

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, 2020

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
Non-accelerated filer

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 23, 2020 was 159,149,785 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2020

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Cautionary Note Concerning Forward-Looking Statements

This document contains and incorporates by reference “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, these statements can be identified by the use of forward-looking terminology such as “may,” “will,” “could,” “should,” “would,” “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate,” “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 (this “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, payer, and legislative, regulatory and policy landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and competitive development programs, barriers to access or coverage of our products and changes in reimbursement of our products, and legislation, regulations, executive orders, guidance or other measures that may limit pricing and reimbursement of, and access to, our products;
- 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 expectations regarding 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 products and intellectual property (“IP”), including our patents;
- our expectations regarding the impact of the ongoing novel coronavirus (“COVID-19”) pandemic on our business and operations; 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. These forward-looking statements are subject to risks, assumptions and uncertainties. In light of these risks, assumptions and uncertainties, the forward-looking events discussed in this Form 10-Q might not occur. You are cautioned not to place undue reliance on the forward-looking statements in this Form 10-Q, 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. For more information regarding the risks, assumptions and uncertainties of our business, see “Part I, Item 1A—Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019 (the “Annual Report”) and “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

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. This Form 10-Q also may include data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source and, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Part I, Item 1A—Risk Factors” in our Annual Report and “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. 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 marketed products focused on central nervous system (“CNS”) disorders such as addiction and schizophrenia and a pipeline of product candidates in the fields of neuroscience 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 to “licensees” in this Form 10-Q 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® and VIVITROL®.

The following are trademarks of the respective companies listed: ANJESOTM—Baudax Bio, Inc.; INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION®, and RISPERDAL CONSTA®—Johnson & Johnson (or its affiliates); VUMERITY®—Biogen MA Inc. (together with its affiliates, “Biogen”); and ZYPREXA®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2020	December 31, 2019
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$240,866	\$203,771
Investments—short-term	328,516	331,208
Receivables, net	265,644	257,086
Contract assets	14,395	8,386
Inventory	122,823	101,803
Prepaid expenses and other current assets	52,697	59,716
Total current assets	1,024,941	961,970
PROPERTY, PLANT AND EQUIPMENT, NET	355,215	362,168
INTANGIBLE ASSETS, NET	121,108	150,643
RIGHT-OF-USE ASSETS	106,681	12,379
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	86,336	96,558
INVESTMENTS—LONG-TERM	27,774	79,391
CONTINGENT CONSIDERATION	46,200	32,400
OTHER ASSETS	15,692	17,021
TOTAL ASSETS	\$1,876,820	\$1,805,403
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$354,780	\$373,037
Operating lease liabilities—short-term	13,375	8,466
Contract liabilities—short-term	7,153	6,766
Long-term debt—short-term	2,843	2,843
Total current liabilities	378,151	391,112
LONG-TERM DEBT	272,663	274,295
OPERATING LEASE LIABILITIES—LONG-TERM	96,717	5,342
CONTRACT LIABILITIES—LONG-TERM	18,635	22,068
OTHER LONG-TERM LIABILITIES	26,296	27,144
Total liabilities	792,462	719,961
COMMITMENTS AND CONTINGENT LIABILITIES (Note 15)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 162,208,145 and 160,489,888 shares issued; 159,105,433 and 157,779,002 shares outstanding at September 30, 2020 and December 31, 2019, respectively	1,619	1,602
Treasury shares, at cost (3,102,712 and 2,710,886 shares at September 30, 2020 and December 31, 2019, respectively)	(125,993)	(118,386)
Additional paid-in capital	2,659,699	2,586,030
Accumulated other comprehensive loss	(760)	(1,816)
Accumulated deficit	(1,450,207)	(1,381,988)
Total shareholders' equity	1,084,358	1,085,442
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$1,876,820	\$1,805,403

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,	
	2020	2019	2020	2019
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	\$ 142,658	\$ 138,774	\$ 402,799	\$ 374,890
Manufacturing and royalty revenues	120,351	103,783	353,107	340,595
Research and development revenue	953	12,686	1,805	41,732
License revenue	1,050	—	1,050	1,000
Total revenues	<u>265,012</u>	<u>255,243</u>	<u>758,761</u>	<u>758,217</u>
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	43,129	42,319	135,394	133,903
Research and development	94,980	107,671	282,481	314,676
Selling, general and administrative	127,653	148,701	393,049	444,996
Amortization of acquired intangible assets	9,917	10,173	29,535	30,187
Total expenses	<u>275,679</u>	<u>308,864</u>	<u>840,459</u>	<u>923,762</u>
OPERATING LOSS	<u>(10,667)</u>	<u>(53,621)</u>	<u>(81,698)</u>	<u>(165,545)</u>
OTHER INCOME (EXPENSE), NET:				
Interest income	1,376	3,509	5,924	10,785
Interest expense	(1,811)	(3,385)	(6,790)	(10,405)
Change in the fair value of contingent consideration	3,926	1,300	16,626	(27,800)
Other income (expense), net	9,368	(1,664)	11,047	(1,534)
Total other income (expense), net	<u>12,859</u>	<u>(240)</u>	<u>26,807</u>	<u>(28,954)</u>
INCOME (LOSS) BEFORE INCOME TAXES	<u>2,192</u>	<u>(53,861)</u>	<u>(54,891)</u>	<u>(194,499)</u>
INCOME TAX PROVISION (BENEFIT)	<u>2,326</u>	<u>(983)</u>	<u>13,328</u>	<u>(3,233)</u>
NET LOSS	<u>\$ (134)</u>	<u>\$ (52,878)</u>	<u>\$ (68,219)</u>	<u>\$ (191,266)</u>
LOSS PER ORDINARY SHARE:				
Basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.34)</u>	<u>\$ (0.43)</u>	<u>\$ (1.22)</u>
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic and diluted	<u>159,062</u>	<u>157,199</u>	<u>158,685</u>	<u>156,845</u>
COMPREHENSIVE LOSS:				
Net loss	\$ (134)	\$ (52,878)	\$ (68,219)	\$ (191,266)
Unrealized (loss) gain, net of a tax (benefit) provision of \$(193), \$(15), \$303 and \$479, respectively	(659)	(24)	1,056	1,642
COMPREHENSIVE LOSS	<u>\$ (793)</u>	<u>\$ (52,902)</u>	<u>\$ (67,163)</u>	<u>\$ (189,624)</u>

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,	
	2020	2019
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (68,219)	\$ (191,266)
Adjustments to reconcile net loss to cash flows from operating activities:		
Share-based compensation expense	65,279	79,590
Depreciation and amortization	61,525	59,901
Deferred income taxes	9,939	(3,025)
Change in the fair value of contingent consideration	(16,626)	27,800
Other non-cash charges	2,105	90
Changes in assets and liabilities:		
Receivables	(8,551)	41,988
Contract assets	(6,009)	3,207
Inventory	(20,748)	(10,324)
Prepaid expenses and other assets	5,597	2,120
Right-of-use assets	13,251	6,306
Accounts payable and accrued expenses	(6,222)	20,542
Contract liabilities	(3,045)	292
Operating lease liabilities	(11,910)	(6,845)
Other long-term liabilities	(867)	(369)
Cash flows provided by operating activities	<u>15,499</u>	<u>30,007</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(36,780)	(58,972)
Proceeds from the sale of equipment	61	900
Proceeds from contingent consideration	2,819	10,000
Return of Fountain Healthcare Partners II, L.P. investment	2,751	—
Purchases of investments	(151,324)	(141,749)
Sales and maturities of investments	206,089	149,459
Cash flows provided by (used in) investing activities	<u>23,616</u>	<u>(40,362)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	7,719	16,381
Employee taxes paid related to net share settlement of equity awards	(7,607)	(9,230)
Principal payments of long-term debt	(2,132)	(2,132)
Cash flows (used in) provided by financing activities	<u>(2,020)</u>	<u>5,019</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	37,095	(5,336)
CASH AND CASH EQUIVALENTS—Beginning of period	203,771	266,762
CASH AND CASH EQUIVALENTS—End of period	<u>\$ 240,866</u>	<u>\$ 261,426</u>
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 2,169	\$ 14,664

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 Capital	Accumulated Other Comprehensive Loss (In thousands, except share data)	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
BALANCE — December 31, 2019	160,489,888	1,602	2,586,030	(1,816)	(1,381,988)	(2,710,886)	(118,386)	1,085,442
Issuance of ordinary shares under employee stock plans	258,137	3	3,068	—	—	—	—	3,071
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	1,020,510	10	(10)	—	—	(372,846)	(7,283)	(7,283)
Share-based compensation expense	—	—	20,125	—	—	—	—	20,125
Unrealized gain on marketable securities, net of tax provision of \$87	—	—	—	317	—	—	—	317
Net loss	—	—	—	—	(38,654)	—	—	(38,654)
BALANCE — March 31, 2020	161,768,535	\$ 1,615	\$ 2,609,213	\$ (1,499)	\$ (1,420,642)	(3,083,732)	\$ (125,669)	\$ 1,063,018
Issuance of ordinary shares under employee stock plans	327,251	3	3,845	—	—	—	—	3,848
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	24,175	—	—	—	—	(7,874)	(123)	(123)
Share-based compensation expense	—	—	23,136	—	—	—	—	23,136
Unrealized gain on marketable securities, net of tax provision of \$409	—	—	—	1,398	—	—	—	1,398
Net loss	—	—	—	—	(29,431)	—	—	(29,431)
BALANCE — June 30, 2020	162,119,961	\$ 1,618	\$ 2,636,194	\$ (101)	\$ (1,450,073)	(3,091,606)	\$ (125,792)	\$ 1,061,846
Issuance of ordinary shares under employee stock plans	53,509	—	800	—	—	—	—	800
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	34,675	1	(1)	—	—	(11,106)	(201)	(201)
Share-based compensation expense	—	—	22,706	—	—	—	—	22,706
Unrealized loss on marketable securities, net of tax benefit of \$(193)	—	—	—	(659)	—	—	—	(659)
Net loss	—	—	—	—	(134)	—	—	(134)
BALANCE — September 30, 2020	162,208,145	\$ 1,619	\$ 2,659,699	\$ (760)	\$ (1,450,207)	(3,102,712)	\$ (125,993)	\$ 1,084,358

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
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

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. Alkermes has a diversified portfolio of marketed products focused on CNS disorders such as addiction and schizophrenia and a pipeline of product candidates in the fields of neuroscience and oncology. Headquartered in Dublin, Ireland, the Company has a research and development (“R&D”) center in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and nine months ended September 30, 2020 and 2019 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2019. 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 Chief Executive Officer and Chairman of the Company’s board of directors, reviews the Company’s operating results on an aggregate basis and manages the Company’s operations as a single operating unit.

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Unaudited) (Continued)

Risks and Uncertainties

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. All U.S. states, and many local jurisdictions and countries around the world, including Ireland, have, at times during the pandemic, issued “shelter-in-place” orders, quarantines, executive orders and similar government orders, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses, including healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia, work stoppages, slowdowns and/or delays, work-from-home policies and travel restrictions, among other effects. While the Company has begun to observe a gradual normalization in patient and healthcare provider practices, the impacts and extent of such normalization are not yet known, and it remains difficult to predict the nature and extent of the future impacts that the pandemic will have on such practices and, as a result, on the Company’s business.

The Company continues to closely monitor and rapidly respond to the ongoing impact of COVID-19 on its employees, communities and business operations. Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, the Company is unable to predict the extent of the impact that the COVID-19 pandemic may continue to have on the Company’s future financial condition and operating results. These uncertainties include, among other things, the ultimate severity and duration of the pandemic; governmental, business or other actions that have been, are being or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions, and imposition of social distancing measures; impacts of the pandemic on the vendors or distribution channels in the Company’s supply chain and on the Company’s ability to continue to manufacture its products; impacts of the pandemic on the conduct of the Company’s clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia; impacts of the pandemic on the regulatory agencies with which the Company interacts in the development, review, approval and commercialization of its medicines; impacts of the pandemic on reimbursement for the Company’s products, including the Company’s Medicaid rebate liability, and for services related to the use of its products; and impacts of the pandemic on the U.S., Irish and global economies more broadly.

The Company relies upon third parties for many aspects of its business, including the provision of goods and services related to the manufacture of its clinical products and its and its partners’ marketed products, the conduct of its clinical trials, and the sale of marketed products from which the Company receives manufacturing and royalty revenue. Any prolonged material disruption to the third parties on which the Company relies could negatively impact the Company’s ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on the Company’s business, results of operations and financial condition.

The marketed products from which the Company derives revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including the implementation of “shelter-in-place” policies, social distancing requirements and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees and the Company expects commercial sales of these marketed products to continue to be adversely impacted while the pandemic persists.

As it relates to the Company’s proprietary marketed products, despite continuing COVID-19-related impacts on access to healthcare provider facilities and patient flow, during the three months ended September 30, 2020, the Company saw an increase of 22% in the number of VIVITROL units sold compared to the three months ended June 30, 2020. ARISTADA units sold during the three months ended September 30, 2020 increased 7% compared to the three months ended June 30, 2020. During the three months ended September 30, 2020, the Company continued to take actions to support uninterrupted access to its proprietary marketed products. However, the Company currently expects commercial sales of its marketed products, particularly VIVITROL, to continue to be impacted by the COVID-19 pandemic over the next few quarters, including, for VIVITROL, as a result of the impact that the decrease in patient volume during the previous two quarters is expected to have on overall unit demand in the fourth quarter of 2020 and beyond. These items are discussed in greater detail in the “Results of Operations” section in “Part I, Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Form 10-Q.

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Unaudited) (Continued)

The Company continues to operate its manufacturing facilities and supply its medicines. While the Company continues to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has impacted, and may continue to impact, the timelines of certain of its early-stage discovery efforts and clinical trials. The Company is working with its internal teams, its clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, any potential adverse impacts of COVID-19 on its manufacturing operations and R&D activities.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the “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 standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In June 2016, the FASB issued Accounting Standards Update (“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 standard primarily impacts how firms account for credit losses and requires an impairment model, known as the current expected credit loss model, that is based on expected losses rather than incurred losses. Companies are required to carry an allowance for expected credit losses for most debt instruments (except those carried at fair value), trade receivables, lease receivables, reinsurance receivables, financial guarantee contracts and loan commitments. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which the carrying value exceeds fair value and requires the reversal of previous recognized credit losses if fair value increases. The Company’s investment portfolio primarily consists of available-for-sale securities carried at fair value. Further, the Company’s trade receivables do not have abnormally long terms and the Company has historically rarely written off trade receivables. The Company adopted this standard on January 1, 2020 and the adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *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. The Company adopted this standard on January 1, 2020 and the adoption of this standard had no impact on the Company’s financial statement disclosures.

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. The Company adopted this standard on January 1, 2020 using the prospective transition method, whereby it applied the requirements to any eligible costs incurred after adoption. The Company has not incurred any material eligible costs during the nine months ended September 30, 2020.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles of Accounting Standards Codification (“ASC”) 740, *Income Taxes* (“Topic 740”). The amendments also improve consistent application of, and simplify, GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The Company adopted this standard on January 1, 2020 and the adoption of this standard had no material impact on the Company’s consolidated financial statements.

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In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform*, which provides optional guidance for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. This amendment applies to all entities, subject to meeting certain criteria, that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. This ASU became effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company is currently assessing the impact that this ASU may have on its consolidated financial statements.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Under FASB ASC 606, *Revenue from Contracts with Customers* (“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 specialty 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, 2020 and 2019, the Company recorded product sales, net, as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
VIVITROL	\$ 80,258	\$ 85,164	\$ 230,673	\$ 242,546
ARISTADA/ARISTADA INITIO	62,400	53,610	172,126	132,344
Total product sales, net	<u>\$ 142,658</u>	<u>\$ 138,774</u>	<u>\$ 402,799</u>	<u>\$ 374,890</u>

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2020 and 2019, the Company recorded manufacturing and royalty revenues as follows:

(In thousands)	Three Months Ended September 30, 2020			Nine Months Ended September 30, 2020		
	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	\$ —	\$ 73,366	\$ 73,366	\$ —	\$ 197,678	\$ 197,678
RISPERDAL CONSTA	10,993	3,517	14,510	44,769	10,786	55,555
Other	14,312	18,163	32,475	46,088	53,786	99,874
	<u>\$ 25,305</u>	<u>\$ 95,046</u>	<u>\$ 120,351</u>	<u>\$ 90,857</u>	<u>\$ 262,250</u>	<u>\$ 353,107</u>

(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
Other	11,562	15,506	27,068	42,460	53,953	96,413
	<u>\$ 16,082</u>	<u>\$ 87,701</u>	<u>\$ 103,783</u>	<u>\$ 85,408</u>	<u>\$ 255,187</u>	<u>\$ 340,595</u>

ALKERMES PLC AND SUBSIDIARIES
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Research and Development Revenue

The Company recorded R&D revenue of \$1.0 million and \$1.8 million during the three and nine months ended September 30, 2020, respectively, of which \$0.1 million and \$0.3 million, respectively, related to its license and collaboration agreement with Biogen for VUMERITY. The Company recorded R&D revenue of \$12.7 million and \$41.7 million during the three and nine months ended September 30, 2019, respectively, of which \$12.1 million and \$39.5 million, respectively, related to its license and collaboration agreement with Biogen for VUMERITY.

The Company expects to earn less than \$0.1 million in additional R&D revenue under this agreement with Biogen through the end of 2020.

Contract Assets

Contract assets include unbilled amounts under certain of the Company's contracts with customers where revenue is recognized over time. Total contract assets as of September 30, 2020 include \$14.4 million of assets that are classified as "Current assets" in the accompanying condensed consolidated balance sheet, as they related to manufacturing processes that are completed in ten days to eight weeks, and \$5.0 million that is classified as "Other assets" in the accompanying condensed consolidated balance sheet, as it consists of consideration from the Company's collaboration with Biogen related to VUMERITY, which the Company expects to receive in approximately two years.

Total contract assets at September 30, 2020 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2019	\$ 13,386
Additions	36,569
Transferred to receivables, net	(30,560)
Contract assets at September 30, 2020	<u>\$ 19,395</u>

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue.

Total contract liabilities at September 30, 2020 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2019	\$ 28,834
Additions	—
Amounts recognized into revenue	(3,046)
Contract liabilities at September 30, 2020	<u>\$ 25,788</u>

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

4. INVESTMENTS

Investments consisted of the following (in thousands):

September 30, 2020	Amortized Cost	Gross Unrealized			Allowance for Credit Losses	Estimated Fair Value
		Gains	Losses			
			Less than One Year	Greater than One Year		
Short-term investments:						
Available-for-sale securities:						
Corporate debt securities	\$ 163,511	\$ 1,484	\$ (2)	\$ —	\$ (977)	\$ 164,016
U.S. government and agency debt securities	85,207	535	(1)	—	—	85,741
International government agency debt securities	76,264	659	(8)	—	—	76,915
	<u>324,982</u>	<u>2,678</u>	<u>(11)</u>	<u>—</u>	<u>(977)</u>	<u>326,672</u>
Held-to-maturity securities:						
Fixed term deposit account	1,668	176	—	—	—	1,844
Total short-term investments	<u>326,650</u>	<u>2,854</u>	<u>(11)</u>	<u>—</u>	<u>(977)</u>	<u>328,516</u>
Long-term investments:						
Available-for-sale securities:						
Corporate debt securities	10,505	—	(21)	—	—	10,484
U.S. government and agency debt securities	8,584	—	(1)	—	—	8,583
International government agency debt securities	6,899	—	(12)	—	—	6,887
	<u>25,988</u>	<u>—</u>	<u>(34)</u>	<u>—</u>	<u>—</u>	<u>25,954</u>
Held-to-maturity securities:						
Certificates of deposit	1,820	—	—	—	—	1,820
Total long-term investments	<u>27,808</u>	<u>—</u>	<u>(34)</u>	<u>—</u>	<u>—</u>	<u>27,774</u>
Total investments	<u>\$ 354,458</u>	<u>\$ 2,854</u>	<u>\$ (45)</u>	<u>\$ —</u>	<u>\$ (977)</u>	<u>\$ 356,290</u>
December 31, 2019						
Short-term investments:						
Available-for-sale securities:						
Corporate debt securities	\$ 144,161	\$ 676	\$ —	\$ —	\$ —	\$ 144,837
U.S. government and agency debt securities	112,948	434	(1)	(1)	—	113,380
International government agency debt securities	72,753	248	(10)	—	—	72,991
Total short-term investments	<u>329,862</u>	<u>1,358</u>	<u>(11)</u>	<u>(1)</u>	<u>—</u>	<u>331,208</u>
Long-term investments:						
Available-for-sale securities:						
Corporate debt securities	51,070	—	(45)	(7)	—	51,018
International government agency debt securities	20,806	—	(18)	—	—	20,788
U.S. government and agency debt securities	4,000	—	(4)	—	—	3,996
	<u>75,876</u>	<u>—</u>	<u>(67)</u>	<u>(7)</u>	<u>—</u>	<u>75,802</u>
Held-to-maturity securities:						
Certificates of deposit	1,820	—	—	—	—	1,820
Fixed term deposit account	1,667	102	—	—	—	1,769
	<u>3,487</u>	<u>102</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>3,589</u>
Total long-term investments	<u>79,363</u>	<u>102</u>	<u>(67)</u>	<u>(7)</u>	<u>—</u>	<u>79,391</u>
Total investments	<u>\$ 409,225</u>	<u>\$ 1,460</u>	<u>\$ (78)</u>	<u>\$ (8)</u>	<u>\$ —</u>	<u>\$ 410,599</u>

At September 30, 2020, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were temporary or other-than-temporary. The investments with unrealized losses consisted primarily of corporate debt securities. In making the determination whether 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 of the securities; the Company's intent not to sell these securities; and the assessment that it is

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more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis. At September 30, 2020, the Company determined that the loss on one of its corporate debt securities was other-than-temporary and recorded a \$1.0 million impairment within “Other income (expense), net” in the accompanying condensed consolidated statements of operations and comprehensive loss.

In May 2014, the Company entered into an agreement whereby it committed to provide up to €7.4 million to Fountain Healthcare Partners II, L.P., an Irish partnership (“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. The Company’s commitment to Fountain represents approximately 7% of Fountain’s total funding. As of September 30, 2020, the Company had invested €5.8 million in Fountain. The Company is accounting for its investment in Fountain under the equity method.

During the three months ended September 30, 2020, two of the companies within the Fountain portfolio were acquired by third parties. The Company’s proportional share of the proceeds from these transactions was \$11.1 million, of which \$10.4 million was received in September 2020 and \$0.7 million is held in escrow. The transactions were accounted for under the cumulative earnings approach whereby the return on investment of \$8.3 million was recorded as a gain within “Other income (expense), net” in the accompanying condensed consolidated statements of operations and comprehensive loss and the return of investment of \$2.8 million was recorded as a reduction in the Company’s net investment in Fountain. The Company’s net investment in Fountain was \$4.7 million and \$5.9 million at September 30, 2020 and December 31, 2019, respectively, and was included within “Other assets” in the accompanying condensed consolidated balance sheets.

The proceeds from 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,	
	2020	2019
Proceeds from the sales and maturities of marketable securities	\$ 206,089	\$ 149,459
Realized gains	\$ 8,336	\$ —
Realized losses	\$ 977	\$ 497

The Company’s available-for-sale and held-to-maturity securities at September 30, 2020 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 221,539	\$ 221,770	\$ 3,488	\$ 3,664
After 1 year through 5 years	129,431	130,856	—	—
Total	<u>\$ 350,970</u>	<u>\$ 352,626</u>	<u>\$ 3,488</u>	<u>\$ 3,664</u>

5. FAIR VALUE

The following table presents information about the Company’s assets and liabilities at September 30, 2020 and December 31, 2019 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, 2020	Level 1	Level 2	Level 3
	Assets:			
Cash equivalents	\$ 43,089	\$ 43,089	\$ —	\$ —
U.S. government and agency debt securities	94,324	61,880	32,444	—
Corporate debt securities	174,500	—	173,523	977
International government agency debt securities	83,802	—	83,802	—
Contingent consideration	46,200	—	—	46,200
Total	<u>\$ 441,915</u>	<u>\$ 104,969</u>	<u>\$ 289,769</u>	<u>\$ 47,177</u>

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	December 31, 2019	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 8,064	\$ 8,064	\$ —	\$ —
U.S. government and agency debt securities	117,376	73,795	43,581	—
Corporate debt securities	195,855	—	193,902	1,953
International government agency debt securities	93,779	—	93,779	—
Contingent consideration	32,400	—	—	32,400
Total	\$ 447,474	\$ 81,859	\$ 331,262	\$ 34,353

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, 2020. 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, 2020:

(In thousands)	Fair Value
Balance, January 1, 2020	\$ 34,353
Change in the fair value of contingent consideration	16,626
Payments received by the Company related to contingent consideration	(2,819)
Payments due to the Company related to contingent consideration	(6)
Impairment of corporate debt security	(977)
Balance, September 30, 2020	<u>\$ 47,177</u>

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 Company's sale in April 2015 of its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam (collectively, the "Gainesville Transaction") to Recro Pharma, Inc. ("Recro") and Recro Pharma LLC. As part of the Gainesville Transaction, the Company obtained rights to receive contingent payments upon the achievement by such Meloxicam products of certain regulatory and sales milestones and royalties on future net sales of such Meloxicam products. Additional details regarding the Gainesville Transaction can be found in Note 5, *Fair Value*, in the Notes to Consolidated Financial Statements in the Annual Report.

In November 2019, Recro completed a spin out of its acute care segment into a new entity named Baudax Bio, Inc. ("Baudax"), a publicly traded pharmaceutical company. As part of this transaction, Recro's obligations to pay certain of the contingent consideration from the Gainesville Transaction were assigned and/or transferred to Baudax.

On February 20, 2020, ANJESO (formerly referred to as Meloxicam IV/IM), was approved by the U.S. Food and Drug Administration (the "FDA"). At September 30, 2020 and December 31, 2019, the Company determined that the value of the contingent consideration was \$46.2 million and \$32.4 million, respectively. The Company recorded an increase of \$3.9 million and \$16.6 million during the three and nine months ended September 30, 2020, respectively, and an increase of \$1.3 million and a decrease of \$27.8 million during the three and nine months ended September 30, 2019, respectively, within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss. The fair value of the contingent consideration was developed using the same valuation approaches as described in Note 5, *Fair Value*, in the Notes to Consolidated Financial Statements in the Annual Report, using a discount rate of 16% in all three valuation approaches at September 30, 2020 and December 31, 2019.

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On August 17, 2020, the Company and Baudax agreed to amend the timing of payment of the \$5.0 million milestone payment due to the Company in August 2020 as a result of the approval of the new drug application (“NDA”) for ANJESO, such that the Company received \$2.5 million in August 2020 and will receive: (i) \$1.1 million on or prior to December 20, 2020; and (ii) \$1.4 million on or prior to June 20, 2021. In consideration of the amendment of the timing of this milestone payment, Baudax paid the Company an additional \$0.3 million in August 2020.

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

The estimated fair value of the Company’s long-term debt under its amended and restated credit agreement (such debt, the “2023 Term Loans”), which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been, or will be, realized in the future, was \$274.0 million and \$277.9 million at September 30, 2020 and December 31, 2019, respectively. Please refer to Note 11, *Long-Term Debt* in these “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q for additional information.

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, 2020	December 31, 2019
Raw materials	\$ 42,163	\$ 34,577
Work in process	53,336	54,061
Finished goods(1)	27,324	13,165
Total inventory	<u>\$ 122,823</u>	<u>\$ 101,803</u>

(1) At September 30, 2020 and December 31, 2019, the Company had \$27.2 million and \$7.6 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

As of September 30, 2020 and December 31, 2019, the carrying value of inventory includes \$15.3 million and none, respectively, associated with the Company’s ALKS 3831 development program, which was capitalized in advance of potential regulatory approval.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019
Land	\$ 6,560	\$ 6,560
Building and improvements	178,193	177,087
Furniture, fixtures and equipment	362,936	340,146
Leasehold improvements	52,438	20,737
Construction in progress	103,917	134,683
Subtotal	704,044	679,213
Less: accumulated depreciation	(348,829)	(317,045)
Total property, plant and equipment, net	<u>\$ 355,215</u>	<u>\$ 362,168</u>

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8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	September 30, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,873	\$ —	\$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 465,590	\$ (370,404)	\$ 95,186
NanoCrystal technology	13	74,600	(52,476)	22,124
OCR(1) technologies	12	42,560	(38,762)	3,798
Total		\$ 582,750	\$ (461,642)	\$ 121,108

(1) OCR refers to the Company's oral controlled release technologies.

Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at September 30, 2020 is expected to be approximately \$40.0 million, \$40.0 million, \$35.0 million, \$35.0 million and \$1.0 million in the years ending December 31, 2020 through 2024, 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

In March 2018, the Company entered into a lease agreement for approximately 220,000 square feet of office and laboratory space at 900 Winter Street, Waltham, Massachusetts ("900 Winter Street"). The initial term of the operating lease for 900 Winter Street commenced on January 20, 2020 and expires in 2035, with an option to extend for an additional 10 years. The Company did not assume this option would be exercised in the calculation of its right-of-use asset and lease liability amounts.

The Company has determined that the identified operating lease did not contain non-lease components and required no further allocation of the total lease cost. Additionally, the agreement in place did not contain information to determine the rate implicit in the lease.

At September 30, 2020, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.58% and 14.0 years, respectively. During the three and nine months ended September 30, 2020, cash paid for amounts included for the measurement of lease liabilities was \$5.0 million and \$11.9 million, respectively, compared to \$2.2 million and \$6.8 million during the three and nine months ended September 30, 2019, respectively. The Company recorded operating lease expense of \$4.7 million and \$13.3 million, during the three and nine months ended September 30, 2020, respectively, compared to \$2.1 million and \$6.3 million during the three and nine months ended September 30, 2019, respectively.

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Unaudited) (Continued)

Future lease payments under non-cancelable leases as of September 30, 2020 and December 31, 2019 consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019 (1)
2020	\$ 4,335	\$ 9,053
2021	12,948	2,727
2022	10,788	500
2023	10,913	509
2024	11,040	520
Thereafter	117,994	2,579
Total lease payments	<u>168,018</u>	<u>15,888</u>
Less: imputed interest	(57,926)	(2,080)
Total operating lease liabilities	<u>\$ 110,092</u>	<u>\$ 13,808</u>

- (1) As of December 31, 2019, the term of the 900 Winter Street lease had not commenced and the Company (a) did not have the right to obtain or control the leased premises during the construction period; (b) did not have the right of payment for the partially constructed assets, and thus, the partially constructed assets could have potentially been leased to another tenant; and (c) did not legally own or control the land on which the property improvements were being constructed. As such, the lease assets were not included as right-of-use assets at December 31, 2019. The future lease payments outlined above do not include the 900 Winter Street lease payments as of December 31, 2019 under ASU 2016-02, *Leases* (“Topic 842”).

In July 2020, the Company entered into an amendment to its existing lease at 852 Winter Street, Waltham, Massachusetts (as amended, the “852 Winter Street Lease”). The amendment became effective on October 7, 2020. The 852 Winter Street Lease governs approximately 180,000 square feet of corporate office space, administrative areas and laboratories. The amendment served to, among other things, extend the term of the 852 Winter Street Lease for a period of approximately five years, to commence in March 2021 and expire in April 2026 with respect to approximately 163,000 square feet of the 852 Winter Street Lease premises (the “Base Premises”) and to commence in September 2021 and expire in October 2026 with respect to approximately 17,000 square feet of the 852 Winter Street Lease premises (the “Additional Premises”). The Company expects to make annual lease payments of approximately \$5.7 million for the Base Premises and \$0.5 million for the Additional Premises, subject to annual increases. Under the terms of the 852 Winter Street Lease, the Company will have the option to extend for an additional five-year term. The Company determined that the amendment did not grant an additional right-of-use and therefore was not deemed to be a separate new lease and that the 852 Winter Street Lease should be reassessed and remeasured as of the effective date of the amendment. The Company will account for the amendment prospectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019
Accounts payable	\$ 82,835	\$ 54,261
Accrued compensation	72,832	72,072
Accrued sales discounts, allowances and reserves	145,347	153,902
Accrued other	53,766	92,802
Total accounts payable and accrued expenses	<u>\$ 354,780</u>	<u>\$ 373,037</u>

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Unaudited) (Continued)

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2020	December 31, 2019
2023 Term Loans, due March 26, 2023	\$ 275,506	\$ 277,138
Less: current portion	(2,843)	(2,843)
Long-term debt	<u>\$ 272,663</u>	<u>\$ 274,295</u>

The 2023 Term Loans have a due date of March 26, 2023 and interest payable of LIBOR plus 2.25% with a LIBOR floor of 0%. As of September 30, 2020, the Company was in compliance with its debt covenants.

12. SHARE-BASED COMPENSATION

The following table presents share-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of goods manufactured and sold	\$ 2,344	\$ 2,912	\$ 6,324	\$ 7,395
Research and development	6,762	8,195	19,400	24,076
Selling, general and administrative	13,514	15,622	39,555	48,119
Total share-based compensation expense	<u>\$ 22,620</u>	<u>\$ 26,729</u>	<u>\$ 65,279</u>	<u>\$ 79,590</u>

At September 30, 2020 and December 31, 2019, \$2.2 million and \$1.5 million, respectively, of share-based compensation expense 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 three specified performance criteria over a performance period of three years from the date of the grant.

The Company achieved one of the three performance criteria in December 2018, resulting in the vesting of a portion of the performance-based RSUs. In February 2020, the compensation committee of the Company's board of directors acknowledged that the two remaining performance criteria had not been achieved prior to the expiration of the three-year performance period and the unvested portion of the awards expired.

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, 2020 and 2019, as the Company was in a net loss position, the diluted loss per ordinary share calculation did not assume conversion or exercise of stock options and restricted stock units, as they would have had an anti-dilutive effect on loss per ordinary share.

The following potential ordinary share equivalents have not been included in the loss per ordinary share calculations because the effect would have been anti-dilutive:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock options	15,322	13,867	15,352	14,077
Restricted stock units	2,351	3,344	3,678	3,110
Total	<u>17,673</u>	<u>17,211</u>	<u>19,030</u>	<u>17,187</u>

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Unaudited) (Continued)

14. RESTRUCTURING

In October 2019, the Company approved a restructuring plan following a review of its operations, cost structure and growth opportunities (the “Restructuring”). The Restructuring included a reduction in headcount of approximately 160 employees across the Company. The Company recorded a charge of \$13.4 million in the fourth quarter of 2019 as a result of the Restructuring, which consisted of one-time termination benefits for employee severance, benefits and related costs, all of which were expected to result in cash expenditures and substantially all of which would be paid out within one year. Restructuring activity during the nine months ended September 30, 2020 was as follows:

(In thousands)	
Balance, December 31, 2019	\$ 9,201
Amounts paid during the period:	
Severance	(6,714)
Outplacement services	(108)
Benefits	(1,224)
Balance, September 30, 2020	<u>\$ 1,155</u>

At September 30, 2020 and December 31, 2019, \$1.2 million and \$9.0 million of the restructuring accrual, respectively, was included within “Accounts payable and accrued expenses” and none and \$0.2 million of the restructuring accrual, respectively, was included within “Other long-term liabilities” in the accompanying condensed consolidated balance sheets.

15. 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, 2020, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

INVEGA SUSTENNA ANDA Litigation

Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the U.S. District Court for the District of New Jersey (the “NJ District Court”) in January 2018 against Teva Pharmaceuticals USA, Inc. (“Teva”) and Teva Pharmaceuticals Industries, Ltd. (“Teva PI”), in August 2019 against Mylan Laboratories Limited (“Mylan Labs”), Mylan Pharmaceuticals Inc. (“Mylan”), and Mylan Institutional LLC and in December 2019 against Pharmascience, Inc. (“Pharmascience”), Mallinckrodt plc, and SpecGX LLC, following the respective filings by each of Teva, Mylan Labs, and Pharmascience of an abbreviated new drug application (“ANDA”) seeking approval from the FDA 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 any of these proceedings.

INVEGA TRINZA ANDA Litigation

In September 2020, Janssen Pharmaceuticals NV, Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC, initiated a patent infringement lawsuit in the NJ District Court against Mylan Labs, Mylan, and Mylan Institutional LLC following the filing by Mylan Labs of an ANDA seeking approval from the FDA to market a generic version of INVEGA TRINZA before the expiration of U.S. Patent No. 10,143,693. Requested judicial remedies include recovery of litigation costs and injunctive relief. The Company is not a party to this proceeding.

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 in June 2019. Pharmathen SA submitted a reply on November 5, 2019 and Nanjing Luye Pharmaceutical Co Ltd. and Teva Pharmaceutical Industries Ltd. submitted replies on December 20, 2019. The Company will continue to vigorously defend the EP ’577 Patent.

VIVITROL ANDA Litigation

In September 2020, Alkermes, Inc. and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in the NJ District Court against Teva and Teva PI following the filing by Teva of an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VIVITROL (naltrexone for extended-release injectable suspension) before the expiration of the Company’s U.S. Patent No. 7,919,499. The Company intends to vigorously defend its intellectual property. The filing of the lawsuit triggered a stay of FDA approval of the ANDA for up to 30 months in accordance with the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).

Government Matters

The Company has received a subpoena and civil investigative demands from U.S. state and Federal governmental authorities for documents related to VIVITROL. The Company is cooperating with the investigations.

Securities Litigation

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 U.S. 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. In August 2019, the defendants filed a pre-motion letter (in respect of a requested motion to dismiss filing) with the EDNY District Court and plaintiff filed a response. On November 27, 2019, the defendants served the plaintiff with a motion to dismiss, and on December 27, 2019, the plaintiff served the defendants with its opposition to such motion. On January 17, 2020, the defendants filed the fully-briefed motion, including a reply to the plaintiff’s opposition, with the EDNY District Court.

Product Liability and Other Legal Proceedings

The Company is also involved in product liability cases and other legal proceedings incidental to its normal business activities, including product liability cases alleging that the FDA-approved VIVITROL labeling was inadequate and caused the users of the product to suffer from opioid overdose and death. The Company intends to vigorously defend itself in these matters. While the outcome of any of these proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any of these existing matters would have a material adverse effect on the Company’s business or financial condition.

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 in this Form 10-Q, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited financial statements and notes thereto included in our Annual Report.

Executive Summary

Net loss for the three and nine months ended September 30, 2020 was \$0.1 million and \$68.2 million, respectively, or \$0.00 and \$0.43 per ordinary share—basic and diluted, respectively, as compared to a net loss of \$52.9 million and \$191.3 million, respectively, or \$0.34 and \$1.22 per ordinary share—basic and diluted, respectively, for the three and nine months ended September 30, 2019.

The decrease in net loss in the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to an \$9.8 million increase in revenue and a \$33.2 million decrease in operating expenses. The increase in revenue was primarily due to a \$3.9 million increase in product sales, net and a \$16.6 million increase in manufacturing and royalty revenues, partially offset by an \$11.7 million decrease in R&D revenue. The decrease in operating expenses was primarily due to a \$21.0 million decrease in selling, general and administrative expense and a \$12.6 million decrease in R&D expense.

The decrease in net loss in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to an \$83.3 million decrease in operating expenses. The decrease in operating expenses was primarily due to a \$51.9 million decrease in selling, general and administrative expense and a \$32.2 million decrease in R&D expense. In addition, R&D revenue decreased by \$39.9 million, partially offset by an increase in product sales, net of \$27.9 million and an increase in manufacturing and royalty revenues of \$12.5 million.

These items are discussed in greater detail later in the "Results of Operations" section in this "Part I, Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Form 10-Q.

COVID-19 Update

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. All U.S. states, and many local jurisdictions and countries around the world, including Ireland, have, at times during the pandemic, issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses, including healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia, work stoppages, slowdowns and/or delays, work-from-home policies and travel restrictions, among other effects.

We continue to closely monitor and rapidly respond to the ongoing impact of COVID-19 on our employees, our communities and our business operations. We have adopted a series of precautionary measures and will continue to do so as the circumstances warrant, in an effort to protect our employees and mitigate the potential spread of COVID-19 in a community setting. For example, we instituted a global remote work policy for those of our employees who are able to work remotely. Starting in July 2020, our field-based employees resumed in-person interactions, as appropriate and on a voluntary basis, in accordance with location-specific guidance.

At the same time, we have worked to continue our critical business functions, including continued operation of our manufacturing facilities and our laboratories, and have continued to conduct our discovery efforts and supply our medicines. For those of our employees who work in our manufacturing facilities and laboratories or who otherwise enter any of our sites, we have instituted, and will continue to institute as we deem appropriate and as required, additional safety precautions, including increased sanitization of our facilities, use of personal protective equipment, implementation of a daily health screening application and physical distancing practices to help protect their health and safety. We have also taken actions to support people living with schizophrenia, opioid dependence and alcohol

dependence to help assure that they have access to the information, resources and medicines that may assist in their treatment.

The marketed products from which we derive revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including the implementation of “shelter-in-place” policies, social distancing requirements and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees and we expect commercial sales of these marketed products to continue to be adversely impacted while the pandemic persists.

As it relates to our proprietary marketed products, despite continuing COVID-19-related impacts on access to healthcare provider facilities and patient flow, during the three months ended September 30, 2020, we saw an increase of 22% in the number of VIVITROL units sold compared to the three months ended June 30, 2020. ARISTADA units sold during the three months ended September 30, 2020 increased 7% compared to the three months ended June 30, 2020. During the three months ended September 30, 2020, we continued to take actions to support uninterrupted access to our proprietary marketed products. However, we currently expect commercial sales of our marketed products, particularly VIVITROL, to continue to be impacted by the COVID-19 pandemic over the next few quarters, including, for VIVITROL, as a result of the impact that the decrease in patient volume during the previous two quarters is expected to have on overall unit demand in the fourth quarter of 2020 and beyond. These items are discussed in greater detail later in the “Results of Operations” section in this “Part I, Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Form 10-Q.

While we continue to conduct R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has impacted, and may continue to impact, the timelines of certain of our early-stage discovery efforts and clinical trials. We are working with our internal teams, our clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on our manufacturing operations and R&D activities.

While we have begun to observe a gradual normalization in patient and healthcare provider practices, the impacts and extent of such normalization are not yet known. Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, we are unable to predict the nature and extent of the future impacts that the pandemic will have on our financial condition and operating results. These uncertainties include, among other things, the ultimate severity and duration of the pandemic; governmental, business or other actions that have been, are being, or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions and imposition of social distancing measures; impacts of the pandemic on the vendors or distribution channels in our supply chain and on our ability to continue to manufacture our products; impacts of the pandemic on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia; impacts of the pandemic on the regulatory agencies with which we interact in the development, review, approval and commercialization of our medicines; impacts of the pandemic on reimbursement for our products, including our Medicaid rebate liability, and for services related to the use of our products; and impacts of the pandemic on the U.S., Irish and global economies more broadly. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

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 see “Part I, Item 1A—Risk Factors” in our Annual Report and “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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 see the “Patents and Proprietary Rights” section in “Part I, Item 1—Business” in our Annual Report and in the “Products” section in “Part I, Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

The following table provides summary information regarding our proprietary products that we commercialize:

Product	Indication(s)	Territory
<p>ARISTADA INITIO[®] aripiprazole lauroxil extended-release injectable suspension</p> <p>675 mg</p>	<p>Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia</p>	<p>U.S.</p>
<p>+</p> <p>ARISTADA[®]  aripiprazole lauroxil extended-release injectable suspension</p> <p>441 mg 662 mg 882 mg 1064 mg</p>	<p>Schizophrenia</p>	<p>U.S.</p>
<p>Vivitrol[®] (maltrexone for extended-release injectable suspension) 380 mg/vial</p>	<p>Alcohol dependence and Opioid dependence</p>	<p>U.S.</p>

The following table provides summary information regarding our key licensed products, and key third-party products using our proprietary technologies under license, that are commercialized by our licensees:

Third-Party Products Using Our Proprietary Technologies

Product	Indication(s)	Licensee	Licensed 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 / XEPLION	INVEGA SUSTENNA: Schizophrenia and Schizoaffective disorder XEPLION: Schizophrenia	Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates “Janssen”)	Worldwide
INVEGA TRINZA / TREVICTA	Schizophrenia	Janssen	Worldwide

Our Licensed Products

Product	Indication(s)	Licensee	Licensed Territory
VIVITROL	Alcohol dependence and Opioid dependence	Cilag GmbH International (“Cilag”)	Russia and Commonwealth of Independent States (“CIS”)
VUMERITY	Multiple sclerosis	Biogen	Worldwide

Proprietary Products

We developed and commercialize products designed to address the unmet needs of patients suffering from opioid dependence, alcohol dependence and schizophrenia. For additional information about the proprietary technologies underlying our proprietary products, see the “Proprietary Product Platforms” section in “Part I, Item 1—Business” in 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 and 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 October 2020, U.S. Patent No. 10,813,928 relating to ARISTADA was granted. The patent has claims to methods of treatment by rapid and continuous intramuscular injection and expires in 2035.

ARISTADA INITIO

ARISTADA INITIO (aripiprazole lauroxil) leverages our proprietary NanoCrystal technology and provides an extended-release formulation of aripiprazole lauroxil in a smaller particle size compared to ARISTADA, thereby enabling faster dissolution and more rapid achievement of relevant levels of aripiprazole in the body. ARISTADA INITIO, combined 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. The first ARISTADA dose may be administered on the same day as the ARISTADA INITIO regimen or up to 10 days thereafter. We developed ARISTADA INITIO and exclusively manufacture and commercialize it in the U.S.

VIVITROL (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 VIVITROL, see Note 15, *Commitments and Contingent Liabilities* in the “Notes to Condensed Consolidated Financial Statements” section in this Form 10-Q, and for information about risks relating to such legal proceedings, see “Part I, Item 1A—Risk Factors” in our Annual Report, including the sections entitled “—Patent protection for our products is important and uncertain,” “—Uncertainty over IP 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 and other revenues from the commercialization of these products. Such arrangements include the following:

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate 3-month injection) and RISPERDAL CONSTA (risperidone long-acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies. For additional information about our proprietary technologies, see the “Proprietary Product Platforms” section in “Part I, Item 1—Business” in 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.

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 dosed 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 patents covering INVEGA SUSTENNA, INVEGA TRINZA and/or RISPERDAL CONSTA, see Note 15, *Commitments and Contingent Liabilities* in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q and for information about risks relating to such legal proceedings, see “Part I, Item 1A—Risk Factors” in our Annual Report, including the section entitled “—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers.”

VIVITROL (Russia and CIS)

For a description of VIVITROL, including its approved indications and dosing, please refer to the heading “Proprietary Products” above in this Form 10-Q. We developed and exclusively manufacture VIVITROL for Cilag. Cilag exclusively commercializes VIVITROL in Russia and certain countries of the CIS.

VUMERITY (Diroximel Fumarate)

VUMERITY (diroximel fumarate) is a novel, oral fumarate with a distinct chemical structure that was approved in the U.S. in October 2019 for the treatment of relapsing forms of multiple sclerosis in adults, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Under our license and collaboration agreement with Biogen, Biogen holds the exclusive, worldwide license to develop and commercialize VUMERITY. For more information about the license and collaboration agreement with Biogen, see the “Collaborative Arrangements—Biogen” section in “Part I, Item 1—Business” in our Annual Report.

Key Development Programs

Our R&D is focused on the development of novel, competitively advantaged medications designed to enhance patient outcomes. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key R&D programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in “Part I, Item 1A—Risk Factors” in our Annual Report and “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. See the “Patents and Proprietary Rights” section in “Part I, Item 1—Business” in our Annual Report for information with respect to the IP protection for our key development candidates.

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 which evaluated the antipsychotic efficacy of ALKS 3831 compared to placebo, and ENLIGHTEN-2, a six-month study which assessed weight gain with ALKS 3831 compared to ZYPREXA (olanzapine). The program also includes supportive studies to evaluate the pharmacokinetic (“PK”) and metabolic profile and long-term safety of ALKS 3831, and PK bridging studies comparing ALKS 3831 and ZYPREXA.

In May 2019, we conducted a pre-NDA meeting with the FDA to discuss the FDA’s key requirements for the NDA for ALKS 3831, including those related to efficacy, safety, weight and metabolic profile, and the expansion of the NDA to encompass the treatment of bipolar I disorder in addition to the treatment of schizophrenia. In January 2020, the FDA accepted the ALKS 3831 NDA and assigned a Prescription Drug User Fee Act (“PDUFA”) target action date of November 15, 2020. The FDA held a joint meeting of its Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee to review questions related to the ALKS 3831 NDA on October 9, 2020.

The ALKS 3831 NDA is a 505(b)(2) NDA and includes data from the ENLIGHTEN clinical development program in patients with schizophrenia, as well as PK bridging data comparing ALKS 3831 and ZYPREXA. For more information about 505(b)(2) NDAs, see the “Regulatory, Hatch-Waxman Act” section of “Part I, Item 1—Business” in our Annual Report. We are seeking approval for ALKS 3831 for the treatment of schizophrenia and for the treatment of manic and mixed episodes associated with bipolar I disorder as a monotherapy or adjunct to lithium or valproate and for maintenance treatment of bipolar I disorder, and of fixed dosage strengths of ALKS 3831 composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

In July 2020, U.S. Patent No. 10,716,785 relating to ALKS 3831 was granted. The patent has claims to methods of treatment that cover ALKS 3831 and expires in 2031.

ALKS 4230

ALKS 4230 is an investigational, novel, engineered fusion protein comprised of modified interleukin-2 (“IL-2”) and the high affinity IL-2 alpha receptor chain, designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity 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 development program evaluating ALKS 4230 in patients with advanced solid tumors. ARTISTRY-1 and ARTISTRY-2 are phase 1/2 studies evaluating the safety, tolerability, efficacy and pharmacokinetic and pharmacodynamic effects of ALKS 4230 in patients with refractory advanced solid tumors, in both monotherapy and combination settings with the PD-1 inhibitor pembrolizumab. In ARTISTRY-1, ALKS 4230 is administered as an intravenous infusion daily for five consecutive days. In ARTISTRY-2, ALKS 4230 is administered subcutaneously and is being evaluated with once-weekly and once-every-three-week dosing schedules.

In August 2020, we announced the initiation of ARTISTRY-3, a phase 2 study evaluating the clinical and immunologic effects of ALKS 4230 monotherapy administered intravenously on the tumor microenvironment in a variety of advanced, malignant solid tumors.

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 specialty pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for the sales of VIVITROL, ARISTADA and ARISTADA INITIO in the U.S. during the three and nine months ended September 30, 2020 and 2019:

(In millions, except for % of Sales)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2020	% of Sales	2019	% of Sales	2020	% of Sales	2019	% of Sales
Product sales, gross	\$ 304.8	100.0 %	\$ 269.5	100.0 %	\$ 824.0	100.0 %	\$ 726.7	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(83.3)	(27.3) %	(61.1)	(22.7) %	(210.6)	(25.6) %	(167.3)	(23.0) %
Chargebacks	(28.7)	(9.4) %	(23.8)	(8.8) %	(72.0)	(8.7) %	(61.0)	(8.4) %
Product discounts	(23.3)	(7.7) %	(20.7)	(7.7) %	(64.1)	(7.8) %	(56.3)	(7.7) %
Medicare Part D	(14.7)	(4.8) %	(12.0)	(4.5) %	(40.4)	(4.9) %	(30.5)	(4.2) %
Other	(12.1)	(4.0) %	(13.1)	(4.8) %	(34.1)	(4.1) %	(36.7)	(5.1) %
Total adjustments	(162.1)	(53.2) %	(130.7)	(48.5) %	(421.2)	(51.1) %	(351.8)	(48.4) %
Product sales, net	\$ 142.7	46.8 %	\$ 138.8	51.5 %	\$ 402.8	48.9 %	\$ 374.9	51.6 %

Our product sales, net, for VIVITROL in the three and nine months ended September 30, 2020 were \$80.3 million and \$230.7 million, respectively, as compared to \$85.2 million and \$242.6 million in the three and nine months ended September 30, 2019, respectively. Product sales, net for ARISTADA and ARISTADA INITIO in the three and nine months ended September 30, 2020 were \$62.4 million and \$172.1 million, respectively, as compared to \$53.6 million and \$132.3 million in the three and nine months ended September 30, 2019, respectively.

VIVITROL product sales, gross, increased by 2% in the three months ended September 30, 2020 as compared to the three months ended September 30, 2019, primarily due to a 6% increase in the selling price of VIVITROL, which went into effect in June 2020, partially offset by a 3% decrease in the number of VIVITROL units sold, primarily as a result of COVID-19-related disruptions. VIVITROL product sales, gross, decreased by 3% in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, primarily due to a 5% decrease in the number of VIVITROL units sold, primarily as a result of COVID-19-related disruptions, partially offset by the increase in the selling price of VIVITROL, described above. The increase in Medicaid rebates, as a percentage of sales in both periods presented, is primarily due to an increase in Medicaid rebates, including as a result of the COVID-19 pandemic.

ARISTADA and ARISTADA INITIO product sales, gross, increased by 30% and 43% in the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019, which was primarily due to a 20% and 34% increase in the number of ARISTADA and ARISTADA INITIO units sold, respectively, and a 6% price increase for ARISTADA and ARISTADA INITIO that went into effect in April 2020.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned in the three and nine months ended September 30, 2020 and 2019:

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	\$ 73.4	\$ 68.4	\$ 5.0	\$ 197.7	\$ 189.0	\$ 8.7
RISPERDAL CONSTA	14.5	8.3	6.2	55.5	55.2	0.3
Other	32.5	27.1	5.4	99.9	96.4	3.5
Manufacturing and royalty revenues	\$ 120.4	\$ 103.8	16.6	\$ 353.1	\$ 340.6	12.5

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, 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, 2020, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were \$926.0 million and \$2,688.0 million, respectively, as compared to \$851.0 million and \$2,459.0 million during the three and nine months ended September 30, 2019, respectively.

Under our agreements with Janssen related to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, we earn tiered royalty payments 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 royalty-bearing 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 15 years from the first commercial sale of a product in each individual country, subject to the expiry of the license agreement.

The increase in revenue from RISPERDAL CONSTA in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was due to \$6.5 million and \$1.8 million increases in manufacturing revenue, respectively, partially offset by \$0.3 million and \$1.5 million decreases in royalty revenue, respectively. The increase in manufacturing revenue in the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, was primarily due to a 37% increase in the amount of RISPERDAL CONSTA shipped to Janssen, partially offset by a 9% decrease in the average selling price per unit. The increase in manufacturing revenue in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to a 11% increase in the amount of RISPERDAL CONSTA shipped to Janssen, partially offset by a 6% decrease in the average selling price per unit. The decreases in royalty revenue were due to decreases in end-market sales of RISPERDAL CONSTA, which were \$152.0 million and \$475.0 million during the three and nine months ended September 30, 2020, respectively, as compared to \$167.0 million and \$528.0 million during the three and nine months ended September 30, 2019, respectively.

Research and Development Revenue

(In millions)	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2020	2019		2020	2019	
Research and development revenue	\$ 1.0	\$ 12.7	\$ (11.7)	\$ 1.8	\$ 41.7	\$ (39.9)

R&D revenues earned under our license and collaboration agreement with Biogen for VUMERITY were \$0.1 million and \$0.3 million during the three and nine months ended September 30, 2020, respectively, as compared to \$12.1 million and \$39.5 million in the three and nine months ended September 30, 2019, respectively. The decrease in revenue was due to a decrease in services performed by us under the agreement following FDA approval of the NDA for VUMERITY in October 2019.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2020	2019		2020	2019	
Cost of goods manufactured and sold	\$ 43.1	\$ 42.3	\$ (0.8)	\$ 135.4	\$ 133.9	\$ (1.5)

The increase in cost of goods manufactured and sold in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to an increase in cost of goods manufactured for ARISTADA, which was primarily due to an increase in the number of units manufactured during the period, as discussed above.

Research and Development Expense

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include fees for clinical and non-clinical activities performed by contract research organizations, consulting fees, and costs related to laboratory services, the purchase of drug product materials and third-party manufacturing development activities. 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 can 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, 2020 and 2019 relating to our then current key development programs and all other development programs, and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
External R&D Expenses:						
Development programs:						
ALKS 4230	\$ 16.9	\$ 9.4	\$ (7.5)	\$ 46.6	\$ 23.9	\$ (22.7)
ALKS 3831	7.5	7.1	(0.4)	20.3	23.0	2.7
ALKS 5461	0.5	4.2	3.7	5.9	15.4	9.5
VUMERITY	0.1	7.0	6.9	0.1	25.2	25.1
Other external R&D expenses	16.9	20.7	3.8	48.7	52.1	3.4
Total external R&D expenses	41.9	48.4	6.5	121.6	139.6	18.0
Internal R&D expenses:						
Employee-related	39.5	45.6	6.1	120.2	137.0	16.8
Occupancy	5.8	3.3	(2.5)	15.8	9.3	(6.5)
Depreciation	4.1	3.6	(0.5)	11.5	10.2	(1.3)
Other	3.7	6.8	3.1	13.4	18.6	5.2
Total internal R&D expenses	53.1	59.3	6.2	160.9	175.1	14.2
Research and development expenses	\$ 95.0	\$ 107.7	\$ 12.7	\$ 282.5	\$ 314.7	\$ 32.2

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 increase in expenses related to ALKS 4230 in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to the advancement of the ARTISTRY development program for ALKS 4230. The decrease in expenses related to ALKS 3831 in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to a decrease in clinical activity across the ALKS 3831 program following submission to the FDA of the ALKS 3831 NDA in November 2019. The decrease in expenses related to ALKS 5461 in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to a decrease in activity within the program following receipt in January 2019 of a complete response letter from the FDA relating to our NDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of major depressive disorder, and subsequent winding down of ongoing clinical activity in the development program. The decrease in expenses related to VUMERITY in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to the completion of our elective, randomized, head-to-head phase 3 study. The FDA approved the NDA for VUMERITY in the fourth quarter of 2019. For additional details on the status of our key development programs, see the “Key Development Programs” section of this “Part I, Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Form 10-Q.

The decrease in employee-related expenses in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to a decrease in R&D headcount of 25% from September 30, 2019 to September 30, 2020, due primarily to the Restructuring. The increase in occupancy expenses in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to the commencement of the 900 Winter Street lease.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Sales and marketing expense	\$ 79.0	\$ 97.0	\$ 18.0	\$ 249.7	\$ 287.9	\$ 38.2
General and administrative expense	48.6	51.7	3.1	143.3	157.1	13.8
Selling, general and administrative expense	<u>\$ 127.6</u>	<u>\$ 148.7</u>	<u>\$ 21.1</u>	<u>\$ 393.0</u>	<u>\$ 445.0</u>	<u>\$ 52.0</u>

The decreases in sales and marketing expense during the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, were primarily due to decreases in marketing expense of \$12.4 million and \$30.1 million, respectively, and decreases in employee-related expenses of \$6.6 million and \$5.9 million, respectively. The decrease in marketing expense was primarily due to a reduction in the number of speaker programs and speaker trainings and a reduction in spend related to conferences. The decrease in employee-related expenses was primarily due to a decrease in employee travel related to the impacts of the COVID-19 pandemic.

The decrease in general and administrative expense during the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to a decrease in employee-related expenses of \$4.3 million and \$14.5 million, respectively, and a decrease in professional service fees of \$3.4 million and \$8.3 million, respectively. The decrease in employee-related expenses was primarily due to a decrease in share-based compensation expense and in salaries and benefits, due to a decrease in general and administrative headcount of 13% from September 30, 2019 to September 30, 2020. The decrease in professional service fees was primarily due to expense management measures taken in response to COVID-19-related disruptions to the business.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Amortization of acquired intangible assets	\$ 9.9	\$ 10.2	\$ 0.3	\$ 29.5	\$ 30.2	\$ 0.7

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, 2020 is expected to be approximately \$40.0 million, \$40.0 million, \$35.0 million, \$35.0 million and \$1.0 million in the years ending December 31, 2020 through 2024, respectively.

Other Income (Expense), Net

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Interest income	\$ 1.4	\$ 3.5	\$ (2.1)	\$ 5.9	\$ 10.8	\$ (4.9)
Interest expense	(1.8)	(3.4)	1.6	(6.8)	(10.4)	3.6
Change in the fair value of contingent consideration	3.9	1.3	2.6	16.6	(27.8)	44.4
Other income (expense), net	9.4	(1.7)	11.1	11.1	(1.6)	12.7
Total other income (expense), net	<u>\$ 12.9</u>	<u>\$ (0.3)</u>	<u>\$ 13.2</u>	<u>\$ 26.8</u>	<u>\$ (29.0)</u>	<u>\$ 55.8</u>

The increase in the fair value of contingent consideration in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to the approval by the FDA of the NDA for ANJESO in February 2020. As a result of this product's approval, we increased the probability of success in our fair value analysis to 100%. The \$1.3 million increase and \$27.8 million decrease in the fair value of contingent consideration recorded in the three and nine months ended September 30, 2019, respectively, were primarily due to Recro's receipt of a second complete response letter in March 2019 from the FDA regarding its NDA for ANJESO. As a result of the receipt of that complete response letter, we delayed the expectation of the anticipated date of the FDA's approval of the product, resulting in a corresponding reduction in the amount of forecasted sales used in the 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*, in the "Notes to Consolidated Financial Statements" in our Annual Report.

The increase in other income (expense), net in the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019, was primarily due to the receipt of our proportional share of the proceeds from the sale of two of the companies within the Fountain portfolio. Our investment in Fountain is discussed in greater detail in Note 4, *Investments*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Income Tax Provision (Benefit)

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Income tax provision (benefit)	\$ 2.3	\$ (1.0)	\$ (3.3)	\$ 13.3	\$ (3.2)	\$ (16.5)

The income tax provision (benefit) in the three months ended September 30, 2020 and 2019 primarily related to U.S. federal and state taxes. The unfavorable change in the income tax provision in the three months ended September 30, 2020, as compared to the income tax benefit in the three months ended September 30, 2019, was primarily due to an increase in tax expense from employee equity activity.

The income tax provision in the nine months ended September 30, 2020 primarily related to a \$5.1 million tax expense on income earned in the U.S. and an \$8.0 million discrete tax expense related to employee equity activity. 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 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.

On March 27, 2020 the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) was passed by the U.S. Congress and signed into law by the President of the United States. The CARES Act, among other things, includes certain income tax provisions for individuals and corporations; however, these benefits did not materially impact our income tax provision.

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

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	September 30, 2020			December 31, 2019		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	\$ 151.9	\$ 89.0	\$ 240.9	\$ 63.3	\$ 140.5	\$ 203.8
Investments—short-term	267.2	61.3	328.5	285.3	45.9	331.2
Investments—long-term	19.1	8.7	27.8	40.3	39.1	79.4
Total cash and investments	\$ 438.2	\$ 159.0	\$ 597.2	\$ 388.9	\$ 225.5	\$ 614.4
Outstanding borrowings—short and long-term	\$ 275.5	\$ —	\$ 275.5	\$ 277.1	\$ —	\$ 277.1

At September 30, 2020 our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term available-for-sale	\$ 325.0	\$ 2.7	\$ (1.0)	\$ 326.7
Investments—short-term held-to-maturity	1.7	0.1	—	1.8
Investments—long-term available-for-sale	26.0	—	—	26.0
Investments—long-term held-to-maturity	1.8	—	—	1.8
Total	\$ 354.5	\$ 2.8	\$ (1.0)	\$ 356.3

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 non-U.S. agencies and backed by non-U.S. 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, 2020, 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. We are closely monitoring ongoing developments in connection with the COVID-19 pandemic that may have an adverse impact on our commercial prospects and projected cash position.

Information about our cash flows, by category, is presented in “Part I, Item 1—Condensed Consolidated Financial Statements of Cash Flows” in this Form 10-Q. The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2019:

(In millions)	Nine Months Ended September 30,	
	2020	2019
Cash and cash equivalents, beginning of period	\$ 203.8	\$ 266.8
Cash flows provided by operating activities	15.5	30.0
Cash flows provided by (used in) investing activities	23.6	(40.4)
Cash flows (used in) provided by financing activities	(2.0)	5.0
Cash and cash equivalents, end of period	<u>\$ 240.9</u>	<u>\$ 261.4</u>

The decrease in cash flows provided by operating activities in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to an 8% decrease in the amount of cash received from our customers and a 74% increase in our operating lease payments, partially offset by the return on investment related to Fountain, described in Note 4, *Investments*, in the “Notes to Condensed Consolidated Financial Statements” section in this Form 10-Q, a 7% decrease in cash paid to our suppliers and a 5% decrease in cash paid to our employees.

The change in cash flows from investing activities in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was primarily due to a \$47.1 million increase in net sales of investments, a \$22.2 million decrease in cash paid for property, plant and equipment, and a return of investment related to Fountain described in Note 4, *Investments*, in the “Notes to Condensed Consolidated Financial Statements” section in this Form 10-Q. These changes were partially offset by a \$7.2 million decrease in payments we received in connection with the contingent consideration resulting from the Gainesville Transaction in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019.

The change in cash flows from financing activities in the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019, was due to a \$7.0 million decrease in the amount of cash we received from our employees upon the exercise of stock options, net of employee taxes.

Borrowings

At September 30, 2020, the principal balance of our borrowings consisted of \$277.1 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

See the “Contractual Obligations” section in “Part II, Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report for a discussion of our contractual obligations. In addition, in January 2020, our lease at 900 Winter Street commenced and our operating lease liabilities increased as a result. Our future operating lease liabilities are disclosed in Note 9, *Leases*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Off-Balance Sheet Arrangements

At September 30, 2020, 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. See the “Critical Accounting Estimates” section in “Part II, Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report for a discussion of our critical accounting estimates.

New Accounting Standards

See the “New Accounting Pronouncements” section 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 recent accounting standards applicable to us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks related to our investment portfolio, and the ways we manage such risks, are summarized in “Part II, Item 7A—Quantitative and Qualitative Disclosures About Market Risk” in 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, 2019, 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” in our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since December 31, 2019.

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 Exchange Act), as of September 30, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that our disclosure controls and procedures were effective as of September 30, 2020 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, see the discussion of legal proceedings in Note 15, *Commitments and Contingent Liabilities* in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q, which discussion 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 the additional risk factor disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. Further discussion of our risk factors appears in “Part I, Item 1A—Risk Factors” in our Annual Report and “Part II, Item 1A—Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

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, 2020. As of September 30, 2020, 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, 2020, we acquired 11,106 of our ordinary shares, at an average price of \$18.09 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
2.1 #	Third Amendment to Purchase and Sale Agreement, dated August 17, 2020, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. (as successor in interest to Eagle Holdings USA, Inc.) and Baudax Bio, Inc. (as successor in interest to Recro Pharma, Inc. and Recro Gainesville LLC).
10.1 #	Sixth Amendment to Lease between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of July 24, 2020.
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 29, 2020

THIRD AMENDMENT TO PURCHASE AND SALE AGREEMENT

This Third Amendment to Purchase and Sale Agreement (this “Amendment”), dated August 17, 2020, by and among Alkermes Pharma Ireland Limited, a private company limited by shares and incorporated in Ireland (“APIIL”), Daravita Limited, a private company limited by shares and incorporated in Ireland (“Daravita”), Alkermes US Holdings, Inc. (as successor in interest to Eagle Holdings USA, Inc.), a Delaware corporation (together with APIIL, “Sellers”), and Baudax Bio, Inc. (as successor in interest to Recro Pharma, Inc. (“Recro Pharma”) and Recro Gainesville LLC (successor to Recro Pharma LLC)), a Pennsylvania corporation (“Baudax”), amends that certain Purchase and Sale Agreement, dated as of March 7, 2015 and amended on each of December 8, 2016 and December 20, 2018, by and among Sellers, Daravita, Recro Gainesville and Recro Pharma (as amended, the “Agreement”).

RECITALS

WHEREAS, Recro Pharma and Baudax are parties to that certain Separation Agreement, dated as of November 20, 2019, pursuant to which Recro Pharma assigned, or caused its subsidiaries to assign, certain of its assets, rights and obligations to Baudax, including the Agreement; and

WHEREAS, pursuant to Section 11.9 of the Agreement, Daravita, Sellers and Baudax now desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

ARTICLE I**DEFINITIONS**

1.1 Defined Terms. Capitalized terms used but not defined in this Amendment shall have the meanings ascribed to them in the Agreement.

ARTICLE II**AMENDMENT**

2.1 Exhibit E. Section 2.1(a) of Exhibit E to the Agreement is hereby deleted in its entirety and replaced with the following:

“(a) Development Milestone Earn-Out Consideration.

(i) The following amounts (“Development Milestone Earn-Out Consideration”) shall be payable in accordance with Section 2.8 of the Agreement and this Exhibit E upon achievement of the following events (“Development Milestones”) by Purchaser and its Affiliates, licensees and sublicensees, and shall be non-refundable and non-creditable and not subject to deduction or set-off:

(A) Within thirty (30) calendar days following December 20, 2018, Purchaser shall pay to APIL Five Million U.S. Dollars (US\$5,000,000.00) and within thirty (30) calendar days following March 24, 2019, Purchaser shall pay to APIL Five Million U.S. Dollars (US\$5,000,000.00); and (B) the following amounts:

<i>Development Milestone</i>	<i>Amount of Development Milestone Earn-Out Consideration (U.S. Dollars)</i>
Approval of an NDA for the first Earn-Out Product (the “ <u>First Approval</u> ”)	\$5,000,000.00
First anniversary of the First Approval	\$6,429,000.00
Second anniversary of the First Approval	\$6,429,000.00
Third anniversary of the First Approval	\$6,429,000.00
Fourth anniversary of the First Approval	\$6,429,000.00
Fifth anniversary of the First Approval	\$6,429,000.00
Sixth anniversary of the First Approval	\$6,429,000.00
Seventh anniversary of the First Approval	\$6,429,000.00

(ii) Purchaser shall notify and pay to APIL (A) with respect to the Development Milestone Earn-Out Consideration payable upon the First Approval, (x) Two Million Five Hundred Thousand U.S. Dollars (US\$2,500,000.00) of such payment amount on or prior to August 18, 2020, (y) One Million Sixty Thousand U.S. Dollars (US\$1,060,000.00) of such payment amount on or prior to December 20, 2020 and (z) One Million Four Hundred Forty Thousand U.S. Dollars (US\$1,440,000.00) of such payment amount on or prior to June 20, 2021 and (B) each Development Milestone Earn-Out Consideration payment other than the First Approval payment within thirty (30) calendar days after the occurrence of the corresponding Development Milestone. Each payment made pursuant to Section 2.1(a) of this Exhibit E shall be made by wire transfer of immediately available funds to such account or accounts as are designated in writing by APIL.”

ARTICLE III

3.1 Fee. In consideration of the amendment of the timing of the Development Milestone Earn-Out Consideration payable upon the First Approval, as set forth in Article II of this Amendment, contemporaneous with the signing of this Amendment Baudax has paid to APIL a one-time, non-refundable and non-creditable (and not subject to deduction or set-off) fee in the amount of Two Hundred Eighty Five Thousand U.S. Dollars (US\$285,000).

ARTICLE IV

GENERAL

4.1 Effect of Amendment. The Agreement is hereby amended as set forth in this Amendment. Except as specifically provided for in this Amendment, all of the terms and

conditions of the Agreement shall remain in full force and effect. Each reference in the Agreement to “hereof,” “hereunder” and “this Agreement” shall, from and after the date of this Amendment, refer to the Agreement, as amended by this Amendment. Each reference in the Agreement to the “date of the Agreement” or similar references (such as “to the date hereof”) shall refer to March 7, 2015.

4.2 Related Agreement. The parties hereto acknowledge and agree that (i) Baudax and APIL are also parties to that certain Asset Transfer and License Agreement, dated as of April 10, 2015, as amended on December 23, 2015 and December 20, 2018 and as partially assigned to Baudax pursuant to the Partial Assignment, Assumption and Bifurcation Agreement, dated as of November 20, 2019 (the “Related Agreement”), pursuant to which Baudax is obligated to pay APIL the Earn-Out Consideration set forth in Exhibit D to the Related Agreement, which payment obligation is replicated in Exhibit E to the Agreement, (ii) the Related Agreement is being further amended concurrently with this Amendment such that the amendments to the Earn-Out Consideration set forth in this Amendment are mirrored in Exhibit D to the Related Agreement and (iii) the Earn-Out Consideration (set forth in Exhibit E to the Agreement, as amended by this Amendment, and Exhibit D to the Related Agreement, as amended) is to be paid by Baudax to APIL only once.

4.3 Miscellaneous Provisions. The provisions of Article XI of the Agreement shall apply *mutatis mutandis* to this Amendment and to the Agreement as modified by this Amendment.

[Signature Page Follows]

IN WITNESS WHEREOF, this Amendment has been signed by or on behalf of each of the parties set forth below as of the date first above written.

ALKERMES PHARMA IRELAND LIMITED

By:/s/ Richie Paul

Name: Richie Paul
Title: Director

DARAVITA LIMITED

By:/s/ Richie Paul

Name: Richie Paul
Title: Director

ALKERMES US HOLDINGS, INC.

By:/s/ Jim Frates

Name: James Frates
Title: Director

BAUDAX BIO, INC.

By:/s/ Ryan Lake

Name: Ryan D. Lake
Title: Chief Financial Officer

[Signature Page to Third Amendment to Purchase and Sale Agreement]

SIXTH AMENDMENT TO LEASE

THIS SIXTH AMENDMENT TO LEASE (this “**Amendment**”) is made and entered into effective as of July 24, 2020, between **GI TC 850 WINTER STREET, LLC**, a Delaware limited liability company (“**Landlord**”), and **ALKERMES, INC.**, a Pennsylvania corporation (“**Tenant**”).

RECITALS

WHEREAS, Landlord (as successor-in-interest to PDM 850 Unit, LLC, a Delaware limited liability company (“**Prior Landlord**”)) and Tenant are parties to that certain Lease dated April 22, 2009 (the “**Original Lease**”), which Original Lease has been amended by (i) that certain First Amendment to Lease dated June 15, 2009, between Prior Landlord and Tenant (the “**First Amendment**”), (ii) that certain Second Amendment to Lease dated November 12, 2013, between Prior Landlord and Tenant (the “**Second Amendment**”), (iii) that certain Third Amendment to Lease dated May 15, 2014, between Prior Landlord and Tenant (the “**Third Amendment**”), (iv) that certain Fourth Amendment to Lease dated December 30, 2014, between Landlord and Tenant (the “**Fourth Amendment**”), and (v) that certain Fifth Amendment to Lease dated October 31, 2018, between Landlord and Tenant (the “**Fifth Amendment**”; the Original Lease, as amended by the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, and the Fifth Amendment is hereinafter referred to as the “**Current Lease**”). Pursuant to the Current Lease, Landlord has leased to Tenant space currently containing approximately 163,381 rentable square feet (as more particularly described in the Current Lease, the “**Current Premises**”) and approximately 353 square feet of storage space in the building located at 850 and 852 Winter Street, Waltham, Massachusetts (the “**Building**”). As used herein, the term “**Lease**” shall hereafter mean the Current Lease, as amended by this Amendment.

WHEREAS, Landlord (as successor-in-interest to Prior Landlord) and Tenant (as successor-in-interest to Millward Brown, Inc.) are parties to that certain Lease dated August 31, 2010 (as amended, the “**MaPs Lease**”), pursuant to which Tenant leases approximately 16,658 rentable square feet located on the first (1st) floor of the Building, which space is shown on Exhibit A hereto (the “**Expansion Space**”).

WHEREAS, Landlord and Tenant desire to expand the Current Premises to include the Expansion Space and to terminate the MaPs Lease, subject to and in accordance with the terms and conditions of this Amendment.

WHEREAS, Landlord and Tenant desire to amend the Current Lease for the purpose of, among other matters, expanding the Current Premises and extending the term of the Current Lease, as hereinafter provided.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. **Recitals Incorporated; Certain Defined Terms.** The Recitals set forth above are incorporated herein by this reference and shall be deemed terms and provisions hereof with the same force and effect as if fully set forth in this Section. Terms which are not otherwise defined

[Signature page to Sixth Amendment to Lease]

herein shall be deemed to have the same meanings herein as are ascribed to such terms in the Current Lease.

2. **Expansion Space.**

2.1 **Addition of the Expansion Space.** Effective March 1, 2021 (the “**Expansion Space Commencement Date**”), the Current Premises shall be expanded to include the Expansion Space and the rentable square feet of the Current Premises shall be increased from approximately 163,381 rentable square feet in the Building to approximately 180,039 rentable square feet in the Building. From and after the Expansion Space Commencement Date, the Current Premises and the Expansion Space shall collectively be deemed to constitute the “Premises” under the Lease, and all references in the Lease to the “Premises” shall be deemed references to the Current Premises, as expanded to include the Expansion Space. The term for the Expansion Space shall commence on the Expansion Space Commencement Date and end on the Expiration Date (as defined below). Except as otherwise expressly provided in this Amendment, Tenant’s leasing of the Expansion Space is subject to all of the terms and conditions of the Current Lease. Except for the Tenant Improvement Allowance (as hereinafter defined), Tenant shall not be entitled to receive any allowances or other Landlord contributions with respect to the Premises. Upon the Expansion Space Commencement Date, the MaPs Lease shall terminate except for any provisions thereof which expressly survive the termination of the MaPs Lease and any liability arising out of or related to Landlord or Tenant’s failure to perform any of its obligations accruing or arising under the MaPs Lease on or before termination of the MaPs Lease.

2.2 **Base Rent.** For and with respect to (i) the Premises First Extension Term (as hereinafter defined), Base Rent with respect to the Premises (excepting only the Fourth Expansion Space (as defined in the Fourth Amendment)) shall be as set forth on Schedule I attached hereto, and (ii) the Fourth Expansion Space First Extension Term (as hereinafter defined), Base Rent with respect to the Fourth Expansion Space shall be as set forth on Schedule I attached hereto.

2.3 **Tenant’s Pro Rata Share.** Upon the Expansion Space Commencement Date, Tenant’s Pro Rata Share with respect to the Premises shall be increased to 100%. The portion of Tenant’s Pro Rata Share allocated to the Fourth Expansion Premises is 7.42%.

2.4 **Additional Rent.** Effective as of the Expansion Space Commencement Date, (i) Tenant shall pay all Additional Rent payable under the Current Lease, including Tenant’s Pro Rata Share of Operating Expenses and Taxes, applicable to the Expansion Space, in accordance with the terms of the Current Lease, and (ii) all charges for electricity consumed within the Expansion Space shall be payable pursuant to the terms and conditions of Section 3.01 of the Original Lease.

2.5 **Condition of the Expansion Space.** Tenant currently occupies the Expansion Space under the MaPs Lease and agrees to accept the same for the Premises First Extension Term (as hereinafter defined) “as-is” and in all respects in the condition in which the Expansion Space are in as of the date of this Amendment, without any agreement, representation, understanding or obligation on the part of Landlord to prepare or construct the Expansion Space for Tenant’s occupancy, or to construct any additional work or improvements therein or in the Building, or, excepting only the Tenant Improvement Allowance, to provide any allowances or inducements.

The foregoing shall in no way limit or detract from Landlord's maintenance, repair and restoration obligations to the extent set forth in the Current Lease.

2.6 **Tenant Improvement Allowance; Tenant Improvements.**

2.6.1 Pursuant to the terms hereof, Landlord shall pay to Tenant an amount not to exceed Two Million Two Hundred Fifty Thousand Four Hundred Eighty-Seven and 50/100 Dollars (\$2,250,487.50) (the "**Tenant Improvement Allowance**"), calculated at the rate of Twelve and 50/100 Dollars (\$12.50) per rentable square foot of the Premises, which shall be applied towards the cost of Tenant's improvements to the Premises (the "**Tenant Improvements**"). The use of the term "Premises" in this Section 2.6 shall refer to the Current Premises, as expanded to include the Expansion Space, notwithstanding that the Expansion Space Commencement Date may not yet have occurred. The Tenant Improvement Allowance shall be payable solely on account of labor directly related to Tenant Improvements and materials delivered to the Premises in connection with the Tenant Improvements; provided, however, a portion of the Tenant Improvement Allowance of up to but not more than \$450,097.50 (i.e., \$2.50 per rentable square foot of the Premises) may be applied against architectural and engineering fees, construction management fees, telephone wiring and computer cabling costs, other telephone and data costs, costs of furniture, fixtures and equipment and other so-called "soft costs" incurred by Tenant in connection with the Tenant Improvements. Excepting only the alterations depicted on Exhibit B attached hereto (the "**Approved Tenant Improvements**"), the Tenant Improvement Allowance shall not be applied towards the costs of exterior alterations, alterations outside of the Premises, alterations (excepting only cosmetic alterations) to the current configuration of the demising walls that separate the Fourth Expansion Premises from the remainder of the Premises, or alterations to the common areas of the Property unless, in each case, Tenant has obtained Landlord's prior consent, which consent shall not be unreasonably withheld or delayed. Following the effectiveness of this Amendment pursuant to Section 6.3 hereof, Landlord shall disburse the Tenant Improvement Allowance funds to Tenant for the costs and expenses of Tenant Improvements incurred by Tenant pursuant to Section 2.6 hereof if no Event of Default (which has not been cured after the giving of any required notice and expiration of any applicable period of grace) then exists; provided however, upon the occurrence of an Event of Default the obligation of Landlord to fund the Tenant Improvement Allowance shall be suspended and tolled during the pendency of such Event of Default, and if, as and when said Event of Default is cured by Tenant in accordance with the terms and conditions of the Lease, then said suspension shall cease and said obligation shall resume, in accordance with and subject to all of the terms and conditions of this Section 2.6.

2.6.2 Following the effectiveness of this Amendment pursuant to Section 6.3 hereof, Landlord shall make progress payments to Tenant of the Tenant Improvement Allowance on a monthly basis, in monthly installments commencing on the commencement of the construction of the Tenant Improvements. Progress payments shall be made within thirty (30) days following the delivery to Landlord of requisitions therefor, signed by a duly authorized representative of Tenant, and shall be accompanied by (i) with the exception of the first requisition, copies of partial waivers of lien from all contractors, subcontractors, and material suppliers covering all work and materials in excess of \$10,000.00 which were the subject of previous progress payments by Landlord to Tenant, and (ii) such other documents and information as Landlord may reasonably request. Landlord shall make the final disbursement of the Tenant

Improvement Allowance within thirty (30) days after submission by Tenant to Landlord of Tenant's requisition therefor accompanied by all documentation required under this Section 2.6.2, together with final lien waivers by all contractors, subcontractors and material suppliers providing work or materials in excess of \$10,000.00. Notwithstanding the foregoing or any provision of the Lease to the contrary, any Tenant Improvements paid for with the Tenant Improvement Allowance shall become a part of the Premises, shall become the property of Landlord upon the expiration or earlier termination of the Lease, and Tenant shall not be obligated to remove any such Tenant Improvements from the Premises.

2.6.3 Notwithstanding the foregoing, if Tenant submits a valid and proper requisition for payment of the Tenant Improvement Allowance, and all of the conditions thereto as set forth above have been satisfied in full, and Landlord shall fail to timely pay the amount requested and such failure shall continue for fifteen (15) days after Tenant provides a written notice to Landlord which expressly and specifically identifies such failure to pay the amount requested and specifically references this Section 2.6.3, then Tenant shall have the right to set-off such unpaid amount against the next monthly installments of Rent payable under the Lease.

2.6.4 The Tenant Improvements shall be performed by Tenant in accordance with the terms and conditions of Section 8.01 of the Original Lease, provided however, (i) the requirement set forth in Section 8.01(a) of the Lease that Tenant provide and record bonds or such other security as is reasonably satisfactory to Landlord shall only apply to Tenant Improvements with a cost in excess of \$3,250,487.50 in the aggregate (such amount decreasing to \$2,500,487.50 in the event Tenant fails to meet the Financial Test), (ii) without limitation, Tenant shall not be responsible for the payment of any supervisory or construction management fees to Landlord or any agent or affiliate of Landlord with respect to the Tenant Improvements, provided, however, Tenant shall reimburse Landlord for Landlord's reasonable third-party costs of review pursuant to Section 8.01(a) of the Original Lease, and (iii) Landlord hereby consents to and approves of the Approved Tenant Improvements.

2.7 **Security Deposit.** Landlord acknowledges that Landlord is currently holding (i) a Letter of Credit under the MaPs Lease in the amount of \$95,672.42 (the "**MaPs Letter of Credit**"), and (ii) a Letter of Credit under the Current Lease in the aggregate amount of \$1,565,499.01 (as amended, the "**Current Lease Letter of Credit**"), a portion of which, in the amount of \$72,393.76, is allocated to the Fourth Expansion Premises and is defined in the Fourth Amendment as the "Fourth Expansion Premises Letter of Credit". From and after the Expansion Space Commencement Date, Landlord shall hold the Current Lease Letter of Credit and the MaPs Letter of Credit (in the aggregate amount of \$1,661,171.45) as security for the performance of the obligations of Tenant under the Lease, and shall be entitled to draw upon such Letters of Credit, in each case subject to and in accordance with the terms and conditions of the Lease, including, without limitation, Section 2.05 of the Original Lease. Promptly following the effectiveness of this Amendment pursuant to Section 6.3 hereof, Landlord shall return to Tenant that certain Letter of Credit issued by Bank of America dated as of October 23, 2018, in the amount of \$29,001.18.

2.8 **Insurance.** On or before the Expansion Space Commencement Date, Tenant shall provide Landlord with an updated certificate of insurance in compliance with Section 4.02 of the Original Lease. Notwithstanding anything contained in the Current Lease to the contrary, any insurance carried by Tenant under Section 4.02 of the Original Lease shall name as

an additional insured Landlord, Landlord's property manager and/or managing agent, any mortgagee (as of the date hereof, Wells Fargo Bank, National Association, as Trustee, on behalf of the registered Holders of GS Mortgage Securities Corporation II, Commercial Mortgage Pass-Through Certificates, Series 2014-GC24 (the "**Existing Mortgagee**")) and the association of unit owners under the Reservoir Woods Primary Condominium, TechCore LLC and California Public Employees' Retirement System (in lieu of The Prudential Insurance Company of America as required by the Original Lease), and any of Landlord agents or contractors providing services to the Building or Premises (provided that Landlord has identified such property manager, managing agent, mortgagee, agents, or contractors by notice to Tenant).

3. **Term.**

3.1 **Lease Term.** The term of the Lease for (a) the Premises (excluding the Fourth Expansion Space) is hereby extended to April 30, 2026 (the "**Expiration Date**") and (b) the Fourth Expansion Space is hereby extended to October 31, 2026 (the "**Fourth Expansion Space Expiration Date**"). With respect to (i) the Premises (excluding the Fourth Expansion Space), the period commencing on the Expansion Space Commencement Date and expiring on the Expiration Date is referred to herein as the "**Premises First Extension Term**", and (ii) the Fourth Expansion Space, the period commencing on September 1, 2021 and expiring on the Fourth Expansion Space Expiration Date is referred to herein as the "**Fourth Expansion Space First Extension Term**".

3.2 **Extension Option.**

3.2.1 Tenant acknowledges and agrees that Tenant shall have one remaining option to extend either, or both, of the Expiration Date and Fourth Expansion Space Expiration Date for one (1) additional Option Term of (i) five (5) years with respect to the Premises (excluding the Fourth Expansion Space), and (ii) four (4) years and six (6) months with respect to the Fourth Expansion Space, in each case pursuant to, and in accordance with, Article 22 of the Original Lease. Notwithstanding any provision of the Current Lease to the contrary, Tenant may elect to exercise Tenant's remaining Option Term with respect to the entire Premises, or either (i) the Premises (excepting only the Fourth Expansion Space) or (ii) the Fourth Expansion Space, by delivering notice to Landlord of such election not earlier than January 31, 2025 and not later than April 30, 2025. Tenant's failure to identify in Tenant's Extension Notice whether Tenant has elected to exercise Tenant's remaining Option Term with respect to the entire Premises, the Premises (excepting only the Fourth Expansion Space) or the Fourth Expansion Space, shall be considered Tenant's election to exercise Tenant's remaining Option Term with respect to the entire Premises. Notwithstanding anything contained in the Current Lease to the contrary, if Tenant timely and properly exercises the extension option for the remaining Option Term pursuant to Article 22 of the Original Lease with respect to the entire Premises or either (i) the Premises (excepting only the Fourth Expansion Space) or (ii) the Fourth Expansion Space, then the term of the Lease with respect to the applicable portion of the Premises shall be extended and shall expire on April 30, 2031.

3.2.2 In the event that Tenant elects to extend the Term of the Lease with respect to the Premises (excluding the Fourth Expansion Space) or the Fourth Expansion Space, but not the entire Premises, then (i) effective as of the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, solely with respect to the portion of the Premises for which Tenant

has not elected to extend the Term (the “**Surrender Premises**”), the Term of the Lease shall end and expire, and all of Tenant’s right, title and interest in and to the Surrender Premises shall terminate and be extinguished, with the same force and effect as if the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, had originally been specified in the Current Lease as the “Expiration Date”, (ii) effective as of the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, Landlord and Tenant shall each be released from any and all obligations thereafter arising or accruing under the Lease with respect to the Surrender Premises except for any provisions under the Lease which expressly survive expiration and any liability arising out of or related to Landlord or Tenant’s failure to perform any of its obligations accruing or arising under the Lease on or before such expiration; (iii) by not later than the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, Tenant shall yield-up and surrender the Surrender Premises in accordance with the terms and conditions of the Lease, including, without limitation, Article 15 of the Lease, (iv) effective as of the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, Tenant’s Pro Rata Share and, subject to Section 4.1 below, Tenant’s parking rights under the Lease shall each be reduced to reflect the expiration of the Term with respect to the Surrender Premises, and (v) within forty-five (45) days following the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, the Letter of Credit (and any and all amendments thereto) and any cash security deposit being held by Landlord under the Lease with respect to the Surrender Premises (i.e., the Current Lease Letter of Credit (less the amount of the Fourth Expansion Premises Letter of Credit), in the event the Lease terminates with respect to the Premises (excluding the Fourth Expansion Space), or the Fourth Expansion Premises Letter of Credit, in the event the Lease terminates with respect to the Four Expansion Space) shall be returned to Tenant, to the extent not applied pursuant to the terms and conditions of the Lease, which shall be accomplished by Tenant through the amendment of the Current Lease Letter of Credit to reflect such reduced amount.

4. **Other Pertinent Provisions.** Landlord and Tenant agree that the Current Lease shall be amended in the following additional respects:

4.1 **Parking.** Effective as of the Expansion Space Commencement Date, Tenant shall have the exclusive right to use all of the parking areas at the Property (i.e., all of Tenant’s parking rights under the MaPs Lease and the Current Lease) subject to the terms of the Lease and this Section. All such parking shall be provided by Landlord to Tenant at no additional charge to Tenant (except for costs properly charged as Operating Expenses). Effective as of the Expiration Date or Fourth Expansion Space Expiration Date, as applicable, Tenant’s parking rights under the Lease shall be reduced by the number of parking spaces determined based on the pro rata rentable square footage to reflect the expiration of the Term with respect to the Surrender Premises. In no event shall Landlord reduce the number of parking spaces at the Property or the number of parking spaces located in the parking garage on the lower level of the Building with direct access to the Building lobby serving the Premises, in each case below the number of spaces existing on the date of this Amendment, excepting only (i) as required by applicable law, regulation or order, or (ii) with respect to any Surrender Premises, as set forth in the immediately preceding sentence.

4.2 **General Indemnity.** References to “The Prudential Life Insurance Company of America” in Section 12.01 of the Original Lease shall be deleted in its entirety and replaced with “TechCore LLC and California Public Employees’ Retirement System” in lieu thereof.

4.3 **Deleted Lease Provisions.** The following terms and provisions are hereby deleted in the entirety and shall be of no further force or effect: (i) Article 24 of the Original Lease (Right of First Offer), (ii) Section 2 of the Second Amendment (Qualifying Conditions), (iii) Section 9 of the Fourth Amendment (Extension Options); (iv) Section 11.8 of the Fourth Amendment (Prior Tenant Lease); and (v) Section 11.8 of the Fifth Amendment (MHTC Lease Amendment).

4.4 **Notices.** The addresses for Landlord and Tenant for purposes of the delivery of notices under the Lease are as follows, or such other address(es) as Landlord or Tenant may designate by written notice to each other after the date of this Amendment.

If to Landlord:	GI TC 850 Winter Street, LLC 125 High Street, Suite 211 Boston, Massachusetts 02110 Attn: Property Manager
With a copy to:	GI TC 850 Winter Street, LLC c/o GI Partners 188 The Embarcadero, Suite 700 San Francisco, California 94105 Attn: Asset Manager for 850 Winter St., Waltham, MA
With a copy to:	Munger, Tolles & Olson LLP 350 South Grand Avenue, 50th Floor Los Angeles, California 90071 Attn: George Fatheree, Esq.
If to Tenant:	Alkermes, Inc. 852 Winter Street Waltham, Massachusetts 02541 Attn: General Counsel
With a copy to:	Goulston & Storrs PC 400 Atlantic Avenue Boston, Massachusetts 02110 Attn: Jonathan N. Nichols, Esq.

5. **Landlord and Tenant Representations and Warranties.** Tenant hereby represents and warrants to Landlord that the following are true as of date hereof: (a) Tenant is a corporation duly formed and existing in good standing under the laws of the state of its organization; (b) Tenant is registered and duly authorized to do business as a foreign entity in the state in which the Premises is located; (c) the execution, delivery and performance by Tenant of this Amendment (i) are within the powers of Tenant, (ii) have been duly authorized on behalf of Tenant by all requisite action, and (iii) will not violate any provision of law or any order of any court or agency of government, or any agreement or other instrument to which Tenant is a party or by which it or any of its property is bound, (d) this Amendment is a valid and binding obligation of Tenant enforceable in accordance with its terms, (e) Tenant has not assigned or encumbered its

interest in the Lease or any part thereof; (f) there exists no sublease, license or other agreement relative to the use or occupancy of the Current Premises or any part thereof; (g) except for the Tenant Improvement Allowance set forth in this Amendment, Landlord has fulfilled all of its obligations, if any, under the Current Lease with respect to the construction of improvements in the Current Premises; and (h) to Tenant's knowledge, neither Landlord nor Tenant is in breach or default of any of its respective obligations under the Current Lease. Landlord hereby represents and warrants to Tenant that the following are true as of the date hereof: (u) Landlord is a limited liability company duly formed and existing in good standing under the laws of the state of its organization; (v) Landlord is registered and duly authorized to do business as a foreign entity in the state in which the Premises is located, (w) the execution, delivery and performance by Landlord of this Amendment (i) are within the powers of Landlord, (ii) have been duly authorized on behalf of Landlord by all requisite action, and (iii) will not violate any provision of law or any order of any court or agency of government, or any agreement or other instrument to which Landlord is a party or by which it or any of its property is bound, (x) this Amendment is a valid and binding obligation of Landlord enforceable in accordance with its terms, and (y) to Landlord's knowledge, neither Landlord nor Tenant is in breach or default of any of its respective obligations under the Current Lease. The representations and warranties set forth in this Section shall survive the expiration or earlier termination of the term of the Lease.

6. **Miscellaneous.**

6.1 This Amendment, including Exhibit A, Exhibit B and Schedule I attached hereto, sets forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements.

6.2 Except as herein modified or amended, the provisions, conditions and terms of the Current Lease shall remain unchanged and in full force and effect. In the case of any inconsistency between the provisions of the Current Lease and this Amendment, the provisions of this Amendment shall govern and control. The capitalized terms used in this Amendment shall have the same definitions as set forth in the Current Lease to the extent that such capitalized terms are defined therein and not redefined in this Amendment.

6.3 Submission of this Amendment by Landlord is not an offer to enter into this Amendment. Landlord, Tenant and Guarantor shall not be bound by this Amendment until this Amendment has been fully-executed and delivered. Landlord and Tenant agree that the effectiveness of this Amendment is expressly conditioned upon the Existing Mortgagee's written consent to this Amendment subject to the terms of this Section 6.3. In the event Tenant does not receive a copy of such written consent from the Existing Mortgagee on or before the date which is ninety (90) days following the date of this Amendment, then, following the expiration of such ninety (90) day period, Tenant shall have thirty (30) days to terminate this Amendment upon written notice to Landlord. If Tenant timely elects in writing to terminate this Amendment, then this Amendment shall terminate immediately and be null and void and of no further force or effect and Tenant shall not be deemed to have withdrawn Tenant's extension notices with respect to the first extension options under the Current Lease and MaPs Lease, or to have waived Tenant's right to submit the determination of Market Rent with respect to Tenant's first extension options to arbitration pursuant to the provisions of the Current Lease and the MaPs Lease. Landlord agrees to use commercially reasonable efforts to obtain written confirmation (which may be in the form of an amendment to

the existing Subordination, Non-Disturbance and Attornment Agreement or an amended and restated Subordination, Non-Disturbance and Attornment Agreement) from the Existing Mortgagee that the Current Lease, as amended by this Amendment, remains subject to the existing Subordination, Non-Disturbance and Attornment Agreement.

6.4 Landlord and Tenant hereby each represent and warrant to the other that it has dealt with no real estate broker, finder or agent in connection with this Amendment, other than JLL, which represented Tenant (the “**Broker**”). Landlord and Tenant each agree to indemnify, protect, defend and hold harmless the other from and against any and all losses, liabilities, damages, claims, demands, costs and expenses (including, without limitation, reasonable attorneys’ fees) suffered or incurred by the other in connection with any leasing commissions or equivalent compensation alleged to be owing on account of the indemnifying party’s dealings with any real estate broker, finder or agent other than the Broker in connection with this Amendment or the transaction contemplated hereby. Landlord and Tenant shall each be responsible for one-half (1/2) of the fees payable to Broker in connection with this Amendment pursuant to separate written agreements.

6.5 Landlord and Tenant represent and warrant to each other that the signatory executing this Amendment on behalf of such respective party has the authority to execute and deliver the same on behalf of such party.

6.6 Notwithstanding anything to the contrary contained in the Lease, (i) redress for any claim against Landlord under the Lease shall be limited to and enforceable only against and to the extent of Landlord’s interest in the Property, and (ii) the obligations of Landlord under the Lease are not intended to and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its trustees or board of directors and officers, as the case may be, its investment manager, the general partners thereof, or any beneficiaries, stockholders, employees, or agents of Landlord or the investment manager, and in no case shall Landlord be liable to Tenant hereunder for any lost profits, damage to business, or any other form of special, indirect or consequential damages.

6.7 This Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

6.8 The counterparts of this Amendment may be executed and delivered by facsimile or other electronic means and the parties may rely on the receipt of such counterpart so executed and delivered by facsimile or other electronic means as if the original had been received. Signatures in pdf form or other electronic means (including, without limitation, DocuSign) delivered by electronic mail shall have the same binding effect as original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

LANDLORD:

GI TC 850 WINTER STREET, LLC,
a Delaware limited liability company

By: /s/ Tony Lin
Name: Tony Lin
Title: Authorized Person

TENANT:

ALKERMES, INC.,
a Pennsylvania corporation

By: /s/ Mike Landine
Name: Mike Landine
Title: SVP

By: /s/ Jim Frates
Name: Jim Frates
Title: CFO

[Signature page to Sixth Amendment to Lease]

The undersigned (“**Guarantor**”): (i) hereby consents and agrees to the modifications and all other matters contained in this Amendment; (ii) reaffirms to Landlord each of the representations, warranties, covenants and agreements of Guarantor set forth in that certain Guaranty dated May 16, 2014, executed by Guarantor in connection with the Current Lease (the “**Guaranty**”), with the same force and effect as if each such representation, warranty, covenant and agreement were separately stated in this Amendment and made as of the date of this Amendment; (iii) reaffirms to Landlord that it satisfies the Financial Test (as defined in the Third Amendment) as of the date of this Amendment; and (iv) acknowledges and agrees that the Guaranty will continue in full force and effect with respect to the Current Lease, as amended by this Amendment, and that all references in the Guaranty to the “Lease” are hereby amended to refer to the Current Lease, as amended by this Amendment.

Guarantor hereby notifies Landlord that the Guarantor’s agent for service of process listed in Section 10 of the Guaranty has been changed to: Goulston & Storrs PC, 400 Atlantic Avenue, Boston, Massachusetts 02110, Attn: Jonathan N. Nichols, Esq.

GUARANTOR:

ALKERMES, PLC,
an Irish public limited company

By: /s/ Tom Riordan
Name: Tom Riordan
Title: Assistant Company Secretary

[Signature page to Sixth Amendment to Lease]

EXHIBIT A

EXPANSION SPACE

EXHIBIT B

APPROVED TENANT IMPROVEMENTS

SCHEDULE I

BASE RENT

1. All such Base Rent set forth below shall be payable by Tenant in accordance with the terms of the Current Lease. Notwithstanding anything contained in the Current Lease to the contrary, Base Rent shall be payable as follows:

a. commencing on the Expansion Space Commencement Date, the Base Rent payable by Tenant for the Premises (excluding the Fourth Expansion Space) shall be Five Million Six Hundred Sixty Six Thousand Nine Hundred Sixteen and 00/100 Dollars (\$5,666,916.00) per annum, payable in equal monthly installments of Four Hundred Seventy-Two Thousand Two Hundred Forty Three and 00/100 Dollars (\$472,243.00), calculated at the rate of Thirty Four Dollars (\$34.00) per rentable square foot of the Premises (excluding the Fourth Expansion Space) per annum, and shall increase on May 1, 2022 and on each May 1 thereafter during the Premises First Extension Term, by two and twenty-five one hundredths percent (2.25%) on a cumulative, compounded basis.

b. commencing on September 1, 2021, the Base Rent payable by Tenant for the Fourth Expansion Premises shall be Four Hundred Fifty Four Thousand Four Hundred Ten and 00/100 Dollars (\$454,410.00) per annum, payable in equal monthly installments of Thirty Seven Thousand Eight Hundred Sixty Seven and 50/100 Dollars (\$37,867.50), calculated at the rate of Thirty Four Dollars (\$34.00) per rentable square foot of the Fourth Expansion Premises per annum, and shall increase on November 1, 2022 and each November 1 thereafter during the Fourth Expansion Space First Extension Term, by two and twenty-five one hundredths percent (2.25%) on a cumulative, compounded basis.

c. commencing on September 1, 2021, the Storage Base Rent (as defined in the Fourth Amendment) payable by Tenant shall be Five Thousand Two Hundred Ninety Five and 00/100 Dollars (\$5,295.00) per annum, payable in equal monthly installments of Four Hundred Forty-One 25/100 Dollars (\$441.25), calculated at the rate of Fifteen Dollars (\$15.00) per rentable square foot of the Storage Space (as defined the Fourth Amendment) per annum, and shall increase on November 1, 2022 and each November 1 thereafter during the Fourth Expansion Space First Extension Term, by two and twenty-five one hundredths percent (2.25%) on a cumulative, compounded basis.

2. Notwithstanding the foregoing, Base Rent (and, as applicable, Storage Base Rent) payable with respect to (i) the Premises (excluding the Fourth Expansion Space) shall be abated for the months of March 2021 and April 2021 and (ii) the Fourth Expansion Space shall be abated for the months of September 2021 and October 2021; provided, however, Tenant shall not be entitled to such abatement so long as an Event of Default has occurred under the Lease which has not been cured after the giving of any required notice and expiration of any applicable period of cure or grace; provided, further, that upon the occurrence of any such Event of Default, Tenant's right to such abatement shall be suspended and tolled during the pendency of such Event of Default, and if, as and when said Event of Default is cured by Tenant in accordance with the terms and conditions of the Lease, then said suspension shall cease and said right to abatement shall resume (such that, provided Tenant cures such Event of Default and there are no other uncured

Events of Default, Base Rent be abated for two (2) months with respect to the Premises (excluding the Fourth Expansion Space) and the Fourth Expansion Space), in accordance with and subject to all of the terms and conditions of this Section. During the period of such abatement, Tenant shall have no obligation to pay Base Rent (or, as applicable, Storage Base Rent); provided however, Tenant shall continue to be responsible for the payment of all other monetary obligations under the Lease, including, without limitation, Additional Rent.

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 29, 2020

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 29, 2020

**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, 2020 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 29, 2020