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, 2022

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of October 28, 2022 was 164,312,356 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022

		Page No.
	PART I - FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (unaudited):	
	Condensed Consolidated Balance Sheets — September 30, 2022 and December 31, 2021	5
	Condensed Consolidated Statements of Operations and Comprehensive Loss — For the Three and Nine Months Ended September 30, 2022 and 2021	6
	Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2022 and 2021	7
	Condensed Consolidated Statements of Shareholders' Equity — For the Three and Nine Months Ended September 30, 2022 and 2021	8
	Notes to Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	37
Item 4.	Controls and Procedures	37
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	39
Item 1A.	Risk Factors	39
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	42
Item 5.	Other Information	42
Item 6.	Exhibits	43
Signatures		44

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") may 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 expectations related to product development; regulatory filings, approvals and timelines; therapeutic and commercial value, scope and potential; and the costs and expenses related to such activities and expectations;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive, payer, legislative, regulatory and policy landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and development programs; barriers to access or coverage of our products and potential changes in reimbursement of our products; and legislation, regulations, executive orders, guidance or other measures that may impact 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 collaborations, licensing arrangements and other significant agreements with third parties relating to our products and our development programs;
- our expectations regarding the impact of new legislation, rules and regulations and the adoption of new accounting pronouncements;
- our expectations regarding 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;
- 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 expenditures for our operations and our ability to finance such capital requirements and expenditures;
- 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;
- our expectations regarding the potential separation of our commercial-stage neuroscience business and development-stage oncology business, including anticipated timing, effects, costs, benefits and tax treatment; and
- other expectations discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. In light of these risks, assumptions and uncertainties, the forward-looking expectations 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 information about 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, 2021, filed with the United States (“U.S.”) Securities and Exchange Commission (the “SEC”) on February 16, 2022, as amended by our Amendment No. 1 to Annual Report on Form 10-K/A, filed with the SEC on April 29, 2022 (our “Annual Report”) and “Part II, Item 1A—Risk Factors” in this Form 10-Q.

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. While we believe that any industry publications and third-party research, surveys and studies from which data is included in this Form 10-Q are reliable, we have not independently verified any such data. This Form 10-Q may also include data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source and 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 this Form 10-Q. These and other factors could cause our results to differ materially from those expressed or implied in this Form 10-Q.

Note Regarding Company and Product References

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. We have a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurodegenerative disorders and cancer. Use of terms such as “us,” “we,” “our,” “Alkermes” or the “Company” in this Form 10-Q is meant to refer to Alkermes plc and its consolidated subsidiaries. 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 licensed products, 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 U.S. federal trademark registrations (“®”) and other trademarks (“™”), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, LinkeRx®, LYBALVI®, NanoCrystal® and VIVITROL®.

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

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

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2022	December 31, 2021
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 263,957	$ 337,544
Receivables, net	257,173	313,193
Investments—short-term	316,225	198,767
Inventory	166,296	150,335
Contract assets	10,105	13,363
Prepaid expenses and other current assets	40,041	48,967
Total current assets	1,053,797	1,062,169
PROPERTY, PLANT AND EQUIPMENT, NET	326,350	341,054
INVESTMENTS—LONG-TERM	166,928	229,430
RIGHT-OF-USE ASSETS	106,980	115,627
INTANGIBLE ASSETS, NET	46,845	74,043
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	137,149	81,833
OTHER ASSETS	10,977	27,455
TOTAL ASSETS	$ 1,941,899	$ 2,024,484
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 211,177	$ 208,491
Accrued sales discounts, allowances and reserves	235,640	237,216
Operating lease liabilities—short-term	15,756	16,240
Contract liabilities—short-term	3,982	6,339
Current portion of long-term debt	3,000	3,000
Total current liabilities	469,555	471,286
LONG-TERM DEBT	290,904	292,804
OPERATING LEASE LIABILITIES—LONG-TERM	95,731	104,162
OTHER LONG-TERM LIABILITIES	42,855	43,648
Total liabilities	899,045	911,900
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, 2022 and December 31, 2021, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 168,864,804 and 165,790,549 shares issued; 164,303,229 and 161,937,327 shares outstanding at September 30, 2022 and December 31, 2021, respectively	1,689	1,658
Treasury shares, at cost (4,561,575 and 3,853,222 shares at September 30, 2022 and December 31, 2021, respectively)	(160,561)	(142,658)
Additional paid-in capital	2,885,594	2,798,325
Accumulated other comprehensive loss	(12,837)	(3,723)
Accumulated deficit	(1,671,031)	(1,541,018)
Total shareholders' equity	1,042,854	1,112,584
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,941,899	$ 2,024,484

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,	
	2022	2021	2022	2021
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	$ 199,380	$ 157,737	$ 561,435	$ 448,508
Manufacturing and royalty revenues	52,941	136,294	243,437	398,435
License revenue	—	—	2,000	1,500
Research and development revenue	36	110	249	845
Total revenues	252,357	294,141	807,121	849,288
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	50,625	49,561	164,144	143,705
Research and development	100,430	118,411	289,256	308,152
Selling, general and administrative	152,777	136,213	448,206	400,569
Amortization of acquired intangible assets	9,166	9,615	27,198	28,532
Total expenses	312,998	313,800	928,804	880,958
OPERATING LOSS	(60,641)	(19,659)	(121,683)	(31,670)
OTHER EXPENSE, NET:				
Interest income	2,239	468	3,708	1,955
Interest expense	(3,552)	(2,437)	(8,271)	(8,814)
Change in the fair value of contingent consideration	(3,553)	(5,195)	(21,750)	(677)
Other (expense) income, net	(1,861)	288	2,380	(327)
Total other expense, net	(6,727)	(6,876)	(23,933)	(7,863)
LOSS BEFORE INCOME TAXES	(67,368)	(26,535)	(145,616)	(39,533)
INCOME TAX (BENEFIT) PROVISION	(3,394)	2,453	(15,603)	9,509
NET LOSS	$ (63,974)	$ (28,988)	$ (130,013)	$ (49,042)
LOSS PER ORDINARY SHARE:				
Basic and diluted	$ (0.39)	$ (0.18)	$ (0.79)	$ (0.31)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic and diluted	164,282	161,456	163,541	160,642
COMPREHENSIVE LOSS:				
Net loss	$ (63,974)	$ (28,988)	$ (130,013)	$ (49,042)
Holding loss, net of a tax benefit of $188, $72, $1,242 and $325, respectively	(2,349)	(249)	(9,114)	(1,122)
COMPREHENSIVE LOSS	$ (66,323)	$ (29,237)	$ (139,127)	$ (50,164)

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,	
	2022	2021
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (130,013)	$ (49,042)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	58,185	57,510
Share-based compensation expense	67,771	68,603
Deferred income taxes	(54,073)	2,015
Change in the fair value of contingent consideration	21,750	677
Loss on debt extinguishment	—	171
Other non-cash charges	3,746	1,803
Changes in assets and liabilities:		
Receivables	56,045	(13,991)
Contract assets	3,258	10,892
Inventory	(15,646)	(13,375)
Prepaid expenses and other assets	1,872	(1,507)
Right-of-use assets	12,470	12,891
Accounts payable and accrued expenses	4,810	15,546
Contract liabilities	(9,191)	(4,642)
Operating lease liabilities	(13,411)	(12,504)
Other long-term liabilities	12,424	(4,353)
Cash flows provided by operating activities	19,997	70,694
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(28,227)	(19,359)
Proceeds from the sale of equipment	—	277
Proceeds from contingent consideration	1,273	7,908
Return of Fountain Healthcare Partners II, L.P. investment	485	—
Payment made for licensed Intellectual Property ("IP")	—	(1,000)
Purchases of investments	(256,806)	(294,370)
Sales and maturities of investments	190,994	241,082
Cash flows used in investing activities	(92,281)	(65,462)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	18,850	24,810
Employee taxes paid related to net share settlement of equity awards	(17,903)	(13,633)
Proceeds from the issuance of long-term debt	—	23,567
Payment made for debt extinguishment	—	(993)
Principal payments of long-term debt	(2,250)	(1,500)
Cash flows (used in) provided by financing activities	(1,303)	32,251
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(73,587)	37,483
CASH AND CASH EQUIVALENTS—Beginning of period	337,544	272,961
CASH AND CASH EQUIVALENTS—End of period	$ 263,957	$ 310,444
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 2,690	$ 2,698

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

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

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
				(In thousands, except share data)				
BALANCE — December 31, 2021	165,790,549	$ 1,658	$ 2,798,325	$ (3,723)	$ (1,541,018)	(3,853,222)	$ (142,658)	$ 1,112,584
Issuance of ordinary shares under employee stock plans	1,953,293	19	1,776	—	—	—	—	1,795
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(678,209)	(17,069)	(17,069)
Share-based compensation	—	—	18,494	—	—	—	—	18,494
Unrealized loss on marketable securities, net of tax benefit of $1,382	—	—	—	(4,511)	—	—	—	(4,511)
Net loss	—	—	—	—	(35,903)	—	—	(35,903)
BALANCE — March 31, 2022	167,743,842	$ 1,677	$ 2,818,595	$ (8,234)	$ (1,576,921)	(4,531,431)	$ (159,727)	$ 1,075,390
Issuance of ordinary shares under employee stock plans	1,038,859	11	16,186	—	—	—	—	16,197
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(18,566)	(514)	(514)
Share-based compensation	—	—	23,641	—	—	—	—	23,641
Unrealized loss on marketable securities, net of tax provision of $326	—	—	—	(2,254)	—	—	—	(2,254)
Net loss	—	—	—	—	(30,136)	—	—	(30,136)
BALANCE — June 30, 2022	168,782,701	$ 1,688	$ 2,858,422	$ (10,488)	$ (1,607,057)	(4,549,997)	$ (160,241)	$ 1,082,324
Issuance of ordinary shares under employee stock plans	82,103	1	857	—	—	—	—	858
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(11,578)	(320)	(320)
Share-based compensation	—	—	26,315	—	—	—	—	26,315
Unrealized loss on marketable securities, net of tax benefit of $188	—	—	—	(2,349)	—	—	—	(2,349)
Net loss	—	—	—	—	(63,974)	—	—	(63,974)
BALANCE — September 30, 2022	168,864,804	$ 1,689	$ 2,885,594	$ (12,837)	$ (1,671,031)	(4,561,575)	$ (160,561)	$ 1,042,854

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

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
				(In thousands, except share data)				
BALANCE — December 31, 2020	162,269,220	$ 1,620	$ 2,685,647	$ (1,349)	$ (1,492,849)	(3,108,079)	$ (126,087)	$ 1,066,982
Issuance of ordinary shares under employee stock plans	1,566,685	18	2,035	—	—	—	—	2,053
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(529,817)	(10,413)	(10,413)
Share-based compensation	—	—	15,552	—	—	—	—	15,552
Unrealized loss on marketable securities, net of tax benefit of $174	—	—	—	(601)	—	—	—	(601)
Net loss	—	—	—	—	(22,418)	—	—	(22,418)
BALANCE — March 31, 2021	163,835,905	$ 1,638	$ 2,703,234	$ (1,950)	$ (1,515,267)	(3,637,896)	$ (136,500)	$ 1,051,155
Issuance of ordinary shares under employee stock plans	1,129,869	12	18,433	—	—	—	—	18,445
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(31,752)	(707)	(707)
Share-based compensation	—	—	26,917	—	—	—	—	26,917
Unrealized loss on marketable securities, net of tax benefit of $79	—	—	—	(272)	—	—	—	(272)
Net income	—	—	—	—	2,364	—	—	2,364
BALANCE — June 30, 2021	164,965,774	$ 1,650	$ 2,748,584	$ (2,222)	$ (1,512,903)	(3,669,648)	$ (137,207)	$ 1,097,902
Issuance of ordinary shares under employee stock plans	473,414	4	4,308	—	—	—	—	4,312
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards		—	—	—	—	(83,317)	(2,513)	(2,513)
Share-based compensation	—	—	25,704	—	—	—	—	25,704
Unrealized loss on marketable securities, net of tax benefit of $72	—	—	—	(249)	—	—	—	(249)
Net loss	—	—	—	—	(28,988)	—	—	(28,988)
BALANCE — September 30, 2021	165,439,188	$ 1,654	$ 2,778,596	$ (2,471)	$ (1,541,891)	(3,752,965)	$ (139,720)	$ 1,096,168

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 the fields of neuroscience and oncology. Alkermes has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder and a pipeline of product candidates in development for neurodegenerative disorders and cancer. 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, 2022 and 2021 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2021. 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 of a normal recurring nature that are necessary to state fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto of the Company, which are contained in the Company's Annual Report. 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 accompanying 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 Company's Annual Report. Intercompany accounts and transactions have been eliminated.

Reclassification

The Company reclassified certain prior year amounts on the condensed consolidated balance sheet to conform to the current year presentation. These reclassifications had no impact on the previously reported total assets, liabilities or shareholders' equity.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires that Company management 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, but not limited to, 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 conditions or using different assumptions.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to address unmet medical needs of patients in major therapeutic areas. The Company's chief decision maker, its Chief Executive Officer and chairman of its board of directors, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

Risks and Uncertainties

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has impacted nearly all regions of the world and resulted in travel and other restrictions and business slowdowns and/or shutdowns in affected areas. Ireland, all U.S. states, and many local jurisdictions and countries around the world have, at times during the pandemic, issued and implemented quarantines, vaccine and masking mandates, restrictive executive orders and other similar government orders, restrictions, and recommendations for their residents to help control the spread of COVID-19, and may continue to do so while the pandemic persists. Such orders, mandates, restrictions and/or recommendations, and/or the perception that additional orders, mandates, restrictions or recommendations could occur, have, at times during the pandemic, resulted in widespread interruptions and closures of businesses, including healthcare systems that serve people living with addiction and serious mental illness, work and supply chain stoppages, slowdowns and/or delays, remote work policies and travel restrictions, among other effects.

The COVID-19 pandemic has caused, and the Company expects may continue to cause, varying degrees of disruption to its employees and its business operations. While the Company has continued to operate its manufacturing facilities and supply its medicines throughout the pandemic, it has at times during the pandemic, experienced labor or supply chain delays or disruptions at its manufacturing facilities, and may continue to experience such delays or disruptions while the pandemic persists. In addition, while the Company has continued to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of its early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. The Company works with its internal teams, its clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on its manufacturing operations and R&D activities.

A number of the marketed products from which the Company derives revenue, including manufacturing and royalty revenue, are injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including business closures, travel restrictions, quarantine, testing and/or vaccine mandates and other protocols, labor shortages, and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees during the pandemic and may continue to be adversely impacted while the pandemic persists.

In addition, 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 its proprietary marketed products and the marketed products of its licensees 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.

Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact of the pandemic on the Company's financial condition and operating results may differ from its current projections. These uncertainties include, among other things, the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new or existing COVID-19 variants, and future developments in response thereto, which are highly uncertain and cannot be predicted as of the date of this Form 10-Q.

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 accounting pronouncements that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Product Sales, Net

The Company's product sales, net consist of sales in the U.S. of VIVITROL, ARISTADA and ARISTADA INITIO and, following its commercial launch in October 2021, LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. During the three and nine months ended September 30, 2022 and 2021, the Company recorded product sales, net, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2022	2021	2022	2021
VIVITROL	$ 96,534	$ 88,864	$ 277,493	$ 251,815
ARISTADA and ARISTADA INITIO	75,719	68,873	222,826	196,693
LYBALVI	27,127	—	61,116	—
Total product sales, net	$ 199,380	$ 157,737	$ 561,435	$ 448,508

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2022 and 2021, the Company recorded manufacturing and royalty revenues as follows:

	Three Months Ended September 30, 2022			Nine Months Ended September 30, 2022		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products[(1)]	$ —	$ 26,737	$ 26,737	$ —	$ 90,439	$ 90,439
VUMERITY	5,584	20,666	26,250	22,629	60,386	83,015
RISPERDAL CONSTA	8,380	1,848	10,228	32,529	5,516	38,045
Other	3,265	(13,539)	(10,274)	26,472	5,466	31,938
	$ 17,229	$ 35,712	$ 52,941	$ 81,630	$ 161,807	$ 243,437

	Three Months Ended September 30, 2021			Nine Months Ended September 30, 2021		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products[(1)]	$ —	$ 79,323	$ 79,323	$ —	$ 221,965	$ 221,965
VUMERITY	8,499	18,250	26,749	17,671	42,866	60,537
RISPERDAL CONSTA	8,725	2,245	10,970	31,411	8,172	39,583
Other	6,762	12,490	19,252	29,282	47,068	76,350
	$ 23,986	$ 112,308	$ 136,294	$ 78,364	$ 320,071	$ 398,435

(1) "Long-acting INVEGA products": INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and INVEGA HAFYERA/BYANNLI (paliperidone palmitate)

On October 13, 2022, an arbitration panel found that the Company must return to Acorda approximately $16.5 million (inclusive of prejudgment interest and administrative fees) previously paid by Acorda under a license agreement between the Company and Acorda. This amount represents royalty revenue paid by Acorda since July 2020 related to AMPYRA. The Company expects it may be required to repay to Acorda an additional $1.8 million in royalty revenue previously paid by Acorda. The Company paid the $16.5 million arbitration award amount in October 2022 and expects to pay the $1.8 million in the fourth quarter of 2022. In addition, during the three months ended June 30, 2022, the Company had recorded $3.2 million of royalty revenue related to AMPYRA as the Company believed that it had met the necessary revenue recognition criteria under Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"). However, as a result of the arbitration ruling, the Company reversed the $3.2 million as

the panel found that the Company was no longer entitled to be paid those royalties. During the three and nine months ended September 30, 2022, the Company recorded both the $18.3 million in repayments and the $3.2 million reversal as reversals of royalty revenue within "Manufacturing and royalty revenue" in the accompanying condensed consolidated statements of operations and comprehensive loss. As a result of the panel's ruling, the Company no longer has a contractual obligation to manufacture and supply AMPYRA or a contractual right to receive future manufacturing or royalty revenue for AMPYRA.

In November 2021, the Company received notice of partial termination of an exclusive license agreement with Janssen Pharmaceutica N.V., a subsidiary of Johnson & Johnson Corporation ("Janssen Pharmaceutica"). Under this license agreement the Company provided Janssen Pharmaceutica with rights to, and know-how, training and technical assistance in respect of, the Company's small particle pharmaceutical compound technology, known as NanoCrystal Technology, to develop dosage forms of paliperidone palmitate, including INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen Pharmaceutica ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and the Company stopped recognizing royalty revenue related to net sales of these products in the U.S. In April 2022, the Company commenced binding arbitration proceedings related to, among other things, Janssen Pharmaceutica's partial termination of the license agreement and Janssen Pharmaceutica's royalty and other obligations under the agreement. Refer to Note 15, *Commitments and Contingencies* within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for additional information regarding the arbitration proceedings with Janssen Pharmaceutica.

Contract Assets

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over time and $5.0 million of expected consideration from the Company's collaboration with Biogen related to VUMERITY. The amounts included in the contract assets table below are classified as "Current assets" in the accompanying condensed consolidated balance sheets, as they relate to manufacturing processes that are completed in ten days to eight weeks and, in the case of the $5.0 million of consideration, an amount that is expected to be received in November 2022.

Total contract assets at September 30, 2022 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2021	$ 13,363
Additions	30,215
Transferred to receivables, net	(33,473)
Contract assets at September 30, 2022	$ 10,105

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue. At September 30, 2022 and December 31, 2021, $4.0 million and $6.3 million of the contract liabilities, respectively, were classified as "Contract liabilities–short-term" in the accompanying condensed consolidated balance sheets and $4.6 million and $11.5 million of the contract liabilities, respectively, were classified as "Other long-term liabilities" in the accompanying condensed consolidated balance sheets.

Total contract liabilities at September 30, 2022 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2021	$ 17,830
Additions	2,595
Amounts recognized into revenue	(5,402)
Amounts recognized into other (expense) income, net	(6,384)
Contract liabilities at September 30, 2022	$ 8,639

4. INVESTMENTS

Investments consisted of the following (in thousands):

September 30, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses: Less than One Year	Gross Unrealized Losses: Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 135,140	$ —	$ (1,860)	$ (712)	$ 132,568
U.S. government and agency debt securities	135,444	4	(823)	(569)	134,056
Non-U.S. government debt securities	50,148	—	(311)	(236)	49,601
Total short-term investments	320,732	4	(2,994)	(1,517)	316,225
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	87,038	—	(2,757)	(606)	83,675
U.S. government and agency debt securities	73,109	—	(1,768)	(1,374)	69,967
Non-U.S. government debt securities	12,021	—	—	(555)	11,466
	172,168	—	(4,525)	(2,535)	165,108
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	173,988	—	(4,525)	(2,535)	166,928
Total investments	$ 494,720	$ 4	$ (7,519)	$ (4,052)	$ 483,153

December 31, 2021					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 85,201	$ 177	$ (39)	$ —	$ 85,339
U.S. government and agency debt securities	45,349	35	(24)	—	45,360
Non-U.S. government debt securities	68,046	75	(53)	—	68,068
Total short-term investments	198,596	287	(116)	—	198,767
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	111,793	—	(654)	—	111,139
U.S. government and agency debt securities	81,296	—	(517)	—	80,779
Non-U.S. government debt securities	35,902	—	(210)	—	35,692
	228,991	—	(1,381)	—	227,610
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	230,811	—	(1,381)	—	229,430
Total investments	$ 429,407	$ 287	$ (1,497)	$ —	$ 428,197

At September 30, 2022, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were temporary. Investments with unrealized losses consisted primarily of corporate debt securities and debt securities issued and backed by U.S. agencies and the U.S. government. At September 30, 2022, the aggregate estimated fair value of investments in an unrealized loss position was $477.0 million. The Company has the intent and ability to hold these investments until recovery, which may be at maturity. In making the determination whether the decline in fair value of these securities was temporary, the Company evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis.

In January 2022, the Company purchased a convertible promissory note in the principal amount of $0.5 million from Synchronicity Pharma, Inc. (“Synchronicity”), a related party. The convertible promissory note was classified as an available-for-sale corporate debt instrument. During the three months ended September 30, 2022, the Company determined there was an other-than-temporary loss related to this investment in Synchronicity and the $0.5 million was

recorded within "Other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss.

In May 2014, the Company entered into an agreement to invest in a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. As of September 30, 2022, the Company's total contribution in Fountain was equal to €8.0 million, and its commitment represented approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method.

During the three months ended March 31, 2022, one of the companies within the Fountain portfolio was acquired by a third party. The Company's proportional share of the proceeds from this transaction was $1.1 million, of which $1.0 million was received during the three months ended March 31, 2022 and the remaining $0.1 million is being held in escrow until May 2023. The transaction was accounted for under the cumulative earnings approach whereby the return on investment of $0.6 million was recorded as a gain within "Other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss and the return of investment of $0.5 million was recorded as a reduction in the Company's net investment in Fountain. The Company's net investment in Fountain was $6.7 million and $6.1 million at September 30, 2022 and December 31, 2021, respectively, and was included within "Other assets" in the accompanying condensed consolidated balance sheets.

During the three and nine months ended September 30, 2022, the Company recorded increases of $0.5 million and $1.6 million, respectively, in its investment in Fountain, which represented the Company's proportional share of Fountain's net gains.

Realized gains and losses on the sales and maturities of investments, which were identified using the specific identification method, were as follows:

	Nine Months Ended September 30,	
(In thousands)	2022	2021
Proceeds from the sales and maturities of investments	$ 190,994	$ 239,228
Realized gains	$ —	$ 34
Realized losses	$ 529	$ 977

The Company's available-for-sale and held-to-maturity securities at September 30, 2022 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$ 318,866	$ 314,355	$ 1,820	$ 1,820
After 1 year through 5 years	174,034	166,978	—	—
Total	$ 492,900	$ 481,333	$ 1,820	$ 1,820

5. FAIR VALUE

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

(In thousands)	September 30, 2022	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 19,927	$ 19,927	$ —	$ —
U.S. government and agency debt securities	204,023	164,218	39,805	—
Corporate debt securities	216,243	—	216,243	—
Non-U.S. government debt securities	61,067	—	61,067	—
Total	$ 501,260	$ 184,145	$ 317,115	$ —

	December 31, 2021	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	$ 126,139	$ 96,597	$ 29,542	$ —
Corporate debt securities	196,478	—	196,478	—
Non-U.S. government debt securities	103,760	—	103,760	—
Contingent consideration	23,048	—	—	23,048
Total	$ 449,425	$ 96,597	$ 329,780	$ 23,048

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 levels during the nine months ended September 30, 2022. The following table is a rollforward of the fair value of the Company's investments with fair values that were determined using Level 3 inputs at September 30, 2022:

(In thousands)	Fair Value
Balance, January 1, 2022	$ 23,048
Purchase of corporate debt security	500
Change in the fair value of contingent consideration	(21,750)
Milestone and royalty payments received by the Company related to contingent consideration	(1,273)
Impairment of corporate debt security	(500)
Royalty payments due to the Company related to contingent consideration	(25)
Balance, September 30, 2022	$ —

The Company's investments in U.S. government and agency debt securities, non-U.S. 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.

In April 2015, the Company sold its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to intravenous/intramuscular ("IV/IM") and parenteral forms of Meloxicam to Recro Pharma, Inc. ("Recro") and Recro Gainesville LLC (such transaction, the "Gainesville Transaction"). The Gainesville Transaction included in the purchase price contingent consideration tied to low double digit royalties on net sales of the IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's IP to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (such products, the "Meloxicam Products"), and milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

In November 2019, Recro spun out its acute care segment to Baudax Bio, Inc. ("Baudax"), a publicly-traded pharmaceutical company. As part of this transaction, Recro's obligations to pay certain contingent consideration from the Gainesville Transaction, including royalties on net sales of Meloxicam Products and development and commercial milestones, were assigned and/or transferred to Baudax.

In Baudax's Quarterly Report on Form 10-Q for the period ended June 30, 2022, Baudax continued to include disclosures regarding its ability to continue as a going concern, which first appeared in its Annual Report on Form 10-K for the period ended December 31, 2021. In March 2022, Baudax reduced its workforce by approximately 80%, which was designed to reduce its operational expenses and conserve its cash resources. As a result of these events and the fact that, as of March 31, 2022, Baudax had only paid $0.5 million of the $6.4 million milestone payment that was due to the Company in March 2022, the Company recorded a reduction in the fair value of the contingent consideration of $19.1 million during the three months ended March 31, 2022. In light of Baudax's continued disclosures regarding its ability to continue as a going concern and the fact that, as of September 30, 2022, Baudax had only paid $1.2 million of the $6.4

million that was due to the Company in March 2022, the Company determined that it was unlikely to collect any further proceeds under this arrangement. During the three months ended September 30, 2022, the Company recorded a $3.6 million charge to reduce the fair value of the contingent consideration to zero within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss. In addition, during the three months ended September 30, 2022, the Company determined that certain construction in progress related to the manufacturing of the approved Meloxicam Product had no future value. See Note 7, *Property, Plant and Equipment*, within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for details related to such construction in progress.

At December 31, 2021, the Company determined that the fair value of the contingent consideration was $23.0 million, $6.4 million of which was included within "Prepaid expenses and other current assets" in the accompanying condensed consolidated balance sheets, and $16.6 million of which was included within "Other assets" in the accompanying condensed consolidated balance sheets. For discussion on the calculation of the fair value of the contingent consideration at December 31, 2021, refer to Note 5, *Fair Value* within the "Notes to Consolidated Financial Statements" in the Company's Annual Report.

The carrying amounts reflected in the accompanying condensed 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 "2026 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 $279.6 million and $285.8 million at September 30, 2022 and December 31, 2021, respectively.

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, 2022	December 31, 2021
Raw materials	$ 57,889	$ 56,125
Work in process	79,816	59,105
Finished goods[(1)]	28,591	35,105
Total inventory	$ 166,296	$ 150,335

(1) At September 30, 2022 and December 31, 2021, the Company had $22.9 million and $25.1 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
Land	$ 6,560	$ 6,560
Building and improvements	194,785	192,920
Furniture, fixtures and equipment	413,721	398,099
Leasehold improvements	52,526	52,526
Construction in progress	84,152	86,512
Subtotal	751,744	736,617
Less: accumulated depreciation	(425,394)	(395,563)
Total property, plant and equipment, net	$ 326,350	$ 341,054

In September 2022, the Company determined that $8.7 million of its construction in progress that related to the manufacturing of the approved Meloxicam Product had no future value. In addition, the Company had previously received $6.4 million from Baudax related to such equipment which it had recorded as contract liabilities within "Other long-term liabilities" in the accompanying condensed consolidated balance sheets. These amounts were recognized through "other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	September 30, 2022 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	$ 465,590	$ (428,609)	$ 36,981
Capitalized IP	11-13	118,160	(108,296)	9,864
Total		$ 583,750	$ (536,905)	$ 46,845

Based on the Company's most recent analysis, amortization of intangible assets included in the accompanying condensed consolidated balance sheet at September 30, 2022 is expected to be approximately $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2022 through 2024, respectively. Although the Company believes that such analysis, and the available information and assumptions underlying such analysis, 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.

In October 2022, the Company determined that an impairment-triggering event occurred as a result of the arbitration with Acorda, referenced in Note 3, *Revenue from Contracts with Customers*, within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, and evaluated certain of its intangible assets for impairment under a held-and-used model. The Company concluded that the long-lived assets evaluated for impairment were recoverable based on an analysis of the undiscounted cash flows to be generated from the use of these assets.

9. LEASES

Future lease payments under non-cancelable leases at September 30, 2022 and December 31, 2021 consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
2022	$ 4,489	$ 17,991
2023	18,148	17,329
2024	18,418	17,535
2025	18,692	17,808
2026	14,661	13,777
Thereafter	95,304	95,229
Total operating lease payments	$ 169,712	$ 179,669
Less: imputed interest	(58,225)	(59,267)
Total operating lease liabilities	$ 111,487	$ 120,402

At September 30, 2022, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.23% and 10.9 years, respectively. Cash paid for lease liabilities was $4.5 million and $13.4 million during the three and nine months ended September 30, 2022, respectively, compared to $4.4 million and $12.5 million during the three and nine months ended September 30, 2021, respectively. The Company recorded operating lease expense of $4.1 million and $12.5 million during the three and nine months ended September 30, 2022, respectively, as compared to $4.3 million and $12.9 million during the three and nine months ended September 30, 2021, respectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
Accounts payable	$ 33,199	$ 55,721
Accrued compensation	60,920	77,256
Accrued other	117,058	75,514
Total accounts payable and accrued expenses	$ 211,177	$ 208,491

A summary of the Company's current provision for sales discounts, allowances and reserves is as follows:

(In thousands)	September 30, 2022	December 31, 2021
Medicaid rebates	$ 189,838	$ 195,413
Product discounts	16,425	14,951
Medicare Part D	17,664	14,348
Other	11,713	12,504
Total accrued sales discounts, allowances and reserves	$ 235,640	$ 237,216

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
2026 Term Loans, due March 12, 2026	$ 293,904	$ 295,804
Less: current portion	(3,000)	(3,000)
Long-term debt	$ 290,904	$ 292,804

In March 2021, the Company amended and refinanced its existing term loans, resulting in the 2026 Term Loans (such refinancing, the "Term Loan Refinancing"). The 2026 Term Loans mature on March 12, 2026 and bear interest payable at LIBOR plus 2.50% with a LIBOR floor of 0.5%. The 2026 Term Loans have an incremental facility capacity in the amount of $175.0 million plus additional amounts, provided that the Company meets certain conditions, including a specified leverage ratio. The Company was in compliance with its debt covenants at September 30, 2022.

Included in "Interest expense" in the accompanying condensed consolidated statement of operations and comprehensive loss in the nine months ended September 30, 2021 was $2.1 million related to the Term Loan Refinancing. Refer to Note 11, *Long-Term Debt* within the "Notes to Consolidated Financial Statements" in the Company's Annual Report for a discussion on accounting for the Term Loan Refinancing.

12. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2022	2021	2022	2021
Cost of goods manufactured and sold	$ 2,623	$ 2,666	$ 7,406	$ 7,527
Research and development	6,858	7,960	19,688	19,154
Selling, general and administrative	16,570	14,974	40,677	41,922
Total share-based compensation expense	$ 26,051	$ 25,600	$ 67,771	$ 68,603

At September 30, 2022 and December 31, 2021, $3.0 million and $2.3 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying condensed consolidated balance sheets.

On July 7, 2022, the Company's shareholders approved an amended version of the Alkermes plc 2018 Stock Option and Incentive Plan that served to, among other things, increase the number of ordinary shares authorized for issuance thereunder by 8,300,000.

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, 2022 and 2021, as the Company was in a net loss position, the diluted loss per share calculation did not assume conversion or exercise of stock options and restricted stock unit awards, as they would have had an anti-dilutive effect on loss per share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2022	2021	2022	2021
Stock options	13,031	11,827	12,784	15,344
Restricted stock unit awards	4,922	4,714	5,459	3,532
Total	17,953	16,541	18,243	18,876

14. INCOME TAXES

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In determining future taxable income, the Company is responsible for assumptions that it utilizes including the amount of Irish and non-Irish pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company uses to manage the underlying business.

The Company recorded income tax benefits of $3.4 million and $15.6 million during the three and nine months ended September 30, 2022, respectively, which were primarily due to a change to Section 174 of the Tax Cuts and Jobs Act of 2017 (as amended, the "TCJA"), which became effective on January 1, 2022. Under the TCJA, the Company is required to capitalize, and subsequently amortize, R&D expenses over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. The capitalization of R&D expenses during these periods resulted in an increase to the Company's U.S. taxable income and foreign derived intangible income ("FDII"), resulting in a significant increase in the Company's FDII deduction.

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, 2022, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

Janssen Arbitration Proceedings

In April 2022, Alkermes Pharma Ireland Limited commenced binding arbitration proceedings to settle, among other things, whether, notwithstanding Janssen Pharmaceutica's partial termination of two license agreements with the Company, Janssen Pharmaceutica has a continuing obligation to pay royalties on sales in the U.S. of INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA. The arbitration is to be conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration. The request for arbitration seeks, among other remedies, a declaration that Janssen Pharmaceutica is in breach of the license agreements and a resumption of royalty payments for sales of the relevant products in the U.S.

INVEGA SUSTENNA ANDA Litigation

Janssen Pharmaceutica 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") (such lawsuit, the "Teva Lawsuit"), in August 2019 against Mylan Laboratories Limited ("Mylan Labs") and other Mylan entities (the "Mylan Lawsuit") and in December 2019 against Pharmascience, Inc. ("Pharmascience"), Mallinckrodt plc, and SpecGX LLC (the "Pharmascience Lawsuit"), and in the U.S. District Court for the District of Delaware in December 2021 against Tolmar Holding, Inc., Tolmar Pharmaceuticals, Inc., Tolmar Therapeutics, Inc., and Tolmar, Inc. ("Tolmar" and such lawsuit, the "Tolmar Lawsuit"), following the respective filings by each of Teva, Mylan Labs, Pharmascience and Tolmar of an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration (the "FDA") to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906. In October 2021, the NJ District Court entered a judgment in favor of the Janssen entities in the Teva Lawsuit. In December 2021, the NJ District Court entered a judgment in favor of the Janssen entities in the Mylan Lawsuit, based on the parties' prior stipulation to be bound by the judgment in the Teva Lawsuit. The Teva entities and Mylan Labs each filed notices of appeal of their respective judgments with the U.S. Court of Appeals for the Federal Circuit, which were consolidated in January 2022 (the "Teva Appeal"). A trial was scheduled in the Tolmar Lawsuit for October 2023. The Pharmascience Lawsuit was administratively terminated in July 2022, pending the outcome of the Teva Appeal. The Company is not a party to any of these proceedings.

INVEGA TRINZA ANDA Litigation

In September 2020, Janssen Pharmaceutica, 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. A trial has been scheduled to begin in November 2022. The Company is not a party to this proceeding.

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. A trial is scheduled to begin on November 14, 2022. The Company intends to vigorously defend its IP. 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.

Product Liability and Other Legal Proceedings

The Company is involved in litigation 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 proceedings would have a material adverse effect on the Company's business or financial condition.

16. SUBSEQUENT EVENT

On November 2, 2022, the Company announced its intent, as approved by its board of directors, to explore a separation of its commercial-stage neuroscience business and development-stage oncology business. The Company plans to explore a separation of the oncology business into an independent, publicly-traded company (referred to herein as "Oncology Co.") as part of an ongoing review of strategic alternatives for the oncology business. Following the planned separation, the Company would retain its focus on driving growth of its proprietary commercial products: LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL, and advancing the development of pipeline programs focused on neurological disorders. The Company also expects to retain manufacturing and royalty revenues related to its licensed products and third-party products using its proprietary technologies under license. Oncology Co. would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and the portfolio of novel, preclinical engineered cytokines. The separation, if consummated, is expected to be completed in the second half of 2023 and is subject to customary closing conditions, including final approval by the Company's board of directors and, if sought, receipt of a private letter ruling from the IRS and/or tax opinion from the Company's tax advisors.

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

The following discussion should be read in conjunction with the accompanying condensed consolidated financial statements and related notes beginning on page 5 in this Form 10-Q, and "Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited financial statements and notes thereto accompanying our Annual Report.

Executive Summary

Net loss was $64.0 million and $130.0 million or $0.39 and $0.79 per ordinary share—basic and diluted, for the three and nine months ended September 30, 2022, respectively, as compared to net loss of $29.0 million and $49.0 million or $0.18 and $0.31 per ordinary share—basic and diluted for the three and nine months ended September 30, 2021, respectively.

The increase in net loss in the three months ended September 30, 2022, as compared to the three months ended September 30, 2021, was primarily due to a decrease of $83.4 million in manufacturing and royalty revenues and an increase of $16.6 million in selling, general and administrative expense, partially offset by an increase of $41.6 million in product sales, net and a decrease of $18.0 million in R&D expense.

The increase in net loss in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was primarily due to a decrease of $155.0 million in manufacturing and royalty revenues, an increase of $47.8 million in operating expenses and a decrease of $21.1 million in the fair value of our contingent consideration as we do not anticipate collecting any further contingent consideration proceeds from Baudax, partially offset by an increase of $112.9 million in product sales, net.

The decreases in manufacturing and royalty revenues in the three and nine months ended September 30, 2022 include $21.5 million in royalty revenue reversals as a result of arbitration proceedings related to AMPYRA.

On November 2, 2022, we announced our intent, as approved by our board of directors, to explore a separation of our commercial-stage neuroscience business and development-stage oncology business. We plan to explore a separation of the oncology business into an independent, publicly-traded company ("Oncology Co.") as part of an ongoing review of strategic alternatives for the oncology business. Following the planned separation, we would focus on driving growth of our proprietary commercial products: LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL and on advancing the development of pipeline programs focused on neurological disorders. We also expect to retain manufacturing and royalty revenues related to our licensed products and third-party products using our proprietary technologies under license. Oncology Co. would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and the portfolio of novel, preclinical, engineered cytokines. The separation, if consummated, is expected to be completed in the second half of 2023 and is subject to customary closing conditions, including final approval by our board of directors and, if sought, receipt of a private letter ruling from the IRS and/or tax opinion from our tax advisors.

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 impacted nearly all regions of the world and resulted in travel and other restrictions and business slowdowns and/or shutdowns in affected areas. Ireland, all U.S. states, and many local jurisdictions and countries around the world have, at times during the pandemic, issued and implemented quarantines, vaccine and masking mandates, restrictive executive orders and other similar government orders, restrictions, and recommendations for their residents to help control the spread of COVID-19, and may continue to do so while the pandemic persists. Such orders, mandates, restrictions and/or recommendations, and/or the perception that additional orders, mandates, restrictions or recommendations could occur, have, at times during the pandemic, resulted in widespread interruptions and closures of businesses, including healthcare systems that serve people living with addiction and serious mental illness, work and supply chain stoppages, slowdowns and/or delays, remote work policies and travel restrictions, among other effects.

The COVID-19 pandemic has caused, and we expect may continue to cause, varying degrees of disruption to our employees and our business operations. While we have continued to operate our manufacturing facilities and supply our

medicines throughout the pandemic, we have, at times during the pandemic, experienced labor or supply chain delays or disruptions at our manufacturing facilities, and may continue to experience such delays or disruptions while the pandemic persists. In addition, while we have continued to conduct R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. We work 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.

A number of the marketed products from which we derive revenue, including manufacturing and royalty revenue, are injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including business closures, travel restrictions, quarantine, testing and/or vaccine mandates and other protocols, labor shortages and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees during the pandemic and may continue to be adversely impacted while the pandemic persists.

In addition, we rely upon third parties for many aspects of our business, including the provision of goods and services related to the manufacture of our clinical products and our and our partners' marketed products, the conduct of our clinical trials, and the sale of our proprietary marketed products and the marketed products of our licensees from which we receive manufacturing and royalty revenue. Any prolonged material disruption to the third parties on which we rely could negatively impact our ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operations and financial condition.

Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact of the pandemic on our financial condition and operating results may differ from our current projections. These uncertainties include, among other things, the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new or existing COVID-19 variants, and future developments in response thereto, which are highly uncertain and cannot be predicted as of the date of this Form 10-Q. 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 I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "—Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the ongoing COVID-19 pandemic or other similar outbreaks of contagious diseases."

Products

Marketed Products

The key marketed products discussed below have generated, or are expected to generate, significant revenues for us. See the descriptions of the marketed products below and "Part I, Item 1A—Risk Factors" in our Annual Report for important factors that could adversely affect our marketed products. 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 these marketed products.

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

Proprietary Products

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

The following provides summary information regarding our key licensed product and certain key third-party products using our proprietary technologies under license, all of which are commercialized by our licensees:

Key Third-Party Products Using Our Proprietary Technologies

Product	Indication(s)	Licensee	Licensed Territory
RISPERDAL CONSTA	Schizophrenia; Bipolar I disorder	Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
INVEGA SUSTENNA* / XEPLION	*INVEGA SUSTENNA*: Schizophrenia; Schizoaffective disorder *XEPLION*: Schizophrenia	Janssen Pharmaceutica (together with Janssen Pharmaceuticals, Inc., Janssen International and their affiliates "Janssen")	Worldwide
INVEGA TRINZA* / TREVICTA	Schizophrenia	Janssen	Worldwide
INVEGA HAFYERA* / BYANNLI	Schizophrenia	Janssen	Worldwide

***** Janssen partially terminated its license agreement related to these products, effective February 2022. See the section entitled "Products Using Our Proprietary Technologies" below and Note 15, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for more information with respect to this partial termination and the arbitration proceedings that we commenced related to this partial termination and other matters in respect of these products.

Our Key Licensed Product

Product	Indication(s)	Licensee	Licensed Territory
VUMERITY	Multiple sclerosis	Biogen	Worldwide

Proprietary Products

We have developed and now commercialize products designed to help address the unmet needs of people living with opioid dependence, alcohol dependence, schizophrenia and bipolar I disorder. 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 proprietary products.

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA utilizes 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 syringe product format. We exclusively manufacture and commercialize ARISTADA in the U.S.

In August 2022, U.S. Patent No. 11,406,632 relating to ARISTADA was granted. The patent has claims to the treatment of schizophrenia by rapid and continuous intramuscular injection and expires in 2035.

ARISTADA INITIO

ARISTADA INITIO (aripiprazole lauroxil) leverages our proprietary LinkeRx and NanoCrystal technologies 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 exclusively manufacture and commercialize ARISTADA INITIO in the U.S.

LYBALVI

LYBALVI (olanzapine and samidorphan) is a once-daily, oral atypical antipsychotic drug approved in the U.S. for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes, as monotherapy or an adjunct to lithium or valproate. LYBALVI is composed of olanzapine, an established antipsychotic agent, co-formulated with samidorphan, a new chemical entity, in a single bilayer tablet. LYBALVI was launched commercially in October 2021 and is available in fixed dosage strengths composed of 10 mg of samidorphan and 5 mg, 10 mg, 15 mg or 20 mg of olanzapine. We exclusively manufacture and commercialize LYBALVI in the U.S.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly, non-narcotic, injectable medication approved in the U.S., Russia and certain countries of the Commonwealth of Independent States 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 exclusively manufacture and 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" 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 and specifically the sections entitled "—Patent and other IP protection for our products is key to our business and our competitive position but is 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 negatively impact commercialization of our products, and could adversely affect our business" and "—Litigation or arbitration filed against Alkermes, including securities litigation, or actions (such as citizens petitions) filed against regulatory agencies in respect of our products, 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. See the "Proprietary Technology Platforms" and "Patents and Proprietary Rights" sections in "Part I, Item 1—Business" in our Annual Report for information with respect to our proprietary technologies and the IP protection for these products. We receive royalties and/or manufacturing and other revenues from the commercialization of these products under our collaborative arrangements with these third parties. Such arrangements include the following:

Products Using Our Proprietary Technologies

INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI

In November 2021, we received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal Technology, to develop dosage forms of paliperidone palmitate, including INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. For additional information regarding the arbitration proceedings with Janssen, 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 this notice of partial termination and our collaborative arrangements more broadly, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically that section entitled "We rely heavily on our licensees in the commercialization and continued development of products from which we receive revenue and, if our licensees are not effective, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected."

The long-acting INVEGA products are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen. We believe that these products were developed using, and incorporate, our technologies.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union ("EU") and other countries outside of the U.S. for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION 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 manufactured by Janssen.

INVEGA HAFYERA 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 or INVEGA TRINZA for at least three months. BYANNLI is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION or TREVICTA. INVEGA HAFYERA/BYANNLI is manufactured by Janssen.

For a discussion of legal proceedings related to certain of the patents covering INVEGA SUSTENNA and INVEGA TRINZA, 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 and specifically the section entitled "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

RISPERDAL CONSTA

RISPERDAL CONSTA (risperidone long-acting injection) is a long-acting atypical antipsychotic owned and commercialized worldwide by Janssen that incorporates our proprietary technologies. 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.

Licensed Product

VUMERITY

VUMERITY (diroximel fumarate) is a novel, oral fumarate with a distinct chemical structure that is approved in the U.S., the EU and several other countries 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 Program

Our R&D is focused on the development of innovative medicines in the fields of neuroscience and oncology that are designed to address unmet patient needs. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting preclinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key development program. 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. 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 program.

Nemvaleukin alfa

Nemvaleukin alfa ("nemvaleukin") 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 preferentially expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by selectively binding to the intermediate-affinity IL-2 receptor complex. The selectivity of nemvaleukin 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 nemvaleukin as a potential immunotherapy for cancer. The ARTISTRY program is comprised of multiple clinical trials evaluating intravenous ("IV") and subcutaneous ("SC") dosing of nemvaleukin, both as a monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with advanced solid tumors. ARTISTRY-1 (evaluating IV nemvaleukin) and ARTISTRY-2 (evaluating SC nemvaleukin) are ongoing phase 1/2 studies evaluating the safety, tolerability, efficacy and pharmacokinetic and pharmacodynamic effects of nemvaleukin in patients with refractory advanced solid tumors, in both monotherapy and combination settings. ARTISTRY-3 is an ongoing phase 2 study evaluating the efficacy, safety and tolerability of less frequent dosing of IV nemvaleukin and pharmacokinetic and pharmacodynamic effects of IV nemvaleukin in the tumor microenvironment as a monotherapy and in combination with pembrolizumab in a variety of advanced solid tumors. ARTISTRY-6 is an ongoing phase 2 study evaluating the anti-tumor activity, safety and tolerability of IV nemvaleukin monotherapy in patients with mucosal melanoma and SC nemvaleukin monotherapy in patients with advanced cutaneous melanoma. ARTISTRY-7 is an ongoing phase 3 study evaluating the efficacy, safety and tolerability of IV nemvaleukin as monotherapy and in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant ovarian cancer.

In March 2021 and August 2021, we announced that the FDA granted Orphan Drug Designation and Fast Track designation, respectively, to nemvaleukin for the treatment of mucosal melanoma. In October 2021, we announced that the FDA granted Fast Track designation to nemvaleukin in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer.

Results of Operations

Product Sales, Net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO, and, following its commercial launch in the U.S. in October 2021, LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for sales of VIVITROL, ARISTADA, ARISTADA INITIO and LYBALVI during the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In millions, except for % of Sales)	2022	% of Sales	2021	% of Sales	2022	% of Sales	2021	% of Sales
Product sales, gross	$ 401.0	100.0 %	$ 338.7	100.0 %	$ 1,130.2	100.0 %	$ 954.8	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(88.9)	(22.2) %	(86.1)	(25.4) %	(254.1)	(22.5) %	(245.1)	(25.7) %
Chargebacks	(43.0)	(10.7) %	(36.5)	(10.8) %	(118.3)	(10.5) %	(95.2)	(9.9) %
Product discounts	(32.6)	(8.1) %	(27.1)	(8.0) %	(90.3)	(8.0) %	(76.9)	(8.1) %
Medicare Part D	(17.1)	(4.3) %	(15.3)	(4.5) %	(49.6)	(4.4) %	(45.2)	(4.7) %
Other	(20.1)	(5.0) %	(16.0)	(4.7) %	(56.5)	(4.9) %	(43.9)	(4.6) %
Total adjustments	(201.7)	(50.3) %	(181.0)	(53.4) %	(568.8)	(50.3) %	(506.3)	(53.0) %
Product sales, net	$ 199.3	49.7 %	$ 157.7	46.6 %	$ 561.4	49.7 %	$ 448.5	47.0 %

The following table compares product sales, net revenues earned during the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2022	2021	Change	2022	2021	Change
VIVITROL	$ 96.5	$ 88.8	$ 7.7	$ 277.5	$ 251.8	$ 25.7
ARISTADA and ARISTADA INITIO	75.7	68.9	6.8	222.8	196.7	26.1
LYBALVI	27.1	—	27.1	61.1	—	61.1
Product sales, net	$ 199.3	$ 157.7	$ 41.6	$ 561.4	$ 448.5	$ 112.9

VIVITROL product sales, gross, increased by 6% and 7% during the three and nine months ended September 30, 2022, respectively, as compared to the three and nine months ended September 30, 2021, primarily due to increases of 1% and 2%, respectively, in the number of VIVITROL units sold and a 6% increase in the selling price of VIVITROL that went into effect in April 2022. ARISTADA and ARISTADA INITIO product sales, gross, increased by 9% and 13% during the three and nine months ended September 30, 2022, respectively, as compared to the three and nine months ended September 30, 2021, primarily due to increases of 2% and 10%, respectively, in the number of ARISTADA units sold and a 3% increase in the selling price of ARISTADA and ARISTADA INITIO that went into effect in April 2022.

The decreases in Medicaid rebates as a percentage of sales during the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to actual Medicaid utilization rates related to VIVITROL being lower than original estimates as such rates normalize from pandemic levels.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned during the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Manufacturing and royalty revenues:						
Long-acting INVEGA products	$ 26.7	$ 79.4	$ (52.7)	$ 90.4	$ 222.0	$ (131.6)
VUMERITY	26.2	26.7	(0.5)	83.0	60.5	22.5
RISPERDAL CONSTA	10.2	11.0	(0.8)	38.0	39.6	(1.6)
Other	(10.2)	19.2	(29.4)	32.0	76.3	(44.3)
Manufacturing and royalty revenues	$ 52.9	$ 136.3	$ (83.4)	$ 243.4	$ 398.4	$ (155.0)

Our agreements with Janssen related to the long-acting INVEGA products provide for 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 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 expiry of the agreement.

The decreases in royalty revenues from the long-acting INVEGA products during the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to the partial termination of our license agreement with Janssen related to such products. When the partial termination of the license agreement became effective in February 2022, we stopped recognizing royalty revenue related to net sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. During the three and nine months ended September 30, 2022, Janssen's rest of world net sales were $348.0 million and $1,097.0 million, respectively, as compared to $355.0 million and $1,111.0 million during the three and nine months ended September 30, 2021, respectively.

In November 2021, we received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal Technology, to develop dosage forms of paliperidone palmitate, including INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and we stopped recognizing royalty revenue related to net sales of these products. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. For additional information regarding the arbitration proceedings with Janssen, see Note 15, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q. For more information about the license agreement with Janssen in respect of the long-acting INVEGA products, see the "Collaborative Arrangements—Janssen" section in "Part I, Item 1—Business" in our Annual Report. For information about risks relating to the notice of partial termination and our collaborative arrangements more broadly, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically that section entitled "We rely heavily on our licensees in the commercialization and continued development of products from which we receive revenue and, if our licensees are not effective, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected." We expect royalty revenues from net sales of XEPLION, TREVICTA and BYANNLI to decrease over time. The amount and timing of royalty revenues from sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA depend upon the outcome of our dispute with Janssen related to the impact of its partial termination of our license agreement in respect of these products.

In addition, each of INVEGA SUSTENNA and INVEGA TRINZA are currently subject to Paragraph IV litigation in response to companies seeking to market generic versions of such products. Increased competition from new products or generic versions of these products may lead to reduced unit sales of such products and increased pricing pressure. For a discussion of these legal proceedings, 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 these legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report, and specifically the section entitled "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

We recognize manufacturing revenue for RISPERDAL CONSTA at the point in time when RISPERDAL CONSTA has been fully manufactured, which is deemed to have occurred when the product is approved for shipment by both us and Janssen. We record royalty revenue, equal to 2.5% of Janssen's end-market net sales, in the period that the end-market sale of RISPERDAL CONSTA occurs. The decrease in revenue from RISPERDAL CONSTA during the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was primarily due to a decrease of $2.7 million in royalty revenue, partially offset by a $1.1 million increase in manufacturing revenue. This decrease in royalty revenue was due to a decrease in end-market sales of RISPERDAL CONSTA, which were $373.0 million during the nine months ended September 30, 2022, as compared to $452.0 million during the nine months ended September 30, 2021. The increase in manufacturing revenue during the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021 was primarily due to an increase in the number of units approved for shipment to Janssen, partially offset by the decrease in our manufacturing fee. Pursuant to the terms of our manufacturing and supply agreement with Janssen, our manufacturing fee decreases as forecasted manufacturing production increases. Based on Janssen's anticipated volume increases, our manufacturing fee decreased from 8.6% to 7.9% of Janssen's net unit sales price.

We expect revenues from RISPERDAL CONSTA to decrease over time. The latest to expire patent covering RISPERDAL CONSTA expired in 2021 in the EU and will expire in 2023 in the U.S., and we are aware of potential generic competition for RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure.

We receive a 15% royalty on worldwide net sales of VUMERITY for product manufactured and packaged by us, subject to increases for VUMERITY manufactured and/or packaged by Biogen or its designees. We also recognize manufacturing revenue related to VUMERITY at cost plus 15%, upon release of bulk batches of VUMERITY manufactured by us and, to the extent we package such product, then also upon shipment of packaged lots of VUMERITY. The decrease in revenue from VUMERITY during the three months ended September 30, 2022, as compared to the three months ended September 30, 2021, was due to a decrease of $2.9 million in manufacturing revenue, partially offset by an increase of $2.4 million in royalty revenue. The increase in revenue from VUMERITY during the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was due to an increase of $17.5 million in royalty revenue and an increase of $5.0 million in manufacturing revenue. The increases in royalty revenue were due to increases in net sales of VUMERITY, which were $137.8 million and $402.6 million during the three and nine months ended September 30, 2022, respectively, as compared to $120.9 million and $285.0 million during the three and nine months ended September 30, 2021, respectively. The decrease in manufacturing revenue in the three months ended September 30, 2022, as compared to the three months ended September 30, 2021, was primarily due to the manufacture of fewer commercial batches. We continue to work to address a manufacturing issue related to VUMERITY, which, if it persists, will continue to negatively impact our manufacturing revenue and may negatively impact our royalty revenues. The increase in manufacturing revenue in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was due to an increase in the number of packaged batches that were manufactured for Biogen.

On October 13, 2022, an arbitration panel found that we must return to Acorda approximately $16.5 million (inclusive of prejudgment interest and administrative fees) previously paid by Acorda under a license agreement between the Company and Acorda. This amount represents royalty revenue paid by Acorda since July 2020 related to AMPYRA. We expect we may be required to repay to Acorda an additional $1.8 million in royalty revenue previously paid by Acorda. We paid the $16.5 million arbitration award amount in October 2022 and expect to pay the $1.8 million in the fourth quarter of 2022. In addition, during the three months ended June 30, 2022, we had recorded $3.2 million of royalty revenue related to AMPYRA as we believed that we had met the necessary revenue recognition criteria under ASC 606. However, as a result of the arbitration ruling, we reversed the $3.2 million as the panel found that we were no longer entitled to be paid those royalties. During the three and nine months ended September 30, 2022, we recorded both the $18.3 million in repayments and the $3.2 million reversal as reversals of royalty revenue within "Manufacturing and royalty revenue" in the accompanying condensed consolidated statements of operations and comprehensive loss. As a result of the panel's ruling, we no longer have a contractual obligation to manufacture and supply AMPYRA or a contractual right to receive future manufacturing or royalty revenue for AMPYRA.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Cost of goods manufactured and sold	$ 50.6	$ 49.6	$ 1.0	$ 164.1	$ 143.7	$ 20.4

The increase in cost of goods manufactured and sold in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was primarily due to increases of $4.5 million and $3.2 million, respectively, in the cost of goods manufactured for VUMERITY and RISPERDAL CONSTA and increases of $5.3 million and $8.5 million, respectively, in the cost of goods sold for VIVITROL and LYBALVI. These increases were all related to an increase in the number of units manufactured and sold for each of these products, as discussed above.

Research and Development Expenses

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, 2022 and 2021 relating to our then current development programs and our internal R&D expenses, listed by the nature of such expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
External R&D expenses:						
Development programs:						
nemvaleukin	$ 21.6	$ 19.8	$ 1.8	$ 58.2	$ 61.1	$ (2.9)
LYBALVI	6.5	6.8	(0.3)	15.7	21.3	(5.6)
ALKS 1140	0.8	25.5	(24.7)	3.1	27.7	(24.6)
Other external R&D expenses	17.9	15.2	2.7	51.6	43.4	8.2
Total external R&D expenses	46.8	67.3	(20.5)	128.6	153.5	(24.9)
Internal R&D expenses:						
Employee-related	39.6	37.9	1.7	120.3	114.7	5.6
Occupancy	4.6	4.9	(0.3)	13.3	14.7	(1.4)
Depreciation	3.1	2.9	0.2	8.8	9.2	(0.4)
Other	6.4	5.4	1.0	18.3	16.1	2.2
Total internal R&D expenses	53.7	51.1	2.6	160.7	154.7	6.0
Research and development expenses	$ 100.5	$ 118.4	$ (17.9)	$ 289.3	$ 308.2	$ (18.9)

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 preclinical and/or clinical trials, our expectations regarding the likelihood of their regulatory approval and our view of their future potential commercial viability, among other factors.

The increase in expenses related to nemvaleukin in the three months ended September 30, 2022, as compared to the three months ended September 30, 2021 was primarily due to increased spend on the ARTISTRY-7 study, and the decrease in expenses related to nemvaleukin in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was primarily due to decreased spend on the ARTISTRY-1 study. For details on the ARTISTRY development program, see the “Key Development Program” 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 decreases in expenses related to LYBALVI in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to decreased R&D activities for the product in light of its commercial launch in October 2021, partially offset by continued spend on ongoing clinical studies. The decreases in expenses related to ALKS 1140 in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to the termination of the ALKS 1140 clinical development program in the second quarter of 2022, as the initial data did not support further clinical development, and a $25.0 million development milestone in the third quarter of 2021 related to the submission of a clinical trial authorization for ALKS 1140. The increases in other external R&D expenses in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to increases of $0.8 million and $8.2 million, respectively, related to our early-stage development programs.

The increases in employee-related expense in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily related to increases of $1.5 million and $5.5 million, respectively, in labor and benefits, primarily due to increases in recruitment costs and temporary labor.

Selling, General and Administrative Expense

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Selling and marketing expense	$ 96.9	$ 88.0	$ 8.9	$ 288.4	$ 253.4	$ 35.0
General and administrative expense	55.9	48.2	7.7	159.8	147.2	12.6
Selling, general and administrative expense	$ 152.8	$ 136.2	$ 16.6	$ 448.2	$ 400.6	$ 47.6

The increases in selling and marketing expense in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to increases in marketing expenses of $4.6 million and $15.2 million, respectively, and increases in professional service fees of $0.3 million and $5.0 million, respectively, in each case primarily due to commercial launch activities for LYBALVI. In addition, employee-related expenses increased by $2.6 million and $12.7 million, respectively, primarily due to increases in selling-and-marketing-related salaries and benefits.

The increases in general and administrative expense in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were primarily due to increases in professional service fees of $1.6 million and $8.9 million, respectively, and increases in employee-related expenses of $4.8 million and $1.8 million, respectively.

Other Expense, Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2022**	**2021**	**Change**	**2022**	**2021**	**Change**
Interest income	$ 2.3	$ 0.5	$ 1.8	$ 3.8	$ 2.0	$ 1.8
Interest expense	(3.6)	(2.4)	(1.2)	(8.3)	(8.8)	0.5
Change in the fair value of contingent consideration	(3.6)	(5.2)	1.6	(21.8)	(0.7)	(21.1)
Other (expense) income, net	(1.8)	0.2	(2.0)	2.4	(0.4)	2.8
Total other expense, net	$ (6.7)	$ (6.9)	$ 0.2	$ (23.9)	$ (7.9)	$ (16.0)

The decrease in total other expense, net in the three months ended September 30, 2022, as compared to the three months ended September 30, 2021, was primarily due to an increase in interest income and the change in the fair value of the contingent consideration, partially offset by an increase in interest expense and an increase in other (expense) income, net. The increases in interest income and interest expense were primarily due to increases in interest rates. Interest income consists primarily of interest earned on our available-for-sale investments. Interest expense consists primarily of interest incurred on our 2026 Term Loans. The increase in other (expense) income, net, was primarily due to the determination that certain construction in progress related to the approved Meloxicam Product had no future value, as discussed in Note 7, *Property, Plant and Equipment*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

The increase in total other expense, net in the nine months ended September 30, 2022, as compared to the nine months ended September 30, 2021, was primarily due to the change in the fair value of contingent consideration, partially offset by increases in interest income and other (expense) income, net and a decrease in interest expense. The increase in interest income was primarily due to an increase in the interest rates, as previously discussed. The decrease in interest expense was primarily due to a decrease in certain financing costs related to the Term Loan Refinancing completed in March 2021, partially offset by an increase in interest rates. The Term Loan Refinancing is discussed in Note 11, *Long-Term Debt* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q. The increase in other (expense) income, net was primarily due to proceeds received in connection with the Fountain transaction in March 2022, partially offset by the write down of certain construction in progress described above. The Fountain transaction is discussed in Note 4, *Investments*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

The changes in the fair value of the contingent consideration in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, were due to the determination that it was unlikely that we would collect any further contingent consideration proceeds from Baudax, and accordingly, we reduced the fair value of the contingent consideration to zero, as discussed in Note 5, *Fair Value*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

Income Tax (Benefit) Provision

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2022	2021	Change	2022	2021	Change
Income tax (benefit) provision	$ (3.4)	2.5	$ (5.9)	$ (15.6)	$ 9.5	$ (25.1)

The income tax (benefit) provision in the three months ended September 30, 2022 and 2021, respectively, primarily related to U.S. federal and state taxes. The favorable change in the income tax (benefit) provision was primarily due to an enhanced FDII deduction as a result of a change to Section 174 of the TCJA in relation to capitalization and amortization of R&D expenses. The income tax (benefit) in the nine months ended September 30, 2022 was primarily due to the enhanced FDII deduction. The FDII deduction is discussed in Note 14, *Income Taxes* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q. The income tax provision in the nine months ended September 30, 2021 primarily related to a $6.8 million discrete tax expense related to employee equity activity.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

	September 30, 2022			December 31, 2021		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 156.4	$ 107.6	$ 264.0	$ 88.6	$ 248.9	$ 337.5
Investments—short-term	181.6	134.6	316.2	144.5	54.3	198.8
Investments—long-term	89.8	77.1	166.9	163.0	66.4	229.4
Total cash and investments	$ 427.8	$ 319.3	$ 747.1	$ 396.1	$ 369.6	$ 765.7
Outstanding borrowings—short and long-term	$ 293.9	$ —	$ 293.9	$ 295.8	$ —	$ 295.8

At September 30, 2022 our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 320.7	$ —	$ (4.5)	$ —	$ 316.2
Investments—long-term available-for-sale	172.2	—	(7.0)	—	165.2
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 494.7	$ —	$ (11.5)	$ —	$ 483.2

Sources and Uses of Cash

We generated $20 million and $70.7 million of cash from operating activities during the nine months ended September 30, 2022 and 2021, respectively. We expect that our existing cash, cash equivalents and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt, for at least the twelve months following the date from which our financial statements were issued. 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, arrangements relating to assets or other financing methods or structures. In addition, the 2026 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional potential amounts, provided that we meet certain conditions, including a specified leverage ratio.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to 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 and backed by non-U.S. governments. Our held-to-maturity investments consist of investments that are 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 twelve months as long-term investments. 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, 2022, we performed an analysis of our investments with unrealized losses for impairment and determined that the loss on one of our corporate debt securities was other-than-temporary and, during the nine months ended September 30, 2022, recorded a $0.5 million impairment charge within "Other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss.

We have no off-balance sheet arrangements that are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources in the next twelve months.

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
(In millions)	**2022**	**2021**
Cash and cash equivalents, beginning of period	$ 337.5	$ 273.0
Cash flows provided by operating activities	20.0	70.7
Cash flows used in investing activities	(92.2)	(65.5)
Cash flows (used in) provided by financing activities	(1.3)	32.2
Cash and cash equivalents, end of period	$ 264.0	$ 310.4

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for non-cash operating items such as depreciation, amortization and share-based compensation and changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our results of operations.

The decrease in cash flows provided by operating activities was primarily due to an increase in our net loss, net of adjustments to reconcile net loss to cash flows from operating activities, partially offset by an increase in cash provided by working capital. The increase in cash from working capital was primarily related to an increase in cash flows from accounts receivable and decreases in cash flows used in inventory and accounts payable and accrued expenses, partially offset by increases in cash flows used for contract assets, inventory. prepaid expenses and other current assets and contract liabilities.

The increase in cash flows used in investing activities was primarily due to a $12.5 million increase in net purchase of investments, a $6.6 million decrease in payments to be received in connection with the contingent consideration resulting from the Gainesville Transaction and an $8.9 million increase in capital expenditures.

The change in cash flows from financing activities was primarily due to $23.6 million in proceeds from the Term Loan Refinancing, which we received in the nine months ended September 30, 2021, and a $10.2 million decrease in the amount of cash that we received upon the exercise of employee stock options, net of employee taxes.

Debt

At September 30, 2022, the principal balance of our borrowings consisted of $295.5 million outstanding under our 2026 Term Loans. See Note 11, *Long-Term Debt*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for further discussion of our 2026 Term Loans.

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 conditions or using different assumptions. 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.

In relation to our contingent consideration, in light of Baudax's disclosures regarding its ability to continue as a going concern, in September 2022 we determined it was unlikely that we would receive any further contingent consideration proceeds from Baudax and, accordingly, we wrote the remaining $3.6 million contingent consideration balance down to zero. For further information regarding the calculation of the fair value of this contingent consideration, refer to Note 5, *Fair Value* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

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 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, 2021, 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 non-U.S. currency exchange risk related to manufacturing and royalty revenues that 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 non-U.S. 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 non-U.S. currency exchange rate risk since December 31, 2021.

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, 2022. 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, 2022 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***

Risks Related to the Potential Separation of Our Oncology Business

The potential separation of our commercial-stage neuroscience and development-stage oncology businesses, including through a potential separation of our oncology business into an independent, publicly traded company, is subject to various risks and uncertainties and may not be completed on the timeline currently contemplated or at all, and will involve significant time, effort and expense, which could disrupt or adversely affect our business and our financial condition, results of operations and cash flows.

On November 2, 2022, we announced our intent, as approved by our board of directors, to explore a separation of our commercial-stage neuroscience business and development-stage oncology business. We plan to explore a separation of the oncology business into an independent, publicly-traded company ("Oncology Co.") as part of an ongoing review of strategic alternatives.

Our business may face significant risks and uncertainties as a result of the announcement, exploration and/or execution of the potential separation, including, without limitation:

- the diversion of management's attention from operating our neuroscience and oncology businesses and the overall disruption of, and impact on, our businesses;
- potential difficulty in maintaining employee morale and retaining and/or recruiting key management and other employees;
- potential difficulty in separating our oncology business from our neuroscience business, including allocation of operations, services, products and personnel;
- difficulty and/or delays in obtaining regulatory approvals related to the potential separation of the businesses, including any approvals needed to effect the separation and/or those related to ongoing clinical trials of our oncology products;
- the need to obtain third-party consents related to the potential separation of the businesses, which may be difficult to obtain and/or cause delay in our intended timelines for the separation or disrupt third-party relationships that are important to our business;
- foreseen and unforeseen dis-synergy costs, costs of restructuring transactions (including potential taxes) and other significant costs and expenses; and
- potential negative reactions from the financial markets, whether as a result of announcement of the potential separation or any delay or failure in completing the separation.

No assurance can be given as to whether we will be successful in managing these or any other significant risks that we may encounter in the potential separation of our businesses, and any of these risks could have a material adverse effect on our businesses, financial condition, results of operations, cash flows and/or the market price of our ordinary shares. We have already incurred certain expenses, and expect to incur significant additional expenses, in connection with the exploration and potential consummation of a separation, and such costs and expenses may be greater than we anticipate, and may not yield the benefits that we or others may anticipate.

We will endeavor to structure any potential separation in a tax efficient manner, seek to minimize the taxes for the Company and seek to qualify the transaction as tax-free to shareholders for U.S. federal and Irish tax purposes. The potential separation, if consummated, is expected to be completed in the second half of 2023, subject to customary closing conditions, including final approval by our board of directors and, if sought, receipt of a private letter ruling from the IRS and/or tax opinion from our tax advisors. Adverse market conditions or tax consequences, litigation or other legal proceedings that may arise as a result of the potential separation, or delays or difficulties effecting the potential separation, including possible delays in obtaining any necessary stock exchange, regulatory or other approval or the failure to obtain any such approvals, possible delays in obtaining any required tax opinions or rulings or the failure to

obtain any such tax opinions or rulings, changes in relevant law and other challenges, could delay, prevent or otherwise adversely impact the anticipated benefits of the potential separation.

No assurance can be given as to whether we will complete any separation on our anticipated timeline or at all. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits we anticipate realizing as a result of the potential separation, and in each case, our business, results of operations and financial condition and/or the market price for our ordinary shares could be adversely affected.

We may fail to realize some or all of the anticipated benefits of the potential separation and the market price of our ordinary shares may fluctuate significantly in connection with the potential separation.

Even if a separation of our commercial-stage neuroscience and development-stage oncology businesses is completed, the anticipated operational, financial, strategic and other benefits of a potential separation may not be achieved. These anticipated benefits are based on a number of assumptions and uncertainties, which may prove to be incorrect or incomplete. Furthermore, if separated, the two independent companies will be smaller and less diversified than the combined company, with a narrower business focus, and may be more vulnerable to changing market conditions. The potential separation also presents a number of significant risks to our internal processes, including the failure to maintain an adequate control environment due to changes to our infrastructure technology systems and financial reporting processes.

In addition, the market price of our ordinary shares may experience volatility around the time of announcement or consummation of the potential separation and thereafter. We also cannot predict the effect of a completed separation on the market price of our ordinary shares, which, following a separation, may be less than, equal to or greater than the market price of our ordinary shares prior to the separation. Further, the combined value of our ordinary shares and those of Oncology Co. may not be equal to or greater than what the value of our ordinary shares would have been had the separation not occurred. The combined value of the ordinary shares of the two companies could be lower than anticipated for a variety of reasons, including, but not limited to, a failure of Oncology Co. to operate and compete effectively as an independent company.

We continue to assess the tax consequences of potential structures for the separation of our oncology business from our neuroscience business, including a potential separation of the oncology business into an independent, publicly-traded company. If such a separation does not qualify as a transaction that is generally tax-free for U.S. federal and Irish tax purposes, we and our shareholders could be subject to significant tax liabilities.

In connection with the potential separation, we may seek a private letter ruling from the IRS (the "IRS Ruling") and/or an opinion from our U.S. tax advisor (the "U.S. Tax Opinion") regarding U.S. federal and state income tax consequences of the separation, including that, among other things, the separation would generally qualify as tax-free for U.S. federal income tax purposes under Sections 368(a)(1)(D) and 355 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The IRS Ruling and/or the U.S. Tax Opinion would be based on and rely on, among other things, certain facts, assumptions, representations, and undertakings from us and Oncology Co., including those relating to the past and future conduct of the companies' respective business operations and other matters. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete, or if we or Oncology Co. breach any of our respective covenants in the separation documents, the IRS Ruling and/or the U.S. Tax Opinion may be invalid and the conclusions reached therein could be jeopardized. Notwithstanding a U.S. Tax Opinion, the U.S. Internal Revenue Service, or the IRS, could determine that a distribution or any related transaction is taxable for U.S. federal income tax purposes if it determines that any of these facts, assumptions, representations or undertakings are not correct or have been violated, or that the distribution should be taxable for other reasons, including if the IRS were to disagree with the conclusions in the U.S. Tax Opinion. The U.S. Tax Opinion will not be binding on the IRS or the courts. Accordingly, the IRS or the courts may challenge the conclusions stated in the U.S. Tax Opinion and such challenge could prevail. If the potential separation transaction is ultimately determined to be taxable, we and our shareholders that are subject to U.S. federal income tax could incur significant tax liabilities.

Furthermore, in connection with the potential separation, we may seek an opinion from our Irish tax advisor (the "Irish Tax Opinion") regarding the Irish tax consequences of the separation. The Irish Tax Opinion would be based on and rely on, among other things, certain facts, assumptions, representations, and undertakings from us, including those relating to the past and future conduct of our business operations and other matters. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete the Irish Tax Opinion may be invalid and the conclusions reached therein could be jeopardized. The Irish Tax Opinion will not be binding on the Irish

Tax Authority or the courts. Accordingly, the Irish Tax Authority or the courts may challenge the conclusions stated in the Irish Tax Opinion and such challenge could prevail. In this case, we and our shareholders could incur significant tax liabilities.

Risks Related to Our Business and Our Industry

Revenues generated by sales of our products depend on the availability from third-party payers of reimbursement for our products and the extent of cost-sharing arrangements for patients (e.g., patient co-payment, co-insurance, deductible obligations) and cost-control measures imposed, and any reductions in payment rate or reimbursement or increases in our or in patients' financial obligation to payers could result in decreased sales of our products and/or decreased revenues.

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payers such as state and federal governments, including Medicare and Medicaid in the U.S. and similar programs in other countries, managed care providers and private insurance plans. Deterioration in the timeliness, certainty and amount of reimbursement for our products, the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), increases in our financial obligation to payers, including government payers, limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments, or deductible amounts, could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, when a new product is approved, the availability of government and private reimbursement for that product and coverage restrictions that may be imposed for such product are uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for, or the prevalence and extent of other access barriers to, our products.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare. In August 2022, the Inflation Reduction Act of 2022 (the "Inflation Reduction Act") was signed into law. The Inflation Reduction Act includes several provisions that will impact our business to varying degrees, including those that impose new manufacturer financial liability on all drugs in Medicare Part D beginning in 2025, allow the U.S. government to negotiate prices for some drugs covered under Medicare Part B and Part D beginning in 2026, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation beginning in 2023.

In addition, economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs, including but not limited to price control initiatives, discounts and other pricing-related actions. Over the past several years, a number of U.S. states have enacted drug pricing transparency laws that require companies to report on drug price increases and justify how drug prices were set and we expect additional state drug pricing initiatives to be proposed and enacted in the future. In addition, state Medicaid programs are increasingly requesting that manufacturers pay supplemental rebates and are requiring prior authorization by the state program for use of any drug. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. U.S. government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

Furthermore, we may face uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act (the "PPACA"), whether by legislative means or through litigation, and further potential reforms to government negotiation or regulation of drug pricing. The PPACA significantly expanded coverage of mental health and substance use disorders and provided federal parity protections to such coverage benefits. If successful, such efforts and proposed legislation or other future federal or state legislative or administrative changes relating to healthcare reform and drug pricing could adversely affect our business and financial results.

In addition, the outcome or settlement of litigation could impact the practices of healthcare providers and patients, and the policies and practices of third-party payers, including Medicare, Medicaid, managed care providers and private insurance plans, in a manner detrimental to our products, which in turn could materially and adversely affect our business and financial condition.

In Europe and many other countries, government-sponsored healthcare systems are the primary payers for healthcare expenditures, including payment for drugs and biologics. We expect that countries may take actions to reduce expenditure on drugs and biologics, including mandatory price reductions, patient access restrictions, suspensions of price increases, increased mandatory discounts or rebates, preference for generic products, reduction in the amount of reimbursement and greater importation of drugs from lower-cost countries. Any such cost-control measures would likely reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, the inability to secure adequate prices in a particular country may not only limit the marketing of products within that country, but may also adversely affect the ability to obtain acceptable prices in other markets.

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the nine months ended September 30, 2022. As of September 30, 2022, we had purchased a total of 8,866,342 shares under this program at an aggregate cost of $114.0 million.

During the three months ended September 30, 2022, we acquired 11,578 of our ordinary shares, at an average price of $27.63 per share, to satisfy withholding tax obligations related to the vesting of employee equity awards.

Item 5. ***Other Information***

Our policy governing transactions in our securities by our directors, officers and employees permits our directors, officers and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the three months ended September 30, 2022, each of Messrs. Iain M. Brown, Blair C. Jackson, Michael J. Landine and Richard F. Pops, executive officers of the Company, entered into a trading plan in accordance with Rule 10b5-1 and our policy governing transactions in our securities by our directors, officers and employees. We undertake no obligation to update or revise the information provided herein, including for any revision or termination of an established trading plan.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1 # *	Fourth Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of August 25, 2022.
10.2 †	Alkermes plc 2018 Stock Option and Incentive Plan, as amended (incorporated by reference from Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299) filed on July 7, 2022).
10.2.1 †	Form of Non-Employee Director New Director Grant Non-Qualified Stock Option Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended (incorporated by reference from Exhibit 10.1.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299) filed on July 27, 2022).
10.2.2 †	Form of Non-Employee Director New Director Grant Restricted Stock Unit Award (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended (incorporated by reference from Exhibit 10.1.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299) filed on July 27, 2022).
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.

* In accordance with Item 601(b)(2)(ii) of Regulation S-K, certain information (indicated by "[**]") has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the Company if publicly disclosed.

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
Richard F. Pops
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Iain M. Brown
Iain M. Brown
Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: November 2, 2022

In accordance with Item 601(b)(2)(ii) of Regulation S-K, certain information (indicated by "[**]") has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

FOURTH AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT

THIS FOURTH AMENDMENT (this "Amendment") is made and entered into as of August 25, 2022 (the "Amendment Effective Date") to amend that certain License and Collaboration Agreement dated November 27, 2017, as amended (the "Agreement"), by and between ALKERMES PHARMA IRELAND LIMITED ("Alkermes") and BIOGEN SWISS MANUFACTURING GMBH ("Biogen"). Unless noted otherwise, capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

RECITALS

WHEREAS, Alkermes and Biogen have entered into the Agreement;

WHEREAS, Alkermes and Biogen now wish to amend the Agreement to add, among other things, detail in respect of an additional royalty payment to be paid to Alkermes on certain Commercial Supplies of the Alkermes 8700 Product;

NOW, THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Section 1.1 of the Agreement is hereby amended to add the following new defined terms:

   "***Bulk Form Only Product***" shall mean Alkermes 8700 Product Commercial Supplies (as that term is defined in the Commercial Supply Agreement) to be Delivered (as that term is defined in the Commercial Supply Agreement) in Bulk Form (as that term is defined in the Commercial Supply Agreement) and for which finished form to be derived therefrom is to be Manufactured (including Packaged) by Biogen or a Third Party in lieu of Alkermes.

   "***Packaging***" (and its cognate expressions) shall mean the filling into bottles, labelling, packaging and/or finishing of Commercial Supplies of Alkermes 8700 Product.

   "[**] ***Annual Net Selling Price***" or "[**] ***ANSP***" means the [**] net selling price (in U.S. Dollars) per capsule of the Alkermes 8700 Product as calculated on a Calendar Year basis based on [**] Alkermes 8700 Product sold [**] during such Calendar Year, excluding any samples or other forms of Alkermes 8700 Product that are provided free of charge. [**].

2. Section 5.1.2 of the Agreement is hereby deleted in its entirety and replaced with the following text:

   5.1.2 Commercial Supplies. Pursuant to this Agreement, Biogen has the right to Manufacture or have Manufactured Commercial Supplies. Biogen has considered in good faith, and hereby appoints, Alkermes as the toll manufacturer for such Commercial Supplies for Commercialization in the Territory at a site outside of the United States, and Biogen and its Affiliates and Sublicensees will purchase Commercial Supplies exclusively from Alkermes; *provided that*, (A) with respect to the Alkermes 8700 Product only and subject to the Manufacturing transition plan referenced in this Section 5.1.2, Biogen's appointment of Alkermes as toll manufacturer, Alkermes' obligation to Manufacture, and the obligations of Biogen and its Affiliates and Sublicensees to purchase Clinical Supplies and Commercial Supplies exclusively from Alkermes will each expire on the Exclusive Manufacturing End

Date, (B) with respect to Bulk Form Only Product, Biogen shall have the right to Manufacture or engage a Third Party to Manufacture the finished form to be derived from such Bulk Form; and (C) for Products other than the Alkermes 8700 Product, Biogen may qualify to Manufacture, or engage and qualify a Third Party to Manufacture, Commercial Supplies as a back-up manufacturer so long as such Third Party Manufacturer does not Manufacture more than [**] percent ([**]%) of Commercial Supplies in the aggregate in any Calendar Year, except in the event of a Force Majeure Delay or a Serious Failure to Supply.

Upon Biogen's written request, Alkermes and Biogen shall work in good faith to (a) enter into a technology transfer plan pursuant to which Alkermes will undertake a Technology Transfer in accordance with Section 3.2.3(iv) of the Agreement, including the reimbursement provisions therein, as promptly as reasonably practicable and, in any event, to be completed no later than [**] after Biogen's written request to transition manufacturing and enter into a technology transfer plan, and (b) enter into a Manufacturing transition plan ([**]) to ensure the orderly transition after the Exclusive Manufacturing End Date to Biogen or its designee of Manufacturing responsibility for Clinical Supplies and Commercial Supplies of the Alkermes 8700 Product in an effort to prevent any interruption in the supply of such product.

Notwithstanding anything to the contrary set forth in this Section 5.1.2, if (i) Alkermes foregoes its exclusive right to Manufacture or have Manufactured Commercial Supplies, (ii) Alkermes undergoes a Change of Control in which the acquirer is a competitor of Biogen set forth on Schedule 5.1 or a Third Party toll manufacturer that Manufactures a competing fumarate product or (iii) there is a Serious Failure to Supply, then in any case ((i)-(iii)), (a) Biogen and its Affiliates and Sublicensees will have no further obligation to exclusively purchase Commercial Supplies from Alkermes, (b) Biogen will have the exclusive right to Manufacture or have Manufactured Commercial Supplies and (c) Alkermes will promptly conduct a transfer (to the extent not already conducted pursuant to any Technology Transfer) of all necessary Manufacturing technology to Biogen or its designee to enable Biogen or such designee to Manufacture Commercial Supplies. In addition, in the event of a Force Majeure Delay (and for the duration thereof), until such time as Alkermes is able to resume sufficient Manufacturing to meet Biogen's demand for Commercial Supplies, Biogen may Manufacture itself or have Manufactured by its back-up manufacturer, all Commercial Supplies for so long as Alkermes is unable to meet Biogen's demand.

3. A new Section 9.5.1(i)(C) of the Agreement is hereby added with the following text:

(C) Additional Royalty Percentage for Bulk Form Only Product.

(I) As further consideration for the performance of Alkermes' obligations under this Agreement and under the Commercial Supply Agreement, Biogen will pay to Alkermes, in addition to the royalties otherwise owing pursuant to this Section 9.5, an additional royalty payment on each Batch (as that term is defined in the Commercial Supply Agreement) of Bulk Form Only Product supplied during a given Calendar Year at the rate of [**] percent ([**]%) of the [**] ANSP, multiplied by the number of capsules yielded from such Batch of Bulk Form Only Product (the "***Bulk Form Only Product Additional Royalty***"), subject to the exclusions set forth in (II) below and in accordance with the payment schedule set forth in (III) below.

(II) Notwithstanding subsection (I) above, the Bulk Form Only Product Additional Royalty shall not apply to and shall not be payable for any Batch of Bulk Form Only Product Packaged by Biogen or its designee due to either:

a) such Batch being in excess of the agreed threshold number of Bulk Form Batches ([**]) to be Packaged by Alkermes in each Calendar Year (the "***Agreed Packaging Core Capacity***"); or

b) the packaging line at the Alkermes Facility (as that term is defined in the Commercial Supply Agreement) not being functional for [**] (excluding any scheduled shutdown) (such [**] period, a "***Prolonged Shutdown***"), *provided that the only* Batches subject to this exclusion are those Batches scheduled to be Packaged by Alkermes during the time period commencing *after* such Prolonged Shutdown and continuing until such time as Alkermes deems its packaging line to be functional again. For clarity, any Batch diverted after a Prolonged Shutdown as set forth in this subsection (II)(b) shall nevertheless be deemed to have been Packaged by Alkermes for purposes of determining whether that Batch or any future Batch is within or in excess of the Agreed Packaging Core Capacity.

(III) The Bulk Form Only Product Additional Royalty shall be payable on an annual basis at the end of each Calendar Year as follows:

(a) At the end of each Calendar Year, a calculation will be performed to determine the number of Batches of Bulk Form Only Product supplied during such Calendar Year for which the Bulk Form Only Product Additional Royalty is payable (such number, the "**Number of Additional Royalty Batches**"). The Bulk Form Only Product Additional Royalty payable for such Calendar Year will be calculated in respect of the first Batches of Bulk Form Only Product supplied to Biogen during such Calendar Year up to the number of Batches equal to the Number of Additional Royalty Batches (such Batches, the "**Additional Royalty Batches**"). For example, if it is determined that the Number of Additional Royalty Batches for a given Calendar Year is three, then the first three Batches of Bulk Form Only Product supplied during such Calendar Year shall be deemed the Additional Royalty Batches and all calculations and assessments relating to the Bulk Form Only Product Additional Royalty (e.g., number of capsules yielded, whether or not such Batch was Packaged, etc.) shall be determined based on those first specific three Batches.

(b) For each Additional Royalty Batch that is Packaged by Biogen or its designee (whether in whole or in part) in the same Calendar Year in which it is supplied by Alkermes to Biogen (regardless of the final use of such Additional Royalty Batch, whether for samples or otherwise), the Bulk Form Only Product Additional Royalty shall become payable in the Calendar Year in which such Additional Royalty Batch was supplied. For each Additional Royalty Batch that is not Packaged by Biogen or its designee in the same Calendar Year in which it is supplied by Alkermes, the Bulk Form Only Product Additional Royalty shall become payable in the Calendar Year immediately following the Calendar Year in which such Additional Royalty Batch was supplied, regardless of whether or when it is ultimately Packaged by Biogen or its designee.

4. Section 9.5.5 of the Agreement is hereby deleted in its entirety and replaced with the following text:

9.5.5. No Valid Claim. On a country-by-country and Product-by-Product basis, in any country in which a Product is Commercialized and there are no remaining Valid Claims of the Licensed Patents that Cover the use or sale of such Product in such country, the royalties payable to Alkermes on Net Sales of such Product pursuant to (i) Section 9.5.1(i)(A) will be reduced to [**] percent ([**]%) of such Net Sales for the Alkermes 8700 Product; (ii) Section 9.5.1(i)(B) will be reduced to [**] percent ([**]%) of such Net Sales for the Alkermes 8700 Product and (iii) Section 9.5.2 will be reduced to [**] percent ([**]%) of the applicable royalty rate for any Product (other than the Alkermes 8700 Product). For clarity, the royalty due under Section 9.5.1(i)(B) is a combined royalty comprised of a portion ([**] percent ([**]%)) that is payable in consideration of the licenses contained herein and a portion ([**] percent ([**]%)) that is payable in consideration of the loss of Manufacturing-related fees, and only that portion payable in consideration of the licenses contained herein ([**] percent ([**]%)) shall be subject to reduction pursuant to this Section 9.5.5. For further clarity, the

royalties payable to Alkermes pursuant to Section 9.5.1(i)(C) are entirely in consideration of the loss of Manufacturing-related fees and are therefore not subject to reduction pursuant to this Section 9.5.5.

5. Section 9.6 of the Agreement is hereby deleted in its entirety and replaced with the following text:

9.6. Reporting and Payments.

(i) For each Calendar Quarter for which royalties are payable by Biogen to Alkermes pursuant to Section 9.5.1(i)(A) or 9.5.1(i)(B) or Section 9.5.2, Biogen will:

(a) deliver to Alkermes, within five (5) days after the end of each such Calendar Quarter, a nonbinding estimated report prepared in good faith;

(b) deliver to Alkermes, within forty-five (45) days after the end of each such Calendar Quarter a true and accurate report;

(c) In each case of (a) and (b), providing in reasonable detail:

(I) an accounting of all Net Sales made on a country-by-country and Product-by-Product basis in the Territory during such Calendar Quarter, including the amount of gross sales of Products and the aggregate allowable deductions therefrom,

(II) the number of units of Products sold,

(III) the currency conversion rates used,

(IV) the U.S. Dollar-equivalent of such Net Sales during such Calendar Quarter and

(V) a calculation of the amount of royalty payment due on such Net Sales;

(d) within forty-five (45) days after the end of each such Calendar Quarter, pay Alkermes the royalties due under Sections 9.5.1(i)(A) and 9.5.1(i)(B) and Section 9.5.2 with respect to such Calendar Quarter as provided for in the report delivered under (b) above. Each of the reports set forth in this Section 9.6(i) will be organized to distinguish whether the Alkermes 8700 Product was Manufactured by Alkermes or Biogen or their respective designees and, in the case of the report set forth in (b), the amount of Alkermes 8700 Product in inventory as of the end of the Calendar Quarter to which the report relates. In addition, within forty-five (45) days after the end of the first Calendar Quarter following each twelve (12)-month period during the Minimum Annual Payment Term, Biogen shall pay Alkermes any amount due under Section 9.5.l(ii) for such twelve (12)-month period; and

(e) Any payments due under this Agreement for less than a full Calendar Quarter will be prorated.

(ii) For each Calendar Year for which Bulk Form Only Product is supplied to Biogen or during which any Bulk Form Only Product Additional Royalty is payable by Biogen to Alkermes pursuant to Section 9.5.1(i)(C), Biogen will:

(a) deliver to Alkermes, within five (5) days after the end of each such Calendar Year, a nonbinding estimated report prepared in good faith;

(b) deliver to Alkermes, within forty-five (45) days after the end of each such Calendar Year a true and accurate report;

(c) In each case of (a) and (b), providing in reasonable detail:

(I) the total number of Batches of Bulk Form Only Product supplied during such Calendar Year,

(II) the [**] ANSP of all Alkermes 8700 Product sold in the Territory during such Calendar Year,

(III) the total number of Batches of Bulk Form Only Product ordered pursuant to Firm POs (as that term is defined in the Commercial Supply Agreement) for Delivery in such Calendar Year,

(IV) the total number of Batches of Bulk Form Only Product supplied during such Calendar Year for which the Bulk Form Only Product Additional Royalty is not payable due to the exclusions set forth in Sections 9.5.1(i)(C)(II)(a) and (b),

(V) the Number of Additional Royalty Batches for such Calendar Year,

(VI) identification (by Batch number) of the specific Additional Royalty Batches for such Calendar Year and the number of Bulk Form capsules yielded from each such Additional Royalty Batch,

(VII) the total number of Additional Royalty Batches supplied by Alkermes during such Calendar Year that were Packaged by or on behalf of Biogen in such Calendar Year and the total number of Additional Royalty Batches supplied by Alkermes during such Calendar Year that were not Packaged by or on behalf of Biogen in such Calendar Year,

(VIII) the total number of Additional Royalty Batches supplied by Alkermes during the previous Calendar Year that were not Packaged by or on behalf of Biogen during the previous Calendar Year (and therefore not included in the calculation of the Bulk Form Only Product Additional Royalty for the previous Calendar Year),

(IX) the currency conversion rates used for calculating the [**] ANSP,

(X) a calculation of the total amount of Bulk Form Only Product Additional Royalty payment due; and

(d) within forty-five (45) days after the end of each such Calendar Year, pay Alkermes the royalties due under Section 9.5.1(i)(C) with respect to such Calendar Year as provided for in the report delivered under (b) above.

(iii) Each report delivered hereunder shall be considered Confidential Information of Biogen, subject to the terms and conditions of Article 8.

(iv) Biogen and Alkermes shall conduct no fewer than four quarterly meetings per Calendar Year to review and discuss the calculation of the Bulk Form Only Product Additional Royalty. The final meeting of each year will occur no later than the first week in December to allow for the preparation of the final reconciliation and Bulk Form Only Product Additional Royalty report for such Calendar Year.

6. For clarity, nothing in this Amendment shall modify or be deemed to have modified Section 9.5.1(i)(B) of the Agreement and Alkermes and Biogen acknowledge and agree that all Batches Manufactured in Bulk Form by Biogen or its designee(s) will also be Manufactured (or deemed to have been Manufactured) in finished form by Biogen or its designee(s) and subject to the royalty rate set forth in Section 9.5.1(i)(B).

7. For clarity, this Amendment does not constitute a waiver of Alkermes exclusive right to Manufacture or have Manufactured Commercial Supplies under Section 5.1.2 of the Agreement, except as specifically set forth therein.

8. This Amendment shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of law provisions.

9. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall continue in full force and effect as provided therein. The Agreement (as amended by this Amendment), this Amendment and the Commercial Supply Agreement (as amended) constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and supersede all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto.

10. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe® PDF sent by electronic mail shall be deemed to be original signatures.

[*Signature page follows*]

IN WITNESS WHEREOF, Alkermes and Biogen have executed and delivered this Amendment effective as of the Amendment Effective Date.

BIOGEN SWISS MANUFACTURING GMBH

By: /s/ Maja Pedersen

Name: Maja Pedersen

Title: VP Global External Manufacturing

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Declan O'Connor

Name: Declan O'Connor

Title: SVP, Operations, Mfg Operations

Exhibit 31.1

CERTIFICATIONS

I, Richard F. Pops, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alkermes plc;

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2022

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Iain M. Brown, 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.

Date: November 2, 2022

/s/ Iain M. Brown

Iain M. Brown

Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Alkermes plc (the "Company") for the period ended September 30, 2022 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 Iain M. Brown, Senior Vice President, 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.

Date: November 2, 2022

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2022

/s/ Iain M. Brown
Iain M. Brown

Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)