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, 2025

OR

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

Commission File Number 001-35299



ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

The number of the registrant's ordinary shares, $0.01 par value, outstanding as of October 24, 2025 was 165,117,509 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2025

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Cautionary Note Concerning Forward-Looking Statements

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

- our expectations regarding our financial performance, including revenues, expenses, liquidity, capital expenditures, income taxes and profitability;
- 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 timing, design 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 acquisitions, collaborations, licensing arrangements and other significant agreements with third parties, including those related to our products, development programs, and other business development opportunities;
- our expectations regarding the impacts of new legislation, rules and regulations, the adoption of new accounting pronouncements, government shutdowns, or other global, political or economic changes, instability or disruptions;
- our expectations regarding near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures;
- our expectations regarding 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, know-how, and related rights or obligations;
- our expectations regarding the Proposed Acquisition (as defined below) and the terms, structure and timing for expected completion of the Proposed Acquisition;
- our expectations regarding the tax treatment and other anticipated benefits of the completed separation of our oncology business; and
- other expectations discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. In light of these risks, assumptions and uncertainties, the forward-looking expectations discussed in this Form 10-Q might not occur. You are cautioned not to place undue reliance on the forward-looking statements in this Form 10-Q, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. For information about the risks, assumptions and uncertainties of our business, see "Part I, Item 1A—Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the United States ("U.S.") Securities and Exchange Commission (the "SEC") on February 12, 2025 (our "Annual Report") and "Part II, Item 1A—Risk Factors" in this Form 10-Q.

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

Note Regarding Company and Product References

Alkermes plc is a global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. We have a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy and idiopathic hypersomnia. Use of terms such as "us," "we," "our," "Alkermes" or the "Company" in this Form 10-Q is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Form 10-Q include our marketed products, marketed products using our proprietary technologies, our licensed products, our product candidates and product candidates using our proprietary technologies, (b) references to the "biopharmaceutical industry" in this Form 10-Q are intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references to "licensees" in this Form 10-Q are used interchangeably with references to "partners."

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations ("®") and other trademarks ("™"), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, LinkeRx®, LYBALVI®, NanoCrystal® and VIVITROL®.

The following are trademarks of the respective companies listed: BYANNLI®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, RISPERDAL CONSTA®, TREVICTA®, and XEPLION®—Johnson & Johnson or its affiliated companies; FAMPYRA™—Merz Pharmaceuticals, LLC; and VUMERITY®—Biogen MA Inc. (together with its affiliates, "Biogen"). Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q may be referred to without the ® or ™ symbol, 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, 2025	December 31, 2024
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 616,449	$ 291,146
Investments—short-term	494,665	460,522
Receivables, net	354,394	384,528
Inventory	190,997	182,887
Prepaid expenses and other current assets	84,442	91,282
Contract assets	717	4,990
Total current assets	1,741,664	1,415,355
PROPERTY, PLANT AND EQUIPMENT, NET	246,982	227,564
INVESTMENTS—LONG-TERM	27,869	73,148
RIGHT-OF-USE ASSETS	79,128	84,245
INTANGIBLE ASSETS, NET AND GOODWILL	83,861	83,917
DEFERRED TAX ASSETS	130,344	154,835
OTHER ASSETS	19,664	16,503
TOTAL ASSETS	$ 2,329,512	$ 2,055,567
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 214,985	$ 185,332
Accrued sales discounts, allowances and reserves	252,743	272,452
Operating lease liabilities—short-term	6,632	6,166
Contract liabilities—short-term	—	1,249
Total current liabilities	474,360	465,199
OPERATING LEASE LIABILITIES—LONG-TERM	64,966	69,372
OTHER LONG-TERM LIABILITIES	56,754	56,019
Total liabilities	596,080	590,590
COMMITMENTS AND CONTINGENT LIABILITIES (Note 16)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; and zero issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 180,499,470 and 176,670,785 shares issued; and 165,103,891 and 162,176,994 shares outstanding at September 30, 2025 and December 31, 2024, respectively	1,805	1,767
Treasury shares, at cost (15,395,579 and 14,493,791 shares at September 30, 2025 and December 31, 2024, respectively)	(450,021)	(419,255)
Additional paid-in capital	2,966,842	2,860,890
Accumulated other comprehensive loss	(1,059)	(1,967)
Accumulated deficit	(784,135)	(976,458)
Total shareholders' equity	1,733,432	1,464,977
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 2,329,512	$ 2,055,567

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	$ 317,423	$ 272,999	$ 869,151	$ 775,808
Manufacturing and royalty revenues	76,762	105,144	222,201	351,835
Research and development revenue	—	—	—	3
Total revenues	394,185	378,143	1,091,352	1,127,646
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	51,591	63,099	150,248	183,215
Research and development	81,739	59,892	230,926	187,152
Selling, general and administrative	171,773	150,382	514,326	498,244
Amortization of acquired intangible assets	—	14	—	1,087
Total expenses	305,103	273,387	895,500	869,698
OPERATING INCOME FROM CONTINUING OPERATIONS	89,082	104,756	195,852	257,948
OTHER INCOME, NET:				
Interest income	11,943	10,916	33,174	31,050
Interest expense	—	(6,000)	—	(17,930)
Other (expense) income, net	(280)	558	2,047	2,793
Total other income, net	11,663	5,474	35,221	15,913
INCOME BEFORE INCOME TAXES	100,745	110,230	231,073	273,861
INCOME TAX PROVISION	17,984	17,435	38,750	47,460
NET INCOME FROM CONTINUING OPERATIONS	82,761	92,795	192,323	226,401
LOSS FROM DISCONTINUED OPERATIONS, NET OF TAX	—	(414)	—	(5,834)
NET INCOME	$ 82,761	$ 92,381	$ 192,323	$ 220,567
EARNINGS PER ORDINARY SHARE:				
Earnings per ordinary share from continuing operations - basic	$ 0.50	$ 0.57	$ 1.17	$ 1.36
Loss per ordinary share from discontinued operations - basic	$ —	$ —	$ —	$ (0.04)
Earnings per ordinary share - basic	$ 0.50	$ 0.57	$ 1.17	$ 1.32
Earnings per ordinary share from continuing operations - diluted	$ 0.49	$ 0.56	$ 1.14	$ 1.33
Loss per ordinary share from discontinued operations - diluted	$ —	$ —	$ —	$ (0.03)
Earnings per ordinary share - diluted	$ 0.49	$ 0.55	$ 1.14	$ 1.30
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	165,086	163,368	164,490	166,546
Diluted	168,510	167,025	168,445	170,196
COMPREHENSIVE INCOME:				
Net income	$ 82,761	$ 92,381	$ 192,323	$ 220,567
Holding gain, net of a tax provision of $108, $376, $293 and $293, respectively	341	4,015	908	3,535
COMPREHENSIVE INCOME	$ 83,102	$ 96,396	$ 193,231	$ 224,102

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,	
	2025	2024
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 192,323	$ 220,567
Adjustments to reconcile net income to cash flows from operating activities:		
Depreciation and amortization	23,319	21,686
Share-based compensation expense	72,441	75,889
Deferred income taxes	30,494	32,313
Gain on sale of the Athlone Facility	—	(1,462)
Other non-cash charges	4,396	4,794
Changes in assets and liabilities:		
Receivables	30,134	(34,734)
Contract assets	4,273	(2,263)
Inventory	(9,198)	(6,051)
Prepaid expenses and other assets	(2,984)	1,892
Right-of-use assets	5,628	5,384
Accounts payable and accrued expenses	27,864	(82,978)
Accrued sales discounts, allowances and reserves	(19,709)	18,377
Contract liabilities	(1,249)	(2,435)
Operating lease liabilities	(7,733)	(7,594)
Other long-term liabilities	686	5,342
Cash flows provided by operating activities	350,685	248,727
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(40,440)	(23,711)
Proceeds from the sale of property, plant and equipment	34	454
Proceeds from the sale of the Athlone Facility	1,708	97,933
Purchases of investments	(308,534)	(396,895)
Sales and maturities of investments	320,383	224,786
Cash flows used in investing activities	(26,849)	(97,433)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	32,233	19,354
Employee taxes paid related to net share settlement of equity awards	(30,766)	(29,293)
Payment for the repurchase of ordinary shares	—	(200,281)
Principal payments of long-term debt	—	(2,250)
Cash flows provided by (used in) financing activities	1,467	(212,470)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	325,303	(61,176)
CASH AND CASH EQUIVALENTS—Beginning of period	291,146	457,469
CASH AND CASH EQUIVALENTS—End of period	$ 616,449	$ 396,293
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Cash paid for taxes	$ 3,108	$ 1,930
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 5,263	$ 3,053

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) Income	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
				(In thousands, except share data)				
BALANCE — December 31, 2024	176,670,785	$ 1,767	$ 2,860,890	$ (1,967)	$ (976,458)	(14,493,791)	$ (419,255)	$ 1,464,977
Issuance of ordinary shares under employee stock plans	3,510,611	35	29,493	—	—	—	—	29,528
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(834,590)	(28,781)	(28,781)
Share-based compensation	—	—	22,883	—	—	—	—	22,883
Unrealized gain on marketable securities, net of tax provision of $168	—	—	—	512	—	—	—	512
Net income	—	—	—	—	22,464	—	—	22,464
BALANCE — March 31, 2025	180,181,396	$ 1,802	$ 2,913,266	$ (1,455)	$ (953,994)	(15,328,381)	$ (448,036)	$ 1,511,583
Issuance of ordinary shares under employee stock plans	258,354	3	2,080	—	—	—	—	2,083
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(56,457)	(1,678)	(1,678)
Share-based compensation	—	—	25,443	—	—	—	—	25,443
Unrealized gain on marketable securities, net of tax provision of $16	—	—	—	55	—	—	—	55
Net income	—	—	—	—	87,098	—	—	87,098
BALANCE — June 30, 2025	180,439,750	$ 1,805	$ 2,940,789	$ (1,400)	$ (866,896)	(15,384,838)	$ (449,714)	$ 1,624,584
Issuance of ordinary shares under employee stock plans	59,720	—	622	—	—	—	—	622
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(10,741)	(307)	(307)
Share-based compensation	—	—	25,431	—	—	—	—	25,431
Unrealized gain on marketable securities, net of tax provision of $108	—	—	—	341	—	—	—	341
Net income	—	—	—	—	82,761	—	—	82,761
BALANCE — September 30, 2025	180,499,470	$ 1,805	$ 2,966,842	$ (1,059)	$ (784,135)	(15,395,579)	$ (450,021)	$ 1,733,432

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

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
	(In thousands, except share data)							
BALANCE — December 31, 2023	172,569,051	$ 1,726	$ 2,736,934	$ (3,110)	$ (1,343,528)	(5,589,218)	$ (189,336)	$ 1,202,686
Issuance of ordinary shares under employee stock plans	3,165,169	31	11,195	—	—	—	—	11,226
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(960,486)	(28,349)	(28,349)
Share-based compensation	—	—	32,863	—	—	—	—	32,863
Unrealized loss on marketable securities, net of tax benefit of $75	—	—	—	(491)	—	—	—	(491)
Net income	—	—	—	—	36,828	—	—	36,828
BALANCE — March 31, 2024	175,734,220	$ 1,757	$ 2,780,992	$ (3,601)	$ (1,306,700)	(6,549,704)	$ (217,685)	$ 1,254,763
Issuance of ordinary shares under employee stock plans	225,052	3	2,604	—	—	—	—	2,607
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(26,692)	(651)	(651)
Repurchase of Alkermes' ordinary shares	—	—	—	—	—	(3,496,187)	(84,689)	(84,689)
Share-based compensation	—	—	20,606	—	—	—	—	20,606
Unrealized gain on marketable securities, net of tax benefit of $8	—	—	—	11	—	—	—	11
Net income	—	—	—	—	91,358	—	—	91,358
BALANCE — June 30, 2024	175,959,272	$ 1,760	$ 2,804,202	$ (3,590)	$ (1,215,342)	(10,072,583)	$ (303,025)	$ 1,284,005
Issuance of ordinary shares under employee stock plans	298,898	3	5,518	—	—	—	—	5,521
Receipt of Alkermes' ordinary shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(11,152)	(293)	(293)
Repurchase of Alkermes' ordinary shares	—	—	—	—	—	(4,398,230)	(115,593)	(115,593)
Share-based compensation	—	—	22,070	—	—	—	—	22,070
Unrealized gain on marketable securities, net of tax provision of $376	—	—	—	4,015	—	—	—	4,015
Net income	—	—	—	—	92,381	—	—	92,381
BALANCE — September 30, 2024	176,258,170	$ 1,763	$ 2,831,790	$ 425	$ (1,122,961)	(14,481,965)	$ (418,911)	$ 1,292,106

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

1. THE COMPANY

Alkermes plc is a global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. Alkermes has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy and idiopathic hypersomnia. Headquartered in Ireland, Alkermes also has a corporate office and research and development ("R&D") center in Massachusetts and a manufacturing facility in Ohio.

In May 2024, the Company completed the sale of its research and development business and manufacturing facility in Athlone, Ireland (the "Athlone Facility") to Novo Nordisk ("Novo"). The Company and Novo also entered into subcontracting arrangements to continue certain development and manufacturing activities performed at the Athlone Facility for a period of time after the closing of the transaction, which activities may continue through the end of 2025. In connection with the sale of the Athlone Facility, the Company received approximately $97.9 million from Novo, which included a payment of approximately $91.0 million for the facility and certain related assets, and recorded a gain of approximately $1.5 million within "Other (expense) income, net" in the accompanying condensed consolidated statements of income and comprehensive income for the nine months ended September 30, 2024.

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, 2025 and 2024 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2024. The year-end consolidated balance sheet data, which is presented for comparative purposes, was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. (commonly referred to as "GAAP"). In the opinion of management, the condensed consolidated financial statements include all adjustments of a normal recurring nature that are necessary to state fairly the results of operations for the reported periods.

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

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries as disclosed in Note 2, *Summary of Significant Accounting Policies* in the "Notes to Consolidated Financial Statements" accompanying the Annual Report. Intercompany accounts and transactions have been eliminated. Columns and rows within tables may not sum due to rounding.

Discontinued Operations

The Company determined that the separation of its former oncology business into Mural Oncology plc ("Mural"), a new, independent, publicly-traded company (the "Separation"), completed in November 2023, met the criteria for classification of the oncology business as discontinued operations in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 205, *Discontinued Operations* ("Topic 205").

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires that Company management make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies, including, but not limited to, those related to revenue from contracts with its customers and related allowances, impairment of long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different conditions or using different assumptions.

Segment Information

Operating segments are defined as components of an enterprise engaging in business activities for which separate financial information is available and regularly reviewed by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company has utilized the management approach to determine that the Company is managed as one segment on a consolidated basis and is in the business of developing, manufacturing and commercializing medicines designed to help people living with complex and difficult-to-treat psychiatric and neurological disorders. The Company's CODM, the Chairman and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit. The Company's CODM measures profitability on a reportable segment basis using net income and utilizes this information in allocating resources and in assessing performance by monitoring budget versus actual results. Please refer to Note 15, *Segment Reporting*, in these "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for further information.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies that are adopted by the Company on or prior to the specified effective date. Unless otherwise described in this Form 10-Q, 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 December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures,* to enhance the transparency and decision usefulness of income tax disclosures in order to provide information to assist key stakeholders in better assessing how the Company's operations and related tax risks and tax planning and operational opportunities affect the Company's tax rate and prospects for future cash flows. This ASU becomes effective for public companies for annual periods beginning after December 15, 2024. This guidance will be applied on a prospective basis. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement - *Reporting Comprehensive Income-Expense Disaggregation Disclosures*, to improve disclosures about public business entity expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization and depletion) in commonly-presented expense captions, such as cost of sales, selling, general and administrative expenses, and research and development. All disclosure requirements under this guidance are required for public business entities and will be effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted and the amendments in this guidance will be applied prospectively to financial statements for periods after the effective dates. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Targeted Improvements to the Accounting for Internal-Use Software.* This ASU updates the requirements for capitalization of internal-use software, removing all reference to prescriptive and sequential software development stages (referred to as "project stages"). This ASU is effective for annual periods beginning after December 15, 2027, and for interim periods within those fiscal years. The Company is currently assessing the impact this ASU will have on its consolidated financial statements and related disclosures.

3. DISCONTINUED OPERATIONS

Mural Oncology Separation

In connection with the Separation, the Company and Mural entered into, among other agreements: a separation agreement; a tax matters agreement; and an employee matters agreement, which are described in Note 3, *Discontinued Operations* in the "Notes to Consolidated Financial Statements" accompanying the Annual Report.

Discontinued Operations

The Company determined that the Separation met the criteria for classification of its former oncology business as discontinued operations in accordance with Topic 205. During the three and nine months ended September 30, 2025, the Company recorded no losses from discontinued operations. The following summarizes the losses from discontinued operations for the three and nine months ended September 30, 2024:

(In thousands)	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024
Operating expenses from discontinued operations		
Cost of goods manufactured	$ —	$ —
Research and development	481	6,910
Selling, general and administrative	—	—
Total operating expenses from discontinued operations	481	6,910
Operating loss from discontinued operations	(481)	(6,910)
Income tax benefit from discontinued operations	(67)	(1,076)
Net loss and comprehensive loss from discontinued operations	$ (414)	$ (5,834)

4. REVENUE FROM CONTRACTS WITH CUSTOMERS

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed in accordance with FASB ASC 606, *Revenue from Contracts with Customers*, or Topic 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations.

Product Sales, Net

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

During the three and nine months ended September 30, 2025 and 2024, the Company recorded product sales, net, as follows:

(In thousands)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
VIVITROL	$ 121,125	$ 113,650	$ 343,781	$ 323,182
ARISTADA and ARISTADA INITIO	98,050	84,652	272,820	249,571
LYBALVI	98,248	74,697	252,550	203,055
Total product sales, net	$ 317,423	$ 272,999	$ 869,151	$ 775,808

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers, healthcare providers or payers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from historical practices. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. See the "Revenue from Contracts with Customers" section in Note 2, *Summary of Significant Accounting Policies* in the "Notes to Consolidated Financial Statements" in the Annual Report for information with respect to the Company's significant categories of sales discounts and allowances.

Actual Medicaid rebates related to VIVITROL and ARISTADA/ARISTADA INITIO during the nine months ended September 30, 2025 were lower than original estimates, and as a result the Company reduced its rebate reserve for each product by approximately $25.3 million and $12.1 million, respectively, during the period.

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

	Nine Months Ended September 30, 2025				
(In thousands)	Contractual Adjustments[1]	Discounts[2]	Product Returns	Other	Total
Beginning balance — December 31, 2024	$ 228,978	$ 43,645	$ 50,507	$ 13,297	$ 336,427
Current provisions relating to sales in current year	404,353	312,419	19,841	67,803	804,416
Adjustments relating to prior years	(34,939)	156	(7,302)	(373)	(42,458)
Payments relating to sales in current year	(260,213)	(293,195)	—	(55,560)	(608,968)
Payments relating to sales in prior years	(127,928)	(23,940)	(9,569)	(12,512)	(173,949)
Ending balance — September 30, 2025	$ 210,251	$ 39,085	$ 53,477	$ 12,655	$ 315,468

1. "Contractual Adjustments" include "Medicaid Rebates" and "Medicare Part D" accruals.
2. "Discounts" include "Chargebacks" and "Product Discounts."

Total revenue-related reserves as of September 30, 2025 and December 31, 2024 included in the accompanying consolidated balance sheets are summarized as follows:

(In thousands)	September 30, 2025	December 31, 2024
Reduction of accounts receivable	$ 19,249	$ 22,031
Components of accrued sales discounts, allowances and reserves	252,743	272,452
Components of other long-term liabilities	43,476	41,944
Total revenue-related reserves	$ 315,468	$ 336,427

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2025 and 2024, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

	Three Months Ended September 30, 2025			Nine Months Ended September 30, 2025		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products[1]	$ —	$ 30,180	$ 30,180	$ —	$ 78,240	$ 78,240
VUMERITY	3,494	32,122	35,616	16,852	85,996	102,848
RISPERDAL CONSTA	3,732	19	3,751	16,659	41	16,700
Other	1,562	5,653	7,215	9,171	15,242	24,413
	$ 8,788	$ 67,974	$ 76,762	$ 42,682	$ 179,519	$ 222,201

(In thousands)	Three Months Ended September 30, 2024			Nine Months Ended September 30, 2024		
	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products[1]	$ —	$ 58,448	$ 58,448	$ —	$ 199,860	$ 199,860
VUMERITY	8,753	23,821	32,574	30,740	68,322	99,062
RISPERDAL CONSTA	2,417	11	2,428	8,440	264	8,704
Other	4,777	6,917	11,694	27,077	17,132	44,209
	$ 15,947	$ 89,197	$ 105,144	$ 66,257	$ 285,578	$ 351,835

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

In August 2024, the Company's royalty on U.S. net sales of INVEGA SUSTENNA expired. Accordingly, royalty revenues from net sales of the long-acting INVEGA products have been, and the Company expects will continue to be, lower in 2025, as the royalty revenues related to U.S. net sales of INVEGA SUSTENNA comprised a significant portion of the overall royalty revenues from the long-acting INVEGA products.

Contract Assets

Contract assets include unbilled amounts related to the manufacture of a product that, once complete, will be sold under certain of the Company's manufacturing contracts. The amounts included in the contract assets table below are classified as "Current assets" in the accompanying condensed consolidated balance sheets, as they relate to manufacturing processes that are completed in ten days to eight weeks.

Total contract assets at September 30, 2025 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2024	$ 4,990
Additions	4,483
Transferred to receivables, net	(8,756)
Contract assets at September 30, 2025	$ 717

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue. At September 30, 2025 and December 31, 2024, none and $1.2 million of the contract liabilities, respectively, were classified as "Contract liabilities–short-term" in the accompanying condensed consolidated balance sheets and none of the contract liabilities in either period were classified as "Other long-term liabilities" in the accompanying condensed consolidated balance sheets.

Total contract liabilities at September 30, 2025 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2024	$ 1,249
Additions	1,313
Amounts recognized into revenue	(2,562)
Contract liabilities at September 30, 2025	$ —

5. INVESTMENTS

Investments consist of the following (in thousands):

September 30, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses: Less than One Year	Gross Unrealized Losses: Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	$ 273,690	$ 1,032	$ (3)	$ (6)	$ 274,713
Corporate debt securities	218,685	1,268	—	(1)	219,952
Total short-term investments	492,375	2,300	(3)	(7)	494,665
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	10,062	—	(4)	(6)	10,052
Corporate debt securities	17,690	—	(5)	(13)	17,672
	27,752	—	(9)	(19)	27,724
Held-to-maturity securities:					
Certificates of deposit	145	—	—	—	145
Total long-term investments	27,897	—	(9)	(19)	27,869
Total investments	$ 520,272	$ 2,300	$ (12)	$ (26)	$ 522,534

December 31, 2024					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	$ 266,506	$ 763	$ (58)	$ (6)	$ 267,205
Corporate debt securities	192,617	762	(58)	(4)	193,317
Total short-term investments	459,123	1,525	(116)	(10)	460,522
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	48,856	—	—	(179)	48,677
Corporate debt securities	24,484	—	—	(158)	24,326
	73,340	—	—	(337)	73,003
Held-to-maturity securities:					
Certificates of deposit	145	—	—	—	145
Total long-term investments	73,485	—	—	(337)	73,148
Total investments	$ 532,608	$ 1,525	$ (116)	$ (347)	$ 533,670

At September 30, 2025, the Company's investments in corporate debt securities had a minimum rating of A2 (Moody's)/A (Standard and Poor's), and 26 of the Company's 322 investment securities were in an unrealized loss position with an aggregate estimated fair value of $45.0 million. The primary reason these securities were in an unrealized loss position is that they are fixed-rate securities that were acquired in a rising interest rate environment. In making the determination whether the decline in fair value of these securities was temporary, the Company evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis. The Company has the intent and ability to hold these investments until recovery, which may be at maturity.

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

(In thousands)	Nine Months Ended September 30, 2025	2024
Proceeds from the sales and maturities of investments	$ 320,383	$ 224,786
Realized gains	$ 4	$ —
Realized losses	$ —	$ —

The Company's available-for-sale and held-to-maturity securities at September 30, 2025 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	$ 247,712	$ 248,291	$ 145	$ 145
After 1 year through 5 years	272,415	274,098	—	—
Total	$ 520,127	$ 522,389	$ 145	$ 145

In February 2025, the Company entered into an agreement whereby it is committed to provide up to €10.0 million to a partnership, Fountain Healthcare Partners Fund IV, L.P. ("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 represents approximately 9.2% of the partnership's total funding, and the Company is accounting for its investment in Fountain under the equity method. During each of the three and nine months ended September 30, 2025, the Company recorded a decrease in its investment in Fountain of approximately $0.1 million. The changes recorded represent the Company's proportional share of Fountain's net losses for these periods. As of September 30, 2025, the Company had made payments of, and its investment is equal to, $0.5 million (€0.4 million), which is included within "Other assets" in the accompanying condensed consolidated balance sheets.

6. FAIR VALUE

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

(In thousands)	September 30, 2025	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 186,317	$ 186,317	$ —	$ —
U.S. government and agency debt securities	284,765	250,937	33,828	—
Corporate debt securities	237,624	—	237,124	500
Total	$ 708,706	$ 437,254	$ 270,952	$ 500

	December 31, 2024	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 8,388	$ 8,388	$ —	$ —
U.S. government and agency debt securities	315,882	265,090	50,792	—
Corporate debt securities	217,643	—	217,643	—
Total	$ 541,913	$ 273,478	$ 268,435	$ —

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period. There were no transfers of any securities between levels during the nine months ended September 30, 2025.

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, 2025:

(In thousands)	Fair Value
Balance, January 1, 2025	$ —
Purchase of a corporate debt security	500
Balance, September 30, 2025	$ 500

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

The 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, sales discounts, allowances and reserves approximate fair value due to their short-term nature.

7. INVENTORY

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

(In thousands)	September 30, 2025	December 31, 2024
Raw materials	$ 66,225	$ 72,139
Work in process	89,413	79,871
Finished goods[(1)]	35,359	30,877
Total inventory	$ 190,997	$ 182,887

(1) At September 30, 2025 and December 31, 2024, the Company had $29.3 million and $22.7 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	September 30, 2025	December 31, 2024
Land	$ 957	$ 957
Building and improvements	150,324	134,699
Furniture, fixtures and equipment	267,641	244,113
Leasehold improvements	42,535	42,416
Construction in progress	49,119	58,391
Subtotal	510,576	480,576
Less: accumulated depreciation	(263,594)	(253,012)
Total property, plant and equipment, net	$ 246,982	$ 227,564

9. LEASES

Future lease payments under non-cancelable leases at September 30, 2025 consist of the following:

(In thousands)	September 30, 2025
2025	2,585
2026	10,479
2027	9,613
2028	9,677
2029	9,611
Thereafter	50,371
Total operating lease payments	$ 92,336
Less: imputed interest	(20,738)
Total operating lease liabilities	$ 71,598

At September 30, 2025, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 3.7% and 6.1 years, respectively. Cash paid for lease liabilities was $2.6 million and $7.7 million during the three and nine months ended September 30, 2025, respectively, as compared to $2.5 million and $7.6 million during the three and nine months ended September 30, 2024, respectively. The Company recorded operating lease expense from continuing operations of $1.9 million and $5.6 million during the three and nine months ended September 30, 2025, respectively, as compared to $1.8 million and $5.4 million during the three and nine months ended September 30, 2024, respectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	September 30, 2025	December 31, 2024
Accounts payable	$ 67,998	$ 45,630
Accrued compensation	67,197	70,960
Accrued other	79,790	68,742
Total accounts payable and accrued expenses	$ 214,985	$ 185,332

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

(In thousands)	September 30, 2025	December 31, 2024
Medicaid rebates	$ 191,430	$ 202,044
Product discounts	17,711	19,351
Medicare Part D	18,821	26,933
Other	24,781	24,124
Total accrued sales discounts, allowances and reserves	$ 252,743	$ 272,452

Included in accounts payable was approximately $31.3 million and $11.4 million of amounts payable related to state U.S. Medicaid rebates as of September 30, 2025 and December 31, 2024, respectively.

11. SHAREHOLDERS' EQUITY

In February 2024, the Company announced approval by its board of directors of a share repurchase program authorizing the Company to repurchase its ordinary shares in an aggregate amount of up to $400.0 million (exclusive of any fees, commissions or other expenses related to such repurchases) from time to time (the "Repurchase Program"), with the specific timing and amounts of repurchases under the Repurchase Program dependent on a variety of factors, including but not limited to ongoing assessments of the Company's needs, alternative investment opportunities, the market price of its ordinary shares and general market conditions. The Repurchase Program has no set expiration date

and may be suspended or discontinued at any time. During the nine months ended September 30, 2025, the Company did not repurchase any of its ordinary shares under the Repurchase Program. During the nine months ended September 30, 2024, the Company repurchased approximately $7.9 million of its ordinary shares under the Repurchase Program at an average purchase price of $25.33 per share, resulting in a total cost, exclusive of any fees, commissions or other expenses related to such repurchase, of $200.0 million. As of September 30, 2025, the remaining amount authorized under the Repurchase Program was $200.0 million.

On May 21, 2025, the Company's shareholders approved an amended version of the Alkermes plc 2018 Stock Option and Incentive Plan that served to, among other things, increase the number of ordinary shares authorized for issuance thereunder by 4,250,000.

12. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2025	2024	2025	2024
Cost of goods manufactured and sold	$ 1,621	$ 1,653	$ 4,882	$ 4,280
Research and development	6,435	6,148	18,836	22,447
Selling, general and administrative	16,608	14,732	48,723	49,162
Total share-based compensation expense	$ 24,664	$ 22,533	$ 72,441	$ 75,889

At September 30, 2025 and December 31, 2024, $3.3 million and $3.1 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory", and $1.2 million and none, respectively, of share-based compensation expense was capitalized and recorded as "Property, plant and equipment, net" in the accompanying condensed consolidated balance sheets.

13. EARNINGS PER ORDINARY SHARE

Basic earnings per ordinary share from continuing operations is calculated based upon net income from continuing operations available to holders of ordinary shares, divided by the weighted average number of ordinary shares outstanding. Basic loss per ordinary share from discontinued operations is calculated based upon net loss from discontinued operations available to holders of ordinary shares, divided by the weighted average number of ordinary shares outstanding. For the calculation of diluted earnings (loss) per ordinary share from continuing operations and discontinuing operations, the Company utilizes the treasury stock method and adjusts the weighted average number of ordinary shares outstanding for the potential dilutive effect of outstanding ordinary share equivalents such as stock options and restricted stock unit awards.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2025	2024	2025	2024
Numerator:				
Net income from continuing operations	$ 82,761	$ 92,795	$ 192,323	$ 226,401
Net loss from discontinued operations	—	(414)	—	(5,834)
Net income	$ 82,761	$ 92,381	$ 192,323	$ 220,567
Denominator:				
Weighted average number of ordinary shares outstanding	165,086	163,368	164,490	166,546
Effect of dilutive securities:				
Stock options	1,457	1,310	1,822	1,293
Restricted stock unit awards	1,967	2,347	2,133	2,357
Dilutive ordinary share equivalents	3,424	3,657	3,955	3,650
Shares used in calculating diluted earnings per ordinary share	168,510	167,025	168,445	170,196

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2025	2024	2025	2024
Stock options	9,668	11,047	9,711	12,311
Restricted stock unit awards	2,020	1,276	2,575	2,401
Total	11,688	12,323	12,286	14,712

14. INCOME TAXES

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

The Company recorded income tax provisions on income from continuing operations of $18.0 million and $38.8 million during the three and nine months ended September 30, 2025, respectively, and of $17.4 million and $47.5 million during the three and nine months ended September 30, 2024, respectively. The income tax provisions during each of the three and nine months ended September 30, 2025 and 2024 were primarily attributable to taxes on income earned in Ireland.

The Company's effective tax rate during the nine months ended September 30, 2025 and 2024 was 16.8% and 17.3%, respectively. The decrease in the effective tax rate was primarily due to an increase in windfall benefits from employee equity activity and an expense recorded in 2024 related to the sale of the Athlone Facility. The effective tax rates during the nine months ended September 30, 2025 and 2024 exceeded the Irish statutory tax rate of 12.5%, primarily due to non-deductible expenses and income that was taxable at rates higher than the Irish statutory tax rate.

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law. This legislation permanently extends, with modifications, several individual, business, and international tax provisions originally enacted under the Tax Cuts and Jobs Act of 2017. As of September 30, 2025, the Company analyzed the impact of this legislation and determined that the OBBBA did not have a material impact on its effective tax rate for the current year.

15. SEGMENT REPORTING

Segment Information

Following the adoption of ASU 2023-07, the Company is required to disclose significant segment expenses that are regularly provided to its CODM. The Company's CODM is periodically provided R&D expenses, selling and marketing expenses, and general and administrative expenses. Other external R&D expenses are composed of general research and development expenses and other external projects. Other internal R&D expenses include allocation expenses, travel expenses, and fees, taxes and dues.

The Company's significant segment expenses are as follows:

(In thousands)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
REVENUES:				
Total revenue	$ 394,185	$ 378,143	$ 1,091,352	$ 1,127,646
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	51,591	63,099	150,248	183,215
External R&D expenses:				
Development programs:				
Alixorexton	25,812	11,873	67,461	34,918
LYBALVI	4,759	5,549	13,661	14,296
Other external R&D expenses	12,648	8,552	34,210	27,358
Total external R&D expenses	43,219	25,974	115,332	76,572
Internal R&D expenses:				
Employee-related	30,862	26,844	92,867	87,624
Occupancy	3,241	2,768	9,696	8,538
Depreciation	1,405	1,440	4,346	4,243
Other internal R&D expenses	3,012	2,866	8,685	10,175
Total internal R&D expenses	38,520	33,918	115,594	110,580
R&D expenses	81,739	59,892	230,926	187,152
Selling, general and administrative expenses:				
Selling and marketing expense	115,630	102,043	359,740	347,327
General and administrative expense	56,143	48,339	154,586	150,917
Total selling, general and administrative expense	171,773	150,382	514,326	498,244
Other segment income (expenses)[1]	(6,321)	(11,975)	(3,529)	(32,634)
NET INCOME FROM CONTINUING OPERATIONS	82,761	92,795	192,323	226,401
LOSS ON DISCONTINUED OPERATIONS, NET OF TAX	—	(414)	—	(5,834)
NET INCOME	$ 82,761	$ 92,381	$ 192,323	$ 220,567

1. "Other segment income (expenses)" during the three and nine months ended September 30, 2025 and 2024, includes "Amortization of acquired intangible assets", "Other income, net" and "Income tax provision".

16. 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, 2025, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring. For claims that are reasonably possible, no estimable loss or range of loss can be made.

INVEGA TRINZA ANDA Litigation

In September 2020, Janssen Pharmaceutica, Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC initiated a patent infringement lawsuit in the U.S. District Court for the District of New Jersey (the "NJ District Court") against Mylan Laboratories Limited ("Mylan Labs") and other Mylan entities following the filing by Mylan Labs of an abbreviated new drug application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to market a generic version of INVEGA TRINZA before the expiration of U.S. Patent No. 10,143,693 (the "'693 Patent"). Requested judicial remedies include recovery of litigation costs and injunctive relief. In May 2023, the NJ District Court issued an opinion in favor of the Janssen entities on the issues of infringement and validity of the '693 Patent and the Mylan entities filed a notice of appeal of the decision. In March 2025, the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit Court") issued a decision affirming the NJ District Court opinion and in May 2025, Mylan Labs filed a petition for panel rehearing or rehearing en banc, which was denied on July 1, 2025. The Company is not a party to this proceeding.

VUMERITY ANDA Litigation

In July 2023, Biogen Inc., Biogen Swiss Manufacturing GmbH and Alkermes Pharma Ireland Limited ("APIL"), a wholly-owned subsidiary of the Company, filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware (the "DE District Court") against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus") following the filing by Zydus 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) delayed-release capsules for oral use, 231 mg, before expiration of the Company's U.S. Patent Nos. 8,669,281; 9,090,558; and 10,080,733 (the "VUMERITY patents"). 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"). On July 21, 2025, the parties entered into a confidential settlement agreement, pursuant to which Zydus was granted a license under the VUMERITY patents to engage in the commercial manufacture, use or sale of a generic version of VUMERITY in the United States beginning on an agreed date immediately prior to expiration of the latest to expire of the VUMERITY patents, or earlier under certain customary circumstances. In connection with the settlement agreement, the DE District Court dismissed the litigation pursuant to the parties' stipulation of dismissal.

LYBALVI ANDA Litigation

On August 15, 2025, August 27, 2025 and September 5, 2025, APIL and Alkermes, Inc., two wholly-owned subsidiaries of the Company, filed a patent infringement lawsuit in the NJ District Court against each of Teva, Apotex, and MSN (each as defined herein), respectively, and on August 28, 2025, APIL and Alkermes, Inc. filed a patent infringement lawsuit in the DE District Court against Apotex. As used herein, Teva refers to Teva Pharmaceuticals, Inc., Apotex refers to Apotex Inc. and Apotex Corp., and MSN refers to MSN Laboratories Private Limited ("MSN Labs"), MSN Pharmaceuticals, Inc. and Novadoz Pharmaceuticals LLC. These lawsuits were filed following receipt of a "paragraph IV certification" notice from each of Teva, Apotex and MSN Labs regarding their respective filings of an ANDA with the FDA seeking approval to engage in the commercial manufacture, use or sale of a generic version of LYBALVI (olanzapine and samidorphan tablets, 5mg/10mg, 10mg/10mg, 15mg/10mg and 20mg/10mg) in the U.S. prior to the expiration of certain of the Company's U.S. patents. The notices alleged that certain of the Company's patents related to LYBALVI, with expiration dates between 2032 and 2041, are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed generic products. The Company intends to vigorously defend its intellectual property. The filing of each lawsuit within 45 days of receipt of each of the respective notices triggered stays of FDA approval of each of the respective ANDAs for up to 30 months in accordance with the Hatch-Waxman Act. On August 20, 2025, APIL and Alkermes, Inc. amended the complaint in the lawsuit against Teva to include an additional patent.

Antitrust Class Action Litigation

On October 2, 2025, Value Drug Company filed a complaint asserting antitrust claims against Alkermes, Inc. and APIL in the U.S. District Court for the District of Massachusetts. The complaint was filed on behalf of a putative class of direct purchasers of VIVITROL and alleges that the Company's U.S. Patent No. 7,919,499 related to VIVITROL was fraudulently obtained, improperly listed in the Orange Book, and wrongfully enforced, resulting in delayed market entry for generic forms of VIVITROL. The lawsuit seeks, among other things, unspecified money damages plus interest, reasonable attorneys' fees and other costs. The Company intends to vigorously defend itself in this matter.

Government Matters

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

Product Liability and Other Legal Proceedings

The Company is involved in litigation and other legal proceedings incidental to its normal business activities, including a product liability case alleging that the FDA-approved VIVITROL labeling was inadequate and that VIVITROL caused the individual to suffer from opioid overdose and death. The Company intends to vigorously defend itself in these matters.

In addition, in January 2023, Acorda Therapeutics, Inc. ("Acorda") filed a petition with the U.S. District Court for the Southern District of New York (the "NY Southern District Court") asking the court to confirm in part and modify in part the final arbitral award rendered by an arbitration panel in October 2022 and, as part of the requested modification, seeking an additional approximately $66.0 million in damages. In August 2023, the NY Southern District Court confirmed the final arbitral award and declined to modify the final award to increase the damages awarded thereunder. In September 2023, Acorda filed a notice of appeal of the NY Southern District Court decision to the Federal Circuit Court. On July 25, 2025, the Federal Circuit Court transferred the appeal due to lack of jurisdiction to the U.S. Court of Appeals for the Second Circuit.

Guarantees

In connection with the Separation, the Company entered into an assignment and assumption of lease agreement (the "Assignment") pursuant to which Alkermes, Inc., a wholly owned subsidiary of the Company, assigned to Mural Oncology, Inc. ("Mural US"), a subsidiary of Mural, an operating lease for approximately 180,000 square feet of corporate office space, administrative areas and laboratories located at 852 Winter Street in Waltham, Massachusetts (the "852 Winter Street Lease"), as described in more detail in Note 10, *Leases* in the "Notes to Consolidated Financial Statements" in the Annual Report. Although all of the rights, title and interest in, to and under the 852 Winter Street Lease were transferred to Mural US as of November 15, 2023 pursuant to the Assignment, the Company ratified and reaffirmed for the remainder of the lease term its guarantor obligations in respect of the lease under that certain Guaranty dated as of May 16, 2014. This lease expires in 2026 and we do not expect its term to be extended. Upon completion of the Separation, the Assignment was accounted for as a termination of the original lease and the Company de-recognized the right-of-use asset and lease liability related to the 852 Winter Street Lease. At September 30, 2025, the fair value of the guarantee was not material to the Company.

17. SUBSEQUENT EVENT

On October 22, 2025 (the "Agreement Date"), the Company and Avadel Pharmaceuticals plc ("Avadel") entered into a definitive transaction agreement (the "Transaction Agreement"), pursuant to which the Company has agreed to acquire the entire issued and to be issued ordinary share capital of Avadel (such proposed offer, the "Proposed Acquisition"), for $18.50 per ordinary share, nominal value $0.01 per share, of Avadel (each, an "Avadel Share"), payable in cash at closing (the "Cash Consideration"). In addition, the Company agreed to provide Avadel shareholders with a non-transferable contingent value right entitling holders to a potential additional cash payment of $1.50 per Avadel Share, contingent upon achievement of certain specified milestones, for a total potential consideration of $20.00 per Avadel Share. The Proposed Acquisition was recommended by the boards of directors of both Alkermes and Avadel and is expected to be effected by means of a court-sanctioned scheme of arrangement (the "Scheme") under Irish law. The completion of the Proposed Acquisition is subject to customary conditions, including, among other things, approval by Avadel's shareholders, the sanction of the Scheme by the Irish High Court, and the receipt of required antitrust clearances in the United States. The conditions to the completion of the Proposed Acquisition are set out in full in Appendix III to the announcement related to the Proposed Acquisition issued by the Company and Avadel pursuant to Rule 2.7 of the Irish Takeover Panel Act 1997, Takeover Rules, 2022 (the "Conditions Appendix").

The Transaction Agreement contains customary representations and warranties and customary covenants with respect to Alkermes and Avadel. The Transaction Agreement contains customary termination rights and may be abandoned at any time prior to the Effective Time (as defined in the Transaction Agreement) by mutual written consent of Alkermes and Avadel, subject to the consent of the Irish Takeover Panel. Avadel also has the right, prior to the receipt

of the requisite Avadel shareholder approvals, to terminate the Transaction Agreement to accept a Company Superior Proposal (as defined in the Transaction Agreement) in certain circumstances, and Alkermes also has the right, prior to receipt of the requisite Avadel shareholder approvals, to terminate the Transaction Agreement if a Company Board Change of Recommendation (as defined in the Transaction Agreement) occurs. Subject to the satisfaction or waiver of all applicable closing conditions, the Company currently expects the Proposed Acquisition to be completed in the first quarter of 2026.

In connection with the Proposed Acquisition, on the Agreement Date, the Company, as the TopCo Borrower, together with Alkermes, Inc., as the U.S. Borrower, entered into a bridge term loan credit agreement with JPMorgan Chase Bank, N.A., as Administrative Agent, Sole Lead Arranger and Sole Bookrunner, and the lenders party thereto (the "Bridge Credit Agreement"), which provides for a senior secured bridge term loan facility (the "Bridge Credit Facility") in an aggregate principal amount of up to approximately $1.2 billion that is available to finance the payment of the Cash Consideration and fees and expenses related to the Proposed Acquisition. In addition, the Company placed approximately $700.0 million of its cash into an escrow account to finance the remainder of the consideration for the Proposed Acquisition. Loans under the Bridge Credit Facility will be available after the Agreement Date, subject to the satisfaction of certain conditions set forth in the Bridge Credit Agreement, and will mature on the date that is 364 days after the date on which the loans are funded under the Bridge Credit Facility. The commitments under the Bridge Credit Facility, unless previously terminated, terminate on the earlier of (i) the date on which all of the consideration payable in respect of the Proposed Acquisition has been paid in full without the making of any loans under the Bridge Credit Facility and (ii) the date on which a Mandatory Cancellation Event (as defined in the Bridge Credit Agreement) occurs or exists.

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

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

Executive Summary

Net income from continuing operations was $82.8 million and $192.3 million or $0.50 and $1.17 per ordinary share—basic and $0.49 and $1.14 per ordinary share—diluted, for the three and nine months ended September 30, 2025, respectively, compared to net income from continuing operations of $92.8 million and $226.4 million or $0.57 per and $1.36 ordinary share—basic and $0.56 and $1.33 per ordinary share—diluted, for the three and nine months ended September 30, 2024, respectively.

The decrease in net income from continuing operations of $10.0 million during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, was primarily due to an increase of $31.7 million in total expenses, primarily due to increases in research and development expenses and selling, general and administrative expenses, partially offset by a decrease in cost of goods manufactured and sold. During the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, total revenues increased by $16.0 million, primarily due to an increase in product sales, net, partially offset by a decrease in manufacturing and royalty revenue.

The decrease in net income from continuing operations of $34.1 million during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was primarily due to a decrease of $36.3 million, in revenues, primarily related to lower manufacturing and royalty revenues, partially offset by an increase in product sales, net. During the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, total expenses increased by $25.8 million and income tax provision decreased by $8.7 million.

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

Business Update

On October 22, 2025, we announced our entry into the Transaction Agreement, pursuant to which we agreed to acquire the entire issued and to be issued ordinary share capital of Avadel for a total potential consideration of up to $20.00 per Avadel Share, as described above. The completion of the Proposed Acquisition is subject to customary conditions, including, among other things, approval by Avadel's shareholders, the sanction of the Scheme by the Irish High Court, and the receipt of required antitrust clearances in the United States, and may be terminated by either party under certain circumstances. Subject to the satisfaction or waiver of all applicable closing conditions, we currently expect the Proposed Acquisition to be completed in the first quarter of 2026. We expect to incur costs of approximately $15.0 million to $20.0 million in connection with the Proposed Acquisition during the fourth quarter of 2025.

Products

Marketed Products

The key marketed products discussed below have generated, or are expected to generate, significant revenues for us. See the descriptions of the marketed products below and "Part I, Item 1A—Risk Factors" in our Annual Report and "Part II, Item 1A—Risk Factors" in this Form 10-Q for important factors that could adversely affect our marketed products. See the "Patents and Proprietary Rights" section in "Part I, Item 1—Business" in our Annual Report for information with respect to the IP protection for these marketed products.

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

Proprietary Products

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

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

Key Third-Party Products Using Our Proprietary Technologies

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

Our Key Licensed Product

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

Proprietary Products

We have developed and now commercialize products designed to help address the unmet needs of people living with opioid dependence, alcohol dependence, schizophrenia and bipolar I disorder. See the "Patents and Proprietary Rights" section in "Part I, Item 1—Business" in our Annual Report for information with respect to the IP protection for our proprietary products.

ARISTADA and ARISTADA INITIO

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA utilizes our proprietary LinkeRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is available in four dose strengths with once-monthly dosing options (441 mg, 662 mg and 882 mg), a six-week dosing option (882 mg) and a two-month dosing option (1064 mg). ARISTADA is packaged in a ready-to-use, pre-filled syringe product format. We exclusively manufacture and commercialize ARISTADA in the U.S.

ARISTADA INITIO (aripiprazole lauroxil) leverages our proprietary LinkeRx and NanoCrystal technologies and provides an extended-release formulation of aripiprazole lauroxil in a smaller particle size compared to ARISTADA, thereby enabling faster dissolution and more rapid achievement of relevant levels of aripiprazole in the body. ARISTADA INITIO, combined with a single 30 mg dose of oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults. The first ARISTADA dose may be administered on the same day as the ARISTADA INITIO regimen or up to 10 days thereafter. We exclusively manufacture and commercialize ARISTADA INITIO in the U.S.

LYBALVI

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

In August 2025, U.S. Patent No. 12,390,474 relating to LYBALVI was granted. This patent has claims to a formulation of a fixed dose of olanzapine and samidorphan and expires in 2041.

For a discussion of legal proceedings related to LYBALVI, see Note 16, *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 "Uncertainty over IP in the biopharmaceutical industry has been the source of litigation and other legal proceedings, and we or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly, non-narcotic, injectable medication approved in the U.S. for the treatment of alcohol dependence in patients able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through one intramuscular injection every four weeks. We exclusively manufacture and commercialize VIVITROL in the U.S.

For a discussion of legal proceedings related to VIVITROL, see Note 16, *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 "Uncertainty over IP in the biopharmaceutical industry has been the source of litigation and other legal proceedings, and we or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers" and "Litigation or arbitration filed against Alkermes, including securities litigation, or actions (such as citizens petitions) filed against regulatory agencies in respect of our products, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

Products Using Our Proprietary Technologies and Licensed Product

We have licensed products to third parties for commercialization and have licensed our proprietary technologies to third parties to enable them to develop, commercialize and/or manufacture products. See the "Proprietary Technology Platforms" and "Patents and Proprietary Rights" sections in "Part I, Item 1—Business" in our Annual Report for information with respect to our proprietary technologies and the IP protection for these products. We receive royalties and/or manufacturing and other revenues from the commercialization of these products under our collaborative arrangements with these third parties. Such arrangements, among others, include the following:

Products Using Our Proprietary Technologies

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

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

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

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

INVEGA HAFYERA is approved in the U.S. for the treatment of schizophrenia in patients who have been adequately treated with INVEGA SUSTENNA for at least four months or INVEGA TRINZA for at least three months. BYANNLI is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION or TREVICTA. INVEGA HAFYERA/BYANNLI is manufactured by Janssen.

For a discussion of legal proceedings related to certain of the patents covering INVEGA TRINZA, see Note 16, *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 "Uncertainty over IP in the biopharmaceutical industry has been the source of litigation and other legal proceedings, and we or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

Licensed Product

VUMERITY

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

Under our license and collaboration agreement with Biogen, Biogen holds the exclusive, worldwide license to develop and commercialize VUMERITY. For more information about the license and collaboration agreement with Biogen, see the "Collaborative Arrangements—Biogen" section in "Part I, Item 1—Business" in our Annual Report. For a discussion of legal proceedings related to certain of the patents covering VUMERITY, see Note 16, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q.

Key Development Program

Our R&D is focused on the development of innovative medicines in the field of neuroscience that are designed to address unmet patient needs. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting preclinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current key development program. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in "Part I, Item 1A—Risk Factors" in our Annual Report and "Part II, Item 1A—Risk Factors" in this Form 10-Q. 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.

Alixorexton (formerly referred to as ALKS 2680)

Alixorexton is a novel, investigational, oral, selective orexin 2 receptor agonist in development as a once-daily treatment for narcolepsy type 1 ("NT1"), narcolepsy type 2 ("NT2") and idiopathic hypersomnia ("IH"). Orexin, a neuropeptide produced in the lateral hypothalamus, is considered to be the master regulator of wakefulness due to its activation of multiple, downstream wake-promoting pathways that project widely throughout the brain. Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease. Once-daily oral administration of alixorexton was previously evaluated in a phase 1 study in healthy volunteers and patients with NT1, NT2 and IH and is currently being evaluated in phase 2 studies, including the recently completed Vibrance-1 study in patients with NT1, and the ongoing Vibrance-2 and Vibrance-3 studies in patients with NT2 and IH, respectively. In September 2025, we announced detailed safety and efficacy results from Vibrance-1 and that we are proceeding with plans for initiation of a phase 3 program in narcolepsy.

Results of Operations

Product Sales, Net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO, and LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for sales of VIVITROL, ARISTADA and ARISTADA INITIO, and LYBALVI during the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In millions, except for % of Sales)	2025	% of Sales	2024	% of Sales	2025	% of Sales	2024	% of Sales
Product sales, gross	$ 593.5	100.0 %	$ 543.5	100.0 %	$ 1,631.1	100.0 %	$ 1,543.8	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(113.3)	(19.1) %	(116.3)	(21.4) %	(312.8)	(19.2) %	(343.9)	(22.3) %
Chargebacks	(71.9)	(12.1) %	(61.8)	(11.4) %	(190.2)	(11.7) %	(168.8)	(10.9) %
Product discounts	(43.8)	(7.4) %	(39.9)	(7.3) %	(122.4)	(7.5) %	(112.6)	(7.3) %
Medicare Part D	(18.4)	(3.1) %	(21.1)	(3.9) %	(56.6)	(3.4) %	(60.0)	(3.9) %
Other	(28.7)	(4.8) %	(31.4)	(5.8) %	(79.9)	(4.9) %	(82.7)	(5.4) %
Total adjustments	(276.1)	(46.5) %	(270.5)	(49.8) %	(761.9)	(46.7) %	(768.0)	(49.8) %
Product sales, net	$ 317.4	53.5 %	$ 273.0	50.2 %	$ 869.2	53.3 %	$ 775.8	50.2 %

The increase in product sales, gross during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, was due to increases of 23%, 3% and 2% in the number of units sold for LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL, respectively, and a 3% price increase for each of these products that went into effect on January 1, 2025.

The increase in product sales, gross during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was primarily due to a 19% increase in the number of LYBALVI units sold and the 3% price increase for each of our proprietary products that went into effect on January 1, 2025. These increases were partially offset by 1% decreases in the number of units sold for each of VIVITROL and ARISTADA/ARISTADA INITIO.

The decreases in Medicaid rebates, as a percentage of sales, during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily due to gross-to-net favorability as actual Medicaid rebates related to VIVITROL and ARISTADA/ARISTADA INITIO, were lower than original estimates by approximately $7.6 million and $25.3 million for VIVITROL during the three and nine months ended September 30, 2025, respectively, and by approximately $4.9 million and $12.1 million for ARISTADA/ARISTADA INITIO during the three and nine months ended September 30, 2025, respectively.

The following table compares product sales, net earned during the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2025	2024	Change	2025	2024	Change
VIVITROL	$ 121.1	$ 113.7	$ 7.4	$ 343.8	$ 323.2	$ 20.6
ARISTADA and ARISTADA INITIO	98.1	84.7	13.4	272.8	249.6	23.2
LYBALVI	98.2	74.7	23.5	252.6	203.1	49.5
Product sales, net	$ 317.4	$ 273.0	$ 44.3	$ 869.2	$ 775.8	$ 93.3

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned during the three and nine months ended September 30, 2025 and 2024:

(In millions)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Manufacturing and royalty revenues:						
Long-acting INVEGA products	$ 30.2	$ 58.5	$ (28.3)	$ 78.3	$ 199.9	$ (121.6)
VUMERITY	35.6	32.6	3.0	102.8	99.1	3.7
RISPERDAL CONSTA	3.8	2.4	1.4	16.7	8.7	8.0
Other	7.2	11.6	(4.4)	24.4	44.1	(19.7)
Manufacturing and royalty revenues	$ 76.8	$ 105.1	$ (28.3)	$ 222.2	$ 351.8	$ (129.6)

The decreases in royalty revenues related to the long-acting INVEGA products during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily due to the expiration of our royalty on net sales of INVEGA SUSTENNA in the U.S. in August 2024. Accordingly, royalty revenues from net sales of the long-acting INVEGA products have been, and we expect will continue to be, lower in 2025, as the royalty revenues related to U.S. net sales of INVEGA SUSTENNA comprised a significant portion of the overall royalty revenues from the long-acting INVEGA products. In addition, each of INVEGA SUSTENNA and INVEGA TRINZA is currently subject to Paragraph IV litigation in response to companies seeking to market generic versions of such product. Increased competition from new products or generic versions of any one or more of the long-acting INVEGA products may lead to reduced unit sales of the long-acting INVEGA products, including those not yet genericized, and increased pricing pressure. For a discussion of the legal proceedings related to INVEGA TRINZA, see Note 16, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, and for information about risks relating to these legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report, and specifically the section entitled "Uncertainty over IP in the biopharmaceutical industry has been the source of litigation and other legal proceedings, and we or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

The increases in VUMERITY revenue during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were due to increases of $8.3 million and $17.7 million, respectively, in royalty revenue, offset by decreases of $5.3 million and $14.0 million, respectively, in manufacturing revenue. The increases in VUMERITY royalty revenue were primarily due to increases in end-market sales of the product. The decreases in VUMERITY manufacturing revenue were primarily due to reductions in the number of batches manufactured for sale to Biogen.

The increase in RISPERDAL CONSTA revenue during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was due to an $8.2 million increase in manufacturing revenue, primarily due to an increase in the number of batches made available to Janssen for sale in the U.S., which has a higher selling price than product sold outside of the U.S. The decrease in Other manufacturing and royalty revenue during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, was primarily due to decreases in revenues related to certain of our legacy products. The decrease in Other manufacturing and royalty revenue during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was primarily due to a $13.6 million decrease in revenue from FAMPYRA, as our manufacturing obligations for FAMPYRA concluded on December 31, 2024.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Cost of goods manufactured and sold	$ 51.6	$ 63.1	$ (11.5)	$ 150.2	$ 183.2	$ (33.0)

The decreases in the cost of goods manufactured and sold during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily related to decreases of $7.9 million and $28.7 million, respectively, in the cost of goods manufactured for certain legacy products following the sale of the Athlone Facility in May 2024 and decreases in the cost of goods sold for certain of our proprietary products during each period primarily due to decreases in costs related to out-of-specification batches and investigation costs. These decreases were partially offset by increases in the cost of goods sold for LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, and an increase in the cost of goods sold for LYBALVI during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, due to increases in the number of units sold in each period, as discussed above.

Research and Development Expenses

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include fees for clinical and preclinical 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 development programs or our products or technologies in general.

The following table sets forth our external R&D expenses for the three and nine months ended September 30, 2025 and 2024 relating to our then-current development programs and our internal R&D expenses, listed by the nature of such expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2025	2024	Change	2025	2024	Change
External R&D expenses:						
Development programs:						
Alixorexton	$ 25.8	$ 11.9	$ 13.9	$ 67.5	$ 34.9	$ 32.6
LYBALVI	4.8	5.5	(0.7)	13.7	14.3	(0.6)
Other external R&D expenses	12.6	8.6	4.0	34.2	27.4	6.8
Total external R&D expenses	43.2	26.0	17.2	115.4	76.6	38.8
Internal R&D expenses:						
Employee-related	30.9	26.8	4.1	92.9	87.6	5.3
Occupancy	3.2	2.7	0.5	9.7	8.5	1.2
Depreciation	1.4	1.4	—	4.3	4.2	0.1
Other	3.0	2.9	0.1	8.6	10.2	(1.6)
Total internal R&D expenses	38.5	33.8	4.7	115.5	110.5	5.0
Research and development expenses	$ 81.7	$ 59.8	$ 21.9	$ 230.9	$ 187.1	$ 43.8

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

The increases in expenses related to alixorexton during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily due to increased spend related to the advancement of the development program for the product, including initiation of our Vibrance-3 phase 2 clinical study and costs related to our long-term extension study for the product. The increases in other external R&D expenses during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily due to activities associated with our preclinical development programs.

The increases in employee-related expenses during the three and nine months ended September 30, 2025, as compared to the three and nine months ended September 30, 2024, were primarily due to increases in labor and benefits expense related to a 9% increase in R&D-related headcount.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Selling and marketing expense	$ 115.6	$ 102.1	$ 13.5	$ 359.7	$ 347.4	$ 12.3
General and administrative expense	56.2	48.2	8.0	154.6	150.8	3.8
Selling, general and administrative expense	$ 171.8	$ 150.3	$ 21.5	$ 514.3	$ 498.2	$ 16.1

The increase in selling and marketing expense during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, was primarily due to increases of $11.4 million and $2.2 million in employee-related expenses and marketing expense, respectively. The increase in employee-related expenses was primarily due to a 14% increase in sales and marketing-related headcount. The increase in marketing expense was primarily due to support services related to field expansion during the period. The increase in selling and marketing expense during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was primarily due to an increase of $23.5 million in employee-related expenses, primarily due to the increase in sales and marketing-related headcount, as previously noted, partially offset by a decrease of $11.1 million in marketing spend, primarily related to decreases in media spend for our proprietary products.

The increase in general and administrative expense during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, was primarily due to a $3.4 million increase in employee-related expenses, primarily due to a 7% increase in general and administrative-related headcount, a $2.3 million increase in professional service fees and a $1.5 million increase in branded prescription drug fees. The increase in general and administrative expense during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, was primarily due to a $3.3 million increase in employee-related expenses, primarily due to the increase in general and administrative-related headcount, discussed above, and a $1.1 million increase in professional services fees.

Other Income, Net

(In millions)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Interest income	$ 11.9	$ 10.9	$ 1.0	$ 33.1	$ 31.0	$ 2.1
Interest expense	—	(6.0)	6.0	—	(17.9)	17.9
Other (expense) income, net	(0.2)	0.6	(0.8)	2.1	2.8	(0.7)
Total other income, net	$ 11.7	$ 5.5	$ 6.2	$ 35.2	$ 15.9	$ 19.3

Interest income consists of interest earned on our cash and available-for-sale investments. Interest expense consisted of interest incurred on our previously outstanding term loans (the "Former Term Loans") that were scheduled to become due in 2026 under our former amended and restated credit agreement, which we prepaid in full and terminated in December 2024. See Note 12, *Long-Term Debt* in the "Notes to Consolidated Financial Statements" accompanying our Annual Report for additional information regarding our Former Term Loans.

Income Tax Provision

(In millions)	Three Months Ended September 30, 2025	2024	Change	Nine Months Ended September 30, 2025	2024	Change
Income tax provision	18.0	17.4	$ 0.6	$ 38.8	$ 47.5	$ (8.7)

The income tax provisions in each of the three and nine months ended September 30, 2025, and 2024 were primarily attributable to taxes on income earned in Ireland.

On July 4, 2025, the OBBBA was signed into law. This legislation permanently extends, with modifications, several individual, business, and international tax provisions originally enacted under the Tax Cuts and Jobs Act of 2017. As of September 30, 2025, we analyzed the impact of this legislation and determined that the OBBBA did not have a material impact on its effective tax rate for the current year. We expect that the provisions in the OBBBA will result in a material increase in cash flows provided by operating activities and a material decrease in net U.S. deferred tax assets over the next number of years.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

	September 30, 2025			December 31, 2024		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 155.2	$ 461.2	$ 616.4	$ 70.3	$ 220.8	$ 291.1
Investments—short-term	203.2	291.5	494.7	203.6	256.9	460.5
Investments—long-term	4.8	23.1	27.9	24.6	48.5	73.1
Total cash and investments	$ 363.2	$ 775.8	$ 1,139.0	$ 298.5	$ 526.2	$ 824.7

At September 30, 2025 our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 492.4	$ 2.3	$ —	$ —	$ 494.7
Investments—long-term available-for-sale	27.8	—	—	—	27.8
Investments—long-term held-to-maturity	0.1	—	—	—	0.1
Total	$ 520.3	$ 2.3	$ —	$ —	$ 522.6

Sources and Uses of Cash

We generated $350.6 million and $248.7 million of cash from operating activities during the nine months ended September 30, 2025 and 2024, respectively. We expect that our existing cash, cash equivalents and investments will be sufficient to finance our anticipated working capital and other cash requirements, including capital expenditures, for not less than twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures.

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. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities and corporate debt securities. 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.

In connection with the Proposed Acquisition, Alkermes plc, as the TopCo Borrower, together with Alkermes, Inc., as the U.S. Borrower, entered into the Bridge Credit Agreement, which provides for the Bridge Credit Facility in an aggregate principal amount of up to approximately $1.2 billion that is available to finance the payment of Cash Consideration and fees and expenses related to the Proposed Acquisition. In addition, we placed approximately $700.0 million of our cash into an escrow account to finance the remainder of the consideration for the Proposed Acquisition.

We have no off-balance sheet arrangements that are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources in the next 12 months.

Information about our cash flows, by category, is presented in the accompanying condensed consolidated statements of cash flows. The discussion of our cash flows that follows does not include the impact of any adjustments to remove discontinued operations and is stated on a total company consolidated basis. The following table summarizes our cash flows for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,	
(In millions)	2025	2024
Cash and cash equivalents, beginning of period	$ 291.1	$ 457.5
Cash flows provided by operating activities	350.6	248.7
Cash flows used in investing activities	(26.8)	(97.4)
Cash flows provided by (used in) financing activities	1.5	(212.5)
Cash and cash equivalents, end of period	$ 616.4	$ 396.3

Operating Activities

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

Cash flows provided by operating activities for the nine months ended September 30, 2025 primarily consisted of $192.3 million of net income, adjusted for non-cash items, including $72.4 million of share-based compensation, $30.5 million in deferred income taxes, $23.3 million of depreciation and amortization and $27.7 million of changes in working capital.

Cash flows provided by operating activities for the nine months ended September 30, 2024 primarily consisted of $220.6 million of net income, adjusted for non-cash items including $75.9 million of share-based compensation, $21.7 million of depreciation and amortization and $32.3 million of deferred income taxes, partially offset by changes in working capital of $105.1 million.

Investing Activities

Cash flows used in investing activities for the nine months ended September 30, 2025 were primarily due to the purchase of $40.4 million of property, plant and equipment, partially offset by $11.8 million in net sales of investments. Cash flows used in investing activities for the nine months ended September 30, 2024 were primarily due to $172.1 million in net purchases of investments and $23.7 million in the purchase of property, plant and equipment, partially offset by proceeds related to the sale of the Athlone Facility of approximately $97.9 million, which included a payment of approximately $91.0 million for the facility and certain related assets.

Financing Activities

Cash flows provided by financing activities for the nine months ended September 30, 2025 were due to $32.2 million of cash that we received upon exercises of employee stock options, offset by $30.8 million of employee taxes paid related to the net share settlement of equity awards. Cash flows used in financing activities for the nine months ended September 30, 2024 primarily related to $200.0 million (exclusive of any fees, commissions or other related expenses) used to repurchase our ordinary shares under the Repurchase Program and $29.3 million of employee taxes paid related to the net share settlement of equity awards, partially offset by $19.4 million of cash that we received upon exercises of employee stock options.

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, 2024, 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 primarily to royalty revenues that we receive on certain of our products, partially offset by certain operating costs arising from expenses and payables in connection with our Irish operations that are settled predominantly in euro. These non-U.S. currency exchange rate risks are summarized in "Part II, Item 7A—Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report. There has been no material change in our assessment of our sensitivity to non-U.S. currency exchange rate risk since December 31, 2024.

Item 4. *Controls and Procedures*

a) Evaluation of Disclosure Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2025. Based upon that evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal 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 three months ended September 30, 2025, 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 16, *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

The below risk factors should be read in conjunction with the risk factors disclosed in "Part I, Item 1A—Risk Factors" of our Annual Report.

We may not be able to complete the proposed strategic acquisition of Avadel on the timelines currently contemplated or at all, which could adversely affect our business and financial condition and the price of our ordinary shares.

On October 22, 2025, we announced our entry into a definitive transaction agreement with Avadel pursuant to which we agreed to acquire the entire issued and to be issued ordinary share capital of Avadel for total potential cash consideration of up to $20.00 per Avadel Share, as described in this Form 10-Q. The completion of the Proposed Acquisition is subject to customary conditions, including, among other things, approval by Avadel's shareholders, the sanction of the Scheme by the Irish High Court, and the receipt of required antitrust clearances in the United States, and may be terminated by either party under certain circumstances. Subject to the satisfaction or waiver of all applicable closing conditions, we currently expect the Proposed Acquisition to be completed in the first quarter of 2026; however, we may not be able to satisfy or waive the conditions to the closing of the Proposed Acquisition on the expected timelines or at all, or the agreement may be terminated under certain circumstances.

The Proposed Acquisition may be difficult to complete for a number of reasons, including that we and Avadel may not be able to satisfy the conditions to closing. For example, we and/or Avadel, as applicable, may face difficulty and/or delays in obtaining the requisite shareholder approval, Irish High Court sanction or regulatory clearances in respect of the Proposed Acquisition on the anticipated timelines or at all. In addition, there may be unanticipated significant changes in transaction costs related to the Proposed Acquisition and/or unknown or inestimable liabilities and potential litigation that may arise in connection with the Proposed Acquisition. Further, competing offers may be made for Avadel, or the board of directors of Avadel may, in certain circumstances, change its recommendation regarding consummation of the Proposed Acquisition. The announcement of the Proposed Acquisition and the time and effort taken to consummate the Proposed Acquisition could result in disruption to the Company's or Avadel's respective businesses, including potential disruptions to certain third-party business and operational relationships that are important to Avadel's business, or impacts on the ability of each of Alkermes and Avadel to attract and retain highly qualified management and key personnel. In addition, the Transaction Agreement in respect of the Proposed Acquisition contains customary termination rights that may be invoked in advance of completion of the Proposed Acquisition under certain circumstances. For any of these reasons, we may face difficulty in completing the Proposed Acquisition, and no assurance can be given as to whether we will complete the Proposed Acquisition on our anticipated timeline or at all, which could adversely affect our business strategy and financial planning and condition. Further, any potential negative reactions from the financial markets, whether as a result of the announcement of the Proposed Acquisition or any delay or failure in completing the Proposed Acquisition, could have a negative impact on our business and financial condition or the market price for our ordinary shares.

Even if the proposed acquisition of Avadel is completed, we may fail to realize some or all of the anticipated benefits and synergies of the proposed acquisition or successfully integrate Avadel's business, which could adversely affect our business and financial condition and the price of our ordinary shares.

Even if the Proposed Acquisition is completed, the businesses of Alkermes and Avadel may not be effectively integrated and the anticipated operational, financial, strategic and other benefits and synergies of the Proposed Acquisition may not be achieved. These anticipated benefits and synergies are based on a number of assumptions and uncertainties, which may prove to be incorrect or incomplete. We may not be able to successfully integrate our and Avadel's operations, and difficulties may arise relating to employee morale, such as the potential loss of key employees that may be difficult to replace, diversion of management's attention from operation of the business, the failure to harmonize both companies' corporate cultures, the disruption of each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our or Avadel's ability to maintain third-party

relationships. In addition, there may be general economic, political, market and business conditions, or future exchange and interest rates, changes in tax laws, regulations, rates and policies, that could have a negative impact on Alkermes, Avadel or the combined organization following consummation of the Proposed Acquisition. In addition, Avadel's product could be shown to be ineffective or unsafe, may prove difficult to manufacture be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse and we may not be able to continue to successfully commercialize Avadel's product or support revenue growth from such product. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits and synergies we anticipate realizing as a result of the Proposed Acquisition within the expected timeframe or at all, or they may take longer to realize or cost more than expected, and in each case, our business, results of operations and financial condition and/or the market price for our ordinary shares could be adversely affected.

Our debt obligations could adversely affect our business and limit our ability to plan for or respond to changes in our business.

In connection with the Proposed Acquisition, Alkermes plc and Alkermes, Inc. entered into the Bridge Credit Agreement, which provides for the Bridge Credit Facility in an aggregate principal amount of up to approximately $1.2 billion that is available to finance the payment of Cash Consideration and fees and expenses related to the Proposed Acquisition. While we expect to obtain permanent financing in lieu of utilizing funds available under the Bridge Credit Agreement, we cannot guarantee that we will obtain such permanent financing on terms that are acceptable to us or at all. If we are not successful in obtaining permanent financing due to market conditions or other factors and are required to utilize funds under the Bridge Credit Agreement, we will incur significantly higher borrowing costs than currently contemplated. In addition, the Bridge Credit Agreement requires the maintenance of certain leverage and coverage ratios, in each case, with the levels set forth in the Bridge Credit Agreement, as of the last day of any fiscal quarter ending after the date on which the loans under the Bridge Credit Facility are funded. In addition, the Bridge Credit Agreement contains customary affirmative and negative covenants, including limitations on indebtedness, liens, mergers, consolidations, sales of assets, investments, transactions with affiliates, restricted payments and sales and leasebacks. The Bridge Credit Agreement is guaranteed by certain of the Company's subsidiaries and secured by a lien on substantially all of the assets of Alkermes plc, Alkermes, Inc. and their subsidiary guarantors. Our failure to comply with these restrictions or to make payments could lead to an event of default that could result in an acceleration of the indebtedness. Our future operating results may not be sufficient to ensure our ability to make our debt payments or to remedy any such default.

Changes in global trade or other policies, including tariffs or other restrictions imposed by the U.S. government or governments of other nations, could have an adverse effect on our business, results of operations, or financial condition.

As a global biopharmaceutical company, changes in and uncertainties from global trade or other policies, including tariffs or other restrictions imposed by the U.S. government or governments of other nations, may have an adverse effect on us. For example, since April 2025, the U.S. government and certain other countries have imposed tariffs or negotiated trade agreements for tariffs on certain imports. Although some of these tariffs are temporarily paused, their impact has already been seen, and we expect will continue to be seen, in global markets. Our proprietary products are manufactured at our manufacturing facility in the U.S. and are sold exclusively in the U.S.; however, certain materials in our supply chain are sourced internationally and certain third-party products from which we derive revenue are manufactured outside the U.S. Our related costs, revenues and/or profits may be impacted to varying degrees by recent or future changes in global trade or other policies. In addition, the recent changes, tensions and uncertainties related to global trade policies have caused, and may continue to cause, significant volatility in global markets, including the market for our ordinary shares. The price of our ordinary shares has fluctuated significantly, and may continue to fluctuate, as a result of these and similar developments. The U.S. government has also indicated that it may impose a supplemental tariff on all pharmaceutical imports or take additional actions in respect of pharmaceutical companies incorporated outside of the U.S., which has caused, and may continue to cause, uncertainty as to the extent of the impacts of changes in global trade on the pharmaceutical industry as a whole and on our business. Additional changes to the policies of the U.S. or other nations that affect the geopolitical landscape or global trade, economic or market conditions, and other direct or indirect impacts of such policies, are uncertain and unpredictable, and could, in the future, have a material adverse effect on our business, results of operations, or financial condition and the market price of our ordinary shares.

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

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our affiliated purchasers, as defined in Rule 10b-18(a)(3) under the Exchange Act, during the three months ended September 30, 2025:

Period	Total Number of Ordinary Shares Purchased (a)[1]	Average Price Paid per Ordinary Share (b)	Total Number of Ordinary Shares Purchased as Part of Publicly Announced Program (c)[2]	Approximate Dollar Value (in millions) of Ordinary Shares that May Yet Be Purchased Under the Program (d)[2]
July 1, 2025 – July 31, 2025	1,835	$ 28.90	—	$ 200.0
August 1, 2025 – August 31, 2025	3,254	26.62	—	200.0
September 1, 2025 – September 30, 2025	5,652	29.68	—	200.0
Totals	10,741	$ 28.62	—	

(1) Consists of ordinary shares acquired during the three months ended September 30, 2025 to satisfy tax withholding obligations related to the vesting of equity awards.

(2) In February 2024, we announced approval by our board of directors of the Repurchase Program, which authorized the repurchase of our ordinary shares in an aggregate amount of up to $400.0 million (exclusive of any fees, commissions or other expenses related to such repurchases) from time to time. The specific timing and amounts of repurchases under the Repurchase Program will depend on a variety of factors, including but not limited to ongoing assessments of our needs, alternative investment opportunities, the market price of our ordinary shares and general market conditions. The Repurchase Program has no set expiration date and may be suspended or discontinued at any time.

Item 5. ***Other Information***

During the three months ended September 30, 2025, no officer (as defined in Rule 16a-1(f) under the Exchange Act) or director of the Company adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of the Company's securities that is or was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Actor any trading plan not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
2.1 §	Transaction Agreement, dated as of October 22, 2025 by and among Alkermes plc and Avadel Pharmaceuticals plc (incorporated by reference to Exhibit 2.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299) filed on October 22, 2025).
2.2	Appendix III to the Rule 2.7 Announcement, dated as of October 22, 2025 (Conditions Appendix) (incorporated by reference to Exhibit 2.2 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299) filed on October 22, 2025).
10.1 #*§	Authorized Generic Product Supply Agreement, dated September 9, 2025, by and between Alkermes Pharma Ireland Limited and Amneal Pharmaceuticals LLC.
10.2 †	Form of Employment Agreement entered into by and between Alkermes, Inc. and Joshua Reed, (incorporated herein by reference to Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299), filed with the SEC on November 2, 2016).
10.3 #†	Offer Letter, dated August 27, 2025, by and between Alkermes, Inc. and Joshua Reed.
10.4 §	Bridge Credit Agreement, dated as of October 22, 2025 by and among Alkermes plc, Alkermes, Inc. and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299) filed on October 22, 2025).
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 with Embedded Linkbase Documents.
104 #	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

Filed herewith.

‡ Furnished herewith.

* Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b) of Regulation S-K. The Company undertakes to furnish an unredacted copy of this exhibit upon request by the SEC.

§ Schedules and similar attachments to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company undertakes to furnish copies of any omitted schedules and similar attachments upon request by the SEC.

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

SIGNATURES

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

ALKERMES PLC

(Registrant)

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

By: /s/ Joshua Reed
Joshua Reed
Senior Vice President, Chief Financial Officer
(Principal Financial Officer)

Date: October 28, 2025

Exhibit 10.1

Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b) of Regulation S-K. Schedules and similar attachments to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

CONFIDENTIAL

AUTHORIZED GENERIC PRODUCT SUPPLY AGREEMENT

AMNEAL PHARMACEUTICALS LLC,

– and –

ALKERMES PHARMA IRELAND LIMITED

Dated as of September 9, 2025

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THIS AUTHORIZED GENERIC PRODUCT SUPPLY AGREEMENT is made as of September 9, 2025, by **AMNEAL PHARMACEUTICALS LLC**, a Delaware limited liability company with its principal place of business located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807 (hereinafter "**Amneal**" or "**Distributor**"), and **ALKERMES PHARMA IRELAND LIMITED**, a company incorporated under the laws of Ireland and having its registered office at Connaught House, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland ("**Supplier**"). Distributor and Supplier may be referred to herein by name or individually as "**Party**" and collectively, as the "**Parties**."

WHEREAS:

A. Supplier manufactures and distributes VIVITROL® (naltrexone for extended-release injectable suspension), 380mg per vial, in the United States of America (the "**Territory**") in accordance with and as the holder of approved NDA No. 021897 (the "**Brand Product**").

B. Distributor desires to distribute and sell to certain purchasers in the Territory an authorized generic version of the Brand Product (the "**Authorized Generic Product**").

C. Supplier possesses Dossiers in relation to the Brand Product(s), which includes relevant patents, that may form the basis for Regulatory Filings to Regulatory Authorities for the purposes of obtaining Marketing Authorizations in the Territory.

D. Supplier wishes to grant Distributor, subject to the limitations set forth herein, non-exclusive distribution rights with respect to an Authorized Generic Product, and Supplier wishes to supply such Authorized Generic Product to Distributor and Distributor desires to obtains such rights and supply, upon the terms and subject to the conditions set forth herein.

E. Supplier and Distributor were parties to an *Inter Partes* Review, Case No. 2018-00943 ("**IPR**") and entered into a Settlement and License Agreement dated July 26, 2019, pursuant to which the Parties settled and dismissed the IPR. As part of such settlement, Supplier and Distributer agreed to enter into this Agreement to appoint Distributor as a distributor of the Authorized Generic Product, subject to the terms and conditions set forth herein.

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

ARTICLE 1 -AUTHORIZED GENERIC PRODUCT LICENSE GRANT & LAUNCH

1.1 License Grant.

(a) Authorized Generic Product License. Supplier grants to Distributor a non-exclusive, non-sublicensable (except to Distributor's Affiliates in accordance with Section 10.4), non-transferable license under the Licensed Intellectual Property Rights, the NDA and other Regulatory Filings for the sole purpose of Distributing the Authorized Generic Product in the Territory during the Launch Term. The license granted in this Section 1.1(a) shall include the right to

reference the NDA and other Marketing Authorizations necessary for the Distribution of the Authorized Generic Product in the Territory.

(b) Obligations of Distributor.

(i) Distributor shall comply with all Applicable Law in connection with its Distribution of the Authorized Generic Product, including applicable recordkeeping obligations.

(ii) Distributor shall not solicit or accept orders for sales of the Authorized Generic Product from any existing or prospective customer outside the Territory.

(iii) Distributor shall not solicit or accept orders for sales of the Authorized Generic Product from any existing or prospective customer in the Territory prior to the Launch Date, provided, however, that [**].

(iv) Distributor shall (A) store, handle and distribute the Authorized Generic Product in clean and sanitary conditions as required to maintain the quality and traceability of the Authorized Generic Product and according to the storage conditions described in the United States Pharmacopeia and in the approved Labeling for the Authorized Generic Product, (B) not alter the Authorized Generic Product in any manner, including the Labeling, (C) comply with GMP and all other Applicable Law, including applicable recordkeeping obligations, in connection with the storage, handling, distribution, marketing and sale of the Authorized Generic Product, and (D) not market the Authorized Generic Product in any manner that is inconsistent with the Labeling of the Authorized Generic Product or Applicable Law, or otherwise make any false or misleading representations to customers or others regarding the Authorized Generic Product.

(c) Acknowledgement of IP Ownership. All Licensed Intellectual Property Rights, including those in respect of the Dossier, are, as between Supplier and Distributor, the exclusive property of Supplier and its Affiliates.

(d) Pricing. Distributor shall have sole discretion to establish the prices and terms on which Distributor sells the Authorized Generic Product.

(e) Promotional Materials.

(i) Distributor will ensure that any and all Promotional Materials used by Distributor in the Distribution of the Authorized Generic Product comply with the Labeling, the NDA and Applicable Law. Distributor may develop its own Promotional Materials subject to this Section 1.1(e), and include the Authorized Generic Product's generic name, launch date, available packaging configurations, and pricing and delivery terms in its introduction announcements to the trade, bill sheets and product catalog.

(ii) Distributor shall provide Supplier with a copy of any proposed Promotional Material related to the Authorized Generic Product at least [**] months prior to the Launch Date. Supplier shall have [**] Business Days to review and provide written objection to the use of such materials. If Supplier objects to the Promotional Material within [**] Business Days, then Distributor shall promptly revise such proposed Promotional Materials in accordance with Supplier's comments.

(iii) Distributor shall provide Supplier with the requisite number of copies of the final agreed Promotional Material as set forth in subsection (ii) and in the form required by Supplier in a timely manner to allow Supplier to satisfy its obligation to file such Promotional Materials with the FDA prior to their first use as required by Applicable Law. Supplier will make such filing with the FDA within [**] Business Days after the date Distributor provides Supplier with such copies of the final version of such Promotional Materials. Distributor shall not use any Promotional Material until Distributor has received confirmation from Supplier that the applicable Promotional Material has been filed with the FDA.

(iv) Supplier shall have no liability whatsoever to Distributor or any other Person in connection with Promotional Material created or used by Distributor, and Distributor shall indemnify Supplier pursuant to Article 7 for any Losses arising out of or resulting from Promotional Material created or used by Distributor, except that [**].

(f) Reserved Rights. Any rights of Supplier not expressly granted to Distributor under the provisions of this Agreement are retained by Supplier. Without limiting the generality of the foregoing and notwithstanding any other provision of this Agreement to the contrary, Supplier retains rights (i) to Manufacture, or have Manufactured, the Brand Product, and (ii) to market, sell and distribute, or have marketed, sold or distributed, any products containing naltrexone in the Territory, including a generic product containing naltrexone. Except as expressly provided in this Agreement, no right, title or interest in, to or under the NDA or any patent, trade secret, trademark or any other intellectual property right of Supplier or its Affiliates is granted, whether express or implied, by Supplier to Distributor.

1.2 Launch

(a) Launch. Subject to Section 2.9, Distributor will be entitled to launch the Authorized Generic Product on the date of a Third Party ANDA Product Launch ("**Launch Date**").

(b) Launch Conditions and Notice. The Launch Date of the Authorized Generic Product is January 15, 2027, subject to adjustment to an earlier or later launch date of the Authorized Generic Product pursuant to Section 1.2(b)(i) or 1.2(b)(ii) below.

(i) If the Parties learn that [**].

(ii) If the Parties learn that [**].

Under no circumstances will the Launch Date occur before the date of a Third Party ANDA Product Launch. For the avoidance of doubt, the launch conditions and other terms and conditions discussed in this Section 1.2(b) do not include the price and other sales terms on which Distributor sells the Authorized Generic Product, which Distributor shall have sole discretion to establish.

(c) Unauthorized Launch. Subject to Distributor's rights pursuant to Section 1.1(b)(iii), a launch of the Authorized Generic Product by Distributor prior to a Third Party ANDA Product Launch without Supplier's express written consent will be deemed an unauthorized launch ("**Unauthorized Generic Product Launch**"), cause Supplier irreparable harm, and constitute a material breach of this Agreement, subject to immediate termination of this Agreement. In the event of an Unauthorized Generic Product Launch, Distributor agrees to immediately cancel all orders, remove any Authorized Generic Product from the marketplace and destroy or return such Authorized Generic Product to Supplier at Supplier's sole option and at Distributor's sole cost. Notwithstanding anything to the contrary herein, in the event of an Unauthorized Generic Product Launch, Supplier does not waive any rights or remedies it may have, including the right to seek compensation from Distributor for all damages that it incurred. For the avoidance of doubt, the reference in the first sentence of this Section 1.2(c) to Supplier's express written consent shall only apply in the case of a launch of the Authorized Generic Product by Distributor prior to a Third Party ANDA Product Launch, and no such express written consent of Supplier shall be required for a launch of the Authorized Generic Product by Distributor at or after the time of the Third Party ANDA Product Launch or in connection with exercise of Distributor's rights pursuant to Section 1.1(b)(iii).

ARTICLE 2 -SUPPLY

2.1 Supply of Authorized Generic Product.

(a) Supply. In the first calendar quarter of the Launch Term, Supplier will supply, and Distributor shall exclusively purchase from Supplier, one hundred percent (100%) of Distributor's requirements of the Authorized Generic Product for the Territory for the Launch Term. Supplier shall Manufacture, Package, and deliver Authorized Generic Product to Distributor pursuant to the Final Batch Forecast and Single Purchase Order.

(b) Inventory and Stock. Supplier will be responsible for sourcing the Authorized Generic Product. Supplier shall procure all Components for manufacturing the Authorized Generic Product at Supplier's cost. Supplier shall have established

processes and procedures in place for auditing, qualifying, and monitoring suppliers of such materials in accordance with the Quality Agreement.

(c) Manufacturing Records. Supplier and Distributor shall maintain all records and samples (including retention samples) reasonably necessary to support GMPs and other regulatory requirements. All records relating to the Manufacture and Distribution of all Authorized Generic Product shall be retained for a period of not less than the approved shelf life of the Authorized Generic Product as set forth in the Marketing Authorization plus [**] or for such longer period as required by Applicable Laws. All other such records shall be maintained for a period consistent with current regulations.

2.2 API.

Supplier shall be responsible for procuring API and testing and analyzing such API to verify its compliance with applicable Specifications. Supplier shall maintain true, accurate and complete records of such sampling and analysis in accordance with the Quality Agreement.

2.3 Serialization.

Supplier shall comply with legislative and regulatory serialization requirements applicable in the Territory to the Authorized Generic Product. These efforts will be consistent with those of Supplier for the Brand Product. Distributor shall provide serial numbers via industry standards and provide other support related to serialization as Supplier reasonably requests. [**]

The Parties will initiate a project of work to establish and validate the process for transmission of serialization data no less than [**] months prior to the Launch Date.

2.4 Packaging and Labeling.

(a) Specifications, Technical Drawings. The Authorized Generic Product shall be Packaged in accordance with Applicable Law, the Dossier and Marketing Authorization. Supplier shall provide the Authorized Generic Product to Distributor in finished Packaged form, with artwork provided by Distributor, at Distributor's cost, pursuant to Sections 2.4(a)(i) and 2.4(a)(ii) and labeled with Distributor's NDC Number. Distributor shall only Distribute Authorized Generic Product bearing Distributor's NDC number.

(i) Within [**] Business Days after execution of this Agreement, Supplier shall provide a dieline which describes technical requirements to process each Component during the packaging process.

(ii) Not less than [**] months prior to the Launch Date, Distributor shall provide all artwork required in the Manufacturing of the Authorized Generic Product, including Labeling and Packaging specifications in accordance with the Supplier's dieline. [**].

(iii) Supplier shall destroy all artwork supplied or paid for by or on behalf of Distributor upon the termination or expiration of this Agreement.

(b) Labeling.

(i) Within [**] Business Days after execution of this Agreement, Supplier shall provide the package inserts, labeling, and packaging materials (collectively, "**Labeling**") for the Brand Product.

(ii) Not less than [**] months prior to the Launch Date, Distributor will provide Supplier with recommended changes to the Labeling which are in compliance with Applicable Law and which changes are limited to those that reflect that the product is the Authorized Generic Product and not the Brand Product.

(iii) Distributor and Supplier will mutually agree on the changes to Labeling that are appropriate for the Authorized Generic Product. Supplier will provide Distributor a proof of such Labeling for its review and approval at least [**] months prior to the Launch Date. Distributor shall have [**] Business Days to review and either comment upon, or approve, such Labeling materials. If approval of, or comments to, the Labeling materials is not provided within such [**] Business Day period, then the Labeling materials shall be considered approved. If comments are provided by Distributor, the Parties will work in good faith to resolve such comments within [**] Business Days, with Supplier possessing final decision-making authority in respect of such Labeling materials, should resolution not occur within such period. Notwithstanding the timelines set forth herein, in the event of any change to the Labeling of the Brand Product, the Parties shall work in good faith to discuss revisions to the Labeling of the Authorized Generic Product so as not to delay Distributor's planned launch of the Authorized Generic Product or, if launched, so as to promptly update Labeling of the Authorized Generic Product, to the extent required.

(iv) Supplier will be responsible for procuring all Labeling necessary to enable it to perform its obligations under this Agreement, subject to Distributor providing Supplier with the artwork, design and other content of the Labeling in accordance with the timelines set forth herein. Supplier or its Third Party designee shall maintain complete and accurate records of the usage and disposal of all Labeling related to the Manufacture of Authorized Generic Product(s) for Distributor. Supplier makes no representations or warranties with respect to the content of the Labeling of the Authorized Generic Product to the extent determined by Distributor (artwork, design, etc.).

2.5 Forecasts, Maximum Volume.

(a) Forecasts. [**] days after execution of this Agreement and then, commencing on the first day of the calendar quarter after the Effective Date of this Agreement

and on the first day of each calendar quarter thereafter, Distributor will provide a non-binding forecast of Distributor's requirements of Authorized Generic Product, which Distributor will use commercially reasonable efforts to estimate, stated in full Batch quantities (each, a "**Forecast**" and the first such Forecast, the "**First Forecast**"). Each Forecast shall specify the number of Batches to be Delivered [**] (the "**First Tranche**") and the number of Batches to be Delivered [**] (the "**Second Tranche**").

(b) Forecast Adjustment. [**] prior to each Forecast, and [**] days prior to the Single Purchase Order, Distributor will query Supplier as to [**] ("**Forecast Adjustment**"). For the avoidance of doubt, subject to Section 2.5(c), no upward adjustment of the volume stated in the First Forecast is allowed in any subsequent Forecast, in the Final Batch Forecast or in the Single Purchase Order.

(c) Final Forecast. Not less than [**] months before the Launch Date, Distributor will send Supplier a final binding Forecast with the number of Batches of Authorized Generic Product in the First Tranche and the Second Tranche, where such forecast may amend downward the quantity of Authorized Generic Product specified by Distributor in its First Forecast, as may be modified by the Forecast Adjustment, subject to the Maximum Volume limitation set forth below (such number of Batches of Authorized Generic Product for each of the First Tranche and the Second Tranche, the "**Final Batch Forecast**"). If Distributor's forecasts, including the Final Batch Forecast, do not conform to the allowable adjustments provided for herein, Distributor will have [**] Business Days from receipt of written notice by Supplier to correct such deficiencies. [**]

(d) Maximum Volume. Distributor's requirements of Authorized Generic Product may not exceed [**] Batches, with up to [**] Batches in the First Tranche and up to [**] Batches in the Second Tranche (the "**Maximum Volume**").

2.6 Purchase Order.

(a) Single Purchase Order. On or before [**], Distributor may place a single purchase order for one hundred percent (100%) of its requirements of Authorized Generic Product as stated in the Final Batch Forecast, specifying the number of Batches of Authorized Generic Product in each of the First Tranche and the Second Tranche (the "**Single Purchase Order**"). The Single Purchase Order must specify the quantity of Authorized Generic Product ordered (which must be in full Batch quantities only). Delivery pursuant to the Single Purchase Order shall be in the same calendar quarter as the Launch Date (or, if elected by Distributor pursuant to Section 1.2(b)(i), the immediately following calendar quarter) (such calendar quarter, the "**Delivery Window**"). Supplier shall solely control the number and timing of the deliveries (i.e., the dates on which deliveries are made) within the Delivery Window (each, a "**Delivery Date**"), in accordance with Section 2.7.

(b) Purchase Order Content. Distributor shall issue the Single Purchase Order with the following information:

(i) Supplier material number;

(ii) Single Purchase Order Number;

(iii) First Tranche quantity in full Batch quantities;

(iv) Second Tranche quantity in full Batch quantities:

(v) shipping address;

(vi) billing and email address for receipt of invoices;

(vii) Delivery Window; and

(viii) addressed to:

Commercial Supply Chain
Alkermes Pharma Ireland Limited
Connaught House
1 Burlington Road
Dublin 4
D04 C5Y6
IRELAND
+353 1 772 8000

(ix) e-mailed to:

[**]

(c) Acknowledgment and Acceptance of Single Purchase Order. Supplier shall acknowledge receipt of the Single Purchase Order within [**] Business Days of receipt, [**]. Any terms written on the Single Purchase Order, other than those set forth above will not be binding on Supplier. Supplier shall not reject the Single Purchase Order if it complies with the terms of this Agreement.

2.7 Delivery Timeframe.

(a) First Tranche. Upon Supplier's receipt of payment of the Deposit, Supplier will Deliver, and Distributor shall take Delivery of, the First Tranche of Authorized Generic Product between [**] ("**First Delivery**").

(b) Second Tranche. By [**], Distributor shall notify Supplier in writing of:

(i) the number of Batches set forth in the Second Tranche of the Single Purchase Order that Distributor wishes to take Delivery of as Authorized Generic Product by [**] ("**Second Delivery**"), and

(ii) the number of Batches set forth in the Second Tranche of the Single Purchase Order that Distributor does not wish to take Delivery of as Authorized Generic Product.

(c) Second Delivery. If Distributor notifies Supplier that Distributor would like to take delivery of [**] or more Batches of Authorized Generic Product pursuant to Section 2.7(b)(i), then Supplier will use commercially reasonable efforts to Deliver such Authorized Generic Product by [**].

2.8 Delivery Terms.

(a) Advance Shipping Notification. For the First Delivery, Supplier shall provide Distributor with at least [**] Business Days' advance Delivery notification and at least [**] days' prior written notice of the date on which Authorized Generic Product is anticipated to be made available to Distributor for collection at Supplier's Third Party packaging facility. For the Second Delivery, Supplier shall use commercially reasonable efforts to provide Distributor with at least [**] advance Delivery notification and [**] days' prior written notice of each date on which Authorized Generic Product is anticipated to be made available to Distributor for collection at Supplier's Third Party packaging facility.

(b) Incoterms; Title. All deliveries of the Authorized Generic Product shall be made [**]; for clarity, the Authorized Generic Product will be deemed delivered by Supplier upon Supplier making the Authorized Generic Product available to Distributor for collection [**] ("**Delivery**" or "**Delivered**" or "**Deliver**"). Title to the Authorized Generic Product (for both the First Tranche and the Second Tranche) shall pass from Supplier to Distributor upon Delivery.

(c) Distributor Collection. Distributor will arrange for collection of the Authorized Generic Product from the Supplier's Third Party packaging facility within [**] days of the Authorized Generic Product being Delivered, but in no event shall collection be later than [**]. Distributor will bear the cost of any storage fees at Supplier's Third Party packaging facility (at such Third Party's then customary rates) beyond [**] Business Days of being Delivered.

(d) Risk of Loss. Risk of loss shall pass upon Delivery. Supplier shall pass to Distributor good and marketable title to each Authorized Generic Product at the time of Delivery, free and clear of all liens, claims, security interests, pledges, charges, mortgages, deeds of trusts, options, or other encumbrances of any kind.

2.9 Third Party Launch Failure.

Notwithstanding anything to the contrary in this Agreement, in the event a Third Party ANDA Product Launch does not occur within ninety (90) days after January 15, 2027, or within ninety (90) days of an earlier Launch Date as provided in Section 1.2(b)(i) ("**Third Party ANDA Product Launch Failure**"), Distributor shall no longer have the right to launch the Authorized Generic Product. In the event of a Third Party ANDA Product Launch Failure, upon written request of Distributor, Supplier agrees to discuss and

consider, for a period of thirty (30) days from the date of the Third Party ANDA Product Launch Failure, whether to allow Distributor a second opportunity to launch the Authorized Generic Product. For clarity, Supplier is under no obligation to agree to a second opportunity to launch the Authorized Generic Product.

2.10 Timing and Return of Authorized Generic Product.

(a) For Batches Delivered pursuant to Sections 2.7(a) and 2.7(b)(i), in the event of a Third Party ANDA Product Launch Failure [**].

(b) For Batches that Distributor ordered pursuant to Section 2.7(b)(i) but that were not Delivered by [**]:

(i) [**]

(ii) [**]

(c) For Batches that Distributor did not order pursuant to Section 2.7(b)(ii) (the units in such Batches, "**Non-Ordered Units**"):

(i) In the event that (1) there is a Third Party ANDA Product Launch Failure, and (2) Supplier [**]

(ii) In the event that there is a Third Party ANDA Product Launch within [**] days of the Launch Date, or Supplier [**].

(d) Proof of Destruction. Supplier will provide proof of destruction for all units of Authorized Generic Product for which [**]. For clarity, Supplier is under no obligation to destroy any Brite Stock.

2.11 Returns.

Except as set forth in Sections 1.2(c), 2.10 and 3.4(b), Distributor will not have any right to return any Authorized Generic Product to Supplier, it being acknowledged and agreed that the handling and processing of any and all returns of Authorized Generic Product from Distributor's Third Party customers shall be solely Distributor's responsibility. In the event Supplier receives any Authorized Generic Product from a Third Party, Supplier shall notify Distributor of such returned Authorized Generic Product and destroy such returned Authorized Generic Product at Distributor's sole expense.

2.12 Failure to Supply.

(a) Supply Failure. Supplier will promptly notify Distributor in writing in the event that Supplier is unable, or anticipates that it will be unable, to supply Authorized Generic Product [**] ("**Failure to Supply**"). [**]. Within [**] calendar days of receipt of such notification, the Parties will meet and discuss Supplier's remaining manufacturing capacity in relation to Distributor's requirements of Authorized Generic Product and what Supplier can supply to Distributor by the close of the Delivery Window. For any Failure to Supply, Distributor will have

the right to cancel orders for any quantities of the Authorized Generic Product that are not able to be supplied by the close of the Delivery Window due to such Failure to Supply, effective upon notice to Supplier, and Distributor will have no further obligations to purchase any such cancelled quantities of Authorized Generic Product. In any event, with respect to Supplier's capacity, Distributor's Single Purchase Order with respect to Authorized Generic Product shall rank *pari passu* with any orders (whether of Supplier or its Affiliates or any Third Party) for any other authorized generic version of the Brand Product Manufactured or supplied by Supplier or its subcontractors.

(b) [**] Damages for Failure to Supply. For any Failure to Supply that is not related, in whole or in part, to Distributor's failure to comply with Distributor's obligations as set forth in this Agreement, as Distributor's sole and exclusive remedy under this Agreement, including in lieu of Delivery of the Authorized Generic Product, Supplier will be liable for [**] damages in the amount of [**] per Batch that has been ordered by Distributor as specified in the First Tranche of the Single Purchase Order but not Delivered by Supplier (to the extent a partial Batch is Delivered, Distributor will be compensated on a pro rata basis). For clarity, any quantities of Authorized Generic Product set forth in the Second Tranche of the Single Purchase Order that Supplier is unable to Deliver by [**], are not subject to [**] damages and the sole remedy for any such failure is as provided in Section 2.10(b).

(c) Force Majeure Exception. The [**] damage remedy specified in this section will not apply if the unremedied Failure to Supply arises in whole or in material part due to a Force Majeure Event.

(d) Distributor-Related Supply Delay. For any supply delay related to or caused by, in a material respect, Distributor's failure to comply with the terms set forth in this Agreement, Supplier's failure to supply Distributor per the terms set forth in the Single Purchase Order will not be considered a Failure to Supply ("**Distributor-Related Supply Delay**"). For any Distributor-Related Supply Delay, the Parties will use commercially reasonable efforts to supply Distributor the Authorized Generic Product ordered by Distributor and Manufactured by Supplier ("**Ordered Authorized Generic Product**") within the Delivery Window. If Supplier determines that it is unable to provide Distributor with the Ordered Authorized Generic Product within the Delivery Window having at least [**] months of shelf-life due to the Distributor-Related Supply Delay, Distributor shall have the option to take the Ordered Authorized Generic Product with less than [**] months of shelf-life or ask Supplier to use commercially reasonable efforts to repurpose the Ordered Authorized Generic Product. If Supplier is asked to repurpose the Ordered Authorized Generic Product, and Supplier reasonably believes that it will not be able to sell such Ordered Authorized Generic Product, then Distributor will pay [**] of the Transfer Price for such Ordered Authorized Generic Product and such amount will not be deducted from the Net Sales or Net Profits, after which Supplier will

have no further obligation to supply Distributor with Authorized Generic Product.

(e) Termination by Distributor. Without limiting the other provisions of this Agreement, including this Section 2.12, Distributor shall have the right to terminate this Agreement upon written notice to Supplier following any Failure to Supply that Supplier is not able to remedy by the close of the Delivery Window.

ARTICLE 3 -REGULATORY

3.1 Drug Listing Information and NDC Number.

(a) Drug Listing Information. Supplier shall submit, with the assistance of Distributor as reasonably required by Supplier, drug listing information to the Regulatory Authority with respect to the Authorized Generic Product.

(b) NDC Number. Distributor shall be responsible for complying with Regulatory Authority listing requirements for the Authorized Generic Product. Distributor shall establish NDC Numbers for each packaging configuration for the Authorized Generic Product. Distributor shall sell or distribute the Authorized Generic Product using new NDC Numbers, different than those for the Brand Product, indicating Distributor as the distributing or selling party. Distributor shall obtain such NDC Numbers sufficiently in advance of the launch of the Authorized Generic Product in the Territory to comply with the Labeling enumerated in Article 2 of this Agreement. Supplier shall reasonably assist Distributor in obtaining such NDC Numbers and Regulatory Authority authorization to begin Distributing Authorized Generic Product, including the provision of documentation or materials to the Regulatory Authorities in the Territory.

(c) Manufacturer on Label. Supplier shall be identified as the manufacturer of the Authorized Generic Product on the Label.

(d) Last Mile. Distributor acknowledges that once it takes Delivery of the Authorized Generic Product from Supplier, in accordance with the Quality Agreement, it has certain last mile obligations to ensure the safety of the Authorized Generic Product from Distributor to Distributor's customers including: (i) confirming through audit or documentation that only FDA regulated facilities (as described in 21 CFR Part 211) (hereinafter "**FDA Regulated Facilities**") are utilized for warehousing, storing and distributing the Authorized Generic Product; (ii) confirming through audit or documentation that only FDA licensed distributors that are GMP compliant, possess 21 CFR Part 11 compliance (where applicable), and are DSCSA (Drug Supply Chain Security Act) compliant ("**FDA Licensed Distributors**") are utilized for the transport of Authorized Generic Product; (iii) [**] (iv) providing notification to Supplier of any temperature excursions; (v) maintaining an inventory management system through which Distributor authorizes, provides for release

of and can quarantine, Authorized Generic Product to such FDA Licensed Distributors and FDA Regulated Facilities; and (vi) maintaining records of compliance with these last mile obligations (collectively (i) through (vi), "**Last Mile Obligations**"). Regarding this quality-related matter, in the event of conflict between the Quality Agreement and this Agreement, the Quality Agreement shall govern.

(e) Supplier Audit Right for Compliance with Last Mile. At least [**] months prior to the Launch Date, and thereafter during the Term, Supplier shall be entitled to audit Distributor's facilities where the Authorized Generic Product is stored for compliance with the Last Mile Obligations. During the Term and for [**] years thereafter, or for such longer period as may be required by Applicable Law and in accordance with the Quality Agreement, Distributor shall prepare and retain accurate records pertaining to its Last Mile Obligations under this Agreement. Such records shall be made available for review, audit and inspection by Supplier, upon reasonable advance notice to Distributor, during regular business hours, for the purpose of verifying Distributor's compliance with the Last Mile Obligations.

3.2 Other Regulatory Matters.

(a) Seller Responsibilities. Except as otherwise stated in this Agreement, Supplier shall be responsible for addressing all regulatory matters relating to the Authorized Generic Product in the Territory. Supplier shall maintain the NDA in accordance with Applicable Law and requirements of the applicable Regulatory Authority and be solely responsible for interacting with the FDA in respect of the NDA, including the filing of all annual reports and any other document required by the FDA or other applicable Regulatory Authority in order to enable the Distribution of the Authorized Generic Product by Distributor in the Territory.

(b) Distributor Responsibilities. Distributor is responsible for complying with regulatory requirements and other matters which relate solely to Distributor's role as a distributor of the Authorized Generic Product using the Distributor's NDC Numbers, including Last Mile Obligations as provided for in Section 3.1(d), communications and filings with and submissions to any Regulatory Authority concerning sales of the Authorized Generic Product, and prices, discounts, rebates, fees, charge-backs, and other payments associated with Distributor's distribution and sale of the Authorized Generic Product. Distributor shall obtain and maintain any and all regulatory and governmental permits, licenses and approvals that are necessary for Distributor to Distribute the Authorized Generic Product in accordance with the terms of this Agreement and Applicable Law.

(c) Permits, Licenses and Approvals. Supplier shall also obtain and maintain any and all regulatory and governmental permits, licenses and approvals that are necessary for Supplier to Manufacture the Authorized Generic Product for Distributor in accordance with the terms of this Agreement and Applicable

Law. Distributor shall provide timely assistance to Supplier, as necessary, to obtain and maintain regulatory and governmental permits, licenses and approvals necessary for Distribution of the Authorized Generic Product.

(d) Written Notices. Supplier and Distributor will each promptly notify the other Party of all written notices of violations (including threatened notices of material violations) of Applicable Law and the Quality Agreement related to the Authorized Generic Product, including in respect of Distributor's Distribution of the Authorized Generic Product in the Territory, received from any Governmental Authority or Regulatory Authority or any competitor company or other Person, and shall provide to the other Party copies of all such notices and written responses, provided that Supplier may redact sensitive information not necessary for Distribution of the Authorized Generic Product. In all instances, Distributor and Supplier will work together in good faith to agree upon a course of action and whichever Party is required to respond, assuming a response is necessary, that Party will solicit, and consider in good faith, input from the other Party prior to responding to the notice.

3.3 Facility Compliance and Inspection.

(a) Compliance. Supplier shall maintain the facilities where the Authorized Generic Product is Manufactured, Packaged, Labeled, and tested, including Third Party locations, if any, in compliance with GMP and Applicable Law. Distributor shall maintain the facilities where the Authorized Generic Product is stored prior to shipment to Distributor's customers, including Third Party locations, if any, in compliance with GMP and Applicable Law.

(b) Regulatory Driven Inspections of Supplier. For the period of time between the date that the Final Batch Forecast is provided to Supplier and the end of the Launch Term, if Supplier receives any notification from Regulatory Authorities of any inspection of its manufacturing facilities materially impacting the manufacture, testing or storage of Authorized Generic Product, or any warning letter or similar correspondence from any such Regulatory Authority relating to the Authorized Generic Product, then Supplier shall:

(i) provide Distributor with copies or extracts of (A) such notice of inspection and (B) all such notices, correspondence and related documents received by Supplier from, or sent by Supplier to, the applicable Regulatory Authorities, which may be redacted for sensitive information not necessary for Distribution of the Authorized Generic Product;

(ii) permit the applicable Regulatory Authorities to enter Supplier's facilities for the purpose of regulatory inspection;

(iii) furnish Distributor with relevant copies or extracts of such reports and analyses relating to the Authorized Generic Product received by Supplier as a result of any such inspection relating to the Authorized Generic Product,

which Supplier may redact for any proprietary information not necessary for Distribution of the Authorized Generic Product; and

(iv) ensure that any deficiencies are corrected, at Supplier's expense, as soon as reasonably practicable.

(c) Regulatory Driven Inspections of Distributor. For the period of time between the first Delivery Date and the end of the Launch Term, if Distributor receives any notification from Regulatory Authorities of any inspection of facilities where the Authorized Generic Product is stored prior to shipment to Distributor's customers, or at any time if Distributor receives any warning letter or similar correspondence from any such Regulatory Authority relating to the Authorized Generic Product, then Distributor shall:

(i) provide Supplier with copies or extracts of (A) such notice of inspection and (B) all such notices, correspondence and related documents received by Distributor from, or sent by Distributor to, the applicable Regulatory Authorities;

(ii) permit the applicable Regulatory Authorities to enter Distributor's facilities for the purpose of regulatory inspection;

(iii) furnish Supplier with relevant copies or extracts of such reports and analyses received by Distributor as a result of any such inspection relating to the Authorized Generic Product, which Distributor may redact for any proprietary information; and

(iv) ensure that any deficiencies are corrected, at Distributor's expense, as soon as reasonably practicable.

(d) Distributor Inspections. Within [**] days of the Launch Date, and thereafter until the latest expiration of Authorized Generic Product delivered hereunder, but not more than once every [**] months (or more frequently in the case of a for-cause inspection), Distributor shall be entitled to have a Third Party audit firm reasonably acceptable to Supplier conduct a GMP audit of the facilities where the Authorized Generic Product is Manufactured, Packaged, Labeled, and tested; provided that (i) the Third Party audit firm will disclose to Distributor only whether or not the facilities are in GMP compliance and specific details concerning any GMP non-compliance, (ii) no proprietary information or any patent, trade secret, trademark or any other intellectual property of Supplier will be provided by the Third Party audit firm to Distributor without the prior consent of Supplier, and (iii) the Third Party audit firm shall execute a reasonable confidentiality agreement with Supplier prior to commencing any audit. In lieu of such audit, Supplier may provide a GMP audit report from a reputable Third Party audit firm reasonably acceptable to Distributor.

3.4 Product Testing and Acceptance.

(a) Product Testing and Inspections. Each shipment of the Authorized Generic Product shall be accompanied by certificate of analyses for the Authorized Generic Product and diluent and certificate of release (COA/COC) consistent with those provided for the Brand Product. Supplier will also provide Distributor with the same Material Safety Data Sheets ("**MSDS**"), or equivalent instrument recognized by the applicable Regulatory Authority, as required for the Authorized Generic Product. Supplier is responsible for testing Components and other materials in accordance with the Specifications.

(b) Non-Conforming Goods. Distributor will visually inspect an Authorized Generic Product shipment within [**] Business Days of receipt at Distributor's facility to confirm that the quantity of Batches of Authorized Generic Product shipped is accurate. Distributor shall notify Supplier of any error in quantity shipped within [**] Business Days of receipt of such shipment and, in the event a greater number of Authorized Generic Product Batches were received than ordered, either coordinate with Supplier to return to Supplier, at Supplier's sole expense, any excess Batches of Authorized Generic Product received or retain and pay for such excess quantity, which shall be at Distributor's sole discretion. In the event that fewer Authorized Generic Product Batches were received than ordered, Distributor shall notify Supplier of this shortage. In the event Authorized Generic Product does not meet the Required Standards, as determined pursuant to this Section 3.4(b), Supplier will within [**] Business Days of Delivery or discovery, as applicable under Section 3.4(b)(i) or 3.4(b)(ii) below, at [**] option, either (i) replace such non-conforming Authorized Generic Product as promptly as reasonably practicable (provided that such Authorized Generic Product can be replaced within the same calendar quarter as Delivery of the non-conforming Authorized Generic Product) or (ii) refund the Transfer Price previously paid by Distributor for such non-conforming Authorized Generic Product. In the case of (x) any shortage in quantity of Authorized Generic Product Delivered pursuant to the First Delivery or (y) any non-conforming Authorized Generic Product Delivered pursuant to the First Delivery, in either case of greater than [**] of the quantity specified in the Single Purchase Order, notified pursuant to Section 3.4(b)(i) below, then, in the case of (x), if Supplier is not able to furnish the shortage in Authorized Generic Product within the same calendar quarter of Supplier's Delivery or, in the case of (y), if the Supplier is not able to replace the non-conforming Authorized Generic Product by the close of the Delivery Window, then Distributor's sole remedy is as set forth in Section 2.12(b).

(i) Distributor shall notify Supplier in writing within [**] Business Days of Supplier's Delivery of the Authorized Generic Product if, based on Distributor's visual inspection made with reasonable care, any Authorized Generic Product does not appear to be in compliance with the Specifications. Such notice must include evidence to support such a finding.

(ii) For hidden defects not apparent from a visual inspection made with reasonable care that cause such Authorized Generic Product not to meet Specifications, Distributor shall notify Supplier in writing within [**] Business Days of Distributor's discovery of such defects with evidence to support any finding that one or more units of Authorized Generic Product do not appear to be in compliance with the Specifications.

(iii) If Distributor fails to provide notice as required under Sections 3.4(b)(i) and 3.4(b)(ii), then the Authorized Generic Product is deemed accepted and Supplier is not required to take any action.

(iv) If requested by Supplier, Distributor shall ship a sample of Authorized Generic Product alleged not to meet Specifications to Supplier at Distributor's expense.

(v) If Supplier agrees that all or a portion of the Authorized Generic Product does not meet the Specifications, Supplier and Distributor shall coordinate to destroy, or return to Supplier at Supplier's sole discretion, such Authorized Generic Product at Supplier's expense.

(vi) If Supplier does not agree with Distributor's determination that the Authorized Generic Product fails to conform to the Specifications, then Supplier shall so notify Distributor in writing within [**] Business Days of the later of its receipt of Distributor's notice of non-conformity with respect to the Authorized Generic Product and Supplier's receipt of a requested sample of such allegedly non-conforming product. Supplier and Distributor shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, in the event that Supplier and Distributor are unable to resolve such disagreement within [**] calendar days of the later of Supplier's receipt of Distributor's notice of non-conformity with respect to the Authorized Generic Product and Supplier's receipt of a requested sample of such allegedly non-conforming Authorized Generic Product, then a sample of the allegedly non-conforming Authorized Generic Product may be submitted for testing to an independent testing organization, or to a consultant of recognized repute within the United States pharmaceutical industry, in either case as mutually agreed upon by the Parties (such organization or consultant, the "**Independent Laboratory**") for a determination as to whether or not such Authorized Generic Product conforms to the Specifications, as applicable. If the records from Supplier and Distributor confirm that the Authorized Generic Product was stored and maintained at all times as required by the Specifications, or if neither Party's records confirm that the Authorized Generic Product was stored and maintained at all times as required by the Specifications, the determination of the Independent Laboratory with respect to all or part of the shipment of the Authorized Generic Product shall be final and binding upon the Parties. If only one Party's records confirm storage and maintenance of the Authorized Generic Product according to the

Specifications then, absent a contrary decision by the Independent Laboratory, the other Party (without such confirming records), shall be deemed to have caused the non-conforming Authorized Generic Product. The cost of the Independent Laboratory and all other necessary and related expenses shall be borne by the Party with whom the Independent Laboratory disagrees.

(vii) Notwithstanding anything to the contrary in this Agreement, the remedies set forth in this Section 3.4(b) (including [**] damages for Failure to Supply in accordance with Section 2.12(b)) are only applicable for failure to meet Specifications or non-conformance of the Authorized Generic Product that are not related, in whole or in part, to Distributor's failure to comply with Distributor's obligations as set forth in this Agreement.

ARTICLE 4 -PRICING AND PAYMENT

4.1 **Transfer Price**. The transfer price for the Authorized Generic Product is Supplier's Fully Burdened Manufacturing Cost for the Manufacture of the Authorized Generic Product, plus [**] on a per unit basis (the "**Transfer Price**"). Non-Refundable Costs specified in Section 4.2 are not included in the Transfer Price.

4.2 **Non-Refundable Upfront Costs.** The non-refundable upfront costs are a subset of Supplier's Fully Burdened Manufacturing Costs, plus [**] of such costs, which subset shall be the costs incurred [**] in the amounts set forth in the Single Purchase Order ("**Non-Refundable Costs**"). Costs included in Transfer Price as specified in Section 4.1 are not included in the Non-Refundable Costs.

4.3 **Profit Share.**

(a) Net Profit Split. Distributor and Supplier agree to allocate the Net Profits (subject to Section 4.3(e)) as follows: [**] of Net Profits allocated to Supplier (the "**Supplier's Profit Share Amount**") and [**] of Net Profits allocated to Distributor.

(b) Estimates. Within [**] days after the end of each calendar quarter after Launch and during the Term, Distributor shall provide Supplier with an estimate of the number of units of Authorized Generic Product sold by Distributor and the average sales price for such units during such calendar quarter.

(c) Quarterly Reports. Within [**] days after the end of each calendar quarter after the Launch Date and during the Term, Distributor shall provide Supplier with a quarterly report detailing the amount of Authorized Generic Product sold by Distributor and the type and amount of all items used in Distributor's calculation of Net Sales and Net Profits. Distributor shall also provide Supplier with the number of units of Authorized Generic Product returned to Distributor within the quarter.

(d) True-Ups. Within [**] days after the end of each calendar quarter after the Launch Date and during the Term, Distributor shall provide Supplier with the total amounts of Net Profits and Net Sales. The Parties agree that the Transfer Price paid for non-conforming Authorized Generic Product shall be accounted for separately and not in the calculation of Net Profit or Net Sales.

(e) Negative Net Profit. Notwithstanding anything to the contrary in this Agreement, Supplier will not be obligated to pay Distributor in the event of any negative Net Profit to Supplier. [**]

4.4 Payment Terms.

(a) Invoices; Timing.

(i) Upon Distributor's placement of its Single Purchase Order, Supplier will invoice Distributor (at APNJ@amneal.com) for all Non-Refundable Costs. Distributor shall pay such invoice within [**] days of its receipt. The Non-Refundable Costs will not be included in the Transfer Price and are not subject to refund by Supplier under any circumstances, except as provided in Section 4.4(f).

(ii) Subject to Section 1.2(b), on [**], Supplier will invoice Distributor (at APNJ@amneal.com) for the Transfer Price of the Authorized Generic Product to be shipped pursuant to the Single Purchase Order ("**Transfer Price Invoice**"). Distributor shall make payment within [**] days of receipt of invoice, provided that Distributor shall pay the Deposit by [**], and provided further that Supplier's receipt of such payment of the Deposit is a condition precedent to its Delivery of the Authorized Generic Product ordered in the First Tranche of the Single Purchase Order. For the avoidance of doubt, Distributor will not pay for any fees not explicitly set out in an invoice.

(iii) Payment of Supplier's Profit Share Amount will be made [**] days after the end of each calendar quarter during the Term.

All payments to Supplier are exclusive of any applicable value added, excise, sales or any other similar or substitute tax, for which the Distributor will be additionally liable, if applicable. Applicable taxes shall be included and indicated separately on the invoice. Promptly after the issuance of the Single Purchase Order, Distributor shall furnish to Supplier a valid blanket state resale exemption certificate.

(b) Withholding. Distributor will make all payments to Supplier under this Agreement without deduction or withholding except to the extent that any such deduction or withholding is required by Applicable Law. Any tax required to be withheld by Applicable Law on amounts payable under this Agreement will promptly be paid by Distributor on behalf of Supplier to the appropriate Governmental Authority, and Distributor will furnish Supplier with proof of payment of such tax within [**] calendar month of such payment. Distributor

shall give [**] days advance notice of its intention to begin withholding any such tax in advance of such withholding. Distributor and Supplier will cooperate: (i) in all respects necessary to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available in order for the payments under this Agreement to be made without any deduction or withholding, and (ii) with respect to producing all documentation required by any Governmental Authority with respect to taxes or as reasonably requested by Supplier to secure a reduction in the rate of applicable withholding taxes or to secure a credit or refund for withheld taxes. Supplier shall provide to Distributor a properly completed and executed IRS Form W-8BEN-E prior to Distributor making any payment under this Agreement.

(c) Method of Payment. All payments made by Distributor to Supplier or by Supplier to Distributor under this Agreement shall be made by wire transfer or as Supplier may otherwise agree.

(d) Failure to Pay. Any failure by Distributor to pay the Non-Refundable Costs, Transfer Price Invoice (including Deposit) or Supplier's Profit Share Amount within the timelines and according to the terms set forth herein shall be considered a material breach of this Agreement ("**Distributor Payment Failure**").

(e) Supplier Audit Right. During the Term and for [**] years thereafter, Distributor shall prepare and retain accurate records of its sales of Authorized Generic Product sufficient to accurately calculate the amounts payable to Supplier under this Agreement. Such records shall be made available for review, audit and inspection upon reasonable notice and no more than [**] per calendar year, during regular business hours, by a nationally recognized independent certified public accountant selected by Supplier and reasonably acceptable to Distributor for the purpose of verifying Distributor's calculations of amounts due hereunder, and the basis for such calculations or payments; provided that Distributor may require such accountant(s) to enter into a customary confidentiality agreement for arrangements of such type. Such accountants shall disclose to Supplier, with a copy to Distributor, only whether the particular calculations are correct or incorrect, and the amount of discrepancy, if any. No other information shall be provided to Supplier. Once examined, such books and records will no longer be subject to further examination under this Section 4.4(e). Any amounts shown to be owed but unpaid shall be paid, or any amounts shown to be overpaid shall be refunded, within [**] calendar days from the accountant's report. Supplier shall bear the full cost of such audit unless such audit discloses an underpayment of more than [**] of the amount actually owed during the period audited, in which case Distributor shall reimburse Supplier for its Third Party costs incurred for such audit.

(f) Distributor Audit Right. During the Term and for [**] years thereafter, or for such longer period as may be required by Applicable Law, Supplier shall prepare and retain, and shall cause its subcontractors to prepare and retain, accurate records related to transactions made pursuant to this Agreement resulting in Non-Refundable Costs and the Transfer Price of Authorized

Generic Product. Such records shall be made available for reasonable review, audit and inspection upon reasonable notice during regular business hours, and not more often than once every calendar year, upon Distributor's request for the purpose of verifying Non-Refundable Costs and the Transfer Price of Authorized Generic Product, by a nationally recognized independent certified public accountant, selected by Distributor and reasonably acceptable to Supplier for the limited purpose of verifying Non-Refundable Costs and the Transfer Price of Authorized Generic Product; provided that Supplier may require such accountant(s) to enter into a customary confidentiality agreement for arrangements of such type. Such accountants shall disclose to Distributor, with a copy to Supplier, only whether Non-Refundable Costs and the Transfer Price of Authorized Generic Product are correct or incorrect, and the respective amounts of discrepancy, if any. No other information shall be provided to Distributor. Any amounts shown to be owed but unpaid shall be paid, or any amounts shown to be overpaid shall be refunded, within [**] calendar days from the accountant's report. Distributor shall bear the full cost of such audit unless such audit discloses an overpayment of more than [**] of the amount actually owed during the applicable calendar year, in which case Supplier shall reimburse Distributor for its Third Party costs incurred for such audit.

ARTICLE 5 -WARRANTIES

5.1 Distributor Warranties and Representations.

(a) Good Standing. Distributor is a limited liability company duly incorporated, validly existing and in good standing under the laws of the state of its organization.

(b) Authority and Capabilities. Distributor has all requisite power and authority to enter into this Agreement and has the requisite skill, knowledge, staffing, financial resources, capacity and ability to carry out its obligations hereunder. The Person signing this Agreement has the necessary limited liability company authority to legally bind Distributor to the terms set forth herein.

(c) No Conflicts. Distributor's execution of this Agreement and performance of the terms set forth herein will not cause Distributor to be in conflict with, or constitute a breach of, its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

(d) Valid and Binding. This Agreement is its legal, valid and binding obligation, enforceable against Distributor in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

(e) No Claims or Actions. To Distributor's knowledge, there are no suits, actions, claims, proceedings, or investigations against it that are pending or threatened

by or before any court by any Person relating to the matters set forth herein that would prevent Distributor's performance hereunder.

(f) No Conflicts with Applicable Law. Distributor's execution of this Agreement and performance hereunder are, and will be, in compliance with any Applicable Law.

(g) No Violation of the Application Integrity Policy. Neither Distributor, nor any Distributor Affiliate involved in the commercialization of the Authorized Generic Product or performance of Distributor's obligations under this Agreement, is the subject of any pending or, to Distributor's knowledge, threatened investigation in respect of Distributor by the FDA pursuant to its 'Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities' Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto.

(h) No Off-Label Promotion. Distributor will not engage in any 'off label' promotion of the Authorized Generic Product in violation of Applicable Law.

(i) Last-Mile Obligations. Distributor will have in place by no less than [**] months before the Launch Date, the ability to comply with its Last Mile Obligations, including but not limited to storage of Authorized Generic Product in accordance with the Quality Agreement for the Authorized Generic Product. Distributor represents that not less than [**] months before the Launch Date, Distributor shall provide Supplier with documentation as specified in the Quality Agreement evidencing Distributor's ability to comply with storage and distribution requirements for the Authorized Generic Product pursuant to Section 3.1(d).

(j) Compliance with Applicable Law. Distributor will comply with all requirements of Applicable Law to Distribute the Authorized Generic Product, including Last Mile Obligations.

Distributor will provide Supplier with prompt written notice if it becomes aware that any of the representations or warranties in this Section 5.1 become materially untrue prior to the Launch Date.

5.2 Supplier Warranties and Representations.

(a) Good Standing; Ownership of IP; No Grants that Conflict. Supplier is a company duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization. Supplier owns the entire right, title and interest in the Licensed Intellectual Property Rights and the Marketing Authorization for the Authorized Generic Product in the Territory, or otherwise has the right to grant the rights granted to Distributor herein, and Supplier and its Affiliates have not, and shall not, grant any rights (including any lien or security interest) that conflict with such rights or that would otherwise prevent Distributor from exercising its rights or performing its obligations hereunder.

(b) Authority; Capabilities. Supplier has all requisite power and authority to enter into this Agreement and has the requisite skill, knowledge, staffing, financial resources, capacity and ability to carry out its obligations hereunder. The person signing this Agreement has the necessary authority to legally bind Supplier to the terms set forth herein.

(c) No Claims or Actions. To Supplier's knowledge, there are no suits, actions, claims, proceedings, or investigations against it that are pending or threatened by or before any court by any Person relating to the matters set forth herein that would prevent Supplier's performance hereunder.

(d) No Conflicts. Supplier's execution of this Agreement and performance of the terms set forth herein will not cause Supplier to be in conflict with or constitute a breach of its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound.

(e) Compliance with Applicable Law. Supplier's execution of this Agreement and performance hereunder are, and will be, in compliance with any Applicable Law.

(f) No Violation of the Application Integrity Policy. Supplier is not the subject of any pending or, to Supplier's knowledge, threatened investigation in respect of Supplier or the Authorized Generic Product by the FDA pursuant to its 'Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities' Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. To Supplier's knowledge, all submissions to Governmental Authorities with respect to the Authorized Generic Product were complete and accurate in all material respects or were corrected through a subsequent amendment.

(g) Valid and Binding. This Agreement is its legal, valid and binding obligation, enforceable against Supplier in accordance with the terms and conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

(h) No Third Party Infringement. The Manufacture of the Authorized Generic Product for supply to Distributor and the Distribution and sale of the Authorized Generic Product by Distributor in the Territory to Supplier's knowledge, does not and will not infringe upon the Intellectual Property Rights of any Third Party.

(i) Product and Compliance Warranties. Supplier represents and warrants that Authorized Generic Product will, at the time of Delivery to Distributor [**]:

(i) comply with the Specifications, including those in the Dossiers as approved by the Regulatory Authority or set out in the Marketing Authorization, as well as the terms of this Agreement and the Quality Agreement;

(ii) be manufactured in accordance with applicable GMP, the Marketing Authorization, as well as requirements of the Regulatory Authority and all Applicable Law in the Territory;

(iii) be of merchantable quality and be free from defect and damage;

(iv) have a minimum of[**] months of shelf life remaining, except as otherwise set forth in this Agreement; and

(v) not be adulterated or misbranded under any Applicable Law in the Territory.

Supplier will provide Distributor with prompt written notice if it becomes aware that any of the representations and warranties in this Section 5.2 are untrue as of the Launch Date or date of Delivery.

5.3 Debarred.

Distributor and Supplier each represents and warrants as to itself that neither Distributor nor Supplier has ever been and is currently (i) an individual who has been debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) ("**Debarred Individual**") from providing services in any capacity to a person that has an approved or pending drug product application with FDA; or (ii) a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C. § 335(a) or (b) ("**Debarred Entity**") from submitting or assisting in the submission of an NDA or ANDA.

Distributor and Supplier each further represents and warrants as to itself that:

(a) No Knowledge. Neither has any knowledge of any circumstances which may affect the accuracy of the foregoing representation, including, without limitation, any FDA investigations of, or debarment proceedings against, either or any person or entity performing services or rendering assistance which is in any way related to activities taken pursuant to this Agreement; and

(b) Notification. It shall immediately notify the other in writing, by certified or registered mail if it, at any time during the Launch Term, becomes aware of any such circumstances with respect to itself described in this section.

5.4 Ethics and Anti-Corruption.

Each of Supplier and Distributor represents and warrants that:

(a) it complies with the employment laws and labor laws in the countries in which it operates;

(b) it does not employ, engage or otherwise use any child labor in circumstances such that the tasks performed by any such child labor could reasonably be

foreseen to cause either physical or emotional impairment to the development of such child;

(c) it does not use forced labor in any form (prison, indentured, bonded, or otherwise) and its employees are not required to lodge papers or deposits on starting work;

(d) it provides a safe and healthy workplace, presenting no immediate hazards to its employees;

(e) it does not discriminate against any employees on any ground (including race, religion, disability, or gender);

(f) it does not engage in or support the use of corporal punishment or mental, physical, sexual, or verbal abuse, and does not use cruel or abusive disciplinary practices in the workplace; and

(g) it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, and provides each employee with all legally mandated benefits.

Each of Supplier and Distributor agree that it is responsible for controlling its own supply chain and that it shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by it when performing its obligations pursuant to this Agreement.

5.5 Compliance with Trade Control Laws.

(a) Compliance Generally. Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including the U.S. Export Administration Regulations (Title 15 of the U.S. Code of Federal Regulations Part 730 *et seq*.) and the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S. Code of Federal Regulations Part 500 *et seq*.) (collectively, "**Trade Control Laws**")**.**

(b) Applicability. Each Party acknowledges and confirms that Trade Control Laws apply to its activities, its employees and Affiliates under this Agreement.

(c) Compliance with Economic Sanctions. The Authorized Generic Product will not be directly or knowingly indirectly shipped by either Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses.

(d) Compliance with Restricted Party Lists. Each Party hereby represents and warrants that it is not included on any of the restricted party lists maintained by the U.S. Government, including the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control; the Denied Persons List, Unverified List or Entity List maintained by

the U.S. Commerce Department's Bureau of Industry and Security; or the List of Statutorily Debarred Parties maintained by the U.S. State Department's Directorate of Defense Trade Controls.

(e) Compliance with Trade Sanctions. Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent the Authorized Generic Product from being exported or re-exported to any country, entity or individual subject to U.S. trade sanctions, unless the relevant permission or license from the U.S. government has been obtained.

(f) Records. Each Party will keep accurate and consistent records of all transactions covered by the Trade Control Laws for a minimum of five (5) years from the date of export or re-export; the date of expiration of any applicable license; or other approval or reliance on any application of license exception or exemption.

5.6 Further Compliance with Applicable Anti-Corruption Laws.

(a) Compliance with Anti-Corruption Laws. Supplier and Distributor shall comply with all anti-corruption Applicable Laws (including, without limitation, the United States Foreign Corrupt Practices Act, as amended, the U.S. Anti-Kickback Statute, and any similar or related Applicable Laws in the country(ies) in which Distributor and Supplier will conduct business according to this Agreement) (collectively, the "**Anti-Corruption Laws**").

(b) No Bribes. Supplier and Distributor each represents and warrants that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or other thing of value to anyone as an inducement or reward for favorable action or forbearance from action or the exercise of influence (i) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (ii) to any political party, official of a political party, or candidate, (iii) to an intermediary for payment to any of the foregoing, or (iv) to any other Person or entity in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

(c) Termination. If either Party determines that the other Party failed to comply with the provisions of any Anti-Corruption Law, and such failure is not cured within [**] days after written notice thereof, the complying Party may immediately terminate this Agreement in its sole discretion and without further notice pursuant to Section 9.2(a)(vii).

(d) Compliance with Applicable Law. Supplier and Distributor each warrants that all Persons acting on its behalf will comply with all Applicable Laws in connection with its performance of its obligations under this Agreement, including the Anti-Corruption Laws if any, prevailing in the country(ies) in which Distributor and Supplier each has its principal places of business or in which Supplier performs work on behalf of Distributor.

(e) Notification of Breach. Each Party further warrants and represents that should it learn or have reason to suspect any breach of the covenants in this section, it will immediately notify the other Party.

(f) Accurate Books and Records Covenants. Supplier and Distributor each covenants that all transactions related to this Agreement shall be accurately and fairly recorded in its books and records in all material respects in accordance with GAAP.

(g) Disclaimer.

EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS SET FORTH IN THIS ARTICLE 5, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED OR STATUTORY, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST NON-INFRINGEMENT OR THE LIKE, OR ARISING FROM COURSE OF PERFORMANCE.

5.7 Subcontracting.

(a) Supplier Subcontracting. Supplier may subcontract some or all of the responsibilities set out in this Agreement to an Affiliate or a Third Party. Distributor shall reasonably cooperate with Supplier, as needed, to effect such subcontracting. Supplier shall carry out such reconciliations, checks, and testing as are reasonable to verify the integrity of the work carried out by each subcontractor. Notwithstanding the foregoing, if the appointment of a Third Party subcontractor or the aforementioned changes require a Regulatory Authority's pre-approval, the Parties shall reasonably cooperate with each other to secure the required approvals. Subcontracting shall not release Supplier from responsibility for its obligations under this Agreement. Supplier shall remain fully liable for the compliance of any of its permitted subcontractors with the provisions of this Agreement. Any and all costs and expenses arising from or related to the appointment of a subcontractor by Supplier shall be borne solely by Supplier.

(b) Termination of Subcontractor. Notwithstanding anything to the contrary in this Agreement, Supplier may in its sole discretion, discontinue any subcontracting arrangement in connection with the supply of the Authorized Generic Product.

ARTICLE 6 -QUALITY, PHARMACOVIGILANCE & RECALLS

6.1 Quality.

At least [**] months prior to the Launch Date, the Parties shall discuss a Quality Agreement, which shall be finalized at least [**] months prior to the Launch Date. In the event of conflict between the Quality Agreement and this Agreement, the Quality Agreement shall govern with respect to technical quality-related matters and this

Agreement shall govern with respect to any other matter. Notwithstanding the foregoing, in circumstances where there are financial or commercial implications in a conflict with this Agreement and the Quality Agreement, such financial or commercial implications shall be resolved in accordance with this Agreement.

6.2 Pharmacovigilance.

(a) SDEA. At least [**] months prior to the Launch Date, the Parties shall discuss a separate Pharmacovigilance Agreement (also commonly referred to as a **Safety Data Exchange Agreement** or **SDEA**), which shall be finalized [**] months prior to the Launch Date, that is required before Supplier will supply any Authorized Generic Product to Distributor unless the Parties execute a waiver if they agree that such an agreement is not required. In the event of conflict between the Pharmacovigilance Agreement and this Agreement, the Pharmacovigilance Agreement shall govern with respect to pharmacovigilance-related matters and this Agreement shall govern with respect to any other matter. After the execution of this Agreement by both Parties, the relevant teams of each Party responsible for pharmacovigilance and drug safety reporting will meet to discuss and complete the details of safety exchange in order to meet reporting requirements in the Territory. Supplier shall be responsible for maintaining the safety data base for the Authorized Generic Product and for reporting of Adverse Events to the FDA. Distributor shall be responsible for ensuring timely reporting to Supplier of Adverse Events, Other Reportable Events and Product Complaints Distributor becomes aware of as outlined below consistent with regulations in the Territory.

(b) Pharmacovigilance. The Pharmacovigilance Agreement will include (without limitation) provisions regarding the (i) assignment of roles and responsibilities, (ii) monitoring of the benefit-risk profile, (iii) exchange of pharmacovigilance-relevant information and (iv) meeting of the reporting requirements set forth by any applicable regulatory authority. At a minimum, the Pharmacovigilance Agreement shall require (i) Distributor to notify Supplier, through Supplier's call center, Alkermes Medical Information Call Center (via email at medinfo@alkermes.com, telephone at 1-888-235-8008 or fax at 1-844-FAX-ALKS (1-844-329-2557)), of all serious or non-serious Adverse Events, Other Reportable Events and Brand Product or Authorized Generic Product Complaint reports within one (1) Business Day of Distributor's receipt of such reports. Both Parties and their Affiliates shall strictly comply with the Pharmacovigilance Agreement, which may be amended from time to time in a written agreement by authorized representatives of the Parties. In the event that the Authorized Generic Product is launched prior to completion of a Safety Data Exchange Agreement between the Parties, Distributor shall report to Alkermes Medical Information Call Center all serious and non-serious Adverse Events, Other Reportable Events and Product Complaints involving the Authorized Generic Product that it becomes aware of within one (1) Business Day. The Pharmacovigilance Agreement shall supersede this Section 6.2 upon execution of such Pharmacovigilance Agreement by the Parties.

6.3 Product Recall.

(a) Recalls. Each of Distributor and Supplier will immediately inform the other in writing if it believes one or more lots of the Authorized Generic Product should be subject to recall from distribution, withdrawal or some other field action (the Party that so informs the other Party shall be deemed the Party "initiating the recall", as such phrase is used in Section 6.3(b)). To the extent permitted by Applicable Law and public safety, the Parties will confer before initiating any recall or other field action with respect to the Authorized Generic Product in accordance with Section 6.3(b), provided that Supplier shall have final and sole decision-making authority, as between Supplier and Distributor, as to any such recall or field action by either Party. In all cases, Supplier shall be responsible for communicating with FDA regarding any recall of Authorized Generic Product and Distributor will provide reasonable and timely assistance as requested by Supplier. The Parties shall each maintain traceability records as are sufficient in the event of a recall and as may be necessary to permit a recall of the Authorized Generic Product(s).

(b) Cost for Recall. The Party initiating the recall of the Authorized Generic Product shall carry out the recall in accordance with best industry practices. To the extent the recall resulted from the negligence or intentional misconduct of a Party or its breach of any of its representations, warranties, duties or obligations under this Agreement ("**Negligent Party**"), the Negligent Party shall be responsible for the costs of the recall and shall reimburse the other Party for the Recall Expenses. If the Party not initiating the recall disputes in good faith the recalling Party's decision to initiate any such recall or field action, or if the Parties in good faith dispute whether the recall resulted from the negligence or intentional misconduct of a Party or its breach of any of its representations, warranties, duties or obligations under this Agreement and the Parties fail to resolve the dispute within [**] Business Days, despite negotiating in good faith, then the Parties shall escalate the matter to each Party's respective chief operating officer to attempt to resolve the matter and, if such dispute is not resolved within [**] Business Days of escalation, shall then submit such dispute to an independent Third Party consultant mutually agreed by the Parties for resolution. If such Third Party consultant determines that the recall was not justified, then the recalling Party shall bear the cost of such recall or field action. In the event the Third Party consultant determines that the recall was justified, the Third Party consultant will then determine whether such recall resulted from the negligence or intentional misconduct of a Party or its breach of any of its representations, warranties, duties or obligations under this Agreement, in which case the Negligent Party shall be responsible for the costs of the recall and shall reimburse the other Party for the Recall Expenses; provided that if both Parties share responsibility with respect to such recall, the costs shall be shared in the ratio of the Parties' contributory responsibility. Except as otherwise provided above, the cost of any recall based on, resulting from, or arising in connection with any product class labeling issue, a failure to warn issue or a defect design issue shall be borne by Supplier. For clarity, responsibility for all costs and expenses incurred in connection with recalls are

addressed solely in this Section 6.3(b). "**Recall Expenses**" as used herein means out-of-pocket expenses incurred in connection with a recall, including notification expenses, costs for the return of recalled Authorized Generic Product, costs of reporting to the Regulatory Authorities in the Territory, costs to destroy recalled Authorized Generic Product, and costs related to Third Party Claims related to such recalled Authorized Generic Product.

6.4 Changes or Modifications in Manufacturing Activities.

Supplier shall have the right, in its sole discretion, to make any changes to the Specifications, processes, facilities, raw materials, raw material suppliers or any other item involved in the Manufacture of the Authorized Generic Product, provided that Supplier shall provide Distributor with reasonable advance written notice of the change or modification. Notwithstanding the foregoing, Supplier shall make and implement such changes as are required by Applicable Law within a commercially reasonable time frame but, in any event, within the time frame required by such Applicable Law.

ARTICLE 7 -INDEMNITY & INSURANCE

7.1 Indemnity.

(a) Indemnification by Supplier. Supplier hereby agrees at its sole cost and expense, to defend, indemnify, and hold harmless, to the extent permitted by Applicable Law (collectively, "**Indemnify**"), Distributor and its Affiliates and its and their respective directors, officers, employees and agents and the respective successors and assigns of any of the foregoing ("**Distributor Indemnitees**") from and against all Losses suffered or incurred by any Distributor Indemnitee resulting from Claims brought by a Third Party (a "**Third Party Claim**") arising from or occurring as a result of:

(i) [**];

(ii) the intentional misconduct or gross negligence of Supplier or any of Supplier's Affiliates in connection with this Agreement or the Authorized Generic Product;

(iii) [**];

(iv) [**]; or

(v) [**].

Supplier's obligation to Indemnify a Distributor Indemnitee pursuant to this Section 7.1(a) shall not apply to the extent that any such Losses are the result of a breach by Distributor of its obligations, representations, warranties or covenants under this Agreement or Distributor's negligence or willful misconduct or to the extent Distributor is obligated to indemnify Supplier.

(b) Indemnification by Distributor. Distributor hereby agrees, at its sole cost and expense, to Indemnify Supplier and its Affiliates and its and their respective

agents, directors, officers and employees and the respective successors and assigns of any of the foregoing (the "**Supplier Indemnitees**") from and against any and all Losses resulting from Third Party Claims against any Supplier Indemnitee to the extent arising from or occurring as a result of:

(i) [**];

(ii) [**];

(iii) [**]; or

(iv) the intentional misconduct or gross negligence of Distributor or any of Distributor's Affiliates in connection with this Agreement or the Authorized Generic Product.

Distributor's obligation to Indemnify the Supplier Indemnitees pursuant to this Section 7.1(b) shall not apply to the extent that any such Losses are the result of a breach by Supplier of its obligations, representations, warranties or covenants under this Agreement or Supplier's negligence or willful misconduct or to the extent Supplier is obligated to indemnify Distributor.

7.2 Managing Claims.

(a) Notification of Claims. The Party seeking indemnification ("**Indemnified Party**") shall promptly give written notice to the Party required to indemnify ("**Indemnifying Party**") of any event, assertion, demand, suit, action, claim or proceeding ("**Claim**") that it becomes aware of and that may trigger its indemnification obligations. Such notice will specify the factual basis and amount of the Claim to the extent known.

(b) Late or Ineffective Notification. If the Indemnifying Party does not receive notice of any Claim in time either to effectively contest the determination of any liability or to participate and be aware in any such determination, in each case due to the fault or negligence of the Indemnified Party, then the Indemnifying Party is entitled to set off against the amount claimed by the Indemnified Party the amount of any Losses incurred by the Indemnifying Party as a result of the Indemnified Party's failure to give such notice.

(c) Rights and Duties of the Parties. The Indemnifying Party shall, at its expense, assume control of the negotiation, settlement, or defense of any Claim. The Indemnified Party shall cooperate with the Indemnifying Party, at the Indemnifying Party's request and expense, and shall have the right to participate in the negotiation, settlement, and defense of the Claim on a non-controlling basis. Further, the Indemnified Party shall have the right to retain counsel to act on its behalf, provided that the fees and disbursements of such counsel is paid by the Indemnified Party. The Indemnified Party shall not settle or compromise the Claim without the prior written consent of the Indemnifying Party if the Indemnifying Party assumes control of the Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, settle or compromise the Claim if such settlement or compromise (a) includes a

statement as to, or an admission of, fault, culpability, or a failure to act by or on behalf of such Indemnified Party; (b) imposes any non-monetary damages or injunctive relief against the Indemnified Party; (c) does not provide for the unconditional release of the Indemnified Party; or (d) requires the payment of compensatory monetary damages by the Indemnified Party which is not being paid by the Indemnifying Party.

(d) Neglect of Indemnifying Party. If the Indemnifying Party unreasonably fails to assume control of the defense of any Claim after having been notified of the Claim by the Indemnified Party or, having elected to assume control, thereafter fails to diligently defend the Claim, the Indemnified Party is entitled to contest, settle or pay the amount of the Claim. The Indemnifying Party is bound by the results obtained by the Indemnified Party in such circumstances with respect to the Claim.

7.3 Insurance.

Each Party, on behalf of itself and its successors and assigns, shall, during the Term and for [**] years after termination or expiration of this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company (provided, however, that either Party may satisfy all or part of its obligation through its insurance captive or self-insurance) product liability insurance. The amount of coverage shall be a minimum of [**]. Each Party agrees, upon request, to furnish the other with a certificate of insurance evidencing such insurance coverage (at the execution of this Agreement and at each subsequent renewal) and shall provide the other with a [**] day notice of cancellation or non-renewal of such coverage. Each Party shall provide its current certificate of insurance evidencing such insurance coverage as of the Effective Date. Each Party shall name the other Party as an additional insured on its insurance policies maintained pursuant to this Section 7.3.

ARTICLE 8 -CONFIDENTIALITY

8.1 Confidentiality Definition.

"**Confidential Information**" means the terms and provisions of this Agreement (each of which shall be the Confidential Information of both Parties) and all other information and data, including all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations, oral communications and all other data or information in whatever form, that one Party or any of its Affiliates or representatives (the "**Disclosing Party**") has supplied or otherwise made available to the other Party or its Affiliates or representatives (the "**Receiving Party**") hereunder, including those made prior to the Effective Date of this Agreement.

8.2 Obligations.

The Receiving Party shall protect all Confidential Information of the Disclosing Party against unauthorized use and disclosure to Third Parties with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The Receiving Party shall be permitted to use the Confidential Information of the Disclosing Party solely as reasonably necessary to exercise its rights

and fulfill its obligations under this Agreement (including any surviving rights), including (a) in prosecuting or defending litigation, (b) complying with Applicable Law, or (c) otherwise submitting information to tax or other Governmental Authorities. The Receiving Party shall not disclose the Confidential Information of the Disclosing Party to any Third Party other than to its Affiliates, and its and their respective directors, officers, employees, subcontractors, sublicensees, consultants, and attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need to know such information for purposes related to this Agreement and who are bound by obligations of confidentiality at least as protective of such Confidential Information as those set forth in this Agreement. The Receiving Party shall be responsible for any disclosures made by its Recipients in violation of this Agreement.

8.3 Exceptions.

(a) Restriction Limitations. The restrictions related to use and disclosure under this Article 8 shall not apply to any information to the extent the Receiving Party can demonstrate by competent evidence that such information:

(i) is (at the time of disclosure by the Disclosing Party) or becomes (after the time of such disclosure by the Disclosing Party) (A) known to the public or (B) part of the public domain through no breach of this Agreement by the Receiving Party, or any Recipient to whom the Receiving Party disclosed such information, of its confidentiality obligations to the Receiving Party;

(ii) was known to, or was otherwise in the possession of, the Receiving Party prior to the time of disclosure by the Disclosing Party;

(iii) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is not, to the actual knowledge of the Receiving Party, prohibited from disclosing it without breaching any confidentiality obligation to the Disclosing Party; or

(iv) is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without use of or access to the Confidential Information.

(b) Disclosure Required by Law. The restrictions set forth in this Article 8 shall not apply to the extent that the Receiving Party is required to disclose any Confidential Information under law or by an order of a Governmental Authority; provided that the Receiving Party: (i) provides the Disclosing Party with prompt written notice of such disclosure requirement, if legally permitted, (ii) affords the Disclosing Party an opportunity, and cooperates with the Disclosing Party's efforts, to oppose or limit, or secure confidential treatment for such required disclosure (at the Disclosing Party's expense), and (iii) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (ii), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party's legal counsel.

8.4 Nondisclosure of Terms.

Except as set forth in Section 1.1(b)(iii), each Party agrees not to issue any press releases, reports, or other statements in connection with this Agreement intended for use in the public or private media or otherwise disclose the terms of this Agreement to any Third Party without the prior written consent of the other Party hereto, which consent shall not be unreasonably withheld, provided that such disclosure may be made to such Party's Recipients on a need to know basis in each case consistent with customary practice and under circumstances that protect the confidentiality and non-use of such information. Notwithstanding anything in this Agreement to the contrary, each Party may make announcements concerning the subject matter of this Agreement to the extent such disclosure is reasonably necessary to comply with Applicable Law, including securities laws and the rules of any securities exchange on which such Party's securities are listed or traded, or Governmental Authority or any tax authority to which any Party is subject or submits, in each case as determined by the disclosing Party in its sole discretion. The Party making such announcement shall provide the other Party with a copy of such announcement [**] Business Days prior to issuance, to the extent practicable under the circumstances.

8.5 Right to Injunctive Relief.

Each Party agrees that breaches of this Article 8 may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), to the right to seek injunctive relief enjoining such action.

8.6 Ongoing Obligation for Confidentiality.

The Parties' obligations of confidentiality, non-use and non-disclosure under this Article 8 shall survive any termination of this Agreement for [**] years.

ARTICLE 9 -TERM & TERMINATION

9.1 Term.

(a) Duration of the Agreement. This Agreement shall commence on the date upon which all Parties have signed this Agreement (the "**Effective Date**") and shall continue to be in full force and effect until Distributor's last payment of Supplier's Profit Share (i.e., [**] days after the end of the Launch Term), unless terminated earlier in accordance with the terms herein (the "**Term**").

(b) Remaining Inventory. Any Authorized Generic Product unsold by the end of the Launch Term will be destroyed at Distributor's sole expense, which Distributor shall confirm in writing to Supplier, and will not be returnable to Supplier or eligible to be incorporated into the calculation of Net Profits or Net Sales. For clarity, neither the Transfer Price nor the destruction costs for the unsold Authorized Generic Product will be included in the calculation of Net Profit or Net Sales.

9.2 Events of Default; Termination.

(a) Termination. Notwithstanding anything to the contrary in this Agreement, this Agreement may be terminated:

(i) by mutual written consent of the Parties;

(ii) in its entirety by either Party upon written notice if any Bankruptcy Event has occurred with respect to the other Party;

(iii) in its entirety by either Party upon [**] (except as otherwise set forth in this Agreement) prior written notice to the other Party if the other Party materially breaches any provision of this Agreement (including a violation of an Applicable Law) and fails to cure that breach within such thirty [**] period;

(iv) by either Party upon written notice to the other Party if the FDA or other applicable Regulatory Authority orders a recall of the Brand Product or Authorized Generic Product (other than a recall of individual Batches) or withdraws Marketing Authorization for the Brand Product or Authorized Generic Product;

(v) by Distributor upon written notice to Supplier in the event of a Failure to Supply in accordance with Section 2.12(e);

(vi) by either Party upon written notice in the event of a Force Majeure Event in accordance with Section 10.10;

(vii) by either Party upon written notice if the other Party has violated any Anti-Corruption Laws in accordance with Section 5.6;

(viii) by either Party upon written notice to the other Party if a court of competent jurisdiction makes a final determination against which no appeal may be taken that Supplier or Distributor is precluded from selling any Brand Product or Authorized Generic Product, as applicable, in the Territory due to the infringement of Third Party Intellectual Property Rights;

(ix) by Supplier if Distributor does not provide a First Forecast or Final Batch Forecast as contemplated herein or provides a Final Batch Forecast that does not comply in all material respects with the terms specified in Section 2.5(c) and the deficiencies identified by Supplier are not remedied within [**] Business Days of Distributor's receipt of written notice from Supplier;

(x) by Supplier if Distributor's Single Purchase Order does not comply in all material respects with the terms specified in Section 2.6(a) and the deficiencies identified by Supplier are not remedied within [**] Business Days of Distributor's receipt of written notice from Supplier;

(xi) by Supplier immediately upon written notice in the event of an Unauthorized Generic Product Launch;

(xii) by Supplier, upon Distributor's launch of any generic product in the Territory that is A- rated to VIVITROL, including the Amneal ANDA Product;

(xiii) by Supplier where a Third Party ANDA Product Launch Failure has occurred, the Parties have not reached agreement in accordance with Section 2.9 within thirty (30) days of such Third Party ANDA Product Launch Failure to allow Distributor a second opportunity to launch the Authorized Generic Product, the sixty (60) day period to return the Authorized Generic Product has expired and any refunds of the Transfer Price due Distributor have been paid;

(xiv) by Supplier, upon [**] days prior written notice to Distributor in the event of a Distributor Payment Failure, which Distributor fails to cure within such [**] day period;

(xv) by Supplier, in the event of a Recall, if it is determined pursuant to Section 6.3, that Distributor is responsible for greater than [**] of the Recall Expenses; or

(xvi) by Supplier, upon [**] days prior written notice to Distributor in the event Distributor does not provide reasonably sufficient documentation [**] months in advance of the Launch Date that it is able to fulfill all of its Last Mile Obligations pursuant to Section 3.1(d) in all material respects or if Distributor's facilities fail an audit for Last Mile Obligations as provided by Section 3.1(e) and Distributor fails to cure the deficiencies identified in such audit within such [**] day period.

(b) Convenience. Notwithstanding anything to the contrary in this Agreement, Distributor may terminate this Agreement for convenience upon written notice to Supplier, which must be delivered not less than [**] months prior to the Launch Date, after which Distributor will not have the right to terminate this Agreement for convenience.

9.3 Effects of Termination.

(a) Termination Due to Breach by Supplier. If this Agreement is terminated by Distributor on the basis of a Failure to Supply, Distributor's sole remedy is as provided for in Section 2.10 and Section 2.12(b).

(b) Termination Due to Breach by Distributor. If this Agreement is terminated by Supplier due to the failure of Distributor to perform its obligations under this Agreement, including for any Distributor Payment Failure, then Supplier shall no longer have any obligations to provide Distributor with Authorized Generic Product. In such case, Distributor agrees to reimburse Supplier for, without

duplication, (i) the Fully Burdened Manufacturing Costs related to the Manufacture, Packaging or Delivery of undelivered Authorized Generic Product incurred by Supplier up to the date upon which written notice of termination was sent to Distributor (except to the extent such Authorized Generic Product or Components can be repurposed by Supplier) and (ii) any Transfer Price or Supplier's Profit Share Amount due Supplier through the date of termination. Distributor, upon breach, also agrees to destroy (and confirm destruction) or return, at Distributor's sole cost and expense, all units of Authorized Generic Product delivered to Distributor, as directed by Supplier, within [**] days of such breach.

(c) Termination Due to Convenience. In the event that Distributor terminates the Agreement for convenience pursuant to Section 9.2(b), the Parties shall cooperate to determine and minimize the out-of-pocket wind down costs and expenses (the "**Wind Down Costs**") in connection with the supply of Authorized Generic Product to Distributor. The Wind Down Costs are those documented out-of-pocket costs incurred, or to which Supplier is committed, up to the notice of termination date, that cannot reasonably be cancelled or recouped by Supplier and that Supplier cannot apply to the Brand Product. Wind Down Costs are payable by Distributor within [**] days of the termination date at cost plus [**].

(d) Termination Due to Recall Caused by Supplier. If this Agreement is terminated by Supplier pursuant to Section 9.2(a)(iv) and such recall, suspension or withdrawal was due to Supplier's negligent act or omission, or breach of its obligations under this Agreement, such termination and the Parties' rights and obligations under Section 6.3(b) shall be the sole remedies under this Agreement.

(e) Effects of Termination. Upon expiration or termination, this Agreement shall, except as otherwise provided in Section 9.5, be of no further force or effect.

9.4 Nonexclusive Remedy.

Exercise of any right of termination afforded to either Party under this Agreement shall not prejudice any other legal rights or remedies either Party have against the other in respect of any breach of the terms and conditions of this Agreement.

9.5 Survival.

Expiration or termination of this Agreement (for any reason) shall not affect any accrued rights or liabilities of either Party. Section 2.1(c) (Manufacturing Records); Section 2.11 (Returns); Section 2.12(b) ([**] Damages); Sections 3.2(d) (Written Notices) and 3.3(d) (Regulatory Driven Inspections of Distributor), with respect to Distributor; Article 4 (Pricing and Payment); Article 5 (Warranties); Article 6 (Quality, Pharmacovigilance and Recalls); Article 7 (Indemnity; Suspension and Insurance); Article 8 (Confidentiality); Sections 9.1(b) (Remaining Inventory); Section 9.3 (Effects of Termination); Section 9.4

(Nonexclusive Remedy); this Section 9.5 (Survival); Article 10 (Miscellaneous) and the Schedules attached hereto shall survive any expiration or termination of this Agreement.

ARTICLE 10 -MISCELLANEOUS

10.1 LIMITATION OF LIABILITY.

EXCEPT WITH RESPECT TO ANY BREACH OF SECTION 1.2(C) (UNAUTHORIZED LAUNCH) OR ARTICLE 8 (CONFIDENTIALITY), FRAUD OR WILLFUL MISCONDUCT, OR A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED BY LAW AND NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. THE PARTIES AGREE THAT THE LIMITATIONS SPECIFIED IN THIS SECTION SHALL APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE.

10.2 Notice.

(a) Notice under this Agreement. Any notice or other document required or permitted by this Agreement shall be in writing and delivered by prepaid registered or certified mail with return receipt requested, personally by hand, or by a nationally recognized overnight courier, and in each case addressed with the contact information set out below or such other contact information as the Parties agree in writing:

In the case of Supplier, at:

Alkermes Pharma Ireland Ltd.
Connaught House
1 Burlington Road
Dublin 4
D04 C5Y6
IRELAND
Attention: Secretary

With a copy to:

Alkermes, Inc.
900 Winter Street
Waltham, MA 02451

Attention: Chief Legal Officer
Email: [**]

And in the case of Distributor, at:

Amneal Pharmaceuticals LLC
400 Crossing Boulevard
Bridgewater
New Jersey 08807
Attention: Andrew Boyer, Executive Vice President – Generics

With a copy to:

Amneal Pharmaceuticals LLC.
400 Crossing Boulevard
Bridgewater
New Jersey 08807
Attention: Chief Legal Officer
Email: [**]

(b) Other Notice. Any such notice or other document shall:

(i) if delivered by prepaid registered or certified mail, be deemed to have been received on the earlier of the date of actual receipt or five (5) Business Days after the date of mailing; and

(ii) if delivered by any other means provided for herein, be deemed to have been received either on the same day as delivered if delivered during business hours (9:00 a.m. to 5:00 p.m., local time) on a Business Day or on the next Business Day.

10.3 Relationship of Parties.

The Parties are independent contractors, and this Agreement does not constitute any one Party as the agent or legal representative of the other Party for any purpose whatsoever. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, nor shall this Agreement create or establish an employment, agency or any other relationship. Neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

10.4 Affiliates and Third Party Designees.

Subject to Article 2, Distributor shall have the right to have its Affiliate, or a Third Party designee, exercise certain of Distributor's rights or perform certain of Distributor's responsibilities under this Agreement, including auditing, forecasting and ordering of the Authorized Generic Product hereunder, Delivery of the Authorized Generic Product so ordered, and testing and acceptance or rejection of the Authorized Generic Product.

Distributor shall remain fully liable for the performance of its obligations hereunder by such Affiliate or Third Party designee. Distributor shall ensure that any such Affiliate or Third Party designee exercising Distributor's rights or performing Distributor's responsibilities under this Agreement are responsible for complying with the terms hereof and for payment of any related fees and costs.

10.5 Assignment.

This Agreement is binding upon and inures to the benefit of the Parties and their respective successors. Neither Party shall assign or transfer its rights or obligations under this Agreement, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, (a) prior written consent is not required in the event of an assignment or transfer to an Affiliate, though prior written notice is required in such event, and (b) either Party may also assign this Agreement, without the consent of the other Party, to any successor or Third Party that acquires all or substantially all of the assets or business to which this Agreement relates by sale, transfer, merger, reorganization, operation of law or otherwise; provided that the assignee agrees in writing to be bound to the terms and conditions of this Agreement and written notice of such assignment is given to the other Party promptly after the occurrence thereof. Any assignment or transfer by Supplier or Distributor other than in accordance with this Agreement is void and is a breach of this Agreement. If Distributor assigns or transfers the Agreement and Supplier incurs material adverse withholding tax consequences as a result of such assignment or transfer, Distributor shall separately compensate Supplier for all such adverse withholding tax consequences within [**] days of written notice by Supplier.

10.6 Waiver.

No Party is deemed to have waived any provision of this Agreement unless such waiver is in writing, in which case such waiver is limited to the circumstances set forth in the written waiver. No failure or delay on the part of a Party in exercising any right, power, or remedy shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power, or remedy preclude any other or further exercise thereof or the exercise of any other right, power, or remedy. All remedies provided for hereunder are cumulative of and in addition to all other remedies which any Party may have under this Agreement or under the law, and the exercise of any one or more of such remedies shall not preclude the exercise of any others.

10.7 Entire Agreement.

(a) Integration. This Agreement, together with the Schedules, the Quality Agreement, and the Pharmacovigilance Agreement, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all previous agreements, representations, warranties, covenants, undertakings, or understandings, oral or otherwise, in respect thereof.

(b) Recitals. The recitals set forth above are and for all purposes shall be interpreted as being an integral part of this Agreement and are incorporated in this Agreement by reference.

10.8 Amendment.

No provision of this Agreement shall be amended except in writing signed by the Parties.

10.9 Severability.

If any provision in this Agreement is held to be invalid, void or unenforceable by a court of competent jurisdiction, then that provision shall be severed from this Agreement and the remainder of this Agreement shall remain in full force and effect to the extent permitted by law. The Parties agree to renegotiate any severed provision in good faith to uphold the intention of this Agreement.

10.10 Force Majeure.

(a) Performance. No Party (the "**Affected Party**") shall be liable for a failure or delay in performing any of its obligations under this Agreement to the extent that such failure or delay in performing any obligation is due, in whole or in any material respect, directly or indirectly, to the occurrence of a Force Majeure Event; provided that the Affected Party:

(i) gives the other Party written notice of the Force Majeure Event within ten (10) days of becoming reasonably aware of the Force Majeure Event, which notice shall include a reasonable estimate of the duration and the likely impact of the Force Majeure Event;

(ii) does not suspend or delay performance of its obligations under this Agreement more or longer than is reasonably required by the Force Majeure Event; and

(iii) uses reasonable commercial efforts to correct, cure, or overcome the Force Majeure Event.

(b) Termination. If the performance of any such obligation under this Agreement by Supplier is delayed due to such a Force Majeure Event for any continuous period of more than sixty (60) Business Days, Distributor shall have the right to terminate this Agreement pursuant to Section 9.2(a)(vi). If the performance of any such obligation under this Agreement by Distributor is delayed due to such a Force Majeure Event for any continuous period of more than sixty (60) Business Days, Supplier shall have the right to terminate this Agreement pursuant to Section 9.2(a)(vi).

10.11 Governing Law and Dispute Resolution.

(a) Discussion by Executives. Except as otherwise provided herein, and except in the event of a Party's need for a temporary restraining order and preliminary

injunctive relief due to any breach or threatened breach of this Agreement by either Party that the other Party believes will cause immediate irreparable harm and damage to it (in which case the other Party shall be entitled, but not required, to seek to obtain in any court of competent jurisdiction equitable relief, including injunctive relief ("**TRO Action**")), any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Section 10.11-to any such dispute, controversy or claim) (each a "**Dispute**") shall be first submitted to an executive officer of each of the Parties having authority to resolve such Dispute for attempted resolution by good faith negotiations within [**] Days. In such event, each Party shall cause its designated executive officer to meet and be available to attempt to resolve such issue. If the Parties should resolve such Dispute, a memorandum setting forth their agreement will be prepared and signed by both Parties if requested by either Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute. If the Parties fail to resolve such issue, the Parties shall submit to binding arbitration, as discussed in Section 10.11(b).

(b) Binding Arbitration. Except for any TRO Action, any controversy or claim arising out of or relating to this Agreement shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules and that judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Claims shall be heard by a single arbitrator who previously was a Federal Court judge, and the place of arbitration shall be the City and County of New York, New York. Time is of the essence for any arbitration, and unless otherwise agreed by the Parties, arbitration hearings shall take place within [**] days of the arbitrator being appointed and arbitration awards shall be rendered within [**] days following the close of the arbitration proceedings. Each Party shall bear its own costs and expenses and an equal share of the arbitrator costs and administrative fees of arbitration. Except as may be required by law or as part of any enforcement or other ancillary court proceedings, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

(c) Governing Law. This Agreement is governed by and construed in accordance with the laws of New York and the laws of United States of America applicable therein without giving effect any conflict of law rules.

10.12 Further Assurances.

The Parties shall, in a timely manner and as required from time to time, take all actions as may be necessary to give full effect to the provisions of this Agreement and shall abstain from taking any actions that would contravene or interfere with the provisions of this Agreement.

10.13 Headings.

The division of this Agreement into articles, sections and further subdivisions, and the insertion of headings are for convenience only and shall not affect the construction or interpretation of this Agreement. The captions and headings in this Agreement are not intended to be full or precise descriptions of the provisions to which they refer and shall not be considered part of this Agreement.

10.14 Expenses.

Except as otherwise expressly provided herein, each Party shall bear its own costs, fees and expenses incurred by such Party in connection with this Agreement.

10.15 Licenses and Permits.

Each Party shall, at its sole cost and expense, maintain in full force and effect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.

10.16Interpretation; References.

As necessary, words importing the singular number include the plural and vice-versa and words importing gender include all genders. Unless the context otherwise requires, the words "include", "includes" and "including" when used in this Agreement shall be deemed to be followed by the phrase "without limitation." The word "will" when used in this Agreement shall be construed to have the same meaning as the word "shall." Reference in this Agreement to any time shall be to Eastern time unless otherwise expressly provided herein. The word "or" shall not be exclusive. Unless the context otherwise requires, the words "hereof", "hereby," "herein" and "hereunder" and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Article, Section or provision of this Agreement. References in this Agreement to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement, as the same may be amended as provided herein, unless the context otherwise requires. When a reference is made to any other agreement, instrument or document, such reference shall include any exhibit, schedule or annex to such agreement, instrument or other document. References to any "statute" or "regulation" are to such statute or regulation as amended, modified, supplemented or replaced from time to time (and, in the case of any statute, include any rules and regulations promulgated under such statute) and to any "section of any statute or regulation" include any successor to such section.

10.17Compliance with the Law.

Both Supplier and Distributor shall perform their obligations under this Agreement in accordance with Applicable Law and each Party shall bear its own costs in ensuring compliance therewith. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or which it reasonably believes may violate, any Applicable Law.

10.18 No Third Party Beneficiaries.

Except for the rights to indemnification provided for under Article 7 above, all rights, benefits and remedies under this Agreement are solely intended for the benefit of Distributor and Supplier as set forth herein. Except for such rights to indemnification expressly provided pursuant to Article 7, no Third Party shall have any rights whatsoever to (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

10.19 Review by Legal Counsel.

Each Party agrees that it has read and had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

10.20 [**]

10.21 Bankruptcy.

For avoidance of doubt, all rights, licenses and covenants not to sue granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (the "**Bankruptcy Code**"), licenses of "intellectual property" as defined under the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

10.22 Counterparts and Delivery.

This Agreement may be executed in any number of counterparts, each of which is deemed an original and all of which, taken together, shall constitute one and the same instrument. This Agreement may be delivered by email and the Parties may rely on an electronic signature as though it were an original signature.

10.23 Language.

The language of this Agreement and all proceedings taken in relation thereto shall be English.

[*Signature Page Follows*]

IN WITNESS WHEREOF the Parties have caused this Agreement to be executed by their duly authorized representatives.

AMNEAL PHARMACEUTICALS LLC	**ALKERMES PHARMA IRELAND LIMITED**
By: /s/ Kerri Contreras Signed by: Kerri Contreras on behalf of Name: Gregory Sgammato Title:SVP, Chief Corporate Development Officer	By: /s/ Declan O'Connor Name: Declan O'Connor Title: SVP, Operations

SCHEDULE A - DEFINITIONS

In addition to terms defined elsewhere in this Agreement, the terms set forth below are defined in this Agreement (including the recitals) as follows:

1. "**Adverse Event**" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product, as defined by (*ICH Guideline E2D)*.

2. "**Affected Party**" has the meaning set out in Section 10.10.

3. "**Affiliate**" means, in relation to a Party, any corporation, limited liability company or other business entity that directly or indirectly controls, is controlled by, or is under common control with that Party. A corporation or other business entity shall be regarded as controlling another corporation or business entity if it: (a) directly or indirectly owns more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity, or (b) if it directly or indirectly possesses the power to direct affirmatively the management and policies of such corporation, limited liability company or business entity whether through ownership of voting securities or by contract relating to voting rights or corporate governance.

4. "**Agreement**" means this Authorized Generic Product Supply Agreement together with all attached schedules and amendments.

5. "**Allocable Overhead**" means costs incurred by Supplier that would ordinarily be included as Fully Burdened Manufacturing Cost under GAAP and that are attributable to supervisory services, general and administrative activities to the extent allowable under GAAP, occupancy (including utilities and property taxes), equipment, registrations, permits and licenses, insurance, depreciation, payroll, non-cash compensation, information systems, human resources and purchasing, as allocated to company departments based on space occupied, headcount or activity-based methods, in all cases, allocable to Supplier's Manufacturing activities under this Agreement, excluding any idle plant cost, and as determined in accordance with GAAP as consistently applied by Supplier.

6. "**Amneal**" has the meaning set out in the preamble.

7. "**Amneal ANDA**" means any ANDA or 505(b)(2) application filed by Amneal for which VIVITROL is the reference drug thereto; or any ANDA or 505(b)(2) application for which VIVITROL is the reference listed drug that is acquired, licensed or otherwise becomes owned or controlled by Amneal after the date on which this Agreement is signed, from a Third Party.

8. "**Amneal ANDA Product"** means a naltrexone product that Amneal seeks approval for in the Amneal ANDA, wherein naltrexone is the sole active ingredient or any ANDA or 505(b) (2) product for which VIVITROL is the reference listed drug that is acquired, licensed or otherwise becomes owned or controlled by Amneal after the date on which this Agreement is signed, from a Third Party.

9. "**ANDA(s)**" means abbreviated new drug application(s) submitted or to be submitted to the FDA pursuant to 21 C.F.R. Part 314 (including any amendments and supplements thereto).

10. "**Anti-Corruption Laws**" has the meaning set forth in Section 5.6(a).

11. "**API**" means the active pharmaceutical ingredient for the Authorized Generic Product.

12. "**Applicable Law**" means all laws, ordinances, rules, rulings, directives and regulations of any Governmental Authority that apply to the development, manufacture or supply of the Authorized Generic Product or the other activities contemplated under this Agreement, including (i) all applicable federal, state and local laws, rules and regulations; (ii) the U.S. Federal Food, Drug and Cosmetic Act; (iii) regulations and guidelines of the FDA and other Regulatory Authorities, including GMPs; and (iv) any applicable non-U.S. equivalents of any of the foregoing, including guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as amended from time to time).

13. "**Authorized Generic Product**" has the meaning set out in the preamble.

14. "**Bankruptcy Code**" has the meaning set forth in Section 10.21.

15. "**Bankruptcy Event**" means, with respect to a Party, (a) the making by it of a general assignment for the benefit of creditors, (b) the commencement by it of any voluntary petition in bankruptcy or suffering by it of the filing of an involuntary petition of its creditors, which involuntary petition is not dismissed within [**] days, (c) the suffering by it of the appointment of a receiver to take possession of all, or substantially all, of its assets, (d) the suffering by it of the attachment or other judicial seizure of all, or substantially all, of its assets, (e) the admission by it in writing of its inability to pay its debts as they come due, or (f) the making by it of an offer of settlement, extension or composition to its creditors generally.

16. "**Batch(es)**" means quantity of material that is uniform in character and quality, and which has been produced during a defined cycle of Manufacture as described in the manufacturing instructions for the Brand Product. All Batches must have a unique identifier, either through a unique Batch number or a Batch number in combination with the API code (or equivalent). The estimated yield per Batch is [**] vials.

17. "**Brand Product**" has the meaning set out in the preamble.

18. **"Brite Stock"** means naltrexone for extended-release injectable suspension, 380 mg per vial, Manufactured in accordance with NDA No. 021897 and this Agreement that remains in bulk and has not been finally Packaged and Labeled as Authorized Generic Product.

19. "**Business Day**" means any day other than a Saturday, a Sunday or any day on which commercial banks located in New York City, New York, U.S.A. are authorized or required to remain closed.

20. "**Claim**" has the meaning set out in Section 7.2(a).

21. "**COA/COC**" means the certificates for each Batch or lot of API delivered hereunder listing the tests performed, the Specifications and the test results and certifying that such Batch was manufactured in accordance with Applicable Law, including GMP.

22. "**Components**" means the API, excipients, and any other product or material used in the Manufacture of the Authorized Generic Product including the packaging materials, syringe and diluent.

23. "**Confidential Information**" has the meaning set forth in Section 8.1.

24. "**Debarred Entity**" has the meaning set out in Section 5.3.

25. "**Debarred Individual**" has the meaning set out in Section 5.3.

26. "**Delivery**" or "**Delivered**" or "**Deliver"** has the meaning set out in Section 2.8(b).

27. "**Delivery Date**" has the meaning set out in Section 2.6(a).

28. "**Delivery Window**" has the meaning set out in Section 2.6(a).

29. "**Deposit**" means [**] of the Transfer Price Invoice.

30. "**Diluent Costs**" means the Fully Burdened Manufacturing Costs for the Manufacturing of the diluent Component of the Authorized Generic Product, plus [**] on a per unit basis.

31. "**Dispute**" has the meaning set out in Section 10.11(a).

32. "**Distribute**" or "**Distribution**" or **"Distributing"** means, with respect to a pharmaceutical product, to market, promote, distribute (including to store and handle product in the course of such distribution), offer for sale and sell such product.

33. "**Distributor Affiliate**" means an Affiliate of Distributor.

34. "**Distributor Indemnitee**" has the meaning set out in Section 7.1(a).

35. "**Distributor Payment Failure**" has the meaning set out in Section 4.4(d).

36. "**Distributor-Related Supply Delay**" has the meaning set out in Section 2.12(d).

37. "**Dossier**" means all processes, techniques, studies, and data, which may be used as the basis for a Regulatory Filing sufficient for the receipt of Marketing Authorization, which Dossier is prepared in the format required by the Regulatory Authorities, for example common technical document format. The Dossier with respect to the Authorized Generic Product shall be consistent with the specifications in the NDA for VIVITROL. For the avoidance of doubt, Supplier shall not be required to share any VIVITROL Dossier with Distributor.

38. **"Drug Master File"** means one or more files, owned by Supplier, that provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products.

39. "**Effective Date**" has the meaning set out in Section 9.1(a).

40. "**Failure to Supply**" has the meaning set out in Section 2.12(a).

41. "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto performing similar functions.

42. "**FDA Licensed Distributors**" has the meaning set out in Section 3.1(d).

43. "**FDA Regulated Facilities**" has the meaning set out in Section 3.1(d).

44. "**Final Batch Forecast**" has the meaning set out in Section 2.5(c).

45. "**First Delivery**" has the meaning set out in Section 2.7(a).

46. "**First Forecast**" has the meaning set out in Section 2.5(a).

47. "**First Tranche**" has the meaning set out in Section 2.5(a).

48. "**Force Majeure Event**" means an external event which the affected Party could not have avoided by reasonable diligence and commercially reasonable efforts, including but not limited to: (a) acts of God; (b) fire, explosion, or unusually severe weather; (c) war, invasion, riot, terrorism, or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargo or blockages; (e) national or regional emergency; (f) strikes or industrial disputes at a national level which directly impact the affected Party's performance under this Agreement, or (g) other similar cause outside of the reasonable control of such Party.

49. "**Forecast**" has the meaning set out in Section 2.5(a).

50. "**Forecast Adjustment**" has the meaning set out in Section 2.5(b).

51. "**Fully Burdened Manufacturing Cost**" means the costs incurred (i.e., paid or accrued) by Supplier in the [**] as determined in accordance with GAAP as consistently applied by Supplier.

52. "**GAAP**" means generally accepted accounting principles in the Territory.

53. "**GMPs**" means current good manufacturing practices and standards as set forth (and as amended from time to time) in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations, including 21 C.F.R. Sections 210 and 211, and any corresponding practices and standards under Applicable Law in the Territory, or the country in which the Authorized Generic Product is Manufactured hereunder, subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

54. "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, state, country, city or other political subdivision, including any Regulatory Authority.

55. "**Gross Price"** means the price invoiced by Distributor to arm's length Third Party customers for the Authorized Generic Product.

56. "**Indemnify**" has the meaning set out in Section 7.1(a).

57. "**Indemnified Party**" has the meaning set out in Section 7.2(a).

58. "**Indemnifying Party**" has the meaning set out in Section 7.2(a).

59. "**Independent Laboratory**" has the meaning set out in Section 3.4(b)(vi).

60. "**Infringement Action**" means an action brought against Distributor for patent infringement due to Distributor's sale of Authorized Generic Product.

61. "**Intellectual Property Right**" means all intellectual property and other similar proprietary rights in any jurisdiction, whether owned or licensed, whether registered or unregistered. Without limitation to the foregoing, Intellectual Property Rights shall include, such rights in and to (a) issued patents and all provisional and pending patent applications, any and all divisions, continuations, continuations in part, reissues, continuing patent applications, re-examinations and extensions thereof, any counterparts claiming priority therefrom, utility models, patents of importation/confirmation, certificates of invention, certificates of registration and like rights, and any patent disclosures, invention disclosures, discoveries and improvements, whether or not patentable; (b) copyrights and copyrightable works, including databases (or other collections of information, data, works or other materials), packaging artwork and design rights; (c) technology, know-how, recipes, processes, trade secrets, inventions, business information, technical information, methods, marketing information and materials, business plans, proprietary data, formulae, techniques, specifications, research and development data, non-public information and confidential information and rights to limit the use or disclosure of any of the foregoing by any person; (d) computer software (including source code and object code, data files, application programming interfaces, computerized databases and other software-related specifications); (e) trademarks; (f) Internet domain names; (g) rights of publicity and other rights to use the names and likeness of individuals and (h) claims, causes of action and defenses relating to any of the foregoing; in each case, including registrations, applications, recordings, and extensions and common-law rights relating to any of the foregoing.

62. "**IPR**" has the meaning set out in the preamble.

63. "**Labeling**" has the meaning set out in Section 2.4(b)(i).

64. "**Last Mile Obligations**" has the meaning set out in Section 3.1(d).

65. "**Launch Date**" has the meaning set out in Section 1.2(a).

66. "**Launch Term**" means the period of three hundred and sixty five (365) days from the Launch Date of the Authorized Generic Product. For example, if the Launch Date was January 15, 2027, the Launch Term would expire on January 14, 2028.

67. "**Licensed Intellectual Property Rights**" means any and all Intellectual Property Rights owned or controlled by Supplier or any of its Affiliates during the Launch Term (including any Intellectual Property Rights with respect to any jointly-owned subject matter) that are reasonably necessary or useful for the Distribution of the Authorized Generic Product, including the Licensed Patent.

68. "**Licensed Patent(s)**" means U.S. Patent No. 7,919,499 and any continuations, continuations-in-part, divisionals, reissues and re-examinations thereof, and any other patents currently listed or listed in the future in the Orange Book covering VIVITROL.

69. "**Loss**" or "**Losses**" means actual damages, liabilities, obligations, costs, expenses or losses, including without limitation, reasonable legal fees and expenses, court costs, arbitration fees, penalties, fines, and amounts paid in settlement of claims.

70. "**Manufacture**" or "**Manufactured**" or "**Manufacturing**" means the processes and procedures for the supply of the Authorized Generic Product, including: (a) the supply and quality control of the Components; (b) the manufacture of the Authorized Generic Product in bulk; (c) the bulk Packaging, and subsequent final Packaging and Labeling of the Authorized Generic Product; (d) the quality control of the finished version of the Authorized Generic Product; (e) the storage of the Authorized Generic Product until shipment; and (f) Delivery of the Authorized Generic Product.

71. "**Marketing Authorization**" means the approval to market and sell a drug product in the Territory issued by the responsible Regulatory Authority.

72. "**Maximum Volume**" has the meaning set out in Section 2.5(d).

73. "**MSDS**" has the meaning set out in Section 3.4(a).

74. "**NDA**" means the new drug application number 021897, as filed with the FDA (including any amendments and supplements thereto).

75. "**NDC Number**" means the unique identifying numbers assigned to a drug product, including the labeler code, product code and package code, in connection with the drug listing requirements of Section 510(j) of the United States *Federal Food, Drug, and Cosmetic Act*.

76. "**Negligent Party**" has the meaning set out in Section 6.3(b).

77. "**Net Profit**" means Net Sales of the Authorized Generic Product less:

    a. The Transfer Price paid by Distributor; and

    b. [**] incurred by Distributor in connection with the distribution of the Authorized Generic Product in the Territory in respect of arm's length transactions, all of which costs covered by this clause (b) shall be deemed to be equivalent to [**] of Net Sales; and

All components of Net Profit shall be determined in accordance with US GAAP and applied on a basis consistent with Distributor's annual audited financial statements.

78. "**Net Sales**" means the aggregate net revenues actually received by Distributor and its Affiliates in relation to sales of the Authorized Generic Product in the Territory to arm's length Third Party customers, being the Gross Price invoiced for the sale of the Authorized Generic Product in the Territory by Distributor and its affiliates to arm's length Third Party customers, less the sum of following items (with each item below counted only once in calculating Net Sales and not counted in calculating Net Profits):

[**]

All components of Net Sales shall be determined in accordance with GAAP and applied on a basis consistent with Distributor's annual audited financial statements.

79. "**Non-Ordered Units**" has the meaning set out in Section 2.10(c).

80. "**Non-Refundable Costs**" has the meaning set forth in Section 4.2.

81. "**Ordered Authorized Generic Product**" has the meaning set out in Section 2.12(d).

82. "**Other Reportable Event**" means an event that does not necessarily meet the ICH definition of an Adverse Event, including pregnancy, breast-feeding, product diversion, adulteration of product, off-label use, lack of effect or loss of therapeutic efficacy, underdose and occupational or accidental exposure.

83. "**Package**" or "**Packaged**" or "**Packaging**" means packaging the finished Authorized Generic Product in accordance with applicable Specifications.

84. "**Party**" or "**Parties**" means any party to this Agreement referred to individually or collectively.

85. "**Person**" means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency thereof.

86. "**Pharmacovigilance Agreement,**" "**Safety Data Exchange Agreement**" or "**SDEA**" means an agreement to be entered into by the Parties about their obligations in relation to the collection, assessment, monitoring, reporting, and prevention of adverse effects, Adverse Events, or adverse reactions relating to the Authorized Generic Product and which is incorporated by reference into this Agreement as Schedule B.

87. "**Product Complaint**" means any written, electronic, or oral communication concerning a potential deficiency or defect (perceived or real) related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a marketed drug product or device.

88. **"Promotional Material**" means all materials used to promote a drug or biologic, such as promotional Labeling and advertisements. regardless of the format, manner, or medium by which such materials are presented, including brochures, booklets, detailing pieces, internet

websites, print ads, exhibits, sound recordings and advertisements (e.g., radio and television advertising).

89. "**Quality Agreement**" means an agreement to be entered into by the Parties about their obligations in relation to the Manufacture, Packaging, testing, and release of the Authorized Generic Product in accordance with GMP and which is incorporated by reference into this Agreement as Schedule B.

90. "**Recall Expenses**" has the meaning set out in Section 6.3(b).

91. "**Recipients**" has the meaning set out in Section 8.2.

92. "**Regulatory Authority**" means the applicable government agency, department, bureau or other governmental entity responsible for regulating pharmaceutical drugs in the Territory, including the FDA, Centers for Medicare & Medicaid Services (CMS), and others.

93. "**Regulatory Filing**" means all materials, including both Dossiers and Drug Master Files, comprising the application to the Regulatory Authorities in the Territory to obtain a Marketing Authorization for a drug product.

94. "**Required Standards**" means Applicable Law, the Regulatory Filing, the Specifications, and the Quality Agreement.

95. "**SDEA**" has the meaning set out in Section 6.2(a).

96. "**Second Delivery**" has the meaning set out in Section 2.7(b).

97. "**Second Tranche**" has the meaning set out in Section 2.5(a).

98. "**Single Purchase Order**" has the meaning set out in Section 2.6(a).

99. "**Specifications**" means, with respect to the Authorized Generic Product or applicable Component thereof, all written product, regulatory, Manufacturing, quality control and quality assurance procedures, processes, practices, standards, instructions and specifications applicable to the Manufacture of such Authorized Generic Product or Component, as applicable, including storage and handling conditions, as set forth in the Regulatory Filing for the Authorized Generic Product. The Specifications shall be consistent with the specifications in the NDA for the Brand Product. With respect to release, "Specification" also means the combination of physical, chemical, biological, and microbiological tests and acceptance criteria that determine the suitability of the Authorized Generic Product at the time of release. For further clarity, "Specifications" also include the chemistry, manufacturing and controls requirements for the Authorized Generic Product and the applicable Components. For the avoidance of doubt, other than the COA/COC and MSDS, Supplier shall not be required to share the Specifications with Distributor.

100. "**Supplier**" has the meaning set out in the preamble.

101. "**Supplier Indemnitees**" has the meaning set out in Section 7.1(b).

102. "**Supplier's Profit Share Amount**" has the meaning set out in Section 4.3(a).

103. “**Term**” has the meaning set out in Section 9.1(a).

104. “**Territory**” has the meaning set out in the preamble.

105. “**Third Party**” means any Person other than the Parties and their respective Affiliates.

106. “**Third Party ANDA Product**” means a Third Party product, approved by FDA through an ANDA, that is A- rated to VIVITROL.

107. “**Third Party ANDA Product Launch**” means the first commercial sale in the Territory of a Third Party ANDA Product, pursuant to an arms-length transaction.

108. “**Third Party ANDA Product Launch Failure**” has the meaning set out in Section 2.9.

109. “**Third Party Claim**” has the meaning set out in Section 7.1(a).

110. “**Trade Control Laws**” has the meaning set out in Section 5.5(a).

111. **“Transfer Price”** has the meaning set out in Section 4.1.

112. “**Transfer Price Invoice**” has the meaning set out in Section 4.4(a)(ii).

113. “**TRO Action**” has the meaning set out in Section 10.11(a).

114. “**Unauthorized Generic Product Launch**” has the meaning set out in Section 1.2(c).

115. “**Wind Down Costs**” has the meaning set out in Section 9.3(c).

SCHEDULE B – PHARMACOVIGILANCE AGREEMENT & QUALITY AGREEMENT

[**]

SCHEDULE C – NON-REFUNDABLE COSTS

[**]

Exhibit 10.3

Alkermes Inc.
900 Winter Street, Waltham, MA 02451-1420 USA
T +1 781 609 6000 **F** +1 781 890 0524
www.alkermes.com

August 27, 2025

Dear Joshua,

On behalf of Alkermes Inc. (the "Company"), I am pleased to offer you the position of Senior Vice President, Chief Financial Officer, in the Finance 10-101 department, reporting to Richard Pops, Chairman and Chief Executive Officer. This is a Full time Exempt position and will be located in Waltham, MA.

This letter, and its accompanying documents, confirms the terms of the offer.

Base Pay: Your starting annual salary will be $615,000 subject to applicable taxes and withholdings. You will be paid bi-weekly.

Annual Bonus: You will be eligible to participate in the annual Reporting Officer Performance Pay Plan. Your annual Performance Pay target will be 50%. Your actual Performance Pay bonus will be based on individual and company performance and will be prorated, based on your date of hire, to reflect your actual months of Plan participation. You must be actively employed by Alkermes on October 1st in order to be eligible to receive a prorated bonus for that year. You must be actively employed by Alkermes on the date the bonus is paid to receive a Performance Pay bonus.

Equity Participation: You will be granted the following equity grants: 1) a ten (10) year stock option grant of Alkermes plc ordinary shares having a value of $2,345,000.00 as calculated by the company on the date of grant and 2) a restricted stock unit grant (RSU) having a value of $1,155,000.00 as calculated by the company on the date of grant. The Compensation Committee of the Board of Directors of Alkermes plc (the "Compensation Committee" approves new hire equity grants once per month on a pre-determined date for employees who began employment at the Company during the previous month.

All of the above equity grants will be subject to the terms and conditions of the applicable Alkermes plc equity plan. The exercise price of the stock options will be the closing price of Alkermes plc shares on the date of grant. The stock option grant and the RSU grant will each vest ratably over four (4) years on the anniversary of the grant date, provided that you remain employed by an Alkermes plc affiliated company.

You will receive notice of your equity award grant via Alkermes/Merrill Lynch's Benefits
On-line system. Information regarding your equity grant including the grant award certificate(s) can also be found in the Alkermes/Merrill Lynch's Benefits On-line system and in the applicable Alkermes plc equity plan. In the event you cease to be employed by an Alkermes plc affiliated company, vesting of the equity grants shall cease. We will provide you with a copy of the Alkermes plc equity plan from which your equity grant was made for complete details.

The above compensation terms are subject to approval by the Compensation Committee.

Vacation: You shall be entitled to paid vacation in accordance with the Company vacation policy applicable to similarly situated employees of Alkermes in effect from time to time.

Benefits: You will also be eligible to participate in the Alkermes benefits program as described in the accompanying *Decision Guide*. Medical, Dental, and Vision coverage will begin on your start date. Complete details and enrollment information will be included with your New Employee Welcome Packet.

Offer Contingencies:	This employment offer is contingent upon successful completion of all aspects of the Alkermes pre-employment screening process. This process includes the verification of information you will provide to us for a background check.
Background Verification Process:	This process will verify the information you have provided concerning your prior employment and education. As Alkermes is concerned with the security of our customers, employees, business partners and the general public, we will perform a criminal history check to determine whether you have criminal convictions of record and to verify your identity. For positions within our Finance department, a credit check will also be performed.
Employment Eligibility Verification	Please note that all persons in the United States are required to complete an Employment Eligibility Verification Form on the first day of employment and submit an original document or documents that establish identity and employment eligibility within three (3) business days of employment. For your convenience, HireRight will be sending you an electronic version of the Form I -9. You will need to complete Section 1 through HireRight on or before your first day of work. You will need to present original document(s) of your choice as listed on the HireRight site on your first day. Alkermes participates in the E-Verify program. E-Verify is a Social Security Administration/Department of Homeland Security program which allows employers to electronically verify each new employee's work authorization using information provided on Form I-9. The verification process will occur within three (3) business days of employment. If you would like further information regarding E-Verify, please contact Alkermes Human Resources department.
Proprietary Information, No Conflicts:	You agree to execute the Company's standard Employee Agreement With Respect to Inventions and Proprietary Information and Non-Solicitation and to be bound by all of the provisions thereof. A copy will be enclosed in your new hire onboarding paperwork. You hereby represent that you are not presently bound by any employment agreement, confidential or proprietary information agreement or similar agreement with any current or previous employer that would impose any restriction on your acceptance of this offer or that would interfere with your ability to fulfill the responsibilities of your position with the Company.
Employment Period:	This letter, and its accompanying documents, set out the complete terms of our offer of employment but are not intended as, and should not be considered, a contract of employment for a fixed period of time. If you accept this offer of employment with the Company, you accept that your employment is at-will, which means that you or Alkermes are free to end the employment relationship at any time, with or without cause.

Joshua, all of us here at Alkermes are very enthusiastic about the prospect of you joining the Company and have the highest expectation of your future contributions.

Please indicate your understanding of and agreement with the foregoing by accepting and electronically signing below by August 29, 2025. The offer will lapse on this date.

Best Regards,



/s/ Peter Mello
Executive Director, Talent Acquisition, Human Resources
Alkermes, Inc.

By clicking "Accept" below you acknowledge and agree that such acceptance shall constitute your electronic signature of the Offer Letter and any associated agreement(s) (e.g., Sign-On Repayment Agreement, Relocation Agreement, etc.) referenced in the Offer Letter, all of which you acknowledge may be accepted in electronic form via electronic signature, and further which you acknowledge together will constitute the entire offer Alkermes is making to you. Neither party may contest the validity or enforceability of the Offer Letter and any associated agreements, including under any applicable statute of frauds, because it was accepted or signed in electronic form. Electronically maintained records when produced in hard copy form shall constitute business records and shall have the same validity as any other generally recognized business records.

The foregoing is signed and accepted as of the date indicated below by:

Joshua Reed	8/27/25
Candidate Name	Date

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 28, 2025

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Joshua Reed, 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 28, 2025

/s/ Joshua Reed
Joshua Reed

Senior Vice President, Chief Financial Officer
(Principal Financial 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, 2025 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 Joshua Reed, 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 28, 2025

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: October 28, 2025

/s/ Joshua Reed
Joshua Reed

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