectively and the Company recorded operating lease expense of $2.1 million and $6.3 million, respectively.

Future lease payments under non-cancelable leases as of September 30, 2019 and December 31, 2018 consisted of the following:

(In thousands)	September 30, 2019	December 31, 2018
2019	$ 2,219	$ 9,394
2020	8,610	10,717
2021	2,482	4,706
2022	500	2,455
2023	509	2,389
Thereafter	3,101	23,940
Total lease payments	$ 17,421	$ 53,601
Less: imputed interest	(2,137)	—
Total operating lease liabilities	$ 15,284	$ 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 the later of (a) 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 September 30, 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 as of September 30, 2019, under Topic 842.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2019	December 31, 2018
Accounts payable	$ 81,417	$ 39,767
Accrued compensation	69,191	67,613
Accrued sales discounts, allowances and reserves	130,107	152,911
Accrued other	76,411	73,471
Total accounts payable and accrued expenses	$ 357,126	$ 333,762

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2019	December 31, 2018
2023 Term Loans, due March 26, 2023	$ 277,681	$ 279,308
Less: current portion	(2,843)	(2,843)
Long-term debt	$ 274,838	$ 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 LIBOR floor of 0% and increased 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 $273.3 million and $274.7 million at September 30, 2019 and December 31, 2018, respectively.

12. SHARE-BASED COMPENSATION

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Cost of goods manufactured and sold	$ 2,912	$ 2,140	$ 7,395	$ 6,012
Research and development	8,195	7,937	24,076	23,203
Selling, general and administrative	15,622	14,991	48,119	46,828
Total share-based compensation expense	$ 26,729	$ 25,068	$ 79,590	$ 76,043

At September 30, 2019 and December 31, 2018, $2.5 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 September 30, 2019, there was $31.6 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 and nine months ended September 30, 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 share equivalents have not been included in the net loss per ordinary share calculation because the effect would have been anti-dilutive:

(In thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Stock options	13,867	11,553	14,077	10,274
Restricted stock units	3,344	2,678	3,110	2,621
Total	17,211	14,231	17,187	12,895

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 September 30, 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 and in August 2019, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Teva entities (Teva Pharmaceuticals USA, Inc.("Teva") and Teva Pharmaceuticals Industries, Ltd. ("Teva PI")) and Mylan entities (Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals Inc. ("Mylan"), and Mylan Institutional LLC), respectively, following filings by each of Teva and Mylan Labs of 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 in each of the lawsuits included recovery of litigation costs and injunctive relief. The Company is not a party to either of these proceedings.

For information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "Part I, Item 1A—Risk Factors" of the 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 had 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; 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 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. In October 2018, Acorda filed a petition for rehearing and rehearing en banc of the Federal Circuit's decision. In January 2019, the Federal Circuit denied Acorda's petition. In April 2019, Acorda filed a petition for writ of certiorari to the Supreme Court of the United States (the "Supreme Court"). On October 7, 2019, the Supreme Court denied Acorda's petition requesting review of the case, rendering the Federal Circuit decision as final.

For information about risks relating to the AMPYRA Paragraph IV litigation and other proceedings see "Part I, Item 1A—Risk Factors" of the 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

In April 2018, Amneal Pharmaceuticals LLC ("Amneal") 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, and specifically requesting the cancellation of claims 1-13 of the '499 Patent. In November 2018, the PTAB instituted an IPR of all of the challenged claims. On July 26, 2019, the Company entered into a settlement and license agreement (the "Settlement Agreement") with Amneal. Under the terms of the Settlement Agreement, the parties agreed to request termination of the IPR and Alkermes granted Amneal the non-exclusive right to market a generic formulation of VIVITROL in the U.S. beginning sometime in 2028 or earlier under certain circumstances. The PTAB subsequently cancelled the scheduled IPR hearing and terminated the IPR.

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co., Ltd., Pharmathen SA, Teva PI 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 in January 2019, the EPO issued a written decision revoking the EP'577 Patent in April 2019. The Company filed a notice of appeal of the decision to the EPO's Technical Boards of Appeal on June 12, 2019 and 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 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 ANDA Litigation

On July 17, 2019, the Company, together with Janssen Pharmaceuticals, Inc., initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Nanjing Luye Pharmaceutical Co., Ltd. and Shandong Luye Pharmaceutical Co., Ltd. (collectively, "Luye"). Luye filed a 505(b)(2) NDA seeking approval to market a competing product to RISPERDAL CONSTA before the expiration of U.S. Patent No. 6,667,061. Requested judicial remedies included, among other things, recovery of litigation costs and injunctive relief. On July 23, 2019, Luye filed its answer and affirmative defenses.

For information about risks relating to the RISPERDAL CONSTA Paragraph IV litigation, see "Part I, Item 1A—Risk Factors" of the 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."

Government Matters

In June 2017 and January 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

In November 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 (the "SDNY District Court") 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 Exchange Act 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. In June 2018, Defendants filed a motion to dismiss the second amended complaint and in March 2019, the SDNY District Court issued an order granting Defendants' motion to dismiss and dismissing the case in its entirety and with prejudice. In April 2019, the plaintiff filed a motion for partial reconsideration, which was denied by the SDNY District Court on July 2, 2019. Plaintiff did not file a notice of appeal to the United States Court of Appeals for the Second Circuit, rendering the SDNY District Court's decision dismissing the action final.

In December 2018 and January 2019, purported stockholders of the Company filed putative class actions against the Company and certain of its officers in the United States District Court for the Eastern District of New York (the "EDNY District Court") captioned *Karimian v. Alkermes plc, et al., No. 1:18-cv-07410* and *McDermott v. Alkermes plc, et al., No. 1:19-cv-00624*, respectively. In March 2019, the EDNY District Court consolidated the two cases and appointed a lead plaintiff. The plaintiff filed an amended complaint on July 9, 2019 naming one additional officer of the Company and one former officer of the Company as defendants. The amended complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of July 31, 2014 through November 1, 2018 and alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding the Company's clinical methodologies and regulatory submission for ALKS 5461 and the FDA's review and consideration of that submission. The lawsuit seeks, among other things, unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. On August 8, 2019, the defendants filed a pre-motion letter (in respect of a requested motion to dismiss filing) with the EDNY District Court and on August 23, 2019, plaintiff filed a response. On October 8, 2019, the EDNY District Court ordered the defendants to file their motion to dismiss by November 27, 2019. Plaintiff's opposition to such motion to dismiss, if any, and defendants' reply to any such opposition, are due in December 2019. For information about risks relating to this action, see "Part I, Item 1A—Risk Factors" of the 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."

15. SUBSEQUENT EVENTS

Following a review of the Company's operations, cost structure and growth opportunities, on October 18, 2019, the Board of Directors of the Company approved a plan of restructuring, which includes the elimination of approximately 160 current positions across the Company and other cost-saving measures (the "Restructuring"). The Company expects to record a charge in the range of $13.0 million to $15.0 million in the fourth quarter of 2019 as a result of the Restructuring, consisting of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out over the next 12 months.

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 and nine months ended September 30, 2019 was $52.9 million and $191.3 million, or $0.34 and $1.22 per ordinary share—basic and diluted, as compared to a net loss of $34.4 million and $129.6 million, or $0.22 and $0.84 per ordinary share—basic and diluted, for the three and nine months ended September 30, 2018, respectively.

The increase in the net loss in the three and nine months ended September 30, 2019 as compared to the three and nine months ended September 30, 2018 was primarily due to increases in selling, general and administrative ("SG&A") expenses of 15% and 16% in the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. In addition, we recorded a reduction of $27.8 million in the fair value of our contingent consideration in the nine months ended September 30, 2019 related to the second CRL that Recro received in March 2019 regarding its NDA for IV Meloxicam and recognized $48.3 million in license revenue related to our license and collaboration agreement with Biogen relating to BIIB098 during the nine months ended September 30, 2018. These items are discussed in greater detail later in the "*Results of Operations*" section of this Part I, Item 2 of this Form 10-Q.

Following a review of our operations, cost structure and growth opportunities, on October 18, 2019, the Board of Directors of the Company approved a plan of restructuring, which includes the elimination of approximately 160 current positions across the company and other cost-saving measures. We expect to record a charge in the range of $13.0 million to $15.0 million in the fourth quarter of 2019 as a result of the Restructuring, consisting of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out over the next 12 months.

Products

Marketed Products

Our portfolio of marketed products is designed to address unmet medical needs of patients in major therapeutic areas. See the descriptions 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. For information with respect to the IP protection for these marketed products, see the descriptions of the marketed products below and refer to the "Patents and Proprietary Rights" section in "Part I, Item 1—Business" of our Annual Report and the "Products" section in "Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Q2 Quarterly Report and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

Summary information regarding our proprietary products that we commercialize is as follows:

Product	Indication(s)	Territory
	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	U.S.
	Schizophrenia	U.S.
	Alcohol dependence and Opioid dependence	U.S.

Summary information regarding our licensed products and third-party products using our proprietary technologies under license that are commercialized by our licensees includes:

Third-Party Products Using Our Proprietary Technologies

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

Our Licensed Products

Product	Indication(s)	Licensee	Territory
VIVITROL	Alcohol dependence and Opioid dependence	Cilag GmbH International ("Cilag")	Russia and Commonwealth of Independent States ("CIS")

Proprietary Products

We develop and commercialize products designed to address the unmet needs of patients suffering from addiction and schizophrenia. For additional information about the proprietary technologies underlying our proprietary products, refer to the "Proprietary Product Platforms" section in "Part I, Item 1—Business" of our Annual Report.

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 options (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 exclusively manufacture and commercialize it in the U.S.

In July 2019, U.S. Patent No. 10,351,529 and U.S. Patent No. 10,342,877 relating to ARISTADA were granted. U.S. Patent No. 10,351,529 has claims that cover compositions of N-Hydroxymethyl aripiprazole and expires in 2030. U.S. Patent No. 10,342,877 has claims to methods that confer long-term stability of the ARISTADA formulation and expires in 2033.

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.

In July 2019, U.S. Patent No. 10,351,529 relating to ARISTADA INITIO was granted. This patent has claims that cover compositions of N-Hydroxymethyl aripiprazole and expires in 2030.

VIVITROL (U.S.)

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 and we commercialize VIVITROL in the U.S.

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" of 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."

Licensed Products and Products Using Our Proprietary Technologies

We have licensed products to third parties for commercialization and have licensed our proprietary technologies to third parties to enable them to develop, commercialize and/or manufacture products. We receive royalties and/or manufacturing revenues from the commercialization of these products. Such arrangements include the following:

VIVITROL (Russia and CIS)

VIVITROL is described more fully above under the heading "Proprietary Products" in this Item 2. We developed and exclusively manufacture VIVITROL for Cilag. Cilag exclusively commercializes VIVITROL in Russia and certain countries of the CIS.

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. For additional information about our proprietary technologies, refer to the "Proprietary Product Platforms" section in "Part I, Item 1—Business" of our Annual Report.

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" of 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 in patients who have been adequately 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 certain 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" of 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 developing novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia, bipolar I disorder, 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 advancing 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 and in "Part II, Item 1A—Risk Factors" of our Q2 Quarterly 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. BIIB098 is designed to rapidly convert to monomethyl fumarate in the body. If approved, Biogen intends to market BIIB098 under the brand name VUMERITY, which has been conditionally accepted by the FDA.

The pivotal clinical program for BIIB098 consisted of pharmacokinetic bridging studies comparing BIIB098 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of BIIB098, which we initiated in December 2015. We submitted a 505(b)(2) NDA for BIIB098 in December 2018. For more information about 505(b)(2) NDAs, see "Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act" of our Annual Report. On October 11, 2019, we received notice from the FDA of its tentative approval of BIIB098 for the treatment of relapsing forms of MS. The tentative approval letter stated that final approval of BIIB098 is subject to the expiration of a period of patent protection and/or exclusivity.

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

In July 2019, we announced positive topline results for EVOLVE-MS-2, an elective, randomized, head-to-head phase 3 study of the gastrointestinal tolerability of BIIB098 versus TECFIDERA in patients with relapsing-remitting MS.

ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder. 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 in patients with schizophrenia: 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. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of ALKS 3831.

In May 2019, we conducted a pre-NDA meeting with the FDA to discuss the FDA's key requirements for our planned NDA for ALKS 3831, including those related to efficacy, safety, weight and metabolic profile, and the expansion of the planned NDA for ALKS 3831 to encompass the treatment of bipolar I disorder in addition to the treatment of schizophrenia. We anticipate submitting a single 505(b)(2) NDA for the two indications in the fourth quarter of 2019, which will include data from the ENLIGHTEN clinical development program in patients with schizophrenia and pharmacokinetic bridging data comparing ALKS 3831 and ZYPREXA® (olanzapine). For more information about 505(b)(2) NDAs, see "Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act" of our Annual Report.

ALKS 4230

ALKS 4230 is a novel, engineered fusion protein designed to selectively expand tumor-killing immune cells while avoiding the activation 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.

ARTISTRY is our clinical program that evaluates ALKS 4230 in patients with advanced solid tumors. ARTISTRY-1, an ongoing phase 1/2 study of ALKS 4230 administered via intravenous infusion as a monotherapy and in combination with the anti-PD-1 therapy, pembrolizumab, is designed to evaluate the safety profile and anti-tumor activity of ALKS 4230 in patients with select advanced solid tumors. ARTISTRY-2, an ongoing phase 1/2 study of ALKS 4230 administered subcutaneously as monotherapy and in combination with pembrolizumab in patients with advanced solid tumors, is designed to explore the safety, tolerability and efficacy of ALKS 4230 and assess once-weekly and once-every-three-week subcutaneous dosing schedules. ARTISTRY-2, which we initiated in February 2019, is being conducted in two stages: dose-escalation followed by dose-expansion.

In June 2019, we announced the initiation of the monotherapy expansion stage of ARTISTRY-1, following the identification of 6 µg/kg/day administered intravenously as the recommended phase 2 monotherapy dose of ALKS 4230 to evaluate in patients with renal cell carcinoma or melanoma. The dose escalation stage of ARTISTRY-1 is still ongoing, as the maximum tolerated dose of ALKS 4230 has not yet been reached. 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 September 2019, U.S. Patent No. 10,407,481 relating to ALKS 4230 was granted. The patent has claims that cover compositions of ALKS 4230 and expires in 2033.

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 was submitted to the FDA in January 2018 and, 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.

Results of Operations

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 and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In millions, except for % of Sales)	**2019**	**% of Sales**	**2018**	**% of Sales**	**2019**	**% of Sales**	**2018**	**% of Sales**
Product sales, gross	$ 269.5	100.0 %	$ 217.4	100.0 %	$ 726.7	100.0 %	$ 604.1	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(61.1)	(22.7) %	(48.2)	(22.2) %	(167.3)	(23.0) %	(144.0)	(23.8) %
Chargebacks	(23.8)	(8.8) %	(18.2)	(8.4) %	(61.0)	(8.4) %	(48.6)	(8.0) %
Product discounts	(20.7)	(7.7) %	(17.1)	(7.9) %	(56.3)	(7.7) %	(46.5)	(7.7) %
Medicare Part D	(12.0)	(4.5) %	(8.1)	(3.7) %	(30.5)	(4.2) %	(20.3)	(3.4) %
Other	(13.1)	(4.8) %	(9.8)	(4.5) %	(36.7)	(5.1) %	(27.0)	(4.5) %
Total adjustments	(130.7)	(48.5) %	(101.4)	(46.6) %	(351.8)	(48.4) %	(286.4)	(47.4) %
Product sales, net	$ 138.8	51.5 %	$ 116.0	53.4 %	$ 374.9	51.6 %	$ 317.7	52.6 %

Product sales, net, for VIVITROL in the three and nine months ended September 30, 2019 were $85.2 million and $242.6 million, respectively, as compared to $79.9 million and $218.8 million in the three and nine months ended September 30, 2018, respectively. Product sales, net for ARISTADA/ARISTADA INITIO in the three and nine months ended September 30, 2019 were $53.6 million and $132.3 million, respectively, as compared to $36.1 million and $98.9 million in the three and nine months ended September 30, 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 11% in each of the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, 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 to date in 2019. ARISTADA and ARISTADA INITIO product sales, gross, increased by 52% and 43%, in the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018, which was due to a 42% and 30% increase in the number of ARISTADA and ARISTADA INITIO units sold, respectively, and a 4% and a 6% price increase that went into effect in July 2018 and February 2019, respectively.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned in the three and nine months ended September 30, 2019 and 2018:

(In millions)	Three Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 68.4	$ 65.6	$ 2.8	$ 189.0	$ 175.0	$ 14.0
RISPERDAL CONSTA	8.3	11.6	(3.3)	55.2	56.2	(1.0)
AMPYRA/FAMPYRA	7.7	20.3	(12.6)	29.7	68.2	(38.5)
Other	19.4	18.9	0.5	66.7	59.9	6.8
Manufacturing and royalty revenues	$ 103.8	$ 116.4	$ (12.6)	$ 340.6	$ 359.3	$ (18.7)

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, was primarily due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three and nine months ended September 30, 2019, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $851.0 million and $2,459.0 million, respectively, as compared to $749.0 million and $2,165.0 million, during the three and nine months ended September 30, 2018, respectively. Under our agreement with Janssen, we earn tiered royalty payments on INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, which consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the patents with valid claims applicable to the product in such country. The know-how royalty is a tiered royalty of 3.5% on calendar year net sales up to $250 million; 5.5% on calendar year net sales of between $250 million and $500 million; and 7.5% on calendar year net sales exceeding $500 million. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until the later of 15 years from the first commercial sale of a product in each individual country or expiry of the license agreement.

The decrease in revenues from RISPERDAL CONSTA in the three months ended September 30, 2019, as compared to the three months ended September 30, 2018, was due to a 38% and 12% decrease in manufacturing revenue and royalty revenue, respectively. The decrease in revenues from RISPERDAL CONSTA in the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was due to a 12% decrease in royalty revenue, partially offset by a 2% increase in manufacturing revenue. The decrease in manufacturing revenue in the three months ended September 30, 2019 was primarily due to a 38% decrease in the amount of RISPERDAL CONSTA shipped to Janssen. The decrease in royalty revenue was due to a decrease in end-market sales of RISPERDAL CONSTA, which were $167.0 million and $528.0 million in the three and nine months ended September 30, 2019, respectively, as compared to $175.0 million and $559.0 million in the three and nine months ended September 30, 2018, respectively. 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 in both the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, was primarily due to the entry of generic forms of AMPYRA to the U.S. market in September 2018. AMPYRA revenues decreased by 100% and 89%, respectively, in the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018. This was partially offset by a 15% and 30% increase in FAMPYRA revenues in the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018, which was primarily due to an increase in the amount of FAMPYRA manufactured during the periods. We do not anticipate manufacturing any AMPYRA for Acorda during the remainder of 2019. 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.

Research and Development Revenue

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change Favorable/ (Unfavorable)
Research and development revenue	$ 12.7	$ 16.3	$ (3.6)	$ 41.7	$ 53.3	$ (11.6)

The decrease in R&D revenue in the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, 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 $12.1 million and $39.5 million in the three and nine months ended September 30, 2019, respectively, as compared to $15.7 million and $51.0 million in the three and nine months ended September 30, 2018, respectively. These decreases were due to the timing of activity within the program. We submitted a 505(b)(2) NDA for BIIB098 in December 2018.

License Revenue

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change Favorable/ (Unfavorable)
License revenue	$ —	$ —	$ —	$ 1.0	$ 48.3	$ (47.3)

During the nine months ended September 30, 2018, we recognized $48.3 million in license revenue related to the license and collaboration agreement with Biogen for BIIB098, which was triggered by Biogen's decision to pay the $50.0 million option payment following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098, including certain data from our long-term safety clinical trial and part A of the elective, randomized, head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and dimethyl fumarate.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	$ 42.3	$ 39.4	$ (2.9)	$ 133.9	$ 127.3	$ (6.6)

The increase in cost of goods manufactured and sold in the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, was primarily due to a 48% and 31% increase, respectively, in VIVITROL cost of goods sold, due to the increase in gross sales of VIVITROL, partially offset by a 27% and 15% decrease, respectively, in cost of goods sold related to RISPERDAL CONSTA, due to the decrease in

manufacturing revenue of RISPERDAL CONSTA, as described under the heading “Manufacturing and Royalty Revenues” above.

Research and Development Expense

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

The following table sets forth our external R&D expenses for the three and nine months ended September 30, 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 September 30, 2019	Three Months Ended September 30, 2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change Favorable/ (Unfavorable)
External R&D Expenses:						
Development programs:						
BIIB098	$ 7.0	$ 9.7	$ 2.7	$ 25.2	$ 31.9	$ 6.7
ALKS 4230	9.4	3.1	(6.3)	23.9	12.3	(11.6)
ALKS 3831	7.1	9.0	1.9	23.0	39.7	16.7
ALKS 5461	4.2	6.3	2.1	15.4	23.1	7.7
ARISTADA and ARISTADA line extensions	1.2	6.2	5.0	5.9	17.5	11.6
Other external R&D expenses	19.5	13.6	(5.9)	46.2	35.8	(10.4)
Total external R&D expenses	48.4	47.9	(0.5)	139.6	160.3	20.7
Internal R&D expenses:						
Employee-related	45.6	42.2	(3.4)	137.0	122.8	(14.2)
Depreciation	3.6	3.0	(0.6)	10.2	8.8	(1.4)
Occupancy	3.3	2.9	(0.4)	9.3	8.5	(0.8)
Other	6.8	5.3	(1.5)	18.6	16.0	(2.6)
Total internal R&D expenses	59.3	53.4	(5.9)	175.1	156.1	(19.0)
Research and development expenses	$ 107.7	$ 101.3	$ (6.4)	$ 314.7	$ 316.4	$ 1.7

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 in both periods presented was primarily due to the completion of our elective, randomized, head-to-head phase 3 study designed to compare the gastrointestinal tolerability of BIIB098 and TECFIDERA in patients with relapsing-remitting MS, for which we presented positive topline results in July 2019. The increase in expenses related to ALKS 4230 in both periods presented was primarily related to the timing of the ARTISTRY development program for ALKS 4230, as described under the heading “Key Development Programs” above. The decrease in expenses related to ALKS 3831 in both periods presented 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 in both periods presented 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 in both periods presented was primarily due to the timing of ALPINE, our six-month study that evaluated 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 to maintain treatment in an outpatient setting.

The increase in employee-related expenses in both periods was primarily due to an increase in R&D headcount of 9% from September 30, 2018 to September 30, 2019.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)
Selling, general and administrative expense	$ 148.7	$ 128.8	$ (19.9)	$ 445.0	$ 385.2	$ (59.8)

The increase in SG&A expense in the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018, was primarily due to an increase in employee-related expenses of $15.8 million and $46.3 million, respectively, which was primarily due to an increase in our SG&A-related headcount of 17% from September 30, 2018 to September 30, 2019. In addition, marketing and professional services fees increased by $3.3 million and $11.8 million in the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018, which 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 September 30, 2019	2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)
Amortization of acquired intangible assets	$ 10.2	$ 16.4	$ 6.2	$ 30.2	$ 48.7	$ 18.5

We amortize our amortizable intangible assets using the economic-use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at September 30, 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) Income, net

(In millions)	Three Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)
Interest income	$ 3.5	$ 2.6	$ 0.9	$ 10.8	$ 5.9	$ 4.9
Interest expense	(3.4)	(3.4)	—	(10.4)	(11.9)	1.5
Change in the fair value of contingent consideration	1.3	4.2	(2.9)	(27.8)	(17.3)	(10.5)
Other expense, net	(1.7)	(0.1)	(1.6)	(1.6)	(2.8)	1.2
Total other (expense) income, net	$ (0.3)	$ 3.3	$ (3.6)	$ (29.0)	$ (26.1)	$ (2.9)

The decrease in the fair value of contingent consideration for both periods presented 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) Provision

(In millions)	Three Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)	Nine Months Ended September 30, 2019	2018	Change Favorable/ (Unfavorable)
Income tax (benefit) provision	$ (1.0)	$ 0.6	$ 1.6	$ (3.2)	$ 4.3	$ 7.5

The income tax benefit in the three months ended September 30, 2019 and the income tax provision in the three months ended September 30, 2018 primarily related to U.S. federal and state taxes. The favorable change in income

taxes in the three months ended September 30, 2019, as compared to the corresponding period, was primarily due to discrete tax benefits recorded during the three months ended September 30, 2019.

The income tax benefit in the nine months ended September 30, 2019 primarily related to a $8.4 million discrete tax benefit to reflect the foreign derived intangible income ("FDII") proposed regulations issued by the U.S. Department of the Treasury and the U.S. Internal Revenue Service in March 2019. The benefit is partially offset by a $4.6 million discrete tax expense for employee equity activity. The income tax provision in the nine months ended September 30, 2018 primarily related to $9.5 million in U.S. federal and state taxes on ordinary income, partially offset by $5.1 million of discrete tax benefits related to the exercise and vesting of stock-based awards. The favorable change in income taxes in the nine months ended September 30, 2019, as compared to the corresponding period, was primarily due to a reduction to ordinary income earned in the U.S. and the recognition of FDII tax benefits, partially offset by increased tax expense from employee equity activity.

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:

	September 30, 2019			December 31, 2018		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 197.2	$ 64.2	$ 261.4	$ 139.3	$ 127.5	$ 266.8
Investments—short-term	261.9	63.9	325.8	203.3	69.2	272.5
Investments—long-term	8.7	12.7	21.4	51.5	29.2	80.7
Total cash and investments	$ 467.8	$ 140.8	$ 608.6	$ 394.1	$ 225.9	$ 620.0
Outstanding borrowings—short and long-term	$ 277.7	$ —	$ 277.7	$ 279.3	$ —	$ 279.3

At September 30, 2019 our investments consisted of the following:

		Gross Unrealized		
(In millions)	Amortized Cost	Gains	Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 324.2	$ 1.6	$ —	$ 325.8
Investments—long-term available-for-sale	17.9	—	(0.1)	17.8
Investments—long-term held-to-maturity	3.5	—	—	3.5
Total	$ 345.6	$ 1.6	$ (0.1)	$ 347.1

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, that do not mature within 12 months, as long-term investments. Available-for-sale investments in an unrealized gain position are classified as short-term investments, regardless of maturity date. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 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 12 months following the date on which this Form 10-Q is filed. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, debt refinancings, arrangements relating to assets or other financing methods or structures.

Information about our cash flows, by category, is presented in "Part I, Item 1–Condensed Consolidated Financial Statements of Cash Flows" of this Form 10-Q. The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
(In millions)	**2019**	**2018**
Cash and cash equivalents, beginning of period	$ 266.8	$ 191.3
Cash flows provided by operating activities	30.0	38.7
Cash flows used in investing activities	(40.4)	(14.4)
Cash flows provided by financing activities	5.0	0.4
Cash and cash equivalents, end of period	$ 261.4	$ 216.0

The change in cash flows from operating activities in the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, was primarily due to a 20% increase in cash paid to our employees, which was primarily due to a 10% increase in our headcount from September 30, 2018 to September 30, 2019. This was partially offset by a 6% increase in cash received from our customers, which was primarily due to the increase in our product sales, net, as described under the heading "Product Sales, net" above.

The increase in cash flows used in investing activities in the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, was primarily due to a $29.3 million decrease in the net sales of investments, partially offset by the $10.0 million that we received from Recro in connection with the contingent consideration from the Gainesville Transaction.

The increase in cash flows provided by financing activities in the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, was due to a $4.6 million increase in the amount of cash we received from our employees upon the exercise of stock options.

Borrowings

At September 30, 2019, the principal balance of our borrowings consisted of $280.0 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 September 30, 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 September 30, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 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***

There have been no material changes from the risk factors disclosed in our Annual Report and Q2 Quarterly Report. Further discussion of our risk factors appears in "Part I, Item 1A—Risk Factors" of our Annual Report and "Part II, Item 1A—Risk Factors" of our Q2 Quarterly 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 nine months ended September 30, 2019. As of September 30, 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 September 30, 2019, we acquired 7,215 of our ordinary shares, at an average price of $21.65 per share, related to the vesting of employee equity awards to satisfy withholding tax obligations.

Item 5. ***Other Information***

None.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
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.SCH #	Inline XBRL Taxonomy Extension Schema Document.
101.CAL #	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB #	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE #	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF #	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

Filed herewith.

‡ Furnished herewith.

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

SIGNATURES

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

ALKERMES plc

(Registrant)

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

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

Date: October 23, 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: October 23, 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: October 23, 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 September 30, 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: October 23, 2019