UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

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

Connaught House
1 Burlington Road
Dublin 4, Ireland, D04 C5Y6
(Address of principal executive offices)

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

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

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

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

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

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

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

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

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of October 22, 2021 was 161,705,367 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

Cautionary Note Concerning Forward-Looking Statements

This document contains and incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, these statements can be identified by the use of forward-looking terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue," "believe," "plan," "estimate," "intend," or other similar words. These statements discuss future expectations and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q (this "Form 10-Q") include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including 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 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. These risks, assumptions and uncertainties include, among others:

- 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;
- we receive substantial revenue from our key proprietary products, and our success depends on our ability to successfully manufacture and commercialize such products;
- 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, our revenues could be materially adversely affected;

- we face competition in the biopharmaceutical industry;
- our revenues may decrease or grow at a slower than expected rate due to many factors;
- revenues generated by sales of our products depend on the availability from third-party payers of reimbursement for our products and the extent of cost-sharing arrangements for patients (e.g., patient co-payment, co-insurance, deductible obligations) and cost-control measures imposed, and any reductions in payment rate or reimbursement or increases in our financial obligation to payers could result in decreased sales of our products and/or decreased revenues;
- clinical trials for our product candidates are expensive, may take several years to complete, and their outcomes are uncertain;
- preliminary, topline or interim data from our clinical trials that we may announce, publish or report from time to time may change as more patient data become available or based on subsequent audit and verification procedures, and may not be indicative of final data from such trials;
- the U.S. Food and Drug Administration (the "FDA") or other regulatory agencies may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and the adequacy of the data and other information included in our submissions, and may not approve, or may delay approval of, our products;
- the FDA or other regulatory agencies may impose limitations or post-approval requirements on approvals for our products;
- we are subject to risks related to the manufacture of our products;
- we rely on third parties to provide goods and services in connection with the manufacture and distribution of the products we manufacture;
- our success largely depends upon our ability to attract and retain key personnel;
- 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;
- we or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers;
- litigation or arbitration filed against us, including securities litigation, or regulatory 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;
- if there are changes in, or we fail to comply with, the extensive legal and regulatory requirements affecting the healthcare industry, we could face costs, penalties and business losses;
- we may not become profitable on a sustained basis;
- our level of indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business;
- the business combination of Alkermes, Inc. and the drug technology business of Elan Corporation, plc may limit our ability to use our tax attributes to offset taxable income, if any, generated from such business combination;
- the market price for our ordinary shares has been volatile and may continue to be volatile in the future, and could decline significantly;
- our business could be negatively affected as a result of the actions of activist shareholders; and
- security breaches and other disruptions could compromise our information and expose us to liability, which could cause our business and reputation to suffer.

For additional discussion regarding these risks, assumptions and uncertainties, and other material risks to our business, see "Part I, Item 1A—Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission (the "SEC") on February 11, 2021, as amended by Amendment No. 1 to Annual Report on Form 10-K/A, filed with the SEC on April 29, 2021 (as so amended, our "Annual Report"). In light of these risks, assumptions and uncertainties, the forward-looking events discussed in this Form 10-Q might not occur. You are cautioned not to place undue reliance on the forward-looking statements in this Form 10-Q, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

This Form 10-Q may include data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Form 10-Q 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, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Part I, Item 1A—Risk Factors" in our Annual Report. These and other factors could cause our results to differ materially from those expressed in this Form 10-Q.

Note Regarding Company and Product References

Alkermes plc 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 addiction, 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 United States ("U.S.") federal trademark registrations ("®") and other trademarks ("™"), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, LinkeRx®, LYBALVI®, NanoCrystal® and VIVITROL®.

The following are trademarks of the respective companies listed: AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc. ("Acorda"); ANJESO®—Baudax Bio, Inc.; 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)

	September 30, 2021	December 31, 2020
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$310,444	$272,961
Receivables, net	289,160	275,143
Investments—short-term	249,856	362,066
Inventory	138,696	125,738
Contract assets	3,509	14,401
Prepaid expenses and other current assets	61,341	60,662
Total current assets	1,053,006	1,110,971
PROPERTY, PLANT AND EQUIPMENT, NET	340,594	350,003
INVESTMENTS—LONG-TERM	187,855	24,780
RIGHT-OF-USE ASSETS	118,764	131,718
INTANGIBLE ASSETS, NET	83,659	111,191
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	84,498	86,228
CONTINGENT CONSIDERATION	17,411	24,651
OTHER ASSETS	16,772	17,315
TOTAL ASSETS	$1,995,432	$1,949,730
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$428,032	$412,171
Operating lease liabilities—short-term	15,548	15,732
Contract liabilities—short-term	6,404	7,512
Current portion of long-term debt	3,000	2,843
Total current liabilities	452,984	438,258
LONG-TERM DEBT	293,437	272,118
OPERATING LEASE LIABILITIES—LONG-TERM	107,860	119,464
CONTRACT LIABILITIES—LONG-TERM	12,864	16,397
OTHER LONG-TERM LIABILITIES	32,119	36,511
Total liabilities	899,264	882,748
COMMITMENTS AND CONTINGENT LIABILITIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 165,439,188 and 162,269,220 shares issued; 161,686,223 and 159,161,141 shares outstanding at September 30, 2021 and December 31, 2020, respectively	1,654	1,620
Treasury shares, at cost (3,752,965 and 3,108,079 shares at September 30, 2021 and December 31, 2020, respectively)	(139,720)	(126,087)
Additional paid-in capital	2,778,596	2,685,647
Accumulated other comprehensive loss	(2,471)	(1,349)
Accumulated deficit	(1,541,891)	(1,492,849)
Total shareholders' equity	1,096,168	1,066,982
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,995,432	$1,949,730

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	$ 157,737	$ 142,658	$ 448,508	$ 402,799
Manufacturing and royalty revenues	136,294	120,351	398,435	353,107
License revenue	—	1,050	1,500	1,050
Research and development revenue	110	953	845	1,805
Total revenues	294,141	265,012	849,288	758,761
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	49,561	43,129	143,705	135,394
Research and development	118,411	94,980	308,152	282,481
Selling, general and administrative	136,213	127,653	400,569	393,049
Amortization of acquired intangible assets	9,615	9,917	28,532	29,535
Total expenses	313,800	275,679	880,958	840,459
OPERATING LOSS	(19,659)	(10,667)	(31,670)	(81,698)
OTHER (EXPENSE) INCOME, NET:				
Interest income	468	1,376	1,955	5,924
Interest expense	(2,437)	(1,811)	(8,814)	(6,790)
Change in the fair value of contingent consideration	(5,195)	3,926	(677)	16,626
Other income (expense), net	288	9,368	(327)	11,047
Total other (expense) income, net	(6,876)	12,859	(7,863)	26,807
(LOSS) INCOME BEFORE INCOME TAXES	(26,535)	2,192	(39,533)	(54,891)
INCOME TAX PROVISION	2,453	2,326	9,509	13,328
NET LOSS	$ (28,988)	$ (134)	$ (49,042)	$ (68,219)
LOSS PER ORDINARY SHARE:				
Basic and diluted	$ (0.18)	$ (0.00)	$ (0.31)	$ (0.43)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic and diluted	161,456	159,062	160,642	158,685
COMPREHENSIVE LOSS:				
Net loss	$ (28,988)	$ (134)	$ (49,042)	$ (68,219)
Holding (loss) gain, net of a tax (benefit) provision of $(72), $(193), $(325) and $303, respectively	(249)	(659)	(1,122)	1,056
COMPREHENSIVE LOSS	$ (29,237)	$ (793)	$ (50,164)	$ (67,163)

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

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

	Nine Months Ended September 30,	
	2021	2020
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (49,042)	$ (68,219)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	57,510	61,525
Share-based compensation expense	68,603	65,279
Deferred income taxes	2,015	9,939
Change in the fair value of contingent consideration	677	(16,626)
Loss on debt extinguishment	171	—
Other non-cash charges	1,803	2,105
Changes in assets and liabilities:		
Receivables	(13,991)	(8,551)
Contract assets	10,892	(6,009)
Inventory	(13,375)	(20,748)
Prepaid expenses and other assets	(1,507)	5,597
Right-of-use assets	12,891	13,251
Accounts payable and accrued expenses	15,546	(6,222)
Contract liabilities	(4,642)	(3,045)
Operating lease liabilities	(12,504)	(11,910)
Other long-term liabilities	(4,353)	(867)
Cash flows provided by operating activities	70,694	15,499
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(19,359)	(36,780)
Proceeds from the sale of equipment	277	61
Proceeds from contingent consideration	7,908	2,819
Return of Fountain Healthcare Partners II, L.P. investment	—	2,751
Payment made for licensed IP	(1,000)	—
Purchases of investments	(294,370)	(151,324)
Sales and maturities of investments	241,082	206,089
Cash flows (used in) provided by investing activities	(65,462)	23,616
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	24,810	7,719
Employee taxes paid related to net share settlement of equity awards	(13,633)	(7,607)
Proceeds from the issuance of long-term debt	23,567	—
Payment made for debt extinguishment	(993)	—
Principal payments of long-term debt	(1,500)	(2,132)
Cash flows provided by (used in) financing activities	32,251	(2,020)
NET INCREASE IN CASH AND CASH EQUIVALENTS	37,483	37,095
CASH AND CASH EQUIVALENTS—Beginning of period	272,961	203,771
CASH AND CASH EQUIVALENTS—End of period	$ 310,444	$ 240,866
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 2,698	$ 2,169

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, 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	134,163	4	2,049	—	—	—	—	2,053
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	1,432,522	14	(14)	—	—	(529,817)	(10,413)	(10,413)
Share-based compensation	—	—	15,552	—	—	—	—	15,552
Unrealized loss on marketable securities, net of tax (benefit) of $(174)	—	—	—	(601)	—	—	—	(601)
Net loss	—	—	—	—	(22,418)	—	—	(22,418)
BALANCE — March 31, 2021	163,835,905	$ 1,638	$ 2,703,234	$ (1,950)	$ (1,515,267)	(3,637,896)	$ (136,500)	$ 1,051,155
Issuance of ordinary shares under employee stock plans	1,035,941	11	18,434	—	—	—	—	18,445
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	93,928	1	(1)	—	—	(31,752)	(707)	(707)
Share-based compensation	—	—	26,917	—	—	—	—	26,917
Unrealized loss on marketable securities, net of tax (benefit) of $(79)	—	—	—	(272)	—	—	—	(272)
Net income	—	—	—	—	2,364	—	—	2,364
BALANCE — June 30, 2021	164,965,774	$ 1,650	$ 2,748,584	$ (2,222)	$ (1,512,903)	(3,669,648)	$ (137,207)	$ 1,097,902
Issuance of ordinary shares under employee stock plans	256,718	2	4,310	—	—	—	—	4,312
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	216,696	2	(2)	—	—	(83,317)	(2,513)	(2,513)
Share-based compensation	—	—	25,704	—	—	—	—	25,704
Unrealized loss on marketable securities, net of tax (benefit) of $(72)	—	—	—	(249)	—	—	—	(249)
Net loss	—	—	—	—	(28,988)	—	—	(28,988)
BALANCE — September 30, 2021	165,439,188	$ 1,654	$ 2,778,596	$ (2,471)	$ (1,541,891)	(3,752,965)	$ (139,720)	$ 1,096,168

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

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

1. THE COMPANY

Alkermes plc is a fully-integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. Alkermes has a portfolio of proprietary commercial products focused on addiction, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurodegenerative disorders and cancer. Headquartered in Dublin, Ireland, the Company has a research and development ("R&D") center in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three and nine months ended September 30, 2021 and 2020 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2020. 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.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires that 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 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 the Company's assets and liabilities. Actual results may differ from these estimates under different conditions or using different assumptions.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines. 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, restrictive executive orders and other similar government orders, restrictions, and recommendations for their residents to help control the spread of COVID-19. Such orders, restrictions and/or recommendations, and/or the perception that additional orders, 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, work-from-home policies and travel restrictions, among other effects.

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

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.

The marketed products from which the Company derives revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including business closures, social distancing requirements 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.

The Company has continued to operate its manufacturing facilities and supply its medicines throughout the pandemic. While the Company continues to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has, at times, impacted the timelines of certain of the Company's 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, potential adverse impacts of COVID-19 on its manufacturing operations and R&D activities.

New Accounting Pronouncements

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

In March 2020, the FASB issued Accounting Standards Update ("ASU") 2020-04, *Reference Rate Reform*, which provides optional guidance for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. This ASU applies to all entities, subject to meeting certain criteria, that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. This ASU became effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company believes this ASU will not have a material impact on its consolidated financial statements.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Under FASB Accounting Standards Codification 606, *Revenue from Contracts with Customers* ("Topic 606"), the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. This approach to revenue recognition utilizes the following five-step model, as prescribed under Topic 606: (i) identify contract(s) with a customer; (ii) identify the performance obligation(s) in the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract(s); and (v) recognize revenues when (or as) the Company satisfies the performance obligation(s).

Product Sales, Net

The Company's product sales, net consist of sales of VIVITROL and ARISTADA (together with ARISTADA INITIO) in the U.S., primarily to wholesalers, specialty distributors and specialty pharmacies. Product sales, net are recognized when the customer obtains control of the product, which is when the product has been received by the customer.

During the three and nine months ended September 30, 2021 and 2020, the Company recorded product sales, net, as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
VIVITROL	$ 88,864	$ 80,258	$ 251,815	$ 230,673
ARISTADA and ARISTADA INITIO	68,873	62,400	196,693	172,126
Total product sales, net	$ 157,737	$ 142,658	$ 448,508	$ 402,799

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2021 and 2020, the Company recorded manufacturing and royalty revenues as follows:

	Three Months Ended September 30, 2021			Nine Months Ended September 30, 2021		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 79,323	$ 79,323	$ —	$ 221,965	$ 221,965
VUMERITY	8,499	18,250	26,749	17,671	42,866	60,537
RISPERDAL CONSTA	8,725	2,245	10,970	31,411	8,172	39,583
AMPYRA/FAMPYRA	4,716	2,828	7,544	20,343	15,189	35,532
Other	2,046	9,662	11,708	8,939	31,879	40,818
	$ 23,986	$ 112,308	$ 136,294	$ 78,364	$ 320,071	$ 398,435

	Three Months Ended September 30, 2020			Nine Months Ended September 30, 2020		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 73,366	$ 73,366	$ —	$ 197,678	$ 197,678
VUMERITY	579	2,134	2,713	3,211	3,787	6,998
RISPERDAL CONSTA	10,993	3,517	14,510	44,769	10,786	55,555
AMPYRA/FAMPYRA	6,748	5,592	12,340	21,724	18,094	39,818
Other	6,985	10,437	17,422	21,153	31,905	53,058
	$ 25,305	$ 95,046	$ 120,351	$ 90,857	$ 262,250	$ 353,107

Contract Assets

Contract assets include unbilled amounts under certain of the Company's contracts with customers where revenue is recognized over time. Total contract assets at September 30, 2021 included $3.5 million of assets that were classified as "Current assets" in the accompanying condensed consolidated balance sheets, as they related to manufacturing processes that are completed in ten days to eight weeks, and $5.0 million that was classified as "Other assets" in the accompanying condensed consolidated balance sheets, as it consisted of consideration from the Company's collaboration with Biogen related to VUMERITY, which the Company expects to receive in the fourth quarter of 2022.

Total contract assets at September 30, 2021 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2020	$ 19,401
Additions	22,384
Transferred to receivables, net	(33,276)
Contract assets at September 30, 2021	$ 8,509

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue.

Total contract liabilities at September 30, 2021 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2020	$ 23,909
Additions	—
Amounts recognized into revenue	(4,641)
Contract liabilities at September 30, 2021	$ 19,268

4. INVESTMENTS

Investments consisted of the following (in thousands):

September 30, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses Less than One Year	Gross Unrealized Losses Greater than One Year	Allowance for Credit Losses	Estimated Fair Value
Short-term investments:						
Available-for-sale securities:						
Corporate debt securities	$ 121,003	$ 388	$ (16)	$ (3)	$ —	$ 121,372
U.S. government and agency debt securities	66,064	83	—	—	—	66,147
Non-U.S. government debt securities	62,202	141	(6)	—	—	62,337
Total short-term investments	249,269	612	(22)	(3)	—	249,856
Long-term investments:						
Available-for-sale securities:						
Corporate debt securities	78,936	—	(64)	—	—	78,872
U.S. government and agency debt securities	69,534	—	(53)	—	—	69,481
Non-U.S. government debt securities	37,728	—	(46)	—	—	37,682
	186,198	—	(163)	—	—	186,035
Held-to-maturity securities:						
Certificates of deposit	1,820	—	—	—	—	1,820
Total long-term investments	188,018	—	(163)	—	—	187,855
Total investments	$ 437,287	$ 612	$ (185)	$ (3)	$ —	$ 437,711
December 31, 2020						
Short-term investments:						
Available-for-sale securities:						
Corporate debt securities	$ 176,937	$ 1,105	$ (7)	$ —	$ (977)	$ 177,058
U.S. government and agency debt securities	103,011	336	(2)	—	—	103,345
Non-U.S. government debt securities	79,346	469	(6)	—	—	79,809
	359,294	1,910	(15)	—	(977)	360,212
Held-to-maturity securities:						
Fixed term deposit account	1,667	187	—	—	—	1,854
Total short-term investments	360,961	2,097	(15)	—	(977)	362,066
Long-term investments:						
Available-for-sale securities:						
Corporate debt securities	7,908	—	(10)	—	—	7,898
Non-U.S. government debt securities	15,077	—	(15)	—	—	15,062
	22,985	—	(25)	—	—	22,960
Held-to-maturity securities:						
Certificates of deposit	1,820	—	—	—	—	1,820
Total long-term investments	24,805	—	(25)	—	—	24,780
Total investments	$ 385,766	$ 2,097	$ (40)	$ —	$ (977)	$ 386,846

At September 30, 2021, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were other-than-temporary. Investments with unrealized losses consisted primarily of corporate debt securities, debt securities issued by U.S. agencies and backed by the U.S. government and debt securities issued and backed by non-U.S. governments. In making the determination whether the decline in fair value of these securities was other-than-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.

If the Company intends to sell a security, or it is more likely than not that the Company would be required to sell a security prior to recovering its amortized cost basis, an other-than-temporary impairment is deemed to have occurred.

The amount of an other-than-temporary impairment related to a credit loss, or investments that the Company intends to sell before recovery, is recognized in earnings.

In September 2019, the Company purchased a convertible promissory note in the principal amount of $1.9 million from Synchronicity Pharma, Inc., a related party. The convertible promissory note was classified as an available-for-sale corporate debt instrument. In September 2020, the Company recorded an other-than-temporary credit loss of $1.0 million against the value of this investment. In June 2021, the Company determined that the remaining $0.9 million of the investment was impaired and recorded an additional other-than-temporary credit loss of $0.9 million. These losses were recorded within "Other (expense) income, net" in the accompanying condensed consolidated statements of operations and comprehensive loss.

In May 2014, the Company entered into an agreement whereby it committed to provide up to €8.3 million to Fountain Healthcare Partners II, L.P., an Irish partnership ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. The Company's commitment to Fountain represents approximately 7% of Fountain's total funding commitments. As of September 30, 2021, the Company had invested €7.7 million in Fountain. The Company is accounting for its investment in Fountain under the equity method.

The Company's net investment in Fountain was $6.3 million and $6.2 million at September 30, 2021 and December 31, 2020, respectively, and was included within "Other assets" in the accompanying condensed consolidated balance sheets.

The proceeds from sales and maturities of marketable securities, which were identified using the specific identification method and were primarily reinvested, were as follows:

(In thousands)	Nine Months Ended September 30, 2021	2020
Proceeds from the sales and maturities of marketable securities	$ 239,228	$ 206,089
Realized gains	$ 34	$ 52
Realized losses	$ 977	$ 977

The Company's available-for-sale and held-to-maturity securities at September 30, 2021 had contractual maturities in the following periods:

(In thousands)	Available-for-sale Amortized Cost	Available-for-sale Estimated Fair Value	Held-to-maturity Amortized Cost	Held-to-maturity Estimated Fair Value
Within 1 year	$ 178,529	$ 178,780	$ 1,820	$ 1,820
After 1 year through 5 years	256,938	257,111	—	—
Total	$ 435,467	$ 435,891	$ 1,820	$ 1,820

5. FAIR VALUE

The following table presents information about the Company's assets and liabilities at September 30, 2021 and December 31, 2020 that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques that the Company utilized to determine such fair value:

(In thousands)	September 30, 2021	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	$ 135,628	$ 100,270	$ 35,358	$ —
Corporate debt securities	200,244	—	200,244	—
Non-U.S. government debt securities	100,019	—	100,019	—
Contingent consideration	23,840	—	—	23,840
Total	$ 459,731	$ 100,270	$ 335,621	$ 23,840

	December 31, 2020	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 41,849	$ 41,849	$ —	$ —
U.S. government and agency debt securities	103,345	73,451	29,894	—
Corporate debt securities	184,956	—	183,979	977
Non-U.S. government debt securities	94,871	—	94,871	—
Contingent consideration	32,451	—	—	32,451
Total	$ 457,472	$ 115,300	$ 308,744	$ 33,428

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period.

There were no transfers of any securities between the fair value hierarchies during the nine months ended September 30, 2021. The following table is a rollforward of the fair value of the Company's assets with fair values that were determined using Level 3 inputs at September 30, 2021:

(In thousands)	Fair Value
Balance, January 1, 2021	$ 33,428
Change in the fair value of contingent consideration	(677)
Milestone and royalty payments received by the Company related to contingent consideration	(7,908)
Impairment of corporate debt security	(977)
Royalty payments due to the Company related to contingent consideration	(26)
Balance, September 30, 2021	$ 23,840

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

In April 2015, the Company sold its Gainesville, GA manufacturing facility, the 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 IV/IM Meloxicam 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 the Company certain contingent consideration from the Gainesville Transaction were assigned and/or transferred to Baudax.

In Baudax's Quarterly Report on Form 10-Q for the period ended June 30, 2021, Baudax included disclosures regarding its ability to continue as a going concern. At September 30, 2021, the Company determined the fair value of the contingent consideration due to the Company from Baudax as follows:

- The Company is due to receive $38.6 million related to the FDA approval in February 2020 of the New Drug Application ("NDA") for ANJESO, the first Meloxicam Product, to be paid in six remaining equal, annual installments on each anniversary of such approval through 2027;
- The Company is entitled to receive royalties on future net sales of Meloxicam Products; and

- The Company is entitled to receive payments of up to $80.0 million upon achieving certain sales milestones on future net sales of Meloxicam Products. The fair value of the sales milestones was determined through the use of a real options approach, in which net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of ANJESO, adjusted by an appropriate factor to capture market risk.

In order to address the substantial doubt about Baudax's ability to continue as a going concern, the Company split its fair value analysis into two scenarios. In the first scenario, to which the Company applied a 45% and 50% likelihood at September 30, 2021 and December 31, 2020, respectively, the amounts above were discounted using a rate of 13% at each of September 30, 2021 and December 31, 2020, which the Company believes captures a market participant's view of the risk associated with the expected payments assuming Baudax is able to continue as a going concern. In the second scenario, to which the Company applied a 55% and 50% likelihood at September 30, 2021 and December 31, 2020, respectively, the Company used the undiscounted values derived from the amounts summarized above and applied a recovery rate of 18% at each of September 30, 2021 and December 31, 2020, based on an analysis performed by Moody's Investor Service regarding recoveries in a pandemic-driven default cycle.

At September 30, 2021 and December 31, 2020, the Company determined that the fair value of the contingent consideration related to the Gainesville Transaction was $23.8 million and $32.5 million, respectively. At September 30, 2021 and December 31, 2020, $6.4 million and $7.8 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 $17.4 million and $24.7 million, respectively, of the fair value of the contingent consideration was included within "Contingent consideration" in the accompanying condensed consolidated balance sheets. The Company recorded a decrease of $5.2 million and $0.7 million during the three and nine months ended September 30, 2021, respectively, and an increase of $3.9 million and $16.6 million during the three and nine months ended September 30, 2020, respectively, within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the 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, 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 $296.6 million and $275.1 million at September 30, 2021 and December 31, 2020, respectively. See Note 11, *Long-Term Debt* in these "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for additional information.

6. INVENTORY

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

(In thousands)	September 30, 2021	December 31, 2020
Raw materials	$ 46,252	$ 44,944
Work in process	50,890	53,243
Finished goods(1)	41,554	27,551
Total inventory	$ 138,696	$ 125,738

(1) At September 30, 2021 and December 31, 2020, the Company had $25.2 million and $26.5 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

Beginning in September 2020, the carrying value of inventory included amounts associated with LYBALVI, which were capitalized in advance of validation of LYBALVI's manufacturing line. The manufacturing line was validated in September 2021, and LYBALVI was launched commercially in October 2021.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Land	$ 6,560	$ 6,560
Building and improvements	192,662	178,194
Furniture, fixtures and equipment	392,477	366,051
Leasehold improvements	52,641	52,508
Construction in progress	80,490	102,833
Subtotal	724,830	706,146
Less: accumulated depreciation	(384,236)	(356,143)
Total property, plant and equipment, net	$ 340,594	$ 350,003

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

		September 30, 2021		
(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	$ 465,590	$ (399,630)	$ 65,960
Capitalized IP	11-13	118,160	(100,461)	17,699
Total		$ 583,750	$ (500,091)	$ 83,659

Based on the Company's most recent analysis, amortization of intangible assets included in the accompanying condensed consolidated balance sheet at September 30, 2021 is expected to be approximately $40.0 million, $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2021 through 2024, respectively. Given the assumptions and inherent risks and uncertainties underlying the Company's expectations regarding future revenues, the Company's actual results may vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets would change in proportion to the projected change in revenues.

9. LEASES

Future lease payments under non-cancelable leases at September 30, 2021 and December 31, 2020 consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
2021	$ 4,372	$ 16,882
2022	17,032	17,001
2023	17,266	17,266
2024	17,536	17,536
2025	17,810	17,810
Thereafter	109,002	109,311
Total operating lease payments	$ 183,018	$ 195,806
Less: imputed interest	(59,610)	(60,610)
Total operating lease liabilities	$ 123,408	$ 135,196

At September 30, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.27% and 12.0 years, respectively. During the three and nine months ended September 30, 2021, cash paid for lease liabilities was $4.4 million and $12.5 million, respectively, and $5.0 million and $11.9 million, respectively, during the three and nine months ended September 30, 2020. The Company recorded operating lease expense of $4.3 million and $12.9 million during the three and nine months ended September 30, 2021, respectively, and $4.7 million and $13.3 million during the three and nine months ended September 30, 2020, respectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Accounts payable	$ 36,875	$ 46,034
Accrued compensation	68,001	71,178
Accrued sales discounts, allowances and reserves	221,720	218,877
Accrued other	101,436	76,082
Total accounts payable and accrued expenses	$ 428,032	$ 412,171

At September 30, 2021, the Company determined that achievement of a development milestone related to submission of an investigational new drug application or equivalent for ALKS 1140 was probable and accrued $25.0 million for such milestone payment, which the company expects to pay in the fourth quarter of 2021. ALKS 1140 is the Company's novel CoREST-selective histone deacetylase (HDAC) inhibitor candidate for the treatment of neurodegenerative and neurodevelopmental disorders. This accrual is included within "Accounts payable and accrued expenses" in the accompanying condensed consolidated balance sheets.

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
2026 Term Loans, due March 12, 2026	$ 296,437	$ —
2023 Term Loans, due March 26, 2023	—	274,961
Less: current portion	(3,000)	(2,843)
Long-term debt	$ 293,437	$ 272,118

In March 2021, the Company amended and refinanced its existing term loans, previously referred to as the 2023 Term Loans, in order to, among other things, provide for a new class of replacement term loans equal to $300.0 million; extend the due date for the loans from March 26, 2023 to March 12, 2026; amend the interest payable on the loans from LIBOR plus 2.25% with no LIBOR floor to LIBOR plus 2.50% with a LIBOR floor of 0.50%; and increase covenant flexibility (such refinancing, the "Term Loan Refinancing" and the 2023 Term Loans as so amended and refinanced the "2026 Term Loans").

Under the 2026 Term Loans, the Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds set forth in the 2026 Term Loans are met. To date, the Company has not been required to make any such mandatory prepayments. The 2026 Term Loans have an incremental facility capacity in the amount of $175.0 million plus potential additional amounts, provided that the Company meets certain conditions, including a specified leverage ratio. The 2026 Term Loans include a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The 2026 Term Loans also contain customary affirmative covenants and events of default. At September 30, 2021, the Company was in compliance with its debt covenants under the 2026 Term Loans.

The Term Loan Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Term Loan Refinancing should be accounted for as a debt extinguishment or a debt modification, the Company considered whether, prior to and following the Term Loan Refinancing, creditors remained the same or changed, and whether the changes in debt terms were substantial. A change in the debt terms was considered to be substantial if the present value of the remaining cash flows under the 2026 Term Loans was at least 10% different from the present value of the remaining cash flows under the 2023 Term Loans (commonly referred to as the "10% Test"). The Company performed a separate 10% Test for each individual creditor participating in the loan syndicate.

With the exception of three lenders with respective holdings ranging from 2%-7% of the total outstanding principal amount of the 2023 Term Loans immediately prior to the Term Loan Refinancing whose holding amounts were accounted for as a debt extinguishment, the Term Loan Refinancing was otherwise accounted for as a debt modification.

The Term Loan Refinancing resulted in a $2.1 million charge in March 2021, which was included in “Interest expense” in the accompanying condensed consolidated statement of operations and comprehensive loss.

12. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2021	2020	2021	2020
Cost of goods manufactured and sold	$ 2,666	$ 2,344	$ 7,527	$ 6,324
Research and development	7,960	6,762	19,154	19,400
Selling, general and administrative	14,974	13,514	41,922	39,555
Total share-based compensation expense	$ 25,600	$ 22,620	$ 68,603	$ 65,279

At September 30, 2021 and December 31, 2020, $2.1 million and $2.6 million, respectively, of share-based compensation expense was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

On June 14, 2021, the Company’s shareholders approved amendments to the Alkermes plc 2018 Stock Option and Incentive Plan that served to, among other things, increase the number of ordinary shares authorized for issuance thereunder by 8,000,000.

13. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the three and nine months ended September 30, 2021 and 2020, as the Company was in a net loss position, the diluted loss per ordinary share calculation did not assume conversion or exercise of stock options and restricted stock unit awards, as they would have had an anti-dilutive effect on loss per ordinary share.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2021	2020	2021	2020
Stock options	11,827	15,322	15,344	15,352
Restricted stock unit awards	4,714	2,351	3,532	3,678
Total	16,541	17,673	18,876	19,030

14. COMMITMENTS AND CONTINGENT LIABILITIES

Litigation

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates, utilizing all available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At September 30, 2021, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

INVEGA SUSTENNA ANDA Litigation

Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the U.S. District Court for the District of New Jersey (the "NJ District Court") in January 2018 against Teva Pharmaceuticals USA, Inc. ("Teva") and Teva Pharmaceuticals Industries, Ltd. ("Teva PI"), in August 2019 against Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals Inc. ("Mylan"), and Mylan Institutional LLC and in December 2019 against Pharmascience, Inc. ("Pharmascience"), Mallinckrodt plc, and SpecGX LLC, following the respective filings by each of Teva, Mylan Labs, and Pharmascience of an Abbreviated New Drug Application ("ANDA") seeking approval from the FDA to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906. Requested judicial remedies in each of the lawsuits include recovery of litigation costs and injunctive relief. The Company is not a party to any of these proceedings. In October 2020, a trial was held in the lawsuit between the Janssen entities and the Teva entities and on October 8, 2021, the NJ District Court issued an order in favor of the Janssen entities.

INVEGA TRINZA ANDA Litigation

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

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co., Ltd., Pharmathen SA, Teva PI and Dehns Ltd (a law firm representing an unidentified opponent) filed notices of opposition with the European Patent Office (the "EPO") in respect of EP 2 269 577 B (the "EP '577 Patent"), a patent directed to certain risperidone microsphere compositions, including RISPERDAL CONSTA. Following a hearing on the matter in January 2019, the EPO issued a written decision revoking the EP '577 Patent in April 2019. The Company filed a notice of appeal of the decision to the EPO's Technical Boards of Appeal in June 2019. Pharmathen SA submitted a reply in November 2019 and Nanjing Luye Pharmaceutical Co., Ltd. and Teva PI submitted replies in December 2019. Oral proceedings are scheduled to be held on November 29, 2022. The Company will continue to vigorously defend the EP '577 Patent.

VIVITROL ANDA Litigation

In September 2020, Alkermes, Inc. and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in the NJ District Court against Teva and Teva PI following the filing by Teva of an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VIVITROL (naltrexone for extended-release injectable suspension) before the expiration of the Company's U.S. Patent No. 7,919,499. 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 Term Restoration Act of 1984 (the "Hatch-Waxman Act").

VUMERITY ANDA Litigation

In March 2021, Biogen Inc., Biogen Swiss Manufacturing GmbH and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware (the "Delaware District Court") against Teva Pharmaceuticals Development Inc. ("Teva PD") following the filing by Teva PD of an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VUMERITY (diroximel fumarate) before the expiration of the Company's U.S. Patent Nos. 8,669,281, 9,090,558 and 10,080,733. The filing of the lawsuit triggered a stay of FDA approval of the ANDA for up to 30 months in accordance with the Hatch-Waxman Act. On October 8, 2021, the Delaware District Court granted the parties' joint stipulation of dismissal, which terminated the litigation.

Government Matters

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

Securities Litigation

In December 2018 and January 2019, purported stockholders of the Company filed putative class actions against the Company and certain of its officers in the U.S. District Court for the Eastern District of New York (the "EDNY District Court") captioned *Karimian v. Alkermes plc, et al., No. 1:18-cv-07410 and McDermott v. Alkermes plc, et al., No. 1:19-cv-00624*, respectively. In March 2019, the EDNY District Court consolidated the two cases and appointed a lead plaintiff. The plaintiff filed an amended complaint in July 2019 naming one additional officer of the Company and one former officer of the Company as defendants. The amended complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of July 31, 2014 through November 1, 2018 and alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding the Company's clinical methodologies and regulatory submission for ALKS 5461 and the FDA's review and consideration of that submission. The lawsuit seeks, among other things, unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. In February 2021, the EDNY District Court entered a final judgment and order dismissing the action in its entirety (the "Final Judgment and Order"). In March 2021, the plaintiff filed a notice of appeal captioned *In re Alkermes Public Limited Co. Securities Litig., No. 21-801*, appealing the Final Judgment and Order to the United States Court of Appeals for the Second Circuit. Oral arguments for the appeal are scheduled to be held on November 16, 2021.

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 matters would have a material adverse effect on the Company's business or financial condition.

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

The following discussion should be read in conjunction with 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 and nine months ended September 30, 2021 was $29.0 million and $49.0 million, respectively, or $0.18 and $0.31 per ordinary share—basic and diluted, respectively, as compared to a net loss of $0.1 million and $68.2 million, respectively, or $0.00 and $0.43 per ordinary share—basic and diluted, respectively, for the three and nine months ended September 30, 2020.

The increase in net loss in the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to a $38.1 million increase in operating expenses, primarily due to the $25.0 million milestone related to ALKS 1140 included within R&D expense, a $9.1 million decrease in the fair value of our contingent consideration related to increased risk of non-payment and a $9.1 million decrease in other income (expense), net, due to the receipt in September 2020 of our proportional share of the proceeds from the sale of two companies within the Fountain portfolio, partially offset by a $29.1 million increase in revenue.

The decrease in net loss in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to a $90.5 million increase in revenue, partially offset by a $40.5 million increase in operating expenses, a $17.3 million decrease in the fair value of our contingent consideration, related to increased risk of non-payment and an $11.4 million decrease in other income (expense), net, primarily related to the Fountain proceeds discussed above.

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, 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, restrictions and/or recommendations, and/or the perception that additional orders, 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, work-from-home policies and travel restrictions, among other effects.

We continue to closely monitor and respond to the ongoing impact of COVID-19 on our employees, our communities and our business operations, and have adopted, and adapted as needed, a series of precautionary measures in an effort to protect our employees and mitigate the potential spread of COVID-19 in a community setting. For example, at the start of the pandemic, we instituted a global remote work policy for those of our employees who were able to work remotely. At the same time, we worked to continue our critical business functions, including operation of our manufacturing facilities and our laboratories, and continued to conduct our discovery efforts and supply our medicines. For those of our employees who continued to work on-site in our laboratories and manufacturing facilities, we instituted additional safety precautions, including increased sanitization of our facilities, use of personal protective equipment, implementation of a daily health screening application and physical distancing practices. We provided employees with COVID-19 vaccine information and sponsored vaccine clinics in Massachusetts and Ohio for our employees and their families. We also took actions to support people living with opioid dependence, alcohol dependence, schizophrenia and bipolar I disorder to help support their access to information, resources and medicines that may assist in their treatment.

In recent months, certain of our field-based employees resumed in-person interactions, and certain of our office-based employees began to return to the office, in each case on a voluntary basis and in accordance with location-specific guidance. We are planning for a larger-scale return to the office and have developed flexible work arrangement guidelines to help balance business needs, employee health, wellbeing and safety and the evolving work environment. We will continue to monitor guidance from local health authorities as we increase in-person interactions.

The marketed products from which we derive revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including business closures, social distancing requirements 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.

We have continued to operate our manufacturing facilities and supply our medicines throughout the pandemic. 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.

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; the emergence and prevalence of COVID-19 variants; governmental, business or other actions that have been, are being, or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions and imposition of social distancing measures, vaccine mandates and/or mandatory testing policies; impacts of the pandemic on the labor market and on our employees; impacts of the pandemic on the vendors or distribution channels in our supply chain and on our ability to continue to manufacture our products; impacts of the pandemic on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with addiction and severe mental illness; impacts of the pandemic on the regulatory agencies with which we interact in the development, review, approval and commercialization of our medicines; impacts of the pandemic on reimbursement for our products, including our Medicaid rebate liability, and for services related to the use of our products; and impacts of the pandemic on the Irish, U.S. and global economies more broadly. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see “Part 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 COVID-19 pandemic or other similar outbreaks of contagious diseases.”

Products

Marketed Products

Our portfolio of marketed products is designed to help address unmet medical needs of patients in major therapeutic areas. 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. For information with respect to the IP protection for these marketed products, see the descriptions of the marketed products below and the “Patents and Proprietary Rights” section in “Part I, Item 1—Business” in our Annual Report.

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

Proprietary Products

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

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

Key Third-Party Products Using Our Proprietary Technologies

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

Our Key Licensed Products

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

Proprietary Products

We 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.

In August 2021, U.S. Patent No. 11,097,006 relating to ARISTADA was granted. The patent has claims to pharmaceutical compositions that confer long-term stability of the ARISTADA formulation and expires in 2033.

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 October 2021, U.S. Patent No. 11,154,552 relating to ARISTADA INITIO was granted. The patent has composition claims to aripiprazole lauroxil in the ARISTADA INITIO formulation and expires in 2035.

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.

VIVITROL (U.S.)

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly, non-narcotic, injectable medication approved in the U.S., Russia and certain countries of the CIS for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through one intramuscular injection every four weeks. We developed and exclusively manufacture VIVITROL and we commercialize VIVITROL in the U.S.

For a discussion of legal proceedings related to VIVITROL, see Note 14, *Commitments and Contingent Liabilities* in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q, and for information about risks relating to such legal proceedings, see “Part I, Item 1A—Risk Factors” in our Annual Report 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 regulatory 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. Such arrangements include the following:

Third-Party Products Using Our Proprietary Technologies

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate 3-month injection) and RISPERDAL CONSTA (risperidone long-acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union ("EU") and other countries outside of the U.S. for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA/XEPLION is manufactured by Janssen.

INVEGA TRINZA is approved in the U.S. for the treatment of schizophrenia in patients who have been adequately treated with INVEGA SUSTENNA for at least four months. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA is dosed once every three months. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one intramuscular injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us.

For a discussion of legal proceedings related to certain of the patents covering INVEGA SUSTENNA, INVEGA TRINZA and RISPERDAL CONSTA, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

Our Licensed Products

VIVITROL (Russia and CIS)

VIVITROL is described more fully under the heading "Proprietary Products" above in this Form 10-Q. We developed and exclusively manufacture VIVITROL for Cilag. Cilag exclusively commercializes VIVITROL in Russia and certain countries of the CIS.

VUMERITY

VUMERITY (diroximel fumarate) is a novel, oral fumarate with a distinct chemical structure that is approved in the U.S. and Switzerland 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.

For a discussion of legal proceedings related to certain of the patents covering VUMERITY, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

Key Development Program

Our R&D is focused on the development of novel, competitively advantaged medications designed to enhance patient outcomes. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting preclinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key R&D 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 (formerly referred to as ALKS 4230)

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 clinical and immunologic effects of IV nemvaleukin monotherapy on the tumor microenvironment in a variety of advanced, malignant 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, initiated in October 2021, is a phase 3 study evaluating the anti-tumor activity and safety of IV nemvaleukin in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant ovarian cancer.

In August 2021, the FDA granted Fast Track designation to nemvaleukin for the treatment of mucosal melanoma. In October 2021, 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 in the U.S., primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for sales of VIVITROL, ARISTADA and ARISTADA INITIO in the U.S. during the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In millions, except for % of Sales)	2021	% of Sales	2020	% of Sales	2021	% of Sales	2020	% of Sales
Product sales, gross	$ 338.7	100.0 %	$ 304.8	100.0 %	$ 954.8	100.0 %	$ 824.0	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(86.1)	(25.4) %	(83.3)	(27.3) %	(245.1)	(25.7) %	(210.6)	(25.6) %
Chargebacks	(36.5)	(10.8) %	(28.7)	(9.4) %	(95.2)	(9.9) %	(72.0)	(8.7) %
Product discounts	(27.1)	(8.0) %	(23.3)	(7.7) %	(76.9)	(8.1) %	(64.1)	(7.8) %
Medicare Part D	(15.3)	(4.5) %	(14.7)	(4.8) %	(45.2)	(4.7) %	(40.4)	(4.9) %
Other	(16.0)	(4.7) %	(12.1)	(4.0) %	(43.9)	(4.6) %	(34.1)	(4.1) %
Total adjustments	(181.0)	(53.4) %	(162.1)	(53.2) %	(506.3)	(53.0) %	(421.2)	(51.1) %
Product sales, net	$ 157.7	46.6 %	$ 142.7	46.8 %	$ 448.5	47.0 %	$ 402.8	48.9 %

Our product sales, net, for VIVITROL in the three and nine months ended September 30, 2021 were $88.8 million and $251.8 million, respectively, as compared to $80.3 million and $230.7 million in the three and nine months ended September 30, 2020, respectively. Product sales, net, for ARISTADA and ARISTADA INITIO in the three and nine months ended September 30, 2021 were $68.9 million and $196.7 million, respectively, as compared to $62.4 million and $172.1 million in the three and nine months ended September 30, 2020, respectively.

VIVITROL product sales, gross, increased by 10% and 14% in the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020, primarily due to increases of 7% and 9%, respectively, in the number of VIVITROL units sold due, in part, to an improvement in the COVID-19-related disruptions that began in the second quarter of 2020. In addition, there was 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 13% and 18% in the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020, primarily due to increases of 10% and 13%, respectively, 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.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned in the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2021	2020	Change	2021	2020	Change
Manufacturing and royalty revenues:						
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 79.4	$ 73.4	$ 6.0	$ 222.0	$ 197.7	$ 24.3
VUMERITY	26.7	2.7	24.0	60.5	7.0	53.5
RISPERDAL CONSTA	11.0	14.5	(3.5)	39.6	55.5	(15.9)
AMPYRA/FAMPYRA	7.5	12.3	(4.8)	35.5	39.8	(4.3)
Other	11.7	17.5	(5.8)	40.8	53.1	(12.3)
Manufacturing and royalty revenues	$ 136.3	$ 120.4	$ 15.9	$ 398.4	$ 353.1	$ 45.3

We earn tiered royalty payments for INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, which consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the royalty-bearing patents with valid claims applicable to the product in such country. The know-how royalty is a tiered royalty of

3.5% on calendar year net sales up to $250 million; 5.5% on calendar year net sales of between $250 million and $500 million; and 7.5% on calendar year net sales exceeding $500 million. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until 15 years from the first commercial sale of a product in each individual country, subject to the expiry of the license agreement.

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, was primarily due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. During the three and nine months ended September 30, 2021, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $1,004.0 million and $2,994.0 million, respectively, as compared to $926.0 million and $2,688.0 million, respectively, during the three and nine months ended September 30, 2020.

We recognize manufacturing revenue for RISPERDAL CONSTA at the point in time when RISPERDAL CONSTA has been fully manufactured, which is deemed to have occurred when the product is approved for shipment by both us and Janssen. We record royalty revenue, equal to 2.5% of Janssen's end-market net sales, in the period that the end-market sale of RISPERDAL CONSTA occurs. The decrease in revenue from RISPERDAL CONSTA in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, was due to decreases of $2.3 million and $13.4 million, respectively, in manufacturing revenue and decreases of $1.3 million and $2.6 million, respectively, in royalty revenue. The decreases in manufacturing revenue during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to decreases of 8% and 39%, respectively, in the amount of RISPERDAL CONSTA manufactured for Janssen. This was partially offset by an increase in our manufacturing fee from 7.5% to 8.6% pursuant to the terms of our manufacturing and supply agreement with Janssen due to a decrease in forecasted manufacturing units. The decreases in royalty revenue during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were due to decreases in end-market sales of RISPERDAL CONSTA, which were $140.0 million and $452.0 million during the three and nine months ended September 30, 2021, respectively, as compared to $152.0 million and $475.0 million during the three and nine months ended September 30, 2020, respectively.

We expect revenues from our long-acting, atypical franchise to decrease over time. While we expect continued growth from sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA in the near term, we are aware of potential generic competition for RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure in 2021. We are also aware of generic challenges to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. For a discussion of legal proceedings related to RISPERDAL CONSTA, INVEGA SUSTENNA and INVEGA TRINZA, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q. In addition, a number of companies are working to develop new products to treat schizophrenia and/or bipolar disorder that may compete with INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA. Increased competition from new products or generic versions of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA or RISPERDAL CONSTA may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, and increased pricing pressure.

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 increases in revenue from VUMERITY in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were due to increases of $16.1 million and $39.1 million, respectively, in royalty revenue and increases of $8.0 million and $14.5 million, respectively, in manufacturing revenue. The increases in royalty revenue were due to increases in net sales of VUMERITY, which were $120.9 million and $285.0 million during the three and nine months ended September 30, 2021, respectively, as compared to $14.3 million and $25.3 million during the three and nine months ended September 30, 2020, respectively. The increases in manufacturing revenue during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily the result of increased manufacturing activity to satisfy increased demand for the product. For a discussion of legal proceedings related to VUMERITY, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Cost of goods manufactured and sold	$ 49.6	$ 43.1	$ 6.5	$ 143.7	$ 135.4	$ 8.3

The increases in cost of goods manufactured and sold in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to increases of $6.0 million and $11.8 million, respectively, in the cost of goods manufactured for VUMERITY and increases of $4.8 million and $5.0 million, respectively, in the cost of goods sold for VIVITROL, related to an increase in the number of units manufactured for VUMERITY and the number of units sold for VIVITROL, as discussed above. These increases were partially offset by decreases in the three and nine months ended, September 30, 2021 of $1.8 million and $4.3 million, respectively, in the cost of goods manufactured for RISPERDAL CONSTA, related to decreases in the number of units manufactured for RISPERDAL CONSTA, as discussed above.

Research and Development Expense

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

The following table sets forth our external R&D expenses for the three and nine months ended September 30, 2021 and 2020 relating to our then current key development programs and all other development programs, and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
External R&D expenses:						
Development programs:						
nemvaleukin	$ 19.8	$ 16.9	$ 2.9	$ 61.1	$ 46.6	$ 14.5
LYBALVI	6.8	7.5	(0.7)	21.3	20.3	1.0
ALKS 1140	25.5	0.3	25.2	27.7	1.1	26.6
Other external R&D expenses	15.2	17.2	(2.0)	43.4	53.6	(10.2)
Total external R&D expenses	67.3	41.9	25.4	153.5	121.6	31.9
Internal R&D expenses:						
Employee-related	37.9	39.5	(1.6)	114.7	120.2	(5.5)
Occupancy	4.9	5.8	(0.9)	14.7	15.8	(1.1)
Depreciation	2.9	4.1	(1.2)	9.2	11.5	(2.3)
Other	5.4	3.7	1.7	16.1	13.4	2.7
Total internal R&D expenses	51.1	53.1	(2.0)	154.7	160.9	(6.2)
Research and development expenses	$ 118.4	$ 95.0	$ 23.4	$ 308.2	$ 282.5	$ 25.7

These amounts are not necessarily predictive of future R&D expenses. In an effort to allocate our spending most effectively, we continually evaluate our products under development, based on the performance of such products in pre-clinical and/or clinical trials, our expectations regarding the likelihood of their regulatory approval and our view of their commercial viability, among other factors.

The increases in expenses related to nemvaleukin in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to the advancement of the ARTISTRY development program for the product, including increased patient enrollment in ongoing clinical studies and initiation of the ARTISTRY-6 study. For additional details on the status of 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 increases in expenses related to ALKS 1140, our novel CoREST-selective HDAC inhibitor candidate for the treatment of neurodegenerative and neurodevelopmental disorders, in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to the accrual in the three months ended September 30, 2021 of a $25.0 million development milestone to be paid to the former shareholders of Rodin Therapeutics, Inc. related to the submission of an investigational new drug application or equivalent for ALKS 1140 as we determined this milestone was probable of achievement. The amount is expected to be paid in the fourth quarter of 2021.

The decreases in employee-related expenses in the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020, were primarily due to a $2.3 million and $4.9 million decrease in labor and benefits, respectively, resulting from a 13.5% reduction in R&D headcount from September 30, 2020 to September 30, 2021.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Selling and marketing expense	$ 88.0	$ 79.0	$ 9.0	$ 253.4	$ 249.7	$ 3.7
General and administrative expense	48.2	48.6	(0.4)	147.2	143.3	3.9
Selling, general and administrative expense	$ 136.2	$ 127.6	$ 8.6	$ 400.6	$ 393.0	$ 7.6

The increase in selling and marketing expense in the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to a $7.1 million increase in marketing expense and a $1.5 million increase in professional service fees. The increases in marketing expense and professional service fees were primarily related to pre-launch commercial activities for LYBALVI.

The increase in selling and marketing expense during the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to a $4.1 million increase in professional service fees and a $3.4 million increase in marketing expenses, partially offset by a $5.0 million decrease in employee-related expenses. The increases in marketing expense and professional service fees were primarily related to pre-launch commercial activities for LYBALVI. The decrease in employee-related expenses was primarily due to a decrease in salary expense resulting from a 1.5% reduction in selling and marketing headcount from September 30, 2020 to September 30, 2021.

The increases in general and administrative expense during the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to a $5.0 million increase in professional service fees and a $2.5 million increase in employee-related expenses, partially offset by a $1.9 million decrease in the timing of spend related to new product planning. The increase in professional service fees was primarily related to increased spend on legal fees. The increase in employee-related expense was primarily related to a $2.0 million increase in general and administrative-related share-based compensation expense.

Amortization of Acquired Intangible Assets

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Amortization of acquired intangible assets	$ 9.6	$ 9.9	$ (0.3)	$ 28.5	$ 29.5	$ (1.0)

We amortize our amortizable intangible assets using the economic-use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based on our most recent analysis, amortization of intangible assets included within our condensed consolidated balance sheet at September 30, 2021 is expected to be approximately $40.0 million, $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2021 through 2024, respectively.

Other (Expense) Income, Net

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Interest income	$ 0.5	$ 1.4	$ (0.9)	$ 2.0	$ 5.9	$ (3.9)
Interest expense	(2.4)	(1.8)	(0.6)	(8.8)	(6.8)	(2.0)
Change in the fair value of contingent consideration	(5.2)	3.9	(9.1)	(0.7)	16.6	(17.3)
Other income (expense), net	0.2	9.4	(9.2)	(0.4)	11.1	(11.5)
Total other (expense) income, net	$ (6.9)	$ 12.9	$ (19.8)	$ (7.9)	$ 26.8	$ (34.7)

The decreases in interest income during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to a decrease in interest rates. Interest income consists of interest earned on our available-for-sale investments.

The increases in interest expense during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were due to the Term Loan Refinancing completed in March 2021. The Term Loan Refinancing is discussed in greater detail in Note 11, *Long-Term Debt* in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

The changes in the fair value of contingent consideration in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to an increase in the risk of non-payment. In Baudax’s Quarterly Report on Form 10-Q for the period ended June 30, 2021, Baudax included disclosures regarding its ability to continue as a going concern. As a result of this disclosure, we updated the model used to determine the fair value of the contingent consideration. The valuation approach used to determine the fair value of the contingent consideration is discussed in greater detail in Note 5, *Fair Value*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

The decreases in other income (expense), net in the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, were primarily due to the receipt of $11.1 million, of which $10.4 million was received in September 2020, representing our proportional share of the proceeds from the sale of two companies within the Fountain portfolio. The transactions were accounted for under the cumulative earnings approach whereby the return on investment of $8.3 million was recorded as a gain within “Other (expense) income, net” in the accompanying condensed consolidated statements of operations and comprehensive loss and the return of investment of $2.8 million was recorded as a reduction in the our net investment in Fountain. Our investment in Fountain is discussed in greater detail in Note 4, *Investments*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Income Tax Provision

(In millions)	Three Months Ended September 30, 2021	2020	Change	Nine Months Ended September 30, 2021	2020	Change
Income tax provision	2.5	2.3	$ 0.2	$ 9.5	$ 13.3	$ (3.8)

The income tax provision in the three months ended September 30, 2021 and 2020 primarily related to U.S. federal and state taxes. The unfavorable change in the income tax provision in the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, was primarily due to an increase in income taxes for income earned in the U.S.

The income tax provision in the nine months ended September 30, 2021 primarily related to a $3.9 million tax expense on income earned in the U.S. and a $6.8 million discrete tax expense related to employee equity activity during the period. The income tax provision in the nine months ended September 30, 2020 primarily related to a $5.1 million tax expense on income earned in the U.S. and an $8.0 million discrete tax expense related to employee equity activity during the period.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	September 30, 2021			December 31, 2020		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 91.9	$ 218.5	$ 310.4	$ 152.8	$ 120.2	$ 273.0
Investments—short-term	200.0	49.9	249.9	293.5	68.5	362.0
Investments—long-term	132.5	55.4	187.9	23.2	1.6	24.8
Total cash and investments	$ 424.4	$ 323.8	$ 748.2	$ 469.5	$ 190.3	$ 659.8
Outstanding borrowings—short and long-term	$ 296.4	$ —	$ 296.4	$ 275.0	$ —	$ 275.0

At September 30, 2021 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	$ 249.3	$ 0.6	$ —	$ —	$ 249.9
Investments—long-term available-for-sale	186.2	—	(0.2)	—	186.0
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 437.3	$ 0.6	$ (0.2)	$ —	$ 437.7

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 12 months as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2021, we performed an analysis of our investments with unrealized losses for impairment and determined that the loss on one of our corporate debt securities was other-than-temporary and, during the nine months ended September 30, 2021, recorded a $0.9 million impairment charge within “Other (expense) income, net” in the accompanying condensed consolidated statements of operations and comprehensive loss.

Sources and Uses of Cash

We expect that our existing cash and investments balance will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments, for at least 12 months following the date on which this Form 10-Q is filed. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, debt refinancings, arrangements relating to assets or other financing methods or structures. We are closely monitoring ongoing developments in connection with the COVID-19 pandemic that may have an adverse impact on our commercial prospects and projected cash position.

Information about our cash flows, by category, is presented in "Part I, Item 1—Condensed Consolidated Financial Statements of Cash Flows" in this Form 10-Q. The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
(In millions)	**2021**	**2020**
Cash and cash equivalents, beginning of period	$ 273.0	$ 203.8
Cash flows provided by operating activities	70.7	15.5
Cash flows (used in) provided by investing activities	(65.5)	23.6
Cash flows provided by (used in) financing activities	32.2	(2.0)
Cash and cash equivalents, end of period	$ 310.4	$ 240.9

The increase in cash flows provided by operating activities in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, is primarily due to a decrease in our net loss, net of adjustments to reconcile net loss to cash flows from operating activities and a decrease in cash used for working capital, primarily due to decreases in cash flows used for accounts payable and accrued expenses, contract assets and inventory, partially offset by increases in cash flows used for receivables and prepaid expenses and other assets.

The change in cash flows from investing activities in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to a $108.1 million increase in net purchase of investments, partially offset by a $17.4 million decrease in cash paid for property, plant and equipment and a $5.1 million increase in payments received in connection with the contingent consideration resulting from the Gainesville Transaction.

The change in cash flows from financing activities in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, was primarily due to $23.6 million in proceeds from the Term Loan Refinancing and an $11.1 million increase in the amount of cash we received upon exercises of employee stock options, net of employee taxes.

Borrowings

At September 30, 2021, the principal balance of our borrowings consisted of $298.5 million outstanding under our 2026 Term Loans. See Note 11, *Long-Term Debt*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for further discussion of our 2026 Term Loans.

Contractual Obligations

See the "Contractual Obligations" section in "Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report for a discussion of our contractual obligations.

Off-Balance Sheet Arrangements

At September 30, 2021, we were not party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different 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.

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, 2020, 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, 2020.

Item 4. *Controls and Procedures*

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2021. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that our disclosure controls and procedures were effective as of September 30, 2021 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 14, *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 nine months ended September 30, 2021. As of September 30, 2021, we had purchased a total of 8,866,342 shares under this program at an aggregate cost of $114.0 million.

During the three months ended September 30, 2021, we acquired 83,317 of our ordinary shares, at an average price of $30.17 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 September 30, 2021, Mr. Blair C. Jackson, an executive officer 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: October 27, 2021

Exhibit 31.1

CERTIFICATIONS

I, Richard F. Pops, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 27, 2021

/s/ Richard F. Pops

Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Iain M. Brown, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 27, 2021

/s/ Iain M. Brown

Iain M. Brown

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Alkermes plc (the "Company") for the period ended September 30, 2021 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: October 27, 2021

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: October 27, 2021

/s/ Iain M. Brown
Iain M. Brown

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