

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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

(State or other jurisdiction of incorporation or organization)

98-1007018

(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

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

The number of the registrant's ordinary shares, \$0.01 par value, outstanding as of April 22, 2022 was 163,426,943 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2022

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Cautionary Note Concerning Forward-Looking Statements

This document contains and incorporates by reference “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, these statements can be identified by the use of forward-looking terminology such as “may,” “will,” “could,” “should,” “would,” “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate,” “intend,” or other similar words. These statements discuss future expectations and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q (this “Form 10-Q”) 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; 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 (our “Annual Report”).

This Form 10-Q may include data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified 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. 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: ANJESO®—Baudax Bio, Inc.; 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 are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	March 31, 2022	December 31, 2021
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$282,557	\$337,544
Receivables, net	249,942	313,193
Investments—short-term	246,315	198,767
Inventory	154,786	150,335
Contract assets	20,212	13,363
Prepaid expenses and other current assets	61,018	48,967
Total current assets	1,014,830	1,062,169
PROPERTY, PLANT AND EQUIPMENT, NET	336,740	341,054
INVESTMENTS—LONG-TERM	229,825	229,430
RIGHT-OF-USE ASSETS	115,321	115,627
INTANGIBLE ASSETS, NET	65,077	74,043
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	112,515	81,833
OTHER ASSETS	10,664	27,455
TOTAL ASSETS	\$1,977,845	\$2,024,484
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$173,126	\$208,491
Accrued sales discounts, allowances and reserves	265,172	237,216
Operating lease liabilities—short-term	16,144	16,240
Contract liabilities—short-term	4,919	6,339
Current portion of long-term debt	3,000	3,000
Total current liabilities	462,361	471,286
LONG-TERM DEBT	292,171	292,804
OPERATING LEASE LIABILITIES—LONG-TERM	104,014	104,162
OTHER LONG-TERM LIABILITIES	43,909	43,648
Total liabilities	902,455	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 March 31, 2022 and December 31, 2021, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 167,743,842 and 165,790,549 shares issued; 163,212,411 and 161,937,327 shares outstanding at March 31, 2022 and December 31, 2021, respectively	1,677	1,658
Treasury shares, at cost (4,531,431 and 3,853,222 shares at March 31, 2022 and December 31, 2021, respectively)	(159,727)	(142,658)
Additional paid-in capital	2,818,595	2,798,325
Accumulated other comprehensive loss	(8,234)	(3,723)
Accumulated deficit	(1,576,921)	(1,541,018)
Total shareholders' equity	1,075,390	1,112,584
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$1,977,845	\$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 March 31,	
	2022	2021
(In thousands, except per share amounts)		
REVENUES:		
Product sales, net	\$ 171,268	\$ 129,963
Manufacturing and royalty revenues	105,170	119,847
License revenue	2,000	1,500
Research and development revenue	107	120
Total revenues	<u>278,545</u>	<u>251,430</u>
EXPENSES:		
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	55,159	41,020
Research and development	95,953	92,268
Selling, general and administrative	145,052	125,168
Amortization of acquired intangible assets	8,966	9,406
Total expenses	<u>305,130</u>	<u>267,862</u>
OPERATING LOSS	<u>(26,585)</u>	<u>(16,432)</u>
OTHER EXPENSE, NET:		
Interest income	573	864
Interest expense	(2,350)	(3,970)
Change in the fair value of contingent consideration	(19,067)	1,278
Other income (expense), net	2,431	(393)
Total other expense, net	<u>(18,413)</u>	<u>(2,221)</u>
LOSS BEFORE INCOME TAXES	<u>(44,998)</u>	<u>(18,653)</u>
INCOME TAX (BENEFIT) PROVISION	<u>(9,095)</u>	<u>3,765</u>
NET LOSS	<u>\$ (35,903)</u>	<u>\$ (22,418)</u>
LOSS PER ORDINARY SHARE:		
Basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.14)</u>
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic and diluted	<u>162,483</u>	<u>159,634</u>
COMPREHENSIVE LOSS:		
Net loss	\$ (35,903)	\$ (22,418)
Holding loss, net of a tax benefit of \$(1,382) and \$(174), respectively	(4,511)	(601)
COMPREHENSIVE LOSS	<u>\$ (40,414)</u>	<u>\$ (23,019)</u>

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

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

	Three Months Ended March 31,	
	2022	2021
(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (35,903)	\$ (22,418)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	19,197	19,643
Share-based compensation expense	18,343	15,451
Deferred income taxes	(29,301)	5,255
Change in the fair value of contingent consideration	19,067	(1,278)
Loss on debt extinguishment	—	171
Payment made for debt modification	—	(248)
Other non-cash charges	371	195
Changes in assets and liabilities:		
Receivables	63,290	31,648
Contract assets	(6,849)	5,122
Inventory	(4,285)	(8,652)
Prepaid expenses and other assets	(15,351)	(16,807)
Right-of-use assets	4,129	4,177
Accounts payable and accrued expenses	(5,458)	(71,949)
Contract liabilities	(2,980)	(1,243)
Operating lease liabilities	(4,411)	(3,996)
Other long-term liabilities	1,819	(217)
Cash flows provided by (used in) operating activities	<u>21,678</u>	<u>(45,146)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(7,791)	(7,986)
Proceeds from the sale of equipment	—	176
Proceeds from contingent consideration	501	6,430
Return of Fountain Healthcare Partners II, L.P. investment	485	—
Purchases of investments	(114,615)	(122,545)
Sales and maturities of investments	60,779	86,193
Cash flows used in investing activities	<u>(60,641)</u>	<u>(37,732)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	1,795	2,053
Employee taxes paid related to net share settlement of equity awards	(17,069)	(10,413)
Proceeds from the issuance of long-term debt	—	23,567
Payment made for debt extinguishment	—	(262)
Principal payments of long-term debt	(750)	—
Cash flows (used in) provided by financing activities	<u>(16,024)</u>	<u>14,945</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	(54,987)	(67,933)
CASH AND CASH EQUIVALENTS—Beginning of period	337,544	272,961
CASH AND CASH EQUIVALENTS—End of period	<u>\$ 282,557</u>	<u>\$ 205,028</u>
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 4,058	\$ 995

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

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

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

	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

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

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

1. THE COMPANY

Alkermes plc is a fully-integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in 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 months ended March 31, 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, which are of a normal recurring nature, that are necessary to state fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto of the Company, which are contained in the Company’s Annual Report. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for any full fiscal year.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries as disclosed in Note 2, *Summary of Significant Accounting Policies*, in the “Notes to Consolidated Financial Statements” accompanying the 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.

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

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, the Chief Executive Officer and chairman of the Company's board of directors, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

Risks and Uncertainties

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. 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 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 without interruption throughout the pandemic, it has at times during the pandemic experienced labor or supply chain disruptions at its manufacturing facilities, and may continue to experience such 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.

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

New Accounting Pronouncements

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

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 months ended March 31, 2022 and 2021, the Company recorded product sales, net, as follows:

(In thousands)	Three Months Ended March 31,	
	2022	2021
VIVITROL	\$ 84,854	\$ 74,534
ARISTADA and ARISTADA INITIO	72,485	55,429
LYBALVI	13,929	—
Total product sales, net	<u>\$ 171,268</u>	<u>\$ 129,963</u>

Manufacturing and Royalty Revenues

During the three months ended March 31, 2022 and 2021, the Company recorded manufacturing and royalty revenues as follows:

(In thousands)	Three Months Ended March 31, 2022		
	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products(1)	\$ —	\$ 37,054	\$ 37,054
VUMERITY	11,395	19,200	30,595
RISPERDAL CONSTA	15,578	1,848	17,426
Other	11,854	8,241	20,095
	<u>\$ 38,827</u>	<u>\$ 66,343</u>	<u>\$ 105,170</u>

(In thousands)	Three Months Ended March 31, 2021		
	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products(1)	\$ —	\$ 61,570	\$ 61,570
VUMERITY	2,448	10,992	13,440
RISPERDAL CONSTA	10,683	3,479	14,162
Other	11,954	18,721	30,675
	<u>\$ 25,085</u>	<u>\$ 94,762</u>	<u>\$ 119,847</u>

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

In November 2021, the Company received notice of partial termination in the U.S. of its license agreement with Janssen Pharmaceutica N.V, a subsidiary of Johnson & Johnson Corporation (“Janssen Pharmaceutica”) in respect of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, pursuant to which Janssen Pharmaceutica received access and rights to Alkermes’ small particle pharmaceutical compound technology, known as NanoCrystal Technology. 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 April 2022, the Company commenced binding arbitration proceedings related to, among other things, Janssen Pharmaceutica’s partial termination

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

of the license agreement in the U.S. 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, except for \$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 2022.

Total contract assets at March 31, 2022 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2021	\$ 13,363
Additions	11,451
Transferred to receivables, net	<u>(4,602)</u>
Contract assets at March 31, 2022	<u>\$ 20,212</u>

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue.

Total contract liabilities at March 31, 2022 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2021	\$ 17,830
Additions	83
Amounts recognized into revenue	<u>(3,063)</u>
Contract liabilities at March 31, 2022	<u>\$ 14,850</u>

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4. INVESTMENTS

Investments consisted of the following (in thousands):

March 31, 2022	Amortized Cost	Gains	Gross Unrealized		Estimated Fair Value
			Losses		
			Less than One Year	Greater than One Year	
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	\$ 96,729	\$ 16	\$ (483)	\$ —	\$ 96,262
U.S. government and agency debt securities	83,261	7	(356)	—	82,912
Non-U.S. government debt securities	67,533	14	(406)	—	67,141
Total short-term investments	<u>247,523</u>	<u>37</u>	<u>(1,245)</u>	<u>—</u>	<u>246,315</u>
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	132,275	—	(3,055)	—	129,220
U.S. government and agency debt securities	79,824	—	(2,237)	—	77,587
Non-U.S. government debt securities	21,801	—	(414)	(189)	21,198
	<u>233,900</u>	<u>—</u>	<u>(5,706)</u>	<u>(189)</u>	<u>228,005</u>
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	<u>235,720</u>	<u>—</u>	<u>(5,706)</u>	<u>(189)</u>	<u>229,825</u>
Total investments	<u>\$ 483,243</u>	<u>\$ 37</u>	<u>\$ (6,951)</u>	<u>\$ (189)</u>	<u>\$ 476,140</u>
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	<u>198,596</u>	<u>287</u>	<u>(116)</u>	<u>—</u>	<u>198,767</u>
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
	<u>228,991</u>	<u>—</u>	<u>(1,381)</u>	<u>—</u>	<u>227,610</u>
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	<u>230,811</u>	<u>—</u>	<u>(1,381)</u>	<u>—</u>	<u>229,430</u>
Total investments	<u>\$ 429,407</u>	<u>\$ 287</u>	<u>\$ (1,497)</u>	<u>\$ —</u>	<u>\$ 428,197</u>

At March 31, 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 March 31, 2022, the aggregate estimated fair value of investments in an unrealized loss position was \$445.1 million. In making the determination whether the decline in fair value of these securities were 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 amount of \$0.5 million from Synchronicity Pharma, Inc., a related party, that matures on the earlier of September 30, 2022, the closing of a preferred equity financing, the closing of a merger, business combination or sale of stock resulting in Synchronicity's stockholders owning less than 50% of the surviving entity, or an event of default. The convertible promissory note was classified as an available-for-sale corporate debt instrument.

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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 March 31, 2022, the Company’s total contribution in Fountain was equal to €7.8 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 was held in escrow. 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, 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 \$5.8 million and \$6.1 million at March 31, 2022 and December 31, 2021, respectively, and was included within “Other assets” in the accompanying condensed consolidated balance sheets.

During the three months ended March 31, 2022 and 2021, the Company recorded an increase of less than \$0.1 million and a decrease of \$0.3 million, respectively, in its investment in Fountain, which represented the Company’s proportional share of Fountain’s net gains or losses.

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

(In thousands)	Three Months Ended March 31,	
	2022	2021
Proceeds from the sales and maturities of investments	\$ 60,779	\$ 86,193
Realized gains	\$ —	\$ —
Realized losses	\$ —	\$ —

The Company’s available-for-sale and held-to-maturity securities at March 31, 2022 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 247,523	\$ 246,315	\$ 1,820	\$ 1,820
After 1 year through 5 years	233,900	228,005	—	—
Total	<u>\$ 481,423</u>	<u>\$ 474,320</u>	<u>\$ 1,820</u>	<u>\$ 1,820</u>

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)	March 31,	Level 1	Level 2	Level 3
	2022			
Assets:				
U.S. government and agency debt securities	\$ 160,499	\$ 130,612	\$ 29,887	\$ —
Corporate debt securities	225,482	—	224,982	500
Non-U.S. government debt securities	88,339	—	88,339	—
Contingent consideration	3,440	—	—	3,440
Total	<u>\$ 477,760</u>	<u>\$ 130,612</u>	<u>\$ 343,208</u>	<u>\$ 3,940</u>

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

	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	<u>\$ 449,425</u>	<u>\$ 96,597</u>	<u>\$ 329,780</u>	<u>\$ 23,048</u>

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 three months ended March 31, 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 March 31, 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	(19,067)
Milestone and royalty payments received by the Company related to contingent consideration	(501)
Royalty payments due to the Company related to contingent consideration	(40)
Balance, March 31, 2022	<u>\$ 3,940</u>

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 were assigned and/or transferred to Baudax.

At March 31, 2022, the Company determined the fair value of the contingent consideration to be received as follows:

- As of December 31, 2021, the Company had received \$7.8 million in milestone payments and was due to receive an additional \$38.6 million related to the FDA approval of the New Drug Application ("NDA") for ANJESO. This amount is due in six equal, annual installments from March 2022 through March 2027. At March 31, 2022, Baudax had paid the Company \$0.5 million of the \$6.4 million payment that was due in March 2022;
- The Company is entitled to receive future royalties on net sales of Meloxicam Products; and

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- The Company is entitled to receive payments of up to \$80.0 million related to the achievement of certain sales milestones on future sales of the Meloxicam Products. At March 31, 2022, the Company did not believe it was probable that any of the sales milestones would be achieved.

In Baudax’s Annual Report on Form 10-K for the year ended December 31, 2021, Baudax included disclosures regarding its ability to continue as a going concern and a subsequent event note that announced a plan to reduce expenses including an approximately 80% reduction in its workforce, effective in March 2022. In light of Baudax’s disclosures regarding its ability to continue as a going concern and the fact that Baudax paid \$0.5 million of the \$6.4 million that was due in March 2022, the Company has applied a 100% likelihood that Baudax would default on its obligations and applied a recovery rate of 9% based on an analysis performed by Standard and Poor’s regarding post-default recoveries. However, for avoidance of doubt, the Company has not waived its right to receive any portion of the payments owing by Baudax. 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 Annual Report.

At March 31, 2022 and December 31, 2021, the Company determined that the fair value of the contingent consideration was \$3.4 million and \$23.0 million, respectively. At March 31, 2022 and December 31, 2021, \$3.4 million and \$6.4 million, respectively, of the fair value of the contingent consideration was included within “Prepaid expenses and other current assets” in the accompanying condensed consolidated balance sheets, and none and \$16.6 million, respectively, of the fair value of the contingent consideration was included within “Other assets” in the accompanying condensed consolidated balance sheets. Changes in the fair value of the contingent consideration are recorded within “Change in the fair value of contingent consideration” in the accompanying condensed consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the 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 \$285.1 million and \$285.8 million at March 31, 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)	March 31, 2022	December 31, 2021
Raw materials	\$ 51,430	\$ 56,125
Work in process	64,385	59,105
Finished goods(1)	38,971	35,105
Total inventory	<u>\$ 154,786</u>	<u>\$ 150,335</u>

(1) At March 31, 2022 and December 31, 2021, the Company had \$34.4 million and \$25.1 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

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7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	March 31, 2022	December 31, 2021
Land	\$ 6,560	\$ 6,560
Building and improvements	193,101	192,920
Furniture, fixtures and equipment	401,161	398,099
Leasehold improvements	52,526	52,526
Construction in progress	88,638	86,512
Subtotal	741,986	736,617
Less: accumulated depreciation	(405,246)	(395,563)
Total property, plant and equipment, net	<u>\$ 336,740</u>	<u>\$ 341,054</u>

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	March 31, 2022 Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,873	\$ —	\$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 465,590	\$ (414,132)	\$ 51,458
Capitalized IP	11-13	118,160	(104,541)	13,619
Total		<u>\$ 583,750</u>	<u>\$ (518,673)</u>	<u>\$ 65,077</u>

Based on the Company's most recent analysis, amortization of intangible assets included in the accompanying condensed consolidated balance sheet at March 31, 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 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.

9. LEASES

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

(In thousands)	March 31, 2022	December 31, 2021
2022	\$ 13,561	\$ 17,991
2023	18,271	17,329
2024	18,541	17,535
2025	18,814	17,808
2026	14,783	13,777
Thereafter	95,293	95,229
Total operating lease payments	<u>\$ 179,263</u>	<u>\$ 179,669</u>
Less: imputed interest	(59,105)	(59,267)
Total operating lease liabilities	<u>\$ 120,158</u>	<u>\$ 120,402</u>

At March 31, 2022, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.19% and 11.3 years, respectively. During the three months ended March 31, 2022 and 2021, cash paid for lease liabilities was \$4.4 million and \$3.7 million, respectively. The Company recorded operating lease expense of \$4.1 million and \$4.2 million during the three months ended March 31, 2022 and 2021, respectively.

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10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	March 31, 2022	December 31, 2021
Accounts payable	\$ 27,697	\$ 55,721
Accrued compensation	54,413	77,256
Accrued other	91,016	75,514
Total accounts payable and accrued expenses	<u>\$ 173,126</u>	<u>\$ 208,491</u>

A summary of the Company's provisions for sales and allowances is as follows:

(In thousands)	March 31, 2022	December 31, 2021
Medicaid rebates	\$ 224,216	\$ 195,413
Product discounts	13,204	14,951
Medicare Part D	17,350	14,348
Other	10,402	12,504
Total accrued sales discounts, allowances and reserves	<u>\$ 265,172</u>	<u>\$ 237,216</u>

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	March 31, 2022	December 31, 2021
2026 Term Loans, due March 12, 2026	\$ 295,171	\$ 295,804
Less: current portion	(3,000)	(3,000)
Long-term debt	<u>\$ 292,171</u>	<u>\$ 292,804</u>

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 March 31, 2022.

Included in "Interest expense" in the accompanying condensed consolidated statement of operations and comprehensive loss in the three months ended March 31, 2021 is \$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 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:

(In thousands)	Three Months Ended March 31,	
	2022	2021
Cost of goods manufactured and sold	\$ 2,382	\$ 2,178
Research and development	5,608	4,063
Selling, general and administrative	10,353	9,210
Total share-based compensation expense	<u>\$ 18,343</u>	<u>\$ 15,451</u>

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

At March 31, 2022 and December 31, 2021, \$2.5 million and \$2.3 million, respectively, of share-based compensation expense was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

13. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the three months ended March 31, 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:

(In thousands)	Three Months Ended March 31,	
	2022	2021
Stock options	13,461	15,451
Restricted stock unit awards	5,959	2,877
Total	19,420	18,328

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 utilized 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 is using to manage the underlying business.

During the three months ended March 31, 2022, the Company recorded an income tax benefit of \$9.1 million, which was 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 resulted in an increase to the Company’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 March 31, 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

On April 19, 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, it has a continuing obligation to pay royalties on sales in the U.S. of INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA, products developed under or enabled by these license agreements. 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 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. A trial was scheduled in the Tolmar Lawsuit for October 2022. The Pharmascience Lawsuit remains pending. 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 for October 2022. The Company is not a party to this proceeding.

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co., Ltd., Pharmathen SA, Teva PI and Dehns Ltd (a law firm representing an unidentified opponent) filed notices of opposition with the European Patent Office (the "EPO") in respect of the Company's EP 2 269 577 B (the "EP '577 Patent"), a patent directed to certain risperidone microsphere compositions, including RISPERDAL CONSTA. In April 2019, the EPO issued a written decision revoking the EP '577 Patent and in June 2019, the Company filed a notice of appeal of the decision to the EPO's Technical Boards of Appeal. The EP '577 Patent has since expired, and in February 2022, the Company withdrew its appeal, which terminated the proceedings.

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. Teva filed its answer in November 2020, which included counterclaims against the Company. The Company filed its reply to Teva's counterclaims in December 2020. 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

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

Term Restoration Act of 1984.

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.

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 6 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 included in our Annual Report.

Executive Summary

Net loss for the three months ended March 31, 2022 was \$35.9 million, or \$0.22 per ordinary share—basic and diluted, as compared to a net loss of \$22.4 million, or \$0.14 per ordinary share—basic and diluted, for the three months ended March 31, 2021.

The increase in net loss was primarily due to a \$37.3 million increase in operating expenses and a \$20.3 million decrease in the fair value of our contingent consideration related to increased risk of non-payment, partially offset by a \$41.1 million increase in product sales, net. The increase in operating expenses primarily related to a \$19.8 million increase in selling, general and administrative expense and a \$14.1 million increase in cost of goods manufactured and sold.

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

COVID-19 Update

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. 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 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 without interruption throughout the pandemic, we have, at times during the pandemic experienced labor or supply chain disruptions at our manufacturing facilities, and may continue to experience such 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
<p>ARISTADA INITIO[®] aripiprazole lauroxil extended-release injectable suspension</p> <p>675 mg</p>	<p>Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia</p>	<p>U.S.</p>
<p>+</p> <p>ARISTADA[®]  aripiprazole lauroxil extended-release injectable suspension</p> <p>441 mg 662 mg 882 mg 1064 mg</p>	<p>Schizophrenia</p>	<p>U.S.</p>
<p> LYBALVI[®] olanzapine and samidorphan 5 mg/10 mg · 10 mg/10 mg · 15 mg/10 mg 20 mg/10 mg tablets</p>	<p>Schizophrenia and Bipolar I disorder</p>	<p>U.S.</p>
<p> Vivitrol[®] (naltrexone for extended-release injectable suspension) 380 mg/vial</p>	<p>Alcohol dependence and Opioid dependence</p>	<p>U.S.</p>

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

Key Third-Party Products Using Our Proprietary Technologies

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

* Janssen partially terminated its license agreement related to these products in the U.S., 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 the partial termination and the arbitration proceedings we commenced related to such partial termination.

Our Key Licensed Product

Product	Indication(s)	Licensee	Licensed Territory
<i>VUMERITY</i>	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 developed ARISTADA and exclusively manufacture and commercialize it in the U.S.

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 developed ARISTADA INITIO and exclusively manufacture and commercialize it in the U.S.

In March 2022, U.S. Patent No. 11,273,158 relating to ARISTADA and ARISTADA INITIO was granted. The patent has claims to methods of treating schizophrenia and expires in 2039.

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 developed LYBALVI and exclusively manufacture and commercialize it in the U.S.

In February 2022, the Company announced positive topline results from ENLIGHTEN-Early, a phase 3b study that evaluated the effect of LYBALVI compared to olanzapine on body weight in young adult patients (ages 16 to 39; mean age: 26 years) with schizophrenia, schizophreniform disorder or bipolar I disorder who were early in their illness.

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 developed and exclusively manufacture VIVITROL and we commercialize it 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 in the U.S. of our license agreement with Janssen in respect of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, pursuant to which Janssen received access and rights to Alkermes’ small particle pharmaceutical compound technology, known as NanoCrystal Technology. This partial termination became effective in February 2022. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen’s partial termination of the license agreement in the U.S. 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.

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

Licensed Product

VUMERITY

VUMERITY (diroximel fumarate) is a novel, oral fumarate with a distinct chemical structure that is approved in the U.S., the European Union and certain European 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 months ended March 31, 2022 and 2021:

(In millions, except for % of Sales)	Three Months Ended March 31,			
	2022	% of Sales	2021	% of Sales
Product sales, gross	\$ 342.4	100.0 %	\$ 272.6	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(76.5)	(22.3) %	(70.9)	(26.0) %
Chargebacks	(33.8)	(9.9) %	(25.0)	(9.2) %
Product discounts	(26.9)	(7.9) %	(21.4)	(7.9) %
Medicare Part D	(16.0)	(4.7) %	(13.1)	(4.8) %
Other	(17.9)	(5.2) %	(12.2)	(4.4) %
Total adjustments	(171.1)	(50.0) %	(142.6)	(52.3) %
Product sales, net	\$ 171.3	50.0 %	\$ 130.0	47.7 %

The following table compares product sales, net revenues earned during the three months ended March 31, 2022 and 2021:

(In millions)	Three Months Ended March 31,			Change
	2022	2021		
VIVITROL	\$ 84.9	\$ 74.5	\$	10.4
ARISTADA and ARISTADA INITIO	72.5	55.5		17.0
LYBALVI	13.9	—		13.9
Product sales, net	\$ 171.3	\$ 130.0	\$	41.3

VIVITROL product sales, gross, increased by 9%, primarily due to a 7% increase in the number of VIVITROL units sold and a 2% increase in the selling price of VIVITROL that went into effect in April 2021. ARISTADA and ARISTADA INITIO product sales, gross, increased by 31%, primarily due to a 27% increase in the number of ARISTADA and ARISTADA INITIO units sold and a 3% increase in the selling price of ARISTADA and ARISTADA INITIO that went into effect in April 2021. The increase in LYBALVI product sales, gross is due to LYBALVI's commercial launch in October 2021. The decrease in Medicaid rebates, as a percentage of sales, was primarily due to a decrease in Medicaid utilization as rates began to normalize from pandemic levels.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned during the three months ended March 31, 2022 and 2021:

(In millions)	Three Months Ended		Change
	2022	2021	
Manufacturing and royalty revenues:			
Long-acting INVEGA products:			
Long-acting INVEGA products	\$ 37.1	\$ 61.6	\$ (24.5)
VUMERITY	30.6	13.4	17.2
RISPERDAL CONSTA	17.4	14.2	3.2
Other	20.1	30.6	(10.5)
Manufacturing and royalty revenues	<u>\$ 105.2</u>	<u>\$ 119.8</u>	<u>\$ (14.6)</u>

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.

The decrease in royalty revenues from the long-acting INVEGA products was primarily due to the partial termination in the U.S. of our license agreement with Janssen. When the 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. The decrease in royalty revenue was partially offset by an increase in Janssen's non-U.S. net sales of these products. During the three months ended March 31, 2022, Janssen's rest of world net sales were \$387.0 million, as compared to \$376.0 million during the three months ended March 31, 2021.

We expect revenues from net sales of XEPLION, TREVICTA and BYANLLI to decrease over time. The amount and timing of revenues from sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA depend upon the outcome of our dispute with Janssen related to the basis for its partial termination of our license agreement in respect of these products. In November 2021, we received notice of partial termination of our license agreement with Janssen in respect of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, pursuant to which Janssen received access and rights to Alkermes' small particle pharmaceutical compound technology, known as NanoCrystal Technology. 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 the Company 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 the license agreement in the U.S. 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."

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 increase in revenue from RISPERDAL CONSTA was due to an increase of \$4.9 million in manufacturing revenue, partially offset by a decrease of \$1.6 million in royalty revenue. The increase in manufacturing revenue was primarily due to an increase in Janssen’s net selling price for units sold in the U.S., partially offset by a decrease in our manufacturing fee from 8.6% to 8.3% pursuant to the terms of our manufacturing and supply agreement with Janssen due to an increase in forecasted manufacturing units. The decrease in royalty revenue was due to a decrease in end-market sales of RISPERDAL CONSTA, which were \$129.0 million during the three months ended March 31, 2022, as compared to \$157.0 million during the three months ended March 31, 2021.

We expect revenue 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. For a discussion of legal proceedings related to patents covering RISPERDAL CONSTA, see Note 15, *Commitments and Contingent Liabilities* in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q, and for 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.”

We receive a 15% royalty on worldwide net sales of VUMERITY. We also recognize manufacturing revenue related to VUMERITY at cost plus 15%, upon release for bulk batches of VUMERITY and upon shipment for packaged lots of VUMERITY. The increase in revenue from VUMERITY was due to an increase of \$9.0 million in manufacturing revenue and an increase of \$8.2 million in royalty revenue. The increase in manufacturing revenue was primarily due to increased manufacturing activity to satisfy increased demand for the product. The increase in royalty revenue was due to an increase in net sales of VUMERITY, which were \$128.0 million during the three months ended March 31, 2022, as compared to \$73.3 million during the three months ended March 31, 2021.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended		Change
	March 31,		
	2022	2021	
Cost of goods manufactured and sold	\$ 55.2	\$ 41.0	\$ 14.2

The increase in cost of goods manufactured and sold was primarily due to increases of \$6.6 million and \$3.9 million, respectively, in the cost of goods manufactured for VUMERITY and RISPERDAL CONSTA and increases of \$4.5 million and \$4.4 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 months ended March 31, 2022 and 2021 relating to our then current development programs and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Three Months Ended		Change
	March 31,		
	2022	2021	
External R&D expenses:			
Development programs:			
nemvaleukin	\$ 19.5	\$ 18.6	\$ 0.9
LYBALVI	5.8	6.8	(1.0)
ALKS 1140	1.7	1.3	0.4
Other external R&D expenses	15.7	14.1	1.6
Total external R&D expenses	<u>42.7</u>	<u>40.8</u>	<u>1.9</u>
Internal R&D expenses:			
Employee-related	40.1	37.9	2.2
Occupancy	4.2	4.8	(0.6)
Depreciation	2.8	3.4	(0.6)
Other	6.2	5.4	0.8
Total internal R&D expenses	<u>53.3</u>	<u>51.5</u>	<u>1.8</u>
Research and development expenses	<u>\$ 96.0</u>	<u>\$ 92.3</u>	<u>\$ 3.7</u>

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 was primarily due to the advancement of the ARTISTRY development program for the product, including increased clinical spend on the ARTISTRY-7 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 increase in other external R&D expenses was primarily due to a \$1.4 million increase related to nonclinical studies for early stage development programs and a \$1.8 million increase in general clinical operations and medical affairs support. The decrease in expenses related to LYBALVI was primarily due to the product’s commercial launch in October 2021.

The increase in employee-related expense was primarily related to a \$1.5 million increase in R&D-related share-based compensation expense.

Selling, General and Administrative Expense

(In millions)	Three Months Ended		Change
	March 31,		
	2022	2021	
Selling and marketing expense	\$ 96.2	\$ 79.7	\$ 16.5
General and administrative expense	48.9	45.5	3.4
Selling, general and administrative expense	<u>\$ 145.1</u>	<u>\$ 125.2</u>	<u>\$ 19.9</u>

The increase in selling and marketing expense was primarily due to a \$7.9 million increase in employee-related expenses, a \$6.4 million increase in marketing expense and a \$2.4 million increase in professional service fees. The increase in employee-related expenses was primarily due to a 4% increase in selling and marketing headcount from March 31, 2021 to March 31, 2022. The increases in marketing expense and professional service fees were primarily related to commercial launch activities for LYBALVI.

The increase in general and administrative expense was primarily due to a \$2.0 million increase in professional service fees, primarily due to increased spend on legal fees, and a \$1.4 million increase in expenses related to our branded prescription drug fee.

Other Expense, Net

(In millions)	Three Months Ended March 31,			Change
	2022	2021		
Interest income	\$ 0.6	\$ 0.9	\$ (0.3)	
Interest expense	(2.4)	(4.0)	1.6	
Change in the fair value of contingent consideration	(19.1)	1.3	(20.4)	
Other income (expense), net	2.5	(0.4)	2.9	
Total other expense, net	\$ (18.4)	\$ (2.2)	\$ (16.2)	

The increase in total other expense, net was primarily due to the change in the fair value of contingent consideration as a result of an increase in the risk of non-payment. The reasons for the increase in the risk of non-payment and the valuation approach used to determine the fair value of the contingent consideration are discussed in greater detail in Note 5, *Fair Value*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q. This was partially offset by a decrease in interest expense due to the Term Loan Refinancing completed in March 2021 and proceeds received in connection with the Fountain transaction in March 2022. 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 Fountain transaction is discussed in Note 4, *Investments*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Income Tax (Benefit) Provision

(In millions)	Three Months Ended March 31,			Change
	2022	2021		
Income tax (benefit) provision	\$ (9.1)	3.8	\$ (12.9)	

The income tax (benefit) provision in the three months ended March 31, 2022 and 2021 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 provision in the three months ended March 31, 2021 primarily related to a \$3.8 million discrete tax expense related to employee equity activity.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	March 31, 2022			December 31, 2021		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	\$ 134.5	\$ 148.1	\$ 282.6	\$ 88.6	\$ 248.9	\$ 337.5
Investments—short-term	146.5	99.8	246.3	144.5	54.3	198.8
Investments—long-term	142.6	87.2	229.8	163.0	66.4	229.4
Total cash and investments	\$ 423.6	\$ 335.1	\$ 758.7	\$ 396.1	\$ 369.6	\$ 765.7
Outstanding borrowings—short and long-term	\$ 295.2	\$ —	\$ 295.2	\$ 295.8	\$ —	\$ 295.8

At March 31, 2022 our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Allowance for Credit Losses	Estimated Fair Value
		Gains	Losses		
Investments—short-term available-for-sale	\$ 247.5	\$ —	\$ (1.2)	\$ —	\$ 246.3
Investments—long-term available-for-sale	233.9	—	(5.9)	—	228.0
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	\$ 483.2	\$ —	\$ (7.1)	\$ —	\$ 476.1

Sources and Uses of Cash

We generated \$21.7 million and used \$45.1 million of cash from operating activities during the three months ended March 31, 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 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 March 31, 2022, we performed an analysis of our investments with unrealized losses for impairment and determined that they were not impaired.

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 three months ended March 31, 2022 and 2021:

(In millions)	Three Months Ended March 31,	
	2022	2021
Cash and cash equivalents, beginning of period	\$ 337.5	\$ 273.0
Cash flows provided by (used in) operating activities	21.7	(45.1)
Cash flows used in investing activities	(60.6)	(37.8)
Cash flows (used in) provided by financing activities	(16.0)	14.9
Cash and cash equivalents, end of period	<u>\$ 282.6</u>	<u>\$ 205.0</u>

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

The increase in cash flows used in investing activities was primarily due to a \$17.5 million increase in net purchase of investments and a \$5.9 million decrease in payments received in connection with the contingent consideration resulting from the Gainesville Transaction.

The change in cash flows from financing activities was primarily due to \$23.6 million in proceeds from the Term Loan Refinancing and a \$6.9 million increase in the amount of cash we received upon exercises of employee stock options, net of employee taxes.

Debt

At March 31, 2022, the principal balance of our borrowings consisted of \$297.0 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 and in light of Baudax’s disclosures regarding its ability to continue as a going concern, we increased the likelihood that Baudax would default on its obligations to us to 100% at March 31, 2022 from 55% at December 31, 2021 and adjusted the recovery rate to 9% at March 31, 2022 from 18% at December 31, 2021. For further information regarding the calculation of the fair value of the contingent consideration, refer to Note 5, *Fair Value* 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 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 March 31, 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 March 31, 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

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to \$215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the three months ended March 31, 2022. As of March 31, 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 March 31, 2022, we acquired 678,209 of our ordinary shares, at an average price of \$25.17 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 March 31, 2022, Mr. Shane M. Cooke, a director 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
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.

SIGNATURES

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

ALKERMES PLC

(Registrant)

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

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

Date: April 27, 2022

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: April 27, 2022

/s/ Richard F. Pops

Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

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: April 27, 2022

/s/ Iain M. Brown

Iain M. Brown

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

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

In connection with the Quarterly Report on Form 10-Q of Alkermes plc (the "Company") for the period ended March 31, 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: April 27, 2022

/s/ Richard F. Pops

Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: April 27, 2022

/s/ Iain M. Brown

Iain M. Brown

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