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, 2023

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 20, 2023 was 166,881,286 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

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Cautionary Note Concerning Forward-Looking Statements

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

- our expectations regarding our financial performance, including revenues, expenses, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including expectations related to product development, regulatory filings, approvals and timelines; therapeutic and commercial value, scope and potential; and the costs and expenses related to such activities and expectations;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive, payer, legislative, regulatory and policy landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and development programs; barriers to access or coverage of our products and potential changes in reimbursement of our products; and legislation, regulations, executive orders, guidance or other measures that may impact pricing and reimbursement of, and access to, our products;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding collaborations, licensing arrangements and other significant agreements with third parties relating to our products and our development programs;
- our expectations regarding the impacts of new legislation, rules and regulations, the adoption of new accounting pronouncements and potential U.S. government shutdowns or other 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 our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;
- our expectations regarding future capital requirements and expenditures for our operations and our ability to finance such capital requirements and expenditures;
- our expectations regarding the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our products and intellectual property ("IP"), including our patents;
- our expectations regarding the impact of the coronavirus ("COVID-19") pandemic on our business and operations;
- our expectations regarding the planned separation of our oncology business, including anticipated timing, effects, costs, benefits and tax treatment; and
- other expectations discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. In light of these risks, assumptions and uncertainties, the forward-looking expectations discussed in this Form 10-Q might not occur. You are cautioned not to place undue reliance on the forward-looking statements in this Form 10-Q, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. For information about the risks, assumptions and uncertainties of our business, see "Part I, Item 1A—Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed

with the United States ("U.S.") Securities and Exchange Commission (the "SEC") on February 16, 2023, as amended by our Amendment No. 1 to Annual Report on Form 10-K/A, filed with the SEC on April 26, 2023 (our "Annual Report"), "Part II, Item 1A—Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (our "Q1 Quarterly 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, "Part II, Item 1A—Risk Factors" in our Q1 Quarterly Report and "Part II, Item 1A—Risk Factors" in this Form 10-Q. These and other factors could cause our results to differ materially from those expressed or implied in this Form 10-Q.

Note Regarding Company and Product References

Alkermes plc is a fully-integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. Use of terms such as "us," "we," "our," "Alkermes" or the "Company" in this Form 10-Q is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Form 10-Q include our marketed products, marketed products using our proprietary technologies, our licensed products, our product candidates and product candidates using our proprietary technologies, (b) references to the "biopharmaceutical industry" in this Form 10-Q are intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references to "licensees" in this Form 10-Q are used interchangeably with references to "partners."

Note Regarding Trademarks

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

The following are trademarks of the respective companies listed: AMPYRA®—Acorda Therapeutics, Inc.; ANJESO®—Baudax Bio, Inc.; BYANNLI®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION®, and RISPERDAL CONSTA®—Johnson & Johnson or its affiliated companies; CABENUVA®—ViiV Healthcare UK (No.3) Limited; KEYTRUDA®—Merck Sharp & Dohme Corp.; and VUMERITY®—Biogen MA Inc. (together with its affiliates, "Biogen"). Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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

ALKERMES PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30, 2023	December 31, 2022
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 647,711	$ 292,473
Receivables, net	337,697	287,967
Investments—short-term	241,439	315,992
Inventory	192,186	181,418
Contract assets	2,766	8,929
Prepaid expenses and other current assets	42,982	43,527
Total current assets	1,464,781	1,130,306
PROPERTY, PLANT AND EQUIPMENT, NET	327,517	325,361
INVESTMENTS—LONG-TERM	106,431	131,610
RIGHT-OF-USE ASSETS	103,170	115,855
INTANGIBLE ASSETS, NET	10,987	37,680
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	162,184	115,602
OTHER ASSETS	11,288	14,691
TOTAL ASSETS	$ 2,279,231	$ 1,963,978
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 243,263	$ 220,089
Accrued sales discounts, allowances and reserves	238,467	252,115
Operating lease liabilities—short-term	15,058	15,722
Contract liabilities—short-term	3,319	6,816
Current portion of long-term debt	3,000	3,000
Total current liabilities	503,107	497,742
LONG-TERM DEBT	288,366	290,270
OPERATING LEASE LIABILITIES—LONG-TERM	78,552	89,829
OTHER LONG-TERM LIABILITIES	53,623	42,384
Total liabilities	923,648	920,225
COMMITMENTS AND CONTINGENT LIABILITIES (Note 16)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 172,218,651 and 168,951,193 shares issued; 166,714,095 and 164,377,009 shares outstanding at September 30, 2023 and December 31, 2022, respectively	1,722	1,690
Treasury shares, at cost (5,504,556 and 4,574,184 shares at September 30, 2023 and December 31, 2022, respectively)	(186,942)	(160,862)
Additional paid-in capital	3,003,184	2,913,099
Accumulated other comprehensive loss	(6,074)	(10,889)
Accumulated deficit	(1,456,307)	(1,699,285)
Total shareholders' equity	1,355,583	1,043,753
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 2,279,231	$ 1,963,978

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(In thousands, except per share amounts)			
REVENUES:				
Product sales, net	$ 231,822	$ 199,380	$ 678,026	$ 561,435
Manufacturing and royalty revenues	149,113	52,941	607,888	243,437
License revenue	—	—	—	2,000
Research and development revenue	3	36	16	249
Total revenues	380,938	252,357	1,285,930	807,121
EXPENSES:				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	61,509	50,625	182,944	164,144
Research and development	97,140	100,430	291,565	289,256
Selling, general and administrative	169,446	152,777	549,181	448,206
Amortization of acquired intangible assets	8,995	9,166	26,693	27,198
Total expenses	337,090	312,998	1,050,383	928,804
OPERATING INCOME (LOSS)	43,848	(60,641)	235,547	(121,683)
OTHER INCOME (EXPENSE), NET:				
Interest income	9,370	2,239	21,105	3,708
Interest expense	(6,006)	(3,552)	(16,978)	(8,271)
Change in the fair value of contingent consideration	—	(3,553)	—	(21,750)
Other income (expense), net	149	(1,861)	(415)	2,380
Total other income (expense), net	3,513	(6,727)	3,712	(23,933)
INCOME (LOSS) BEFORE INCOME TAXES	47,361	(67,368)	239,259	(145,616)
INCOME TAX BENEFIT	(397)	(3,394)	(3,719)	(15,603)
NET INCOME (LOSS)	$ 47,758	$ (63,974)	$ 242,978	$ (130,013)
EARNINGS (LOSS) PER ORDINARY SHARE:				
Basic	$ 0.29	$ (0.39)	$ 1.46	$ (0.79)
Diluted	$ 0.28	$ (0.39)	$ 1.42	$ (0.79)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:				
Basic	166,607	164,282	165,996	163,541
Diluted	171,903	164,282	170,981	163,541
COMPREHENSIVE INCOME (LOSS):				
Net income (loss)	$ 47,758	$ (63,974)	$ 242,978	$ (130,013)
Holding gain (loss), net of a tax provision (benefit) of $216, $(188), $803 and $(1,242), respectively	1,363	(2,349)	4,815	(9,114)
COMPREHENSIVE INCOME (LOSS)	$ 49,121	$ (66,323)	$ 247,793	$ (139,127)

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,	
	2023	2022
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 242,978	$ (130,013)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Depreciation and amortization	56,386	58,185
Share-based compensation expense	75,062	67,771
Deferred income taxes	(47,385)	(54,073)
Change in the fair value of contingent consideration	—	21,750
Other non-cash charges	1,394	3,746
Changes in assets and liabilities:		
Receivables	(49,730)	56,045
Contract assets	6,163	3,258
Inventory	(9,866)	(15,646)
Prepaid expenses and other assets	3,947	1,872
Right-of-use assets	12,685	12,470
Accounts payable and accrued expenses	20,958	6,386
Accrued sales discounts, allowances and reserves	(13,649)	(1,576)
Contract liabilities	(5,724)	(9,191)
Operating lease liabilities	(12,569)	(13,411)
Other long-term liabilities	13,466	12,424
Cash flows provided by operating activities	294,116	19,997
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(31,018)	(28,227)
Proceeds from the sale of equipment	6	—
Proceeds from contingent consideration	—	1,273
Return of Fountain Healthcare Partners II, L.P. investment	—	485
Purchases of investments	(186,593)	(256,806)
Sales and maturities of investments	291,944	190,994
Cash flows provided by (used in) investing activities	74,339	(92,281)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	15,113	18,850
Employee taxes paid related to net share settlement of equity awards	(26,080)	(17,903)
Principal payments of long-term debt	(2,250)	(2,250)
Cash flows used in financing activities	(13,217)	(1,303)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	355,238	(73,587)
CASH AND CASH EQUIVALENTS—Beginning of period	292,473	337,544
CASH AND CASH EQUIVALENTS—End of period	$ 647,711	$ 263,957
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 4,209	$ 2,690

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

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

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
				(In thousands, except share data)				
BALANCE — December 31, 2022	168,951,193	$ 1,690	$ 2,913,099	$ (10,889)	$ (1,699,285)	(4,574,184)	$ (160,862)	$ 1,043,753
Issuance of ordinary shares under employee stock plans	2,567,603	25	2,849	—	—	—	—	2,874
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(885,652)	(24,744)	(24,744)
Share-based compensation	—	—	22,778	—	—	—	—	22,778
Unrealized gain on marketable securities, net of tax provision of $488	—	—	—	2,760	—	—	—	2,760
Net loss	—	—	—	—	(41,845)	—	—	(41,845)
BALANCE — March 31, 2023	171,518,796	$ 1,715	$ 2,938,726	$ (8,129)	$ (1,741,130)	(5,459,836)	$ (185,606)	$ 1,005,576
Issuance of ordinary shares under employee stock plans	457,105	5	9,121	—	—	—	—	9,126
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(17,777)	(540)	(540)
Share-based compensation	—	—	28,518	—	—	—	—	28,518
Unrealized gain on marketable securities, net of tax provision of $99	—	—	—	692	—	—	—	692
Net income	—	—	—	—	237,065	—	—	237,065
BALANCE — June 30, 2023	171,975,901	$ 1,720	$ 2,976,365	$ (7,437)	$ (1,504,065)	(5,477,613)	$ (186,146)	$ 1,280,437
Issuance of ordinary shares under employee stock plans	242,750	2	3,111	—	—	—	—	3,113
Receipt of Alkermes' shares for the exercise of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	—	—	(26,943)	(796)	(796)
Share-based compensation	—	—	23,708	—	—	—	—	23,708
Unrealized gain on marketable securities, net of tax provision of $216	—	—	—	1,363	—	—	—	1,363
Net income	—	—	—	—	47,758	—	—	47,758
BALANCE — September 30, 2023	172,218,651	$ 1,722	$ 3,003,184	$ (6,074)	$ (1,456,307)	(5,504,556)	$ (186,942)	$ 1,355,583

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

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

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

1. THE COMPANY

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

In November 2022, the Company announced its intent, as approved by its board of directors, to explore the separation of its oncology business. Following a review of strategic alternatives for the oncology business, the Company is planning a separation of the oncology business into an independent, publicly-traded company (referred to herein as "Mural Oncology"). Following the planned separation, the Company would focus on driving growth of its proprietary commercial products: LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL, and advancing the development of pipeline programs focused on neurological disorders. The Company also expects to retain manufacturing and royalty revenues, including those related to its licensed products and third-party products using its proprietary technologies under license. Mural Oncology would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and the Company's portfolio of novel, preclinical engineered cytokines. The separation, if consummated, is expected to be completed in November 2023 and is subject to customary closing conditions, including final approval by the Company's board of directors and receipt of a private letter ruling from the U.S. Internal Revenue Service (the "IRS") and/or a tax opinion from the Company's tax advisor. Subsequent to the planned separation, the historical results of the oncology business will be reflected as discontinued operations in the Company's consolidated financial statements.

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, 2023 and 2022 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2022. The year-end condensed consolidated balance sheet data, which is presented for comparative purposes, was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. (commonly referred to as "GAAP"). In the opinion of management, the condensed consolidated financial statements include all adjustments of a normal recurring nature that are necessary to state fairly the results of operations for the reported periods.

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

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries as disclosed in Note 2, *Summary of Significant Accounting Policies*, in the "Notes to Consolidated Financial Statements" accompanying the Company's Annual Report. Intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in accordance with GAAP requires that Company management make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies, including, but not limited to, those related to revenue

from contracts with its customers and related allowances, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different conditions or using different assumptions.

Segment Information

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

New Accounting Pronouncements

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

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

Product Sales, Net

The Company's product sales, net consist of sales in the U.S. of VIVITROL, ARISTADA and ARISTADA INITIO and, following its commercial launch in October 2021, LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. During the three and nine months ended September 30, 2023 and 2022, the Company recorded product sales, net, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2023	2022	2023	2022
VIVITROL	$ 99,305	$ 96,534	$ 298,035	$ 277,493
ARISTADA and ARISTADA INITIO	81,834	75,719	244,320	222,826
LYBALVI	50,683	27,127	135,671	61,116
Total product sales, net	$ 231,822	$ 199,380	$ 678,026	$ 561,435

Manufacturing and Royalty Revenues

During the three and nine months ended September 30, 2023 and 2022, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

	Three Months Ended September 30, 2023			Nine Months Ended September 30, 2023		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total	Manufacturing Revenue	Royalty Revenue	Total
Long-acting INVEGA products[(1)]	$ —	$ 76,109	$ 76,109	$ —	$ 410,910	$ 410,910
VUMERITY	9,733	24,828	34,561	32,751	62,979	95,730
RISPERDAL CONSTA	14,732	151	14,883	30,049	957	31,006
Other	16,157	7,403	23,560	48,160	22,082	70,242
	$ 40,622	$ 108,491	$ 149,113	$ 110,960	$ 496,928	$ 607,888

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

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

In October 2022 and November 2022, an arbitration panel found that the Company must return to Acorda Therapeutics, Inc. ("Acorda") $16.5 million (inclusive of prejudgment interest and administrative fees) and $1.8 million (inclusive of prejudgment interest), respectively, previously paid by Acorda under a license agreement between the Company and Acorda. These amounts represented a portion of the royalty revenue paid to the Company by Acorda since July 2020 related to AMPYRA. The Company paid Acorda the aggregate $18.3 million in the fourth quarter of 2022. In addition, during the three months ended June 30, 2022, the Company had recorded $3.2 million of royalty revenue related to AMPYRA as the Company believed that it had met the necessary revenue recognition criteria under the FASB Accounting Standards Codification 606, *Revenue from Contracts with Customers*. However, as a result of the arbitration ruling, the Company reversed the $3.2 million as the panel found that the Company was no longer entitled to be paid those royalties. During the three months ended September 30, 2022, the Company recorded both the $18.3 million in repayments and the $3.2 million reversal as reversals of royalty revenue within "Manufacturing and royalty revenue" in the accompanying consolidated statements of operations and comprehensive loss. As a result of the arbitration ruling, the Company has no contractual obligation to manufacture and supply AMPYRA or contractual right to receive future manufacturing or royalty revenue related to AMPYRA. Refer to Note 16, *Commitments and Contingent Liabilities* within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for information regarding additional legal proceedings related to the arbitration with Acorda.

In November 2021, the Company received notice of partial termination of an exclusive license agreement with Janssen Pharmaceutica N.V., a subsidiary of Johnson & Johnson ("Janssen Pharmaceutica"). Under this license agreement, the Company provided Janssen Pharmaceutica with rights to, and know-how, training and technical assistance in respect of, the Company's small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop the Long-acting INVEGA products. When the partial termination became effective in February 2022, Janssen Pharmaceutica ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. Accordingly, the Company ceased recognizing royalty revenue related to sales of these products in February 2022. In April 2022, the Company commenced binding arbitration proceedings related to, among other things, Janssen Pharmaceutica's partial termination of this license agreement and Janssen Pharmaceutica's royalty and other obligations under the agreement. On May 31, 2023, the arbitral tribunal (the "Tribunal") in the arbitration proceedings issued a final award (the "Final Award") which concluded the arbitration proceedings. The Final Award provided, among other things, that the Company was due back royalties of $195.4 million, inclusive of $8.1 million in late-payment interest related to 2022 U.S. net sales of the Long-acting INVEGA products, which amount the Company received from Janssen Pharmaceutica in the second quarter of 2023, and is entitled to 2023 and future royalty revenues from Janssen Pharmaceutica related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

Following issuance of the Final Award, the Company recognized royalty revenues related to the back royalties noted above and resumed recognizing royalty revenue related to ongoing U.S. sales of the Long-acting INVEGA products. During the nine months ended September 30, 2023, the Company recorded $410.9 million in royalty revenue from sales of the Long-acting INVEGA products, including $195.4 million related to back royalties and associated interest related to net sales of the Long-acting INVEGA products in 2022.

Contract Assets

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over time. 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, 2023 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2022	$ 8,929
Additions	12,881
Transferred to receivables, net	(19,044)
Contract assets at September 30, 2023	$ 2,766

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue. At September 30, 2023 and December 31, 2022, $3.3 million and $6.8 million of the contract liabilities, respectively, were classified as "Contract liabilities–short-term" in the accompanying condensed consolidated balance sheets and $1.7 million and $3.9 million of the contract liabilities, respectively, were classified as "Other long-term liabilities" in the accompanying condensed consolidated balance sheets.

Total contract liabilities at September 30, 2023 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2022	$ 10,701
Additions	(931)
Amounts recognized into revenue	(4,794)
Contract liabilities at September 30, 2023	$ 4,976

4. INVESTMENTS

Investments consisted of the following (in thousands):

September 30, 2023	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	$ 137,689	$ 7	$ (19)	$ (985)	$ 136,692
Corporate debt securities	94,150	12	(32)	(1,068)	93,062
Non-U.S. government debt securities	11,784	—	—	(99)	11,685
Total short-term investments	243,623	19	(51)	(2,152)	241,439
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	67,979	—	(159)	(738)	67,082
Corporate debt securities	38,179	—	(44)	(606)	37,529
	106,158	—	(203)	(1,344)	104,611
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	107,978	—	(203)	(1,344)	106,431
Total investments	$ 351,601	$ 19	$ (254)	$ (3,496)	$ 347,870

December 31, 2022					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 141,418	$ —	$ (424)	$ (2,054)	$ 138,940
U.S. government and agency debt securities	143,710	16	(266)	(1,289)	142,171
Non-U.S. government debt securities	35,455	—	(28)	(546)	34,881
Total short-term investments	320,583	16	(718)	(3,889)	315,992
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	68,229	—	(1,550)	(676)	66,003
U.S. government and agency debt securities	62,220	—	(917)	(1,424)	59,879
Non-U.S. government debt securities	4,099	—	—	(191)	3,908
	134,548	—	(2,467)	(2,291)	129,790
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	136,368	—	(2,467)	(2,291)	131,610
Total investments	$ 456,951	$ 16	$ (3,185)	$ (6,180)	$ 447,602

At September 30, 2023, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were temporary. Investments with unrealized losses consisted primarily of corporate debt securities and debt securities issued and backed by U.S. agencies and the U.S. government. At September 30, 2023, 179 of the Company's 219 investment securities were in an unrealized loss position and had an aggregate estimated fair value of $280.3 million. Approximately 37% and 59% of the Company's investment securities at September 30, 2023 were in corporate debt securities, with a minimum rating of A2 (Moody's)/A (Standard and Poor's), and debt securities issued by the U.S. government or its agencies, respectively. The primary reason for the unrealized losses in the Company's investment portfolio is that its investments are fixed-rate securities 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, 2023	2022
Proceeds from the sales and maturities of investments	$ 291,944	$ 190,994
Realized gains	$ —	$ —
Realized losses	$ —	$ 529

The Company's available-for-sale and held-to-maturity securities at September 30, 2023 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	$ 214,322	$ 212,122	$ 1,820	$ 1,820
After 1 year through 5 years	135,459	133,928	—	—
Total	$ 349,781	$ 346,050	$ 1,820	$ 1,820

5. FAIR VALUE

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

(In thousands)	September 30, 2023	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 37,132	$ 37,132	$ —	$ —
U.S. government and agency debt securities	203,774	166,427	37,347	—
Corporate debt securities	130,591	—	130,591	—
Non-U.S. government debt securities	11,685	—	11,685	—
Total	$ 383,182	$ 203,559	$ 179,623	$ —

	December 31, 2022	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 19,857	$ 19,857	$ —	$ —
U.S. government and agency debt securities	202,050	168,639	33,411	—
Corporate debt securities	204,943	—	204,943	—
Non-U.S. government debt securities	38,789	—	38,789	—
Total	$ 465,639	$ 188,496	$ 277,143	$ —

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, 2023. At September 30, 2023, the Company had no investments with fair values that were determined using Level 3 inputs.

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

In April 2015, the Company sold its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to intravenous/intramuscular ("IV/IM") and parenteral forms of Meloxicam to Recro Pharma, Inc. ("Recro") and Recro Gainesville LLC (such transaction the "Gainesville Transaction"). The Gainesville Transaction included in the purchase price contingent consideration, including milestone payments and royalties on net sales of the IV/IM and parenteral forms of Meloxicam and other products covered under the relevant agreements (such products, the "Meloxicam Products"). In November 2019, Recro spun out its acute care segment to Baudax Bio, Inc. ("Baudax"), a publicly-traded pharmaceutical company. As part of this transaction, Recro's obligations to pay certain contingent consideration from the Gainesville Transaction were assigned and/or transferred to Baudax.

In March 2022, Baudax reduced its workforce by approximately 80%, which was designed to reduce its operational expenses and conserve its cash resources. As a result of these events and the fact that, at September 30, 2022, Baudax had only paid $1.2 million of the $6.4 million that was due to the Company in March 2022, the Company determined that it was unlikely to collect any further proceeds under this arrangement and reduced the fair value of the contingent consideration to zero. Accordingly, the Company recorded a $3.6 million and $21.8 million charge within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive income (loss) in the three and nine months ended September 30, 2022, respectively. In addition, during the three months ended September 30, 2022, the Company determined that certain construction in progress related to the manufacturing of the approved Meloxicam Product had no future value. See Note 7, *Property, Plant and Equipment*, within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for details related to such construction in progress. In December 2022, Baudax announced that it would discontinue sales of ANJESO, the first approved Meloxicam Product, and the U.S. Food and Drug Administration ("FDA") acknowledged the discontinuation of sales of ANJESO via listing in the Orange Book.

In March 2023, the Company and Baudax entered into an agreement pursuant to which Baudax transferred to the Company the rights to certain patents, trademarks, equipment, data and other rights related to ANJESO and agreed to the termination of all prior agreements between the parties and any and all financial and other obligations thereunder.

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.

The estimated fair value of the Company's long-term debt under its amended and restated credit agreement (such debt, the "2026 Term Loans"), which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been, or will be, realized in the future, was $281.9 million and $278.9 million at September 30, 2023 and December 31, 2022, respectively.

6. INVENTORY

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

(In thousands)	September 30, 2023	December 31, 2022
Raw materials	$ 68,315	$ 61,064
Work in process	73,457	76,228
Finished goods[1]	50,414	44,126
Total inventory	$ 192,186	$ 181,418

(1) At September 30, 2023 and December 31, 2022, the Company had $33.7 million and $30.9 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Land	$ 6,570	$ 6,560
Building and improvements	195,766	195,144
Furniture, fixtures and equipment	436,392	418,448
Leasehold improvements	58,051	54,152
Construction in progress	93,434	84,715
Subtotal	790,213	759,019
Less: accumulated depreciation	(462,696)	(433,658)
Total property, plant and equipment, net	$ 327,517	$ 325,361

As of September 30, 2022, the Company determined that $8.7 million of its construction in progress that related to the manufacturing of the approved Meloxicam Product had no future value. In addition, the Company had previously received $6.4 million from Baudax related to such equipment which it had recorded as contract liabilities within “Other long-term liabilities” in the accompanying condensed consolidated balance sheets. These amounts were recognized through “other income (expense), net” in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

		September 30, 2023		
(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	$ 465,590	$ (458,226)	$ 7,364
Capitalized IP	11-13	118,160	(114,537)	3,623
Total		$ 583,750	$ (572,763)	$ 10,987

Based on the Company’s most recent analysis, amortization of intangible assets included in the accompanying condensed consolidated balance sheet at September 30, 2023 is expected to be approximately $35.0 million and $1.0 million in the years ending December 31, 2023 and 2024, respectively. Although the Company believes that such analysis, and the available information and assumptions underlying such analysis, are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is potential for the Company’s actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

9. LEASES

Future lease payments under non-cancelable leases at September 30, 2023 consisted of the following:

(In thousands)	September 30, 2023
Remaining 2023	$ 4,103
2024	16,601
2025	16,848
2026	12,760
2027	9,505
Thereafter	69,474
Total operating lease payments	$ 129,291
Less: imputed interest	(35,681)
Total operating lease liabilities	$ 93,610

At September 30, 2023, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.3% and 8.1 years, respectively. Cash paid for lease liabilities was $4.1 million and $12.6 million during the three and nine months ended September 30, 2023, respectively, as compared to $4.5 million and $13.4 million during the three and nine months ended September 30, 2022, respectively. The Company recorded operating lease expense of $4.2 million and $12.7 million during the three and nine months ended September 30, 2023, respectively, as compared to $4.1 million and $12.5 million during the three and nine months ended September 30, 2022, respectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
Accounts payable	$ 87,036	$ 32,843
Accrued compensation	67,773	79,085
Accrued other	88,454	108,161
Total accounts payable and accrued expenses	$ 243,263	$ 220,089

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

(In thousands)	September 30, 2023	December 31, 2022
Medicaid rebates	$ 192,749	$ 208,332
Product discounts	16,508	13,204
Medicare Part D	16,095	18,409
Other	13,115	12,170
Total accrued sales discounts, allowances and reserves	$ 238,467	$ 252,115

Included in accounts payable was approximately $36.4 million and $0.8 million of amounts payable related to state Medicaid rebates as of September 30, 2023 and December 31, 2022, respectively.

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
2026 Term Loans, due March 12, 2026	$ 291,366	$ 293,270
Less: current portion	(3,000)	(3,000)
Long-term debt	$ 288,366	$ 290,270

The 2026 Term Loans mature on March 12, 2026. In June 2023, the Company amended the 2026 Terms Loans to transition the interest rate available for borrowings thereunder from a London Interbank Offered Rate ("LIBOR")-based interest rate to an interest rate based on the Secured Overnight Financing Rate ("SOFR") and to make other conforming and mechanical changes. The 2026 Term Loans bear interest at SOFR plus a credit spread adjustment applicable to the interest period and an applicable margin of 2.50% with a floor of 0.5%.

The 2026 Term Loans have an incremental facility capacity in the amount of $175.0 million plus additional amounts, provided that the Company meets certain conditions, including a specified leverage ratio. The Company was in compliance with its debt covenants at September 30, 2023.

12. SHARE-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2023	2022	2023	2022
Cost of goods manufactured and sold	$ 2,939	$ 2,623	$ 8,542	$ 7,406
Research and development	7,208	6,858	21,621	19,688
Selling, general and administrative	13,768	16,570	44,899	40,677
Total share-based compensation expense	$ 23,915	$ 26,051	$ 75,062	$ 67,771

At September 30, 2023 and December 31, 2022, $3.2 million and $3.3 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying condensed consolidated balance sheets.

On June 29, 2023, 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 6,500,000.

13. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per ordinary share is calculated based upon net income (loss) 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, the Company utilizes the treasury stock method and adjusts the weighted average number of ordinary shares outstanding for the 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)	2023	2022	2023	2022
Numerator:				
Net income (loss)	$ 47,758	$ (63,974)	$ 242,978	$ (130,013)
Denominator:				
Weighted average number of ordinary shares outstanding	166,607	164,282	165,996	163,541
Effect of dilutive securities:				
Stock options	1,682	—	1,643	—
Restricted stock unit awards	3,614	—	3,342	—
Dilutive ordinary share equivalents	5,296	—	4,985	—
Shares used in calculating diluted earnings (loss) per ordinary share	171,903	164,282	170,981	163,541

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options	12,029	13,031	12,422	12,784
Restricted stock unit awards	1,317	4,922	2,389	5,459
Total	13,346	17,953	14,811	18,243

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 an income tax benefit of $0.4 million and $3.7 million during the three and nine months ended September 30, 2023, respectively, primarily due to enhanced foreign derived intangible income (“FDII”) deductions arising from the capitalization of research and development expenses in accordance with Section 174 of the U.S. Internal Revenue Code of 1986, as amended.

On a quarterly basis, the Company reassesses the valuation allowance on its deferred tax assets, weighing positive and negative evidence to determine the recoverability of such deferred tax assets. In the fourth quarter of 2022, the Company reassessed the valuation allowance and considered all positive and negative evidence, including its cumulative losses over the years ended December 31, 2022, 2021 and 2020 and concluded that it should maintain the valuation allowance on its Irish net operating losses and other deferred tax assets as of December 31, 2022.

The Company may release a significant portion of the valuation allowance upon completion of the planned separation of its oncology business; however, the release of the valuation allowance, as well as the exact timing and the amount of such release, continue to be subject to, among other things, the Company’s level of profitability, revenue growth, clinical program progression, the successful completion of the planned separation of the oncology business and expectations regarding future profitability. The Company’s Irish deferred tax asset balance subject to the valuation allowance was approximately $245.8 million at December 31, 2022.

15. RESTRUCTURING

In July 2023, in conjunction with the Company’s ongoing review of operations and the planned separation of its oncology business, the Company implemented a restructuring plan, which included the elimination of approximately 60 positions across the Company (the “Restructuring”). The Company recorded a charge of $6.0 million during the three and nine months ended September 30, 2023 as a result of the Restructuring, which consisted of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures, and all of which are expected to be paid within 12 months of the Restructuring. During the three and nine months ended September 30, 2023, the Company recognized $4.5 million and $1.5 million of this expense in R&D expense and SG&A expense, respectively, in the accompanying condensed consolidated statements of comprehensive income (loss).

Activity related to the Restructuring during the three months ended September 30, 2023 was as follows:

(In thousands)	
Balance, December 31, 2022	$ —
Restructuring charge	5,969
Amounts paid during the period:	
Severance	(2,098)
Benefits	(319)
Outplacement services	(178)
Balance, September 30, 2023	$ 3,374

At September 30, 2023 and December 31, 2022, $3.4 million and none, respectively, of the restructuring accrual was included within "Accounts payable and accrued expenses" in the accompanying condensed consolidated balance sheets.

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, 2023, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

Janssen Arbitration Proceedings

In April 2022, Alkermes Pharma Ireland Limited commenced binding arbitration proceedings to settle, among other things, whether, notwithstanding Janssen Pharmaceutica's partial termination of two license agreements with the Company, Janssen Pharmaceutica has a continuing obligation to pay royalties on sales in the U.S. of INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA. On May 31, 2023, the Company received a Final Award from the Tribunal in these arbitration proceedings. The Final Award reiterated the Tribunal's findings from, and incorporated by reference, the first interim award and second interim award issued by the Tribunal on December 21, 2022 and April 19, 2023, respectively. As a result of the Final Award, in June 2023 the Company received payment for back royalties, including certain late-payment interest, related to 2022 U.S. net sales of INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA and is entitled to 2023 and future royalty revenues from Janssen Pharmaceutica related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the applicable license agreement expires), INVEGA HAFYERA through May 2030 (when the applicable license agreement expires) and CABENUVA through December 31, 2036. Refer to Note 3, *Revenue from Contracts with Customers* within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for additional information regarding royalty revenue recognized following the issuance of the Final Award. The arbitration was conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration before a panel of three arbitrators. On June 28, 2023, the Company filed an unopposed petition to confirm the Final Award and enter judgment thereon with the U.S. District Court for the Southern District of New York (the "NY Southern District Court"), and on June 30, 2023, Janssen Pharmaceutica filed a notice of non-opposition to such petition. On August 18, 2023, the NY Southern District Court granted the Company's motion to confirm the Final Award.

INVEGA SUSTENNA ANDA Litigation

Janssen Pharmaceutica and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the U.S. District Court for the District of New Jersey (the "NJ District Court") in January 2018 against Teva Pharmaceuticals USA, Inc. ("Teva") and Teva Pharmaceuticals Industries, Ltd. ("Teva PI") (such lawsuit, the "Teva Lawsuit"), in August 2019

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

INVEGA TRINZA ANDA Litigation

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

VIVITROL ANDA Litigation

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

A bench trial was held in February 2023 and closing arguments were heard in June 2023. On August 29, 2023, Alkermes, Inc. and Alkermes Pharma Ireland Limited entered into a confidential settlement and license agreement (the "Settlement Agreement") with Teva to resolve the proceedings between the parties. Pursuant to the terms of the Settlement Agreement, the Company has granted Teva a non-exclusive, royalty-free, non-transferable, non-sublicensable limited license to make, have made, use, import, sell and offer for sale Teva's product made under Teva's ANDA in the U.S. beginning on January 15, 2027, or earlier under certain circumstances. The Company and the Teva entities have submitted the Settlement Agreement for review to the U.S. Federal Trade Commission and the U.S. Department of Justice. Pursuant to the Settlement Agreement, on August 30, 2023, the Company and Teva filed a joint proposed Stipulated Consent Judgment and Injunction with the NJ District Court requesting that the court dismiss the pending litigation proceedings between the parties. On September 18, 2023, the NJ District Court approved such Stipulated Consent Judgment and Injunction.

VUMERITY ANDA Litigation

On July 6, 2023, Biogen Inc., Biogen Swiss Manufacturing GmbH and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in 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 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 October 11, 2023, Zydus filed an answer to the complaint.

Government Matters

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

Product Liability and Other Legal Proceedings

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

In addition, in January 2023, Acorda filed a petition with 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. On August 4, 2023, the NY Southern District Court confirmed the final arbitral award but declined to modify the final award to increase the damages awarded thereunder. On September 1, 2023, Acorda filed a notice of appeal of the NY Southern District Court decision to the U.S. Court of Appeals for the Federal Circuit. On September 22, 2023, the Company filed a motion to transfer the appeal to the U.S. Court of Appeals for the Second Circuit and on October 10, 2023, Acorda filed an opposition to such motion.

While the outcome of any of these proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any of these existing proceedings would have a material adverse effect on the Company’s business or financial condition.

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

The following discussion should be read in conjunction with the accompanying condensed consolidated financial statements and related notes beginning on page 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 was $47.8 million and $243.0 million or $0.29 and $1.46 per ordinary share—basic and $0.28 and $1.42 per ordinary share—diluted, for the three and nine months ended September 30, 2023, respectively, as compared to net loss of $64.0 million and $130.0 million or $0.39 and $0.79 per ordinary share—basic and diluted, for the three and nine months ended September 30, 2022, respectively.

The net income during the three and nine months ended September 30, 2023, as compared to the net loss during the three and nine months ended September 30, 2022, was primarily due to increases of $96.2 million and $364.5 million, respectively, in manufacturing and royalty revenues, primarily from the Long-acting INVEGA products following the successful outcome of the arbitration proceedings in respect of such products, and increases of $32.4 million and $116.6 million, respectively, in product sales, net, partially offset by increases of $16.7 million and $101.0 million, respectively, in selling, general and administrative expense, and increases of $10.9 million and $18.8 million, respectively, in cost of goods manufactured and sold.

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

Planned Separation of Oncology Business

In November 2022, we announced our intent, as approved by our board of directors, to explore the separation of our oncology business. Following a review of strategic alternatives for the oncology business, we are planning a separation of the oncology business into an independent, publicly-traded company, Mural Oncology. Following the planned separation, we would focus on driving growth of our proprietary commercial products: LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL, and advancing the development of pipeline programs focused on neurological disorders. We also expect to retain manufacturing and royalty revenues, including those related to our licensed products and third-party products using our proprietary technologies under license. Mural Oncology would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and our portfolio of novel, preclinical engineered cytokines. The separation, if consummated, is expected to be completed in November 2023 and is subject to customary closing conditions, including final approval by our board of directors and receipt of a private letter ruling from the IRS and/or a tax opinion from our tax advisor. Subsequent to the planned separation, the historical results of the oncology business will be reflected as discontinued operations in our consolidated financial statements.

COVID-19 Impact

A number of the marketed products from which we derive revenue, including manufacturing and royalty revenue, are injectable medications administered by healthcare professionals, which have been adversely impacted to varying degrees as a result of COVID-19 related impacts. We are continuing to monitor any potential COVID-19 related impacts on our employees, business, financial condition and results of operations. For information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see "Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the ongoing COVID-19 pandemic or other similar outbreaks of contagious diseases."

Products

Marketed Products

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

“Part I, Item 1—Business” in our Annual Report for information with respect to the IP protection for these marketed products.

Proprietary Products

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

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.

Key Third-Party Products Using Our Proprietary Technologies

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

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

Our Key Licensed Product

The following provides summary information regarding our key licensed product that is commercialized by our licensees:

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

The following sections provide more detailed information regarding our proprietary products, licensed products and products using our proprietary technology.

Proprietary Products

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

ARISTADA

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

ARISTADA INITIO

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

LYBALVI

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

In July 2023, U.S. Patent No. 11,707,466 relating to LYBALVI was granted. The patent has claims to formulations that cover LYBALVI and expires in 2041. In October 2023, U.S. Patent No. 11,793,805 relating to LYBALVI was granted. The patent has claims to methods of treatment that cover LYBALVI and expires in 2031.

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.

Licensed Products and Products Using Our Proprietary Technologies

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

Key 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 SUSTENNA and 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 "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

RISPERDAL CONSTA

RISPERDAL CONSTA (risperidone long-acting injection) is a long-acting atypical antipsychotic owned and commercialized worldwide by Janssen that incorporates our proprietary technologies. RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one intramuscular injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us.

Licensed Product

VUMERITY

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

Under our license and collaboration agreement with Biogen, Biogen holds the exclusive, worldwide license to develop and commercialize VUMERITY. For more information about the license and collaboration agreement with Biogen, see the "Collaborative Arrangements—Biogen" section in "Part I, Item 1—Business" in our Annual Report. 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 and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

Key Development Programs

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

Nemvaleukin alfa

Nemvaleukin alfa ("nemvaleukin") is an investigational, novel, engineered fusion protein comprised of modified interleukin-2 ("IL-2") and the high affinity IL-2 alpha receptor chain, designed to preferentially expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by selectively binding to the intermediate-affinity IL-2 receptor complex. The selectivity of nemvaleukin is designed to leverage the proven anti-tumor effects of existing IL-2 therapy while mitigating certain limitations.

ARTISTRY is our clinical development program evaluating nemvaleukin as a potential immunotherapy for cancer. The ARTISTRY program is comprised of multiple clinical trials evaluating intravenous ("IV") and subcutaneous ("SC") dosing of nemvaleukin, both as a monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with advanced solid tumors. ARTISTRY-6 is an ongoing phase 2 study evaluating the anti-tumor activity, safety and tolerability of IV nemvaleukin monotherapy in patients with mucosal melanoma and SC nemvaleukin monotherapy in patients with advanced cutaneous melanoma. ARTISTRY-7 is an ongoing phase 3 study evaluating the efficacy, safety and tolerability of IV nemvaleukin as monotherapy and in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant ovarian cancer.

In March 2021 and August 2021, we announced that the FDA granted Orphan Drug designation and Fast Track designation, respectively, to nemvaleukin for the treatment of mucosal melanoma. In October 2021, we announced that the FDA granted Fast Track designation to nemvaleukin in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer. In January 2023, we announced that the Medicines and Healthcare products Regulatory Agency ("MHRA"), the regulatory body of the United Kingdom ("UK"), had granted an Innovation Passport designation for nemvaleukin for the treatment of mucosal melanoma under the UK's Innovative Licensing and Access Pathway ("ILAP").

ALKS 2680

ALKS 2680 is a novel, investigational, oral, selective orexin 2 receptor ("OX2R") agonist in development for the treatment of narcolepsy. Orexin neuropeptides are important regulators of the sleep/wake cycle through OX2R activation, and loss of orexinergic neurons in the brain is associated with excessive daytime sleepiness and cataplexy in narcolepsy. ALKS 2680 was designed to address the underlying pathology of narcolepsy with the goal of improving duration of wakefulness and providing cataplexy control. Once-daily oral administration of ALKS 2680 is currently being evaluated in a phase 1 study in healthy volunteers and people living with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia.

Results of Operations

Product Sales, Net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO, and, following its commercial launch in the U.S. in October 2021, LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for sales of VIVITROL, ARISTADA, ARISTADA INITIO and LYBALVI during the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(In millions, except for % of Sales)	2023	% of Sales	2022	% of Sales	2023	% of Sales	2022	% of Sales
Product sales, gross	$ 469.3	100.0 %	$ 401.0	100.0 %	$ 1,373.0	100.0 %	$ 1,130.2	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(107.2)	(22.8) %	(88.9)	(22.2) %	(317.5)	(23.1) %	(254.1)	(22.5) %
Chargebacks	(48.9)	(10.4) %	(43.0)	(10.7) %	(141.4)	(10.3) %	(118.3)	(10.5) %
Product discounts	(32.7)	(7.0) %	(32.6)	(8.1) %	(101.8)	(7.4) %	(90.3)	(8.0) %
Medicare Part D	(18.7)	(4.0) %	(17.1)	(4.3) %	(55.8)	(4.1) %	(49.6)	(4.4) %
Other	(30.0)	(6.4) %	(20.1)	(5.0) %	(78.5)	(5.7) %	(56.5)	(4.9) %
Total adjustments	(237.5)	(50.6) %	(201.7)	(50.3) %	(695.0)	(50.6) %	(568.8)	(50.3) %
Product sales, net	$ 231.8	49.4 %	$ 199.3	49.7 %	$ 678.0	49.4 %	$ 561.4	49.7 %

The following table compares product sales, net earned during the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2023	2022	Change	2023	2022	Change
VIVITROL	$ 99.3	$ 96.5	$ 2.8	$ 298.0	$ 277.5	$ 20.5
ARISTADA and ARISTADA INITIO	81.8	75.7	6.1	244.3	222.8	21.5
LYBALVI	50.7	27.1	23.6	135.7	61.1	74.6
Product sales, net	$ 231.8	$ 199.3	$ 32.5	$ 678.0	$ 561.4	$ 116.6

VIVITROL product sales, gross, increased by 9% and 14% during the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022, primarily due to increases of 3% and 6%, respectively, in the number of units sold and a 6% increase in the selling price that went into effect in January 2023. ARISTADA and ARISTADA INITIO product sales, gross, increased by 12% and 13% during the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022, primarily due to increases of 9% and 10%, respectively, in the number of units sold and a 3% increase in the selling price that went into effect in January 2023. LYBALVI product sales, gross, increased by 85% and 120% during the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022, primarily due to increases of 76% and 114%, respectively, in the number of units sold and increases in the selling price of 6% and 3% that went into effect in November 2022 and July 2023, respectively.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned during the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2023	2022	Change	2023	2022	Change
Manufacturing and royalty revenues:						
Long-acting INVEGA products	$ 76.1	$ 26.7	$ 49.4	$ 410.9	$ 90.4	$ 320.5
VUMERITY	34.5	26.2	8.3	95.7	83.0	12.7
RISPERDAL CONSTA	14.9	10.2	4.7	31.0	38.0	(7.0)
Other	23.6	(10.2)	33.8	70.3	32.0	38.3
Manufacturing and royalty revenues	$ 149.1	$ 52.9	$ 96.2	$ 607.9	$ 243.4	$ 364.5

Our agreements with Janssen related to the Long-acting INVEGA products provide for tiered royalty payments, which consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the patents with valid claims applicable to the product in such country. The know-how royalty is a tiered royalty of 3.5% on calendar year net sales up to $250 million; 5.5% on calendar year net sales of between $250 million and $500 million; and 7.5% on calendar year net sales exceeding $500 million. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until 15 years from the first commercial sale of a product in each individual country, subject to expiry of the agreement. For more information about the license agreement with Janssen in respect of the Long-acting INVEGA products, see the "Collaborative Arrangements—Janssen" section in "Part I, Item 1—Business" in our Annual Report.

In November 2021, we received notice of partial termination of our license agreement with Janssen under which we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop the Long-acting INVEGA products. The partial termination became effective in February 2022, at which time Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. Accordingly, we ceased recognizing royalty revenue related to sales of these products in February 2022. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. In May 2023, the Tribunal issued the Final Award, which concluded the arbitration proceedings. The Final Award provided that we were due back royalties of $195.4 million, inclusive of $8.1 million in late-payment interest, related to 2022 U.S. net sales of the Long-acting INVEGA products, which we received from Janssen in the second quarter of 2023, and are entitled to 2023 and future royalty revenues from Janssen related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

Following issuance of the Final Award, we recognized royalty revenues related to the back royalties noted above and resumed recognizing royalty revenue related to U.S. sales of the Long-acting INVEGA products. During the three months ended June 30, 2023, we recorded $195.4 million in royalty revenue related to the back royalties, $50.2 million of royalty revenue related to U.S. net sales of the Long-acting INVEGA products earned during the first quarter of 2023 and $75.7 million of royalty revenue related to worldwide net sales of the Long-acting INVEGA products earned during the second quarter of 2023. During the three and nine months ended September 30, 2023, Janssen's worldwide net sales of the Long-acting INVEGA products were $1,029 million and $3,104.0 million, respectively, as compared to $1,031.0 million and $3,132.0 million during the three and nine months ended September 30, 2022, respectively.

We expect royalty revenues from net sales of the Long-acting INVEGA products to decrease in the near-term, as the royalty revenues related to net sales of INVEGA SUSTENNA are expected to end on August 20, 2024, and each of INVEGA SUSTENNA and INVEGA TRINZA are currently subject to Paragraph IV litigation in response to companies seeking to market generic versions of such products. Increased competition from new products or generic versions of these products may lead to reduced unit sales of such products and increased pricing pressure. For a discussion of these legal proceedings, see Note 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 "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

We receive a 15% royalty on worldwide net sales of VUMERITY manufactured and packaged by us, subject to increases in such royalty rate for VUMERITY manufactured and/or packaged by Biogen or its designees, in the period that the end-market sales of VUMERITY occur. We also recognize manufacturing revenue related to VUMERITY at cost plus 15%, upon making available bulk batches of VUMERITY to Biogen and, to the extent we package such product, then also when packaged batches of VUMERITY are made available to Biogen. Manufacturing revenue from VUMERITY increased by $4.1 million and $10.1 million during the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was primarily due to increases in the number of bulk and packaged batches made available to Biogen. The increase during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in the number of bulk batches made available to Biogen, partially offset by a decrease in the number of packaged batches made available to Biogen. Royalty revenue related to VUMERITY increased by $4.2 million and $2.6 million during the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increases in royalty revenue were due to increases in end-market net sales of VUMERITY from $137.8 million and $402.6 million during the three and nine months ended September 30, 2022,

respectively, to $165.5 million and $419.9 million during the three and nine months ended September 30, 2023, respectively.

We recognize manufacturing revenue for RISPERDAL CONSTA at the point in time when RISPERDAL CONSTA has been fully manufactured, which is deemed to have occurred when the product is approved for shipment by both us and Janssen. We record royalty revenue, equal to 2.5% of Janssen's end-market net sales, in the period that the end-market sales of RISPERDAL CONSTA occur. We expect revenues from RISPERDAL CONSTA to continue to decrease over time as patents covering RISPERDAL CONSTA expire in markets where end-market net sales of RISPERDAL CONSTA occur. The latest to expire patent covering RISPERDAL CONSTA expired in 2021 in the EU and in January 2023 in the U.S., and we are aware of potential generic and other competition to RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure. The increase in revenue from RISPERDAL CONSTA during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was primarily due to an increase of $6.4 million in manufacturing revenue, partially offset by a decrease of $1.7 million in royalty revenue. The decrease in revenue from RISPERDAL CONSTA during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to decreases of $4.6 million in royalty revenue and $2.7 million in manufacturing revenue. The decreases in royalty revenue during the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were primarily due to expirations of the patents covering RISPERDAL CONSTA, as noted above. The increase in manufacturing revenue during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was primarily due to an increase in the number of U.S. batches made available to Janssen. The decrease in manufacturing revenue during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to a decrease in the number of U.S. batches made available to Janssen and a 6% decrease in the rest of world average selling price of the product.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2023**	**2022**	**Change**	**2023**	**2022**	**Change**
Cost of goods manufactured and sold	$ 61.5	$ 50.6	$ 10.9	$ 182.9	$ 164.1	$ 18.8

The increase in cost of goods manufactured and sold during the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was primarily due to increases of $3.2 million, $3.2 million and $2.0 million in the cost of goods sold for ARISTADA and ARISTADA INITIO, LYBALVI and VIVITROL respectively, and an increase of $2.4 million in the cost of goods manufactured for RISPERDAL CONSTA, due to increases in the number of units manufactured and sold as discussed above.

The increase in cost of goods manufactured and sold during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to increases of $11.7 million, $5.9 million and $3.5 million in the cost of goods sold for VIVITROL, LYBALVI and ARISTADA and ARISTADA INITIO, respectively, due to increases in the number of units manufactured for each product as discussed above.

Research and Development Expenses

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

The following table sets forth our external R&D expenses for the three and nine months ended September 30, 2023 and 2022 relating to our then-current development programs and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Three Months Ended September 30, 2023	2022	Change	Nine Months Ended September 30, 2023	2022	Change
External R&D expenses:						
Development programs:						
nemvaleukin	$ 20.4	$ 21.6	$ (1.2)	$ 59.4	$ 58.2	$ 1.2
LYBALVI	4.2	6.5	(2.3)	10.8	15.7	(4.9)
ALKS 2680	5.5	3.0	2.5	17.8	7.5	10.3
Other external R&D expenses	13.6	15.7	(2.1)	41.9	47.2	(5.3)
Total external R&D expenses	43.7	46.8	(3.1)	129.9	128.6	1.3
Internal R&D expenses:						
Employee-related	40.5	39.6	0.9	121.7	120.3	1.4
Occupancy	4.5	4.6	(0.1)	13.6	13.3	0.3
Depreciation	2.4	3.1	(0.7)	7.8	8.8	(1.0)
Other	6.1	6.4	(0.3)	18.6	18.3	0.3
Total internal R&D expenses	53.5	53.7	(0.2)	161.7	160.7	1.0
Research and development expenses	$ 97.2	$ 100.5	$ (3.3)	$ 291.6	$ 289.3	$ 2.3

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 decrease in expenses related to nemvaleukin in the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was primarily due to decreased spend on the ARTISTRY-1 and ARTISTRY-2 studies, as activities related to these studies wind down, partially offset by increased spend on the ARTISTRY-7 study. The increase in expenses related to nemvaleukin in the nine months ended September 30, 2023, as compared to the nine months ended September 20, 2022, was primarily due to increased spend on the ARTISTRY-7 study, partially offset by a decrease in spend on the ARTISTRY-1 and ARTISTRY-2 studies. For additional detail on the ARTISTRY development program for nemvaleukin, see the “Key Development Programs” section of this “Part I, Item 2—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Form 10-Q. The decreases in expenses related to LYBALVI in the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were primarily due to decreased spend on ongoing clinical studies. The increases in expenses related to ALKS 2680 in the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were primarily due to increases in early-stage development expenses, including chemistry manufacturing and controls expenses and increased spend on a phase 1b proof-of-concept study, which was initiated in the second quarter of 2023.

In connection with the planned separation of our oncology business, we expect R&D expenses to decrease, as the continued development of nemvaleukin alfa and the discovery and development of our portfolio of novel, preclinical engineered cytokines would be transferred to, and become the responsibility of, Mural Oncology.

Selling, General and Administrative Expense

(In millions)	Three Months Ended September 30, 2023	2022	Change	Nine Months Ended September 30, 2023	2022	Change
Selling and marketing expense	$ 114.8	$ 96.9	$ 17.9	$ 371.2	$ 288.4	$ 82.8
General and administrative expense	54.6	55.9	(1.3)	177.9	159.8	18.1
Selling, general and administrative expense	$ 169.4	$ 152.8	$ 16.6	$ 549.1	$ 448.2	$ 100.9

The increases in selling and marketing expense during the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were primarily due to increases in marketing expense of $11.9 million and $60.9 million, respectively, following the launch of the direct-to-consumer campaign for LYBALVI and increases in employee-related expenses of $6.5 million and $21.8 million, respectively, primarily due to

a 6% increase in sales and marketing headcount, increases in salaries, and increases in employee travel as our in-person activities increased.

The increase in general and administrative expense during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to an increase in employee-related expenses of $11.3 million and an increase in professional service fees of $7.0 million. The increases in employee-related expenses in the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, were primarily due to an increase in salaries and benefits expense, primarily due to a 2% increase in average general and administrative headcount, increases in salaries and increased recruiting and other costs related to the planned separation of our oncology business. The increase in professional service fees in the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was primarily due to increased spend on fees related to the planned separation of our oncology business and expenses related to activist shareholder activities.

Other Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2023	2022	Change	2023	2022	Change
Interest income	$ 9.4	$ 2.3	$ 7.1	$ 21.1	$ 3.8	$ 17.3
Interest expense	(6.0)	(3.6)	(2.4)	(17.0)	(8.3)	(8.7)
Change in the fair value of contingent consideration	—	(3.6)	3.6	—	(21.8)	21.8
Other income (expense), net	0.1	(1.8)	1.9	(0.4)	2.4	(2.8)
Total other income (expense), net	$ 3.5	$ (6.7)	$ 10.2	$ 3.7	$ (23.9)	$ 27.6

Interest income consists primarily of interest earned on our cash and available-for-sale investments. Interest expense consists of interest incurred on our 2026 Term Loans. The increases in interest income and interest expense in the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were primarily due to increases in interest rates over the past twelve months, as we are in a rising interest rate environment.

The changes in the fair value of the contingent consideration in the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, were due to the determination that it was unlikely that we would collect any further contingent consideration proceeds under our agreements with Baudax, and accordingly, we reduced the fair value of the contingent consideration to zero, as discussed in Note 5, *Fair Value*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q.

Income Tax Benefit

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2023	2022	Change	2023	2022	Change
Income tax benefit	$ (0.4)	$ (3.4)	$ 3.0	$ (3.7)	$ (15.6)	$ 11.9

The income tax benefit in the three and nine months ended September 30, 2023 and 2022 primarily related to enhanced FDII deductions arising from the capitalization of research and development expenses in accordance with Section 174 of the U.S. Internal Revenue Code of 1986, as amended.

On a quarterly basis, we reassess the valuation allowance on our deferred tax assets, weighing positive and negative evidence to determine the recoverability of such deferred tax assets. In the fourth quarter of 2022, we reassessed the valuation allowance and considered all positive and negative evidence, including our cumulative losses over the years ended December 31, 2022, 2021 and 2020 and concluded that we should maintain the valuation allowance on our Irish net operating losses and other deferred tax assets as of December 31, 2022.

We may release a significant portion of the valuation allowance upon completion of the planned separation of our oncology business; however, the release of the valuation allowance, as well as the exact timing and the amount of such release, continue to be subject to, among other things, our level of profitability, revenue growth, clinical program progression, the successful completion of the planned separation of the oncology business and expectations regarding

future profitability. Our Irish deferred tax asset balance subject to the valuation allowance was approximately $245.8 million at December 31, 2022.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

	September 30, 2023			December 31, 2022		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 281.2	$ 366.5	$ 647.7	$ 208.4	$ 84.1	$ 292.5
Investments—short-term	148.2	93.2	241.4	207.6	108.4	316.0
Investments—long-term	61.4	45.1	106.5	70.3	61.3	131.6
Total cash and investments	$ 490.8	$ 504.8	$ 995.6	$ 486.3	$ 253.8	$ 740.1
Outstanding borrowings—short and long-term	$ 291.4	$ —	$ 291.4	$ 293.3	$ —	$ 293.3

At September 30, 2023 our investments consisted of the following:

		Gross Unrealized			
(In millions)	Amortized Cost	Gains	Losses	Allowance for Credit Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 243.6	$ —	$ (2.2)	$ —	$ 241.4
Investments—long-term available-for-sale	106.2	—	(1.5)	—	104.7
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 351.6	$ —	$ (3.7)	$ —	$ 347.9

Sources and Uses of Cash

We generated $294.1 million and $20.0 million of cash from operating activities during the nine months ended September 30, 2023 and 2022, respectively. We expect that our existing cash, cash equivalents and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt, for at least the twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. In addition, the 2026 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional potential amounts, provided that we meet certain conditions, including a specified leverage ratio.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities 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 twelve months as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2023, we performed an analysis of our investments with unrealized losses for impairment and determined that they were not impaired.

In connection with the planned separation of our oncology business, we expect to make a cash contribution to Mural Oncology in the amount of $275.0 million upon completion of the separation.

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

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022:

(In millions)	Nine Months Ended September 30, 2023	2022
Cash and cash equivalents, beginning of period	$ 292.5	$ 337.5
Cash flows provided by operating activities	294.1	20.0
Cash flows provided by (used in) investing activities	74.3	(92.2)
Cash flows used in financing activities	(13.2)	(1.3)
Cash and cash equivalents, end of period	$ 647.7	$ 264.0

Operating Activities

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

Cash flows provided by operating activities for the nine months ended September 30, 2023 were $294.1 million and primarily consisted of a net income of $243.0 million adjusted for non-cash items, including share-based compensation of $75.1 million and depreciation and amortization of $56.4 million, partially offset by changes in working capital of $34.3 million and deferred income taxes of $47.4 million. During the nine months ended September 30, 2023, net income included receipt of $195.4 million from Janssen, inclusive of $8.1 million in late-payment interest, related to 2022 U.S. net sales of the Long-acting INVEGA products following the successful outcome of the arbitration proceedings in respect of such products.

Cash flows provided by operating activities for the nine months ended September 30, 2022 were $20.0 million and primarily consisted of a net loss of $130.0 million, adjusted for non-cash items including share-based compensation of $67.8 million, depreciation and amortization of $58.2 million, change in the fair value of contingent consideration of $21.8 million and changes in working capital of $52.6 million, partially offset by deferred income taxes of $54.1 million.

Investing Activities

Cash flows provided by investing activities for the nine months ended September 30, 2023 were primarily due to $105.4 million in net sales of investments, offset by the purchase of $31.0 million of property, plant and equipment. Cash flows used in investing activities for the nine months ended September 30, 2022 were primarily due to $65.8 million in net purchases of investments and the purchase of $28.2 million of property, plant and equipment.

Financing Activities

Cash flows used in financing activities for the nine months ended September 30, 2023 and 2022 primarily related to $26.1 million and $17.9 million of employee taxes paid related to the net share settlement of equity awards, respectively, partially offset by $15.1 million and $18.8 million of cash that we received upon exercises of employee stock options, respectively.

Debt

At September 30, 2023, the principal balance of our borrowings consisted of $292.5 million outstanding under our 2026 Term Loans. See Note 11, *Long-Term Debt*, in the “Notes to Condensed Consolidated Financial Statements” in this Form 10-Q for further discussion of our 2026 Term Loans.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different conditions or using different assumptions. See the "Critical Accounting Estimates" section in "Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report for a discussion of our critical accounting estimates.

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, 2022, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures.

We are exposed to non-U.S. currency exchange risk related to manufacturing and royalty revenues that we receive on certain of our products, partially offset by certain operating costs arising from expenses and payables in connection with our Irish operations that are settled predominantly in Euro. These non-U.S. currency exchange rate risks are summarized in "Part II, Item 7A—Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report. There has been no material change in our assessment of our sensitivity to non-U.S. currency exchange rate risk since December 31, 2022.

Item 4. ***Controls and Procedures***

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of September 30, 2023. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer each concluded that our disclosure controls and procedures were effective as of September 30, 2023 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

b) Change in Internal Control Over Financial Reporting

During the three months ended September 30, 2023, 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***

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and/or the planned separation of our oncology business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business and/or the planned separation of our oncology business.

There have been no other material changes from the risk factors disclosed in "Part I, Item 1A—Risk Factors" of our Annual Report and "Part II, Item 1A—Risk Factors" of our Q1 Quarterly Report. The above risk factor should be read in conjunction with the risk factors disclosed in such reports.

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the nine months ended September 30, 2023. As of September 30, 2023, we had purchased a total of 8,866,342 shares under this program at an aggregate cost of $114.0 million.

During the three months ended September 30, 2023, we acquired 26,943 of our ordinary shares, at an average price of $29.54 per share, to satisfy withholding tax obligations related to the vesting of employee equity awards.

Item 5. ***Other Information***

During the three months ended September 30, 2023, none of the directors or executive officers of the Company adopted, terminated or materially modified a trading plan intended to comply with Rule 10b5-1 or a trading plan not intended to comply with Rule 10b5-1.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1 #*	Confidential Settlement and License Agreement, dated August 29, 2023, by and among Alkermes, Inc., Alkermes Pharma Ireland Limited and Teva Pharmaceuticals USA, Inc.
10.2 #§	Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.
10.3 #§	Development and Supplemental Agreement between Elan Pharma International Limited and Acorda Therapeutics, Inc. dated January 14, 2011.
31.1 #	Rule 13a-14(a)/15d-14(a) Certification.
31.2 #	Rule 13a-14(a)/15d-14(a) Certification.
32.1 ‡	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.SCH #	Inline XBRL Taxonomy Extension Schema Document.
101.CAL #	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB #	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE #	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF #	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104 #	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

Filed herewith.

‡ Furnished herewith.

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

* Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

§ Filed with this Form 10-Q solely for the purpose of transitioning this previously-filed exhibit, which is the subject of an expiring confidential treatment order, to the rules governing the filing of redacted exhibits under Regulation S-K Item 601(b)(10)(iv) pursuant to the SEC's CF Disclosure Guidance: Topic 7. Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

ALKERMES PLC

(Registrant)

By: /s/ Richard F. Pops

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

By: /s/ Iain M. Brown

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

Date: October 25, 2023

Execution Version

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

CONFIDENTIAL SETTLEMENT AND LICENSE AGREEMENT

This Confidential Settlement And License Agreement (the "**Settlement Agreement**") is hereby entered into on August 29, 2023 ("**Execution Date**") by and among

ALKERMES, INC., a Pennsylvania corporation with a place of business at 852 Winter Street, Waltham, MA 02451,

ALKERMES PHARMA IRELAND LIMITED, an entity organized and existing under the laws of Ireland, with a place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland, D04 C5Y6,

(ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED collectively, "**Alkermes**" or "**Plaintiffs**") and

TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 ("**Teva**" or "**Defendant**");

(each individually a "**Party**" and, collectively, the "**Parties**").

RECITALS

WHEREAS Alkermes, Inc. is the registered holder of U.S. Food & Drug Administration approved New Drug Application No. 021897 for VIVITROL® (naltrexone for extended-release injectable suspension) 380mg/vial ("**VIVITROL**");

WHEREAS Alkermes Pharma Ireland Limited is the owner of U.S. Patent No. 7,919,499 (the "**'499 Patent**");

WHEREAS Teva is the owner of ANDA No. 213195 for generic naltrexone for extended-release injectable suspension, 380 mg/vial;

WHEREAS Plaintiffs have filed a lawsuit against Teva in the United States District Court for the District of New Jersey (Case No. 1:20-cv-12470), alleging that the filing of ANDA No. 213195 infringes the '499 Patent ("**Lawsuit**");

WHEREAS the Parties wish to avoid the significant legal expense and legal risks involved in continuing the Lawsuit by settling the Lawsuit on the terms and conditions set forth in this Settlement Agreement;

WHEREAS as a result of this Settlement Agreement, Teva will be permitted to make sales in the Territory of the generic form of VIVITROL for human use in advance of the expiration of the '499 Patent, upon the dates and terms specified herein, which sales otherwise may not have been made until after the expiration of the '499 Patent;

NOW, THEREFORE, in consideration of the mutual execution of this Settlement Agreement and the promises made herein, the Parties agree as follows:

ARTICLE I.DEFINITIONS

"**Affiliate**" of a Party means any person or entity that controls, is controlled by or is under common control with such Party. As used in this definition, "**control**" of an entity means: (a) direct or indirect ownership of more than fifty percent (50%) of the outstanding stock or shares having the right to vote for the election of directors of such entity; or (b) the direct or indirect power to either: (i) direct the management and policies of the entity; or (ii) elect at least fifty percent (50%) of the members of the governing body of such entity.

"**Alkermes NDA**" means NDA No. 021897 for VIVITROL.

"**ANDA**" means an Abbreviated New Drug Application as defined in the U.S. Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder filed with the FDA under 21 U.S.C. § 355(j).

"**Applicable Law**" means all applicable provisions of constitutions, statutes, rules, regulations, ordinances and orders of all Governmental Entities and all orders and decrees of all courts and tribunals.

[**]

"**Confidential Information**" means the terms of this Settlement Agreement and any information furnished in connection with this Settlement Agreement, including any and all know-how, trade secrets, formulae, data, inventions, technology and other information, including manufacturing techniques, processes, trade and financial

information, related to the manufacture, use, sale, offer for sale, or marketing of any products that are the subject of this Settlement Agreement, currently in the possession of, or developed during the term of this Settlement Agreement by, Teva, Plaintiffs or any of their respective Affiliates.

"**FDA**" means the United States Food and Drug Administration and any successor agency having the same functions.

"**Final Court Decision**" means a decision by a U.S. court or the U.S. Patent Trial and Appeal Board that is no longer subject to a right of appeal (other than by a petition to the United States Supreme Court for a writ of certiorari).

"**Generic Extended Release Naltrexone Product**" means a product that has been approved by or submitted for approval to the FDA under an ANDA that relied in whole or in part on data developed for, or the approval of, the NDA Product and that is listed in FDA's Orange Book as a generic version of the NDA Product.

"**Governmental Entity**" means any (i) nation, state, county, city, town, village, district, or other jurisdiction of any nature, (ii) federal, state, local, municipal, foreign, or other government, (iii) governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official, or entity and any court or other tribunal), (iv) multi-national organization or body, or (v) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature.

"**Licensed Patent**" means the '499 Patent, and any extensions, pediatric exclusivities, divisionals, continuations, continuations-in-part, reissues, reexaminations, inter partes reviews, and post-grant reviews thereof, and any other patents prospectively listed in the Orange Book for the NDA Product.

"**Market**" and "**Marketing**" means to sell or distribute a product.

"**NDA**" means a new drug application as defined in the U.S. Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder and filed with the FDA under 21 U.S.C. § 355.

"**NDA Product**" means the naltrexone for extended-release injectable suspension product approved under the Alkermes NDA.

"**Orange Book**" means the FDA's publication "Approved Drug Products With Therapeutic Equivalence Evaluations."

"**Paragraph IV Certification**" means certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or replaced) to any patents listed in the Orange Book in connection with the Alkermes NDA.

"**Proceeding**" means any administrative, judicial or legislative action, audit, litigation, investigation, suit or other proceeding in any court or tribunal.

"**Section 505(b)(2) Applicant**" means a Third Party that has sought approval or has received approval for a Section 505(b)(2) Product.

"**Section 505(b)(2) Application**" means an application as defined in the U.S. Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder filed with the FDA under 21 U.S.C. § 355(b)(2).

"**Section 505(b)(2) Product"** means a product that has been approved by or submitted for approval to the FDA under a Section 505(b)(2) Application for naltrexone for extended-release injectable suspension and for which VIVITROL is the listed drug.

"**Territory**" means the United States of America and its territories, commonwealths and possessions, including the Commonwealth of Puerto Rico and the District of Columbia.

"**Teva ANDA**" means ANDA No. 213195 for a Generic Extended Release Naltrexone Product.

"**Teva Product**" means the Generic Extended Release Naltrexone Product approved under the Teva ANDA. For the sake of clarity, Teva Product does not include any product that is used, sold, offered for sale or marketed outside of the Territory, even if it is the same as the Teva Product covered herein.

"**Teva's Consent Decree**" means the Stipulated Revised Order for Permanent Injunction and Equitable Monetary Relief entered by the United States District Court of

the Eastern District of Pennsylvania on February 21, 2019, in *Federal Trade Commission v. Cephalon, Inc.*, No. 2:08-cv-2141 (MSG), D.I. 409.

"**Third Party**" means any person or entity other than the Parties and their respective Affiliates.

ARTICLE II.DISMISSAL OF LAWSUIT

Final Dismissal of Lawsuit. Within five (5) business days of the Execution Date, the Parties shall enter into and cause to be filed in the Lawsuit a Stipulated Consent Judgment and Injunction in the form attached as Exhibit A hereto. The date upon which the Lawsuit is dismissed against all Parties pursuant to the Stipulated Consent Judgment and Injunction shall be the "**Effective Date**."

ARTICLE III.LICENSE GRANTS

Section 3.01 License Grants. Subject to Article VII, Plaintiffs hereby grant Teva and its Affiliates a non-exclusive, royalty-free, non-transferable, non-sublicensable, limited license under the Licensed Patent to make, have made, use, import, sell and offer for sale in or for the Territory the Teva Product on and after the License Effective Date.

Section 3.02 Date of License of Teva Product. The "**License Effective Date**" shall be the earliest of:

(a) January 15, 2027;

(b) [**];

(c) [**];

(d) [**]; or

(e) [**].

Section 3.03 Notification of Dates. In the event Plaintiffs become aware of the actual date under Section 3.02(b)-(d), Plaintiffs shall notify Teva of such date in advance of such date; such notice should be provided as soon as possible, and no later than ten (10) business days after Plaintiffs become aware of such date. Nothing in this Section 3.03 relieves Plaintiffs of the notice requirements contained in Section 3.05.

Section 3.04[**]:

(a) [**].

(b) It is further agreed that Plaintiffs shall have the right to seek damages from Teva and its Affiliates for sales of Teva Products sold by Teva and its Affiliates prior to the License Effective Date.

ARTICLE IV.ACKNOWLEDGEMENT/NO CHALLENGE

Section 4.01 Acknowledgement of Validity/Enforceability/Infringement. Teva acknowledges, agrees and admits that, in connection with the Teva Product and the Teva ANDA only, the Licensed Patent is valid and enforceable and that the manufacture, use, sale, offer for sale, or importation of Teva Product in or for the Territory infringes one or more claims of the Licensed Patent.

Section 4.02 Agreement Not to Challenge Validity or Enforceability. For as long as this Settlement Agreement is in effect, and except as provided for in Section 4.03 below, Teva and its Affiliates shall not (1) challenge the inventorship, ownership, validity, enforceability or patentability of, or assert the non-infringement of, the Licensed Patent; (2) contest that making, using, selling, offering for sale and/or importing Teva Product infringes the Licensed Patent; and (3) assist, encourage, finance, or otherwise provide any information to any Third Party (specifically including, but not limited to, any party in any other Proceeding involving any of the Licensed Patent) challenging, or who may challenge, the inventorship, ownership, validity, enforceability or patentability of, or assert the noninfringement of, the Licensed Patent.

Section 4.03 Permitted Actions by Teva. Nothing in Section 4.02 shall (i) prohibit Teva from filing and/or maintaining any Paragraph IV Certification in the Teva ANDA, (including any re-certifications required by the FDA), (ii) prohibit Teva and its Affiliates from filing, maintaining and/or supporting the filing of an ANDA (other than the Teva ANDA) that contains and/or maintains a Paragraph IV Certification against the Licensed Patent, and for which the NDA Product is not the reference listed drug or (iii) prohibit Teva and its Affiliates from challenging, disputing, or contesting the validity, enforceability, or infringement of the Licensed Patent or foreign patents, (x) in any Proceeding brought by

Plaintiffs or their Affiliates concerning any Product other than a Generic Extended Release Naltrexone Product or a Section 505(b)(2) Product or (y) if Plaintiffs breach this Settlement Agreement.

ARTICLE V.WAIVER OF REGULATORY EXCLUSIVITIES

Section 5.01 Waiver of Regulatory Exclusivities for Teva Product. If Plaintiffs obtain any regulatory exclusivities concerning VIVITROL on or after the Effective Date of this Settlement Agreement, Plaintiffs will grant Teva a waiver of any such regulatory exclusivities. Within ten (10) calendar days of Teva's request (such request not to be made until after the Effective Date of this Settlement Agreement), Plaintiffs shall submit, and/or shall cause its Affiliates to submit, appropriate and reasonable documentation to the FDA (with copy to Teva) evidencing the licenses, covenant not to sue and waivers (i.e., will selectively waive any such new regulatory exclusivities with respect to Teva) set forth in this Settlement Agreement.

ARTICLE VI.COVENANT NOT TO SUE

Section 6.01 Covenant Not to Sue on Teva Product. Subject to Article VIII and provided that Teva and its Affiliates comply with the terms of this Settlement Agreement, Plaintiffs and their Affiliates hereby covenant not to sue Teva and its Affiliates, and any of their predecessors, successors, parents, subsidiaries, assigns, agents, administrators, attorneys, directors, officers, employees, representatives, manufacturers, importers, suppliers, distributors, customers, and insurers, or support or encourage any Third Party to sue the foregoing:

(a) for infringement of any United States patents owned, licensed or otherwise controlled, wholly or in part, by Plaintiffs and/or any of their Affiliates purporting to cover the Teva Product and/or the making, having made, using, selling, offering for sale, or inducing the use of the Teva Product in the Territory; and

(b) for infringement of any foreign patents owned, licensed or otherwise controlled, wholly or in part, by Plaintiffs and/or any of their Affiliates purporting to cover the Teva Product and the making or having made the Teva Product (including active pharmaceutical ingredients to be used in the Teva Product) for sale solely within

the Territory. For the sake of clarity, Article VI does not apply to any product that is used, sold, offered for sale or marketed outside of the Territory, even if it is the same as the Teva Product covered herein. Teva reserves the right to apply for approval to market a Generic Extended Release Naltrexone Product outside of the Territory, and Plaintiffs reserve the right to exercise all rights and remedies to enforce its intellectual property in respect of such entry.

Section 6.02 Relation to Orange Book Patents. For all patents listed in the Orange Book now or in the future for VIVITROL and/or the Alkermes NDA, the foregoing covenant not to sue shall hereby be treated as a non-exclusive license to such patents for the Teva Product solely for the purpose of allowing Teva and/or its Affiliates to file and maintain with the FDA a Paragraph IV Certification with respect thereto. Teva shall have the right to maintain its existing Paragraph IV Certification as well as to file further Paragraph IV Certifications (including any re-certifications required by the FDA) under 21 C.F.R. § 314.94(a)(12)(v), against any patents listed in the future, and still be covered by the covenant not to sue of Section 6.01.

Section 6.03 No Covenant Not to Sue Other than for Teva Product. Nothing in Section 6.01 shall prevent Plaintiffs or their Affiliates from filing or maintaining any Proceeding against Teva and/or its Affiliates asserting infringement of the Licensed Patent or any other patent by a product that is not a Teva Product.

Section 6.04 No Covenant Not to Sue for Products Sold or Made to be Sold Outside of the Territory. Nothing in Section 6.01 shall prevent Plaintiffs or their Affiliates from filing or maintaining any Proceeding against Teva or its Affiliates asserting infringement of any foreign patent for (i) selling, offering for sale, or inducing the use of any product (including Teva Product) outside of the Territory or (ii) making or having made any product (including Teva Product) for sale outside the Territory.

Section 6.05 Ability to Assert Defenses. In any Proceeding filed by Plaintiffs or their Affiliates as contemplated by Section 6.03 or Section 6.04, Teva or its Affiliates shall be able to assert any and all defenses and claims in response to such Proceeding, including, but not limited to invalidity, unenforceability, unpatentability, and non-infringement of the patents in such Proceeding.

ARTICLE VII.RELEASES

Section 7.01 Plaintiffs' Release. Plaintiffs, for themselves and their agents, successors and assigns, do hereby forever release and discharge Teva and its Affiliates, and any of its past or present agents, employees, officers, directors, attorneys and suppliers, and any past or present distributors, resellers, purchasers and/or end-users of products sold or distributed by Teva or its Affiliates, from any causes of action, losses, promises, damages, costs, expenses, liabilities and/or demands of whatsoever character, nature and kind, known or unknown, suspected or unsuspected, fixed or contingent, arising out of or in any way related to the actions, conduct, omissions, or events alleged, or which could have been alleged, in the Lawsuit as of the Effective Date.

Section 7.02 Teva's Release. Teva, for itself and its Affiliates, does hereby forever release and discharge Plaintiffs and their Affiliates, and any of their past or present agents, employees, officers, directors, attorneys and suppliers, and any past or present distributors, resellers, purchasers and/or end-users of products sold or distributed by Plaintiffs or their Affiliates from any causes of action, losses, promises, damages, costs, expenses, liabilities and/or demands of whatsoever character, nature and kind, known or unknown, suspected or unsuspected, fixed or contingent, arising out of or in any way related to the actions, conduct, omissions, or events alleged, or which could have been alleged, in the Lawsuit as of the Effective Date.

ARTICLE VIII.LICENSE LIMITATIONS

Section 8.01 Termination of License and Covenant. In the event that Teva or its Affiliates: (i) [**], or (ii) [**], then Plaintiffs will have the right to terminate the licenses granted in Article III with immediate effect upon notice to Teva. In such event, the covenant not to sue set forth in Section 6.01 shall be of no further force and effect.

ARTICLE IX.PRE-LICENSE ACTIVITIES

Section 9.01 Restrictions Prior to License Effective Date. Except as set forth in Section 9.02, Teva and its Affiliates do not obtain a license under Licensed Patent to, and agree not to, make, have made, import into, distribute, offer to sell, or sell in the Territory any Generic Extended Release Naltrexone Product prior to the License Effective Date. Teva

agrees that any breach by any of Teva or its Affiliates of this Article IX shall cause irreparable harm to the Plaintiffs. Teva and its Affiliates consent irrevocably and unconditionally to specific performance, or immediate entry of a TRO, PI, and permanent injunction, to enforce this Article IX. Plaintiffs reserve all other rights under Section 15.02.

Section 9.02 Pre-License Activities. Notwithstanding Section 9.01, Teva and its Affiliates shall have the right to engage only in the following activities (together, the "**Pre-License Activities**") solely to the extent necessary to enable Teva to Market the Teva Product in the Territory on or after the License Effective Date:

(a) [**];

(b) [**]; or

(c) [**].

ARTICLE X.MOST FAVORED NATION

More Favorable Terms or Conditions. Alkermes represent that they have not, prior to the Effective Date of this Settlement Agreement, entered into an agreement, license or other authorization with any Third Party granting such Third Party a license or other authorization under Licensed Patent containing any terms or conditions more favorable than those provided to Teva herein, [**]. In the event that, subsequent to the Effective Date, Alkermes, or any of their Affiliates, enter into any agreement, license, or other authorization of any kind with any Third Party granting such Third Party a license or other authorization under the Licensed Patent containing any terms or conditions more favorable than those provided to Teva herein, [**], Alkermes shall, within ten (10) business days of entering into any such agreement, give Teva notice of such agreement specifying the new, more favorable conditions, subject to written confidentiality obligations, and, if Teva accepts all of those more favorable terms, this Settlement Agreement shall be automatically amended to include such more favorable terms, [**].

ARTICLE XI.CONFIDENTIAL INFORMATION

Section 11.01 Treatment of Confidential Information. Each Party shall keep confidential and not disclose to others or use for any purpose, other than as authorized

by this Settlement Agreement, all Confidential Information that was provided to it by any other Party or its Affiliates or their respective employees or representatives pursuant to this Settlement Agreement. This Article XI survives the termination or expiration of the Settlement Agreement.

Section 11.02 Limitation on Confidentiality Restrictions. The restrictions of this Article XI shall not apply to any Confidential Information which (i) is already known to the recipient at the time of disclosure, as reasonably documented by written records; (ii) is or later becomes public knowledge through no fault of the recipient; (iii) is received from a Third Party having the lawful right to disclose the information; or (iv) is independently developed by employees of the recipient without access to the disclosing Party's Confidential Information.

Section 11.03 Permitted Disclosure. A Party may disclose Confidential Information of another Party to (i) its Affiliates, and to its and their directors, employees, consultants, attorneys, and agents, in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use; (ii) any bona fide actual or prospective assignees, underwriters, investors, lenders or other financing sources who are obligated to keep such information confidential, to the extent reasonably necessary to enable such actual or prospective assignees, collaborators, underwriters, investors, licensees, lenders or other financing sources to determine their interest in underwriting, or making an investment in, or otherwise providing financing to, or purchasing the relevant assets of, the receiving Party; and (iii) the extent such disclosure is required or advisable to comply with Applicable Law (including if a Party is subpoenaed or otherwise required by law to give testimony or provide information that related to this Settlement Agreement) or to defend or prosecute litigation or in connection with settlement negotiations, provided, however, that the receiving Party provides prior written notice of such disclosure to the disclosing Party and, unless otherwise required by law, (a) shall make no disclosures until the receiving Party has a reasonable opportunity to contest the right of such disclosure and (b) cooperates with the receiving Party to obtain confidential treatment. If a Governmental Entity directs that Teva transfer the Teva ANDA to a Third Party, Teva may disclose a copy of this Settlement Agreement to a Third Party for purposes of evaluating a possible transfer so

long as the Third Party agrees in writing to confidential treatment of this Settlement Agreement no less restrictive than the confidentiality obligations set forth in Article XI of this Settlement Agreement.

Section 11.04 Return of Confidential Information. This Settlement Agreement does not constitute the conveyance of ownership with respect to, or a license to, any Confidential Information, except as otherwise provided in this Settlement Agreement. Upon the expiration or termination of this Settlement Agreement for any reason, each Party agrees, except as otherwise provided in this Settlement Agreement, to return to the other Party or destroy (and certify such destruction) all documentation or other tangible evidence or embodiment of Confidential Information belonging to the other Party and not to use same, unless otherwise agreed in writing. The Parties agree and acknowledge that the foregoing obligation does not apply to Confidential Information recorded on electronic back-up tapes that are maintained in the ordinary course and are unreasonably difficult to access, provided that such Confidential Information remains subject to the obligations of confidentiality and non-use in this Article XI.

Section 11.05 Disclosures. The terms of this Settlement Agreement shall be maintained in confidence by the Parties except that: (i) the Parties may disclose that Teva has entered into a Settlement Agreement with Plaintiffs regarding the Teva Product and the License Effective Date; (ii) either Party may disclose this Settlement Agreement to its attorneys, advisors, and representatives who are subject to obligations of confidentiality consistent with this Settlement Agreement; (iii) Teva may make disclosures as provided in Article XII; and (iv) either Party may make any disclosure otherwise required by law, including SEC reporting requirements, or by the rules or regulations of any stock exchange that the Parties are subject to. In any such event the Party making such disclosure contemplated in clause (iv) of the preceding sentence shall (A) provide the other Party with as much advance notice as reasonably practicable of the required disclosure, and (B) limit any disclosure to the specific purpose at issue.

Section 11.06 Settlement Agreement Disclosure to Government or in Discovery. Specific terms or conditions of this Settlement Agreement may be disclosed pursuant to a discovery demand; subpoena; order of a court or administrative body; or administrative

guidance that in the opinion of a Party's counsel requires disclosure. If a Party receives a request to disclose any of the terms or conditions of this Settlement Agreement pursuant to a discovery demand; subpoena; order of a court or administrative body; or administrative guidance that in the opinion of such Party's counsel requires disclosure, such Party shall notify the other Party within fourteen (14) days after receiving such request and, to the extent practicable, at least fourteen (14) days prior to disclosing any terms of this Settlement Agreement. Such Party may then disclose the terms and conditions of this Settlement Agreement pursuant to such request, in accordance with any applicable protective orders or applicable confidentiality laws or regulations. Nothing herein shall preclude any Party from complying with an order requiring disclosure, or a guidance that in the opinion of such Party's counsel requires disclosure, of the terms of this Settlement Agreement that has been issued by a court or administrative agency of competent jurisdiction. Nothing herein shall prohibit the Parties from disclosing this Settlement Agreement and its terms to the Federal Trade Commission ("**FTC**") and the Antitrust Division of the Department of Justice ("**DOJ**") pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Teva's Consent Decree.

ARTICLE XII.GOVERNMENT REVIEW

Section 12.01 Submission. The Parties agree to submit this Settlement Agreement to the FTC and the DOJ (the "**Agencies**") as required by statute and Teva's Consent Decree. Confidential Information of either Party submitted to the Agencies, including pursuant to Section 12.03, shall be subject to Article XI.

Section 12.02 Government Investigation. Each Party shall, to the extent permitted by law:

(a) promptly inform the other Parties of any communication made or received by such Party to or from any Governmental Entity regarding this Settlement Agreement and/or any related agreements; and

(b) use reasonable efforts to comply with any investigation or inquiry regarding this Settlement Agreement and/or any related agreements by any Governmental Entity, including by providing requested information to such Governmental Entity

and permitting reasonable access to its documents, officials and data related to this Settlement Agreement and/or any related agreements.

Section 12.03 Good Faith Modification. To the extent that any legal or regulatory issues or barriers arise with respect to this Settlement Agreement or Teva's Consent Decree, or any subpart thereof, the Parties shall work together in good faith and use reasonable efforts to modify this Settlement Agreement to overcome any such legal or regulatory issues (including, for example to comply with Teva's Consent Decree, objections by the FTC, the DOJ, or any applicable court) in a mutually acceptable fashion, but in no event shall either Party be required to agree to any modification of this Settlement Agreement that materially affects the value of the transactions contemplated hereby.

Section 12.04 Termination. If the Parties are unable to agree upon modifications to the terms of this Settlement Agreement that overcome the objections of any Governmental Entity (provided that such modifications do not materially change the value of the transactions contemplated hereby), then either Party may terminate this Settlement Agreement (and as a result of such termination this Settlement Agreement shall become null and void as of the Execution Date).

Section 12.05 No Prejudice. If at any time this Settlement Agreement is rendered null and void as a result of a Proceeding by the Agencies, it is the intent of the Parties that no Party shall be in any way prejudiced with respect to its claims, causes of action, defenses, and counterclaims now pending in the Lawsuit.

ARTICLE XIII.REPRESENTATIONS AND WARRANTIES

Section 13.01 Mutual Representations. Each Party hereby represents, warrants and covenants to the other Parties as follows:

(a) It is a limited partnership, limited liability company, company or corporation duly organized, validly existing and (if applicable) in good standing under the laws of the jurisdiction in which it is incorporated or organized, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in

this Settlement Agreement, including, the ability to grant the rights granted to the other Parties hereunder.

(b) As of the Effective Date: (i) it has the corporate power and authority and the legal right to enter into this Settlement Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Settlement Agreement and the performance of its obligations hereunder; and (iii) this Settlement Agreement has been duly executed and delivered on behalf of such Party and constitutes legal, valid and binding obligations of such Party that are enforceable against it in accordance with their terms except: (1) as limited by applicable bankruptcy; insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally; and (2) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

(c) It has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Parties in this Settlement Agreement; it has not taken and shall not take any action that would in any way prevent it from granting the rights granted to the other Parties under this Settlement Agreement or that would otherwise materially conflict with or adversely affect the rights granted to the other Parties under this Settlement Agreement; and its performance and execution of this Settlement Agreement does not and will not result in a breach of any other contract to which it is a party.

Section 13.02 Plaintiffs Representations and Warranties. Plaintiffs represent and warrant to Teva that, as of the Effective Date, Plaintiffs (i) own all substantive rights in the Licensed Patent; (ii) have the right to grant to Teva the licenses, covenants not to sue, and waivers granted hereunder with respect to the Licensed Patent; and (iii) have the right to settle the Lawsuit.

Section 13.03 Teva's Representations and Warranties. Teva represents and warrants to Plaintiffs that, as of the Effective Date, (i) Teva or its Affiliates own all right, title and interest in, to and under the Teva ANDA, and Teva and its Affiliates have not

granted or assigned to any Third Party, directly or indirectly, any rights under or to the Teva ANDA or Teva Product, (ii) except as provided for in Section 15.03, Teva and its Affiliates will not transfer ownership, in whole or in part, of the Teva ANDA, except to an Affiliate of Teva or to a successor to all or substantially all of the business to which this Settlement Agreement pertains, until the expiration of the license granted herein, and (iii) Teva has the right to settle the Lawsuit.

Section 13.04 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS SETTLEMENT AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE U.S. LAW, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS SUCH WARRANTIES.

ARTICLE XIV.NOTICE

Section 14.01 Manner of Notice. Any notice required to be delivered under or pursuant to this Settlement Agreement shall be in writing in the English language, delivered personally, sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or by e-mail; to the following addresses of the Parties (or such other address for a Party as it specifies by like notice):

For Alkermes:
Chief Legal Officer
Alkermes, Inc.
900 Winter Street
Waltham, MA 02451

External Counsel
Isaac S. Ashkenazi, Esq.
Paul Hastings LLP
200 Park Avenue
New York, NY 10166
Email:isaacashkenazi@paulhastings.com

For Teva:
General Counsel
Teva Pharmaceuticals USA, Inc.
Morris Corporate Center III

400 Interpace Parkway, Bldg. A.
Parsippany, NJ 07054
Email: USLegalNotices@tevapharm.com

External Counsel
John Christopher Rozendaal, Esq.
Sterne, Kessler, Goldstein & Fox
1100 New York Avenue, Suite 600
Washington, DC 20005
Email: jcrozendaal@sternekessler.com

Section 14.02 When Notice Effective. Any notice shall be effective upon receipt by the Party to which it is addressed or within seven (7) days of dispatch, whichever is earlier.

ARTICLE XV.MISCELLANEOUS

Section 15.01 Entire Agreement. This Settlement Agreement (along with the documents attached hereto) constitutes the complete agreement of the Parties with respect to the subject matter hereof and supersedes and replaces any prior negotiations, mediations, proposed agreements or agreements, whether written or oral. This Settlement Agreement may be modified only by a writing signed by all Parties.

Section 15.02 Breach. This Settlement Agreement does not limit or restrict the remedies available to any Party for the breach of another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this Settlement Agreement.

Section 15.03 Successors and Assigns. Neither this Settlement Agreement nor any of the rights or obligations hereunder may be assigned, transferred, licensed, sub-licensed or delegated by either Party, without the prior written consent of the other Party, except (i) to an Affiliate of the assigning Party, (ii) to the successor to all or substantially all of the business or assets of such Party to which this Settlement Agreement relates (whether by merger, sale of stock, sale of assets or other transaction) that agrees in writing to be bound by the terms and conditions of this Settlement Agreement, or (iii) as part of a divestiture as required by the Federal Trade Commission. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations, but the assigning

Party will remain primarily liable and responsible for the performance of all of its obligations under this Settlement Agreement and for causing its assignees to act in a manner consistent herewith. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by any Party in violation of the terms of this paragraph shall be null and void.

Section 15.04 Governing Law and Venue. This Settlement Agreement shall be governed by, and construed in accordance with, the laws of the State of New Jersey, without regard for any conflict of law principles that would dictate the application of the laws of another jurisdiction. The Parties agree that the United States District Court for the District of New Jersey shall have exclusive and sole jurisdiction to enforce any violation of this Settlement Agreement, except that, if for any reason that Court does not accept jurisdiction, then the state courts of New Jersey shall have exclusive and sole jurisdiction to enforce any violation of this Settlement Agreement. The Parties hereby consent to the personal jurisdiction of those courts for any dispute arising from or relating to this Settlement Agreement.

Section 15.05 Severability. If any provision of this Settlement Agreement shall be held by a court of competent jurisdiction to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and the Parties shall negotiate in good faith to replace the invalid or unenforceable provision with a valid and enforceable provision that has the effect nearest to that of the provision to be replaced.

Section 15.06 Advice of Counsel. This Settlement Agreement has been negotiated by the Parties and their respective counsel and shall be interpreted fairly in accordance with its terms and without any strict construction in favor of or against any Party.

Section 15.07 No Waiver. Waiver by a Party of any breach of any provision of this Settlement Agreement by another Party shall not operate or be construed as a waiver of any subsequent or other breach. No provision of this Settlement Agreement may be waived except by a written instrument signed by the Party waiving compliance.

Section 15.08 Regulatory Delay. No provision of this Settlement Agreement shall be affected by any delay in the approval of either of the Teva ANDA by the FDA, or the failure of Teva to obtain FDA approval of the Teva ANDA.

Section 15.09 Costs and Fees. Each Party shall bear its own attorneys' fees and costs associated with the Lawsuit and the negotiation and preparation of this Settlement Agreement.

Section 15.10 Counterparts. This Settlement Agreement may be executed in one or more counterparts (including via facsimile or electronic copy), each of which when so executed and delivered shall be deemed to be an original, but all of which taken together form but one and the same instrument.

Section 15.11 Headings. The headings and captions used in this Settlement Agreement are solely for the convenience of reference and shall not affect its interpretation.

Section 15.12 Interpretation and Construction. The term "including" means "including, without limitation," and "herein," "hereof," and "hereunder" refer to this Settlement Agreement as a whole. The word "will" shall be construed to have the same meaning and effect as the word "shall". Except as otherwise expressly provided herein, references to any NDA or ANDA in this Settlement Agreement shall include such NDA or ANDA as it exists and is comprised as of the Effective Date and any replacements or successors or amendments or supplements to any of the foregoing. For the sake of clarity, all such NDAs, ANDAs, replacements or successors or amendments or supplements are limited specifically to the NDA Product or the Teva Product, as the case may be.

Section 15.13 Bankruptcy. All licenses and rights to licenses granted under or pursuant to this Settlement Agreement by Plaintiffs to Teva are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

ARTICLE XVI.NON-INTERFERENCE

Delisting. From and after the Effective Date, prior to the License Effective Date, unless required, requested or recommended by the FDA or other Governmental Entity or Applicable Law or to address toxicity, efficacy or safety concerns, Plaintiffs shall not (a)

delist the NDA Product with the FDA; (b) seek or otherwise undertake any action with the FDA to withdraw the NDA Product from the market; and/or (c) delete, remove, designate as “obsolete” or cancel any National Drug Code(s) or any other relevant code(s) for the NDA Product from the applicable National Drug Data File maintained by First Databank (or any successor or equivalent organization), or from any other future comparable pricing database. For the avoidance of doubt, nothing in this Article XVI obligates Alkermes to engage in any marketing, sales or other activities with respect to the NDA Product and shall not prohibit Alkermes from taking any action it deems reasonably necessary for the safety or efficacy of the NDA Product.

IN WITNESS HEREOF, the Parties have caused their duly authorized representatives to execute this Settlement Agreement to be effective as of the Effective Date.

ALKERMES, INC.

By: /s/ Michael Landine
Name: Michael Landine
Title: Senior Vice President
Date: August 29, 2023

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Carrie Groff
Name: Carrie Groff
Title: VP, Portfolio and New Product Strategy
Date: August 29, 2023

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Richie Paul
Name: Richie Paul
Title: Director
Date: August 29, 2023

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Colman Ragan
Name: Colman Ragan
Title: VP & GC North America IP Litigation
Date: August 29, 2023

Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

EXECUTION COPY

Date: 26, September 2003

ELAN CORPORATION, PLC.

AND

ACORDA THERAPEUTICS, INC.

SUPPLY AGREEMENT

Fampridine SR

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SCHEDULE 1	**MANUFACTURING COST**

THIS SUPPLY AGREEMENT is made the September 2003

BETWEEN:

(1) Elan Corporation, plc., a public limited company incorporated under the laws of Ireland, and having its registered office at Lincoln House, Lincoln Place, Dublin 2, Ireland ("**Elan**"); and

(2) Acorda Therapeutics, Inc., a corporation organized under the laws of the State of Delaware and having its principal office at 15 Skyline Drive, Hawthorne, New York 10532, United States of America ("**Acorda**").

RECITALS:

(A) Elan and Acorda have entered into a Licence Agreement concerning the Product (as each of those terms are defined below).

(B) Elan is prepared to manufacture and supply the Product to Acorda for onward commercial supply.

(C) Elan and Acorda are desirous of entering into this Agreement to give effect to the arrangements described at Recitals (A) and (B).

NOW IT IS HEREBY AGREED AS FOLLOWS:

CLAUSE 1 PRELIMINARY

1.1. Definitions:

"**Act**" shall mean the United States Federal Food Drug and Cosmetic Act of 1934, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

"**Affiliate**" shall mean any corporation or entity controlling, controlled or under common control with Elan or Acorda, as the case may be. For the purposes of this Agreement, "control" shall mean the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

"**Agreement**" shall mean this supply agreement (which expression shall be deemed to include the Recitals and Schedules hereto).

"**Batch**" shall mean a specific quantity of Product that is produced according to a single manufacturing order during the same cycle of manufacture, which quantity shall be agreed in the Technical Agreement.

"**cGMP**" shall mean current Good Manufacturing Practice as defined in the Act and FDA guidance documents; or as applicable current Good Manufacturing Practice under applicable regulations in the European Union.

"**EEA**" shall mean the countries comprising the European Economic Area, as the same may change from time to time **.**

"**Effective Date**" shall mean the date of this Agreement.

"**Elan's Facility**" shall mean Monksland, Athlone, Co. Westmeath, Ireland or such other facility as Elan may use to perform its obligations hereunder and is in compliance with the NDA and other regulatory requirements.

"**Elan Territory**" shall mean any country or countries in which Elan, or any licensee of Elan other than Acorda, is permitted to commercialise the Product, by virtue of termination of the License Agreement in that country or the grant of a license by Acorda to Elan pursuant to Article 2.11.3 of the License Agreement.

"**EXW**" or "**Ex Works**" shall have the meaning as such term is defined in the ICC Incoterms, 2000, International Rules for the Interpretation of Trade Terms, ICC Publication No. 560.

"**Force Majeure**" shall mean any cause or condition beyond the reasonable control of the party obliged to perform, including acts of God, acts of government (in particular with respect to the refusal to issue necessary import or export licenses), fire, flood, earthquake, war, riots or embargoes, strikes or other labour difficulties affecting a party, or either party's inability to obtain supplies of components of the Product howsoever arising.

"**FTE**" means Elan's full time equivalent charging rate for its appropriate employees or consultants from time to time (based on cost without mark-up) which as of the Amendment Date is [**] per day.

"**Governmental Authority**" shall mean the FDA and /or all other governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, which regulate, direct or control commercial and other related activities in or with the Territory.

"**Launch Stocks**" shall mean the quantities of stocks of the Product required by Acorda in relation to the launch of the Product following Regulatory Approval in a Major Market, as more fully described in Clause 4.7.

"**Launch Year**" shall mean the period commencing on the date of First Commercial Sale and expiring on the last day of the month that is the twelfth (12th) month following the

date in which the First Commercial Sale occurs. For example, if the First Commercial Sale occurs on March 15 of any year, the Launch Year shall commence on March 15 of such year and expire on March 31 of the following year.

"**Licence Agreement**" shall mean that certain Amended and Restated Licence Agreement between Elan and Acorda of even date herewith.

"**Major Market(s)**" shall mean the US, the UK, France, Germany, Italy and Japan.

"**Manufacturing Cost**" shall mean the costs described in **Schedule 1** as they relate to the Product, PROVIDED THAT if Elan is manufacturing the Product for sale in an Elan Territory, in no event shall Manufacturing Cost exceed Elan's own costs for such manufacture, as calculated based on GAAP.

"**Maximum Capacity**" shall mean Elan's maximum quarterly manufacturing capacity for the Product from time to time, as agreed in, or determined pursuant to, the Technical Agreement.

"**Minimum Elan Requirements**" shall mean for any Year, at least seventy five percent (75%) of Acorda's total requirements of the Product **.**

"**Minor Deficiencies**" shall mean shortfalls or delays that are not inconsistent with industry accepted standards, which standards applicable to the Product shall be clarified in the Technical Agreement.

"**Permitted Elan Assignee**" shall mean any entity that purchases all or substantially all of the assets of Elan's Facility and has entered into a written agreement with Elan for the benefit of Acorda whereby (inter alia) it represents to Acorda that it is (i) reasonably experienced in the field of pharmaceutical manufacturing (including the existing management of Elan's Facility), (ii) in possession of sufficient financial resources and liquidity to perform the obligations of Elan under this Agreement and (iii) in good standing with the FDA.

A Permitted Elan Assignee shall also include any entity that has been formed for the purpose of acquiring Elan's Facility, and shall, following such acquisition, be under the management of individuals reasonably experienced in pharmaceutical manufacturing (including the said existing management), in possession of sufficient financial resources and liquidity to perform the obligations of Elan under this Agreement, and none of which are debarred individuals or entities within the meaning of 21 U.S.C. section 335(a) or (b) and have the capacity of being in good standing with the FDA.

"**Product**" shall mean the oral product developed pursuant to the Project, in final packaged and labelled form for commercial sale or for distribution as promotional samples and as defined in the approved NDA or NDA Equivalent.

"**Recall**" means a company's removal or correction of a marketed Product that the FDA or equivalent Governmental Authority considers to be in violation of law and against

which such agency might reasonably be expected to initiate legal action (e.g., a seizure). A Recall does not include market withdrawal for other reasons, or a stock recovery.

"**Serious Failure to Supply**" shall mean that in a period of a Year, for reasons other than Force Majeure or the default of Acorda, Elan fails on at least two occasions to supply Acorda's properly forecasted and ordered requirements of the Product in accordance with the terms of this Agreement, except for Minor Deficiencies, and the cumulative shortfall for such Year attributable to such failure(s) is at least 25% of the aggregate amount properly forecasted and ordered from Elan for delivery in such Year.

"**Term**" shall mean the term of this Agreement, as set out in Clause 11.

"**$**" and "**US$**" shall mean United States Dollars.

"**Year**" means each consecutive four Calendar Quarters.

1.2. Further Definitions:

In addition, the following definitions have the meanings in the Clauses corresponding thereto, as set forth below:

Definition	Clause
"Discount"	9.4
"First Approval"	4.1.1
"Manufacturer"	7.1
"Resumption Quarter"	7.6.1
"Second Source"	7.1
"Second Source Quantity"	7.2.1
"Supply Price"	9.3.1
"Technical Agreement"	5.5

1.3. Definitions in Licence Agreement:

Except as otherwise defined in this Agreement, all capitalised terms used in this Agreement shall have the same meaning as in the Licence Agreement.

1.4. Interpretation:

In this Agreement:

1.4.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa.

1.4.2. any reference to a Clause or Schedule, unless otherwise specifically provided, shall be respectively to a Clause or Schedule of this Agreement.

1.4.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

1.4.4. the expressions “include”, “includes”, “including”, “in particular” and similar expressions shall be construed without limitation.

CLAUSE 2 EXCLUSIVE SUPPLY

2.1. Subject to the terms and conditions of this Agreement, during the Term, Acorda shall purchase its Minimum Elan Requirements of the Product in the Territory from Elan, except as provided in Clause 2.3.

2.2. Subject to the terms and conditions of this Agreement, during the Term, Elan shall not supply the Product to:

2.2.1. any person other than Acorda outside the Elan Territory; or

2.2.2. any person other than Acorda in the Elan Territory who intends, to the actual knowledge of Elan, to sell the Product outside the Elan Territory —

except as requested by Acorda, **PROVIDED THAT** to extent required by applicable law, Elan shall be permitted to:

(a) sell the Product to a person in a country which is both part of the Elan Territory and within the EEA, notwithstanding that such person may re-sell the Product in another part of the EEA which is not part of the Elan Territory; and

(b) if any country of the EEA is part of the Elan Territory, sell the Product to a person in another country of the EEA which is not part of the Elan Territory, provided further that Elan shall not actively solicit any such sales.

2.3. Elan shall not have the obligation to use commercially reasonable efforts to supply the Product where 140% of Manufacturing Cost would exceed the Supply Price, subject to Clauses 2.4 and 2.5

2.4. In the event that either party is of the opinion that the circumstances in Clause 2.3 apply or may shortly apply, it shall promptly notify the other. In such event the parties shall meet to discuss, *inter alia* , the manner in which Manufacturing Cost is calculated by Elan and Acorda’s commercialisation plans.

2.5. If after such discussions Elan is of the opinion that if it continues to supply the Product to Acorda, the circumstances in Clause 2.3 will apply, Elan shall promptly formally so notify Acorda. In such event

2.5.1. Elan shall use commercially reasonable efforts to supply Acorda with Product the subject of binding orders issued prior to Acorda's receipt of such notification, provided that such orders relate to Product scheduled for delivery in the period of three (3) months after the date of the purchase orders, and that such Product shall be invoiced at the applicable price under Clause 9.2 or 9.3; and

2.5.2. After the expiration of the period referred to in Clause 2.5.1, Acorda shall have no further obligation to purchase Product under this Agreement, provide, however, that Acorda may at its option place further purchase orders for delivery during up to a six (6) month period immediately following the period referred to in Clause 2.5.1, subject always to Clause 4 and Clause 5, provided, further, that (i) any such purchase orders are placed not later than three (3) months from the date of Elan's notice under this Clause 2.5; and (ii) any such Product ordered shall be invoiced at a price equal to Manufacturing Cost plus [**].

If following the period referred to in Clause 2.5.2, Acorda wishes to continue to purchase the Product from Elan and Elan is prepared to supply the same, the Parties shall negotiate in good faith the terms of any such supply and purchase.

As from the time of Elan's notice, Acorda shall be entitled to purchase the Product from the Second Source, but without prejudice to binding purchase orders already placed with Elan and subject to the foregoing paragraph.

CLAUSE 3REGULATORY MATTERS

3.1. Elan shall be responsible, at Elan's expense, for filing for and maintaining all license and permits pertinent to Elan's Facility, as distinct from the Regulatory Approvals specific to the Product, without prejudice to Elan's responsibilities under the Licence Agreement in respect of preparation and delivery to Acorda for incorporation into the NDA or any NDA Equivalent, of the CMC Section.

3.2. Upon Elan's prior written notice, Acorda shall permit Elan or any Affiliate to have access to the NDA and any NDA Equivalent and Regulatory Approvals and to take photocopies of same, as required by Elan to fulfil reporting requirements or as otherwise may reasonably be required by Elan in connection with this Agreement.

3.3. **Inspections or Inquiries by Governmental Authorities**. With respect to Product supplied by it, Elan shall be responsible for all process and equipment validation and quality control tests and procedures required by any Governmental Authority and shall take all steps necessary to pass inspection by any Governmental Authorities in the Major Markets, but without prejudice to Article 6.3 of the License Agreement. Elan shall:

3.3.1. notify Acorda as soon as possible, but in any event within the time period to be set forth in the Technical Agreement, of any notification received by Elan from a Governmental Authority to conduct an inspection of its manufacturing or other

facilities used in the development, manufacturing, packaging, storage or handling of the Product;

3.3.2. without delay make available to Acorda a copy of any inspection report received by Elan resulting from any inspection of any of such facilities by such Governmental Authority to the extent such report relates to Product, the formulation, manufacture, testing, storage and delivery of the Product or any premises used by Elan in performing Elan's obligations under this Agreement;

3.3.3. provide Acorda with a written copy of any proposed response(s) thereto at least three Business Days prior to submitting such response to any Governmental Authority as well as a copy of the response actually submitted.

Representatives of Acorda or its Designee shall have the right to be present during the inspection and/or during the close-out session with the inspectors. Any Form 483 observations or warning letter related to the Product shall be provided promptly to Acorda, which shall have the right to review and discuss the proposed written response to such 483 observations or warning letter, and a copy of the response actually submitted shall be promptly provided to Acorda. Copies of all other correspondence with any Governmental Authority relating to that any party's activities under this Agreement will be provided to the other party within forty-eight (48) hours.

3.4. **Inspection by Acorda / Governmental Authority.** Elan shall make (i) any licenses and permits relating to Elan's Facility; and (ii) that portion of Elan's facility where the Product is manufactured, packaged, tested or stored, including all record and reference samples, available for inspection:

3.4.1. by Acorda's duly qualified employee or Designee or, with the consent of Elan, by Acorda's agent or contractor; or

3.4.2. by the relevant Governmental Authority.

An inspection under Clause 3.4.1 shall be limited to determining whether there is compliance with cGMP and other requirements of applicable law, including production or quality issues relating to the Product. Any consent required under this Clause 3.4 shall not be unreasonably withheld or delayed.

3.5. **Preservation Samples/Retained Samples.** Pursuant to all applicable laws, rules and regulations and to the Specifications, Elan shall assign and apply lot numbers and shall take from each lot of (i) the API used to manufacture Product pursuant to this Agreement; (ii) inactive ingredients used in the manufacture of Product pursuant to this Agreement; and (iii) the Product shipped to Acorda or its designee pursuant to this Agreement, preservation samples/retained samples. Elan shall retain and store the particular lot of API, other ingredients or Product, as applicable, in accordance with FDA and other applicable regulations, which currently provide for a period expiring no earlier than two years after the expiration of the shelf life of the particular lot of Product shipped to Acorda or its Designee pursuant to this Agreement. Preservation samples/retained

samples, as referred to herein, do not include samples retained for purposes of stability testing.

3.6. Elan shall at its option be entitled to change the manufacturing process or site for manufacture of the Product, provided that (a) Elan provides Acorda with all required information in form and substance necessary to file any related amendments or supplements to the NDA or any NDA Equivalent or, if applicable, Elan files with applicable regulatory authorities any required amendments or supplements to any DMF; (b) no such change shall take effect until all requisite regulatory approvals have been obtained, and (c) Elan shall be responsible for the costs associated with such change. Acorda shall reasonably co-operate with Elan in obtaining any such changes requested.

CLAUSE 4 FORECASTS AND ORDERS

4.1. Forecasts. Acorda shall provide Elan with bona fide written forecasts of its estimated Minimum Elan Requirements of the Product as follows:

4.1.1. within eighteen (18) months prior to the anticipated date of first Regulatory Approval in any Major Market ("**First Approval**"), Acorda shall provide Elan with an eighteen (18) month forecast, broken down on a quarterly basis, for the period beginning with the anticipated date of First Commercial Sale in such Major Market (which date shall be specified in the forecast);

4.1.2. thereafter, every three months until First Approval, Acorda shall provide Elan with an updated forecast on a quarterly basis;

4.1.3. within thirty (30) days of First Approval, and thereafter each calendar month not later than the 23rd of the month, a rolling 18 month forecast, broken down on a month-by-month and country-by-country basis, for the period commencing at the beginning of the following month; and

4.1.4. not later than 1 August in each year, a five (5) year forecast, broken down on an annual basis.

Except as otherwise provided herein, all forecasts made hereunder shall be made to assist Elan in planning its production and Acorda in planning marketing and sales, shall not be binding purchase orders, and shall be without prejudice to Acorda's subsequent firm orders for the Product in accordance with the terms of this agreement. Each forecast provided by Acorda shall supercede any previous forecast and may be expressed in a reasonable range. After receiving Acorda's forecasts, Elan shall notify Acorda within five (5) days if Elan becomes aware that it will be unable to supply Acorda's forecasted requirements of Product and, in such event, the provisions of Clause 4.6 shall be applicable.

4.2. **Purchase Requirements.** Subject to the agreement between the Parties relating to Launch Stocks under Clause 4.7, Acorda shall be bound to order one hundred percent

(100%) of the forecasted quantities of the Product for each month of the first three (3) months of the most recent rolling forecast referred to in Clause 4.1.3, but otherwise forecasts shall not be binding.

4.3. Forecasts and orders shall not increase or decrease by more than 25% in the aggregate amount of Product required in a calendar quarter compared to the previous calendar quarter, except for Launch Stocks or unless otherwise agreed by Elan. However, Elan shall use reasonable efforts to fulfil Acorda's requirements in excess of duly forecasted and ordered amounts.

4.4. Forecasts and orders shall not exceed the Maximum Capacity during the applicable quarterly period.

4.5. **Firm Orders.** Acorda or its Designee shall provide Elan with purchase orders on the standard purchase order forms of Acorda or its Designee (without prejudice to Clause 5.4) of its Elan Minimum Requirements at least ninety (90) days before it requires each delivery of Product (subject to Clause 4.7 with respect to Launch Stocks), specifying the required delivery date in each purchase order and specifying the quantity of Product requested for commercial use and the quantity of Product for promotional and sample use.

4.6. **Shortages.** Elan agrees that it will use commercially reasonable efforts to prevent an interruption of supply to Acorda and shall immediately notify Acorda of any problems or unusual production situations which may adversely affect production or quality of Product or its Specifications or its timely delivery to Acorda or its designee. If, at any time during the term of this Agreement, Elan becomes aware that it will not be able to satisfy Acorda's forecasts or ordered requirements for Product, then Elan shall: (i) give Acorda prompt notice thereof, (ii) take all commercially reasonable steps to enable Acorda to procure adequate quantities of Product from the Second Source in accordance with the applicable provisions of Clause 7 and (iii) if such inability is partial, Elan shall fulfill firm orders with such quantities of Product as are available. and shall continue to use its commercially reasonable efforts to fulfill orders on a timely basis.

4.7. **Launch Stocks.** Within six months prior to an anticipated Regulatory Approval in a Major Market, the parties shall discuss and agree upon the manufacture and purchase of specific quantities of Launch Stocks for launch of the Product in the applicable Major Market.

4.7.1. Launch Stocks shall be ordered not later than 20 Business Days from receipt by Acorda of an approval letter, from the FDA or equivalent Governmental Authority in respect of the NDA or an NDA Equivalent in another Major Market.

4.7.2. Acorda may use the validation batches of the Product as Launch Stocks, subject to compliance with applicable laws, the Licence Agreement and other provisions of this Agreement, provided that in such event, any amounts previously paid by

Acorda to Elan for such validation batches shall be credited against the applicable price for Launch Stocks under Clause 9.1.

CLAUSE 5 SUPPLY OF THE PRODUCT

5.1. Save as otherwise provided in this Agreement, Elan shall use commercially reasonable efforts to produce and supply to Acorda its entire Elan Minimum Requirements of the Product as set forth in and in response to firm purchase orders, within ninety (90) days of the purchase order, or one hundred and fifty (150) days for Launch Stocks or samples (subject to any required extension due to the lead times of specific components of samples).

5.2. Elan shall have no obligation to supply Product:

5.2.1. For any period, in excess of Acorda's properly forecast requirements for such period (but Elan will nevertheless use its commercially reasonable efforts to fulfil Acorda's requirements in excess of such amounts, having regard to its manufacturing capacity);

5.2.2. for less than a minimum order of one Batch, or such other minimum quantity as may be agreed in the Technical Agreement;

5.2.3. in partial Batches;

5.2.4. where Clause 2.3 applies; or

5.2.5. pursuant to an order which does not conform in all material respects to the provisions of Clause 4 and this Clause 5; provided that if Elan does supply pursuant to such an order in its absolute discretion, that fulfilment shall not affect Elan's right to refuse to fulfil any subsequent order which does not comply in all material respects with those provisions.

5.3. The Product supplied by Elan to Acorda shall:

5.3.1. be delivered in finished packaged form in the dosages and configurations as set forth in the Specifications and agreed by the parties and included in the NDA and any NDA Equivalent;

5.3.2. be shipped EXW Elan's Facility;

5.3.3. be delivered with a certificate of analysis and certificate of release in respect of the Product, in a form reasonably acceptable to Acorda (and Acorda shall be entitled to rely upon such certificate of analysis without the necessity of performing additional testing), in accordance with the terms of the Technical Agreement, cGMPs and the NDA or any NDA Equivalent; and

5.3.4. have a shelf life to be determined in the Technical Agreement.

5.4. The terms of this Agreement are hereby incorporated by reference into each order of Product submitted by Acorda and accepted by Elan. In the event of any conflict between an order or other written instructions and this Agreement, the terms of this Agreement shall prevail.

5.5. Not less than eighteen (18) months before the anticipated First Approval, or such later date as may be determined by the Committee, the parties shall negotiate in good faith to conclude a detailed technical agreement (the " **Technical Agreement** ") regulating the parties' respective obligations from a technical and quality perspective for the supply of the Product by Elan to Acorda, subject in all cases to compliance with cGMPs, the requirements and commitments of the NDA and any NDA Equivalent and any other applicable laws or regulations governing manufacture and supply of Product. Such agreement will include commercially reasonable terms as to:

5.5.1. the precise procedures regulating the alleged failure of any shipment of the Product to conform to the Specifications as a result of an alleged latent defect and the procedures to be adopted for the return and replacement of such Product;

5.5.2. the inspection and testing for compliance with specifications of API to be conducted by Elan prior to incorporation into Product, the testing and quality analysis of Product to be conducted by Elan prior to shipment of the Product and the format of the certificate of analysis and certificate of release to be furnished by Elan to Acorda as well as any quality analysis to be conducted by Acorda or its Designee;

5.5.3. the batch manufacturing records and other documentation to be prepared and maintained by Elan and delivered with each shipment to Acorda to show compliance with cGMP as well as other applicable United States of America and foreign laws and regulations;

5.5.4. the agreed shelf life of the Product as of the date of shipment;

5.5.5. the quantity of Product constituting a Batch and minimum Batch size of each shipment of the Product;

5.5.6. the manner in which Elan may provide Acorda with assistance in relation to field alerts, recalls, complaints and adverse events;

5.5.7. the notification of change by both parties;

5.5.8. the responsibility to collate and write annual product review and annual reports;

5.5.9. technical agreements with any subcontracted parties;

5.5.10. the stability commitments in NDA or amendments thereto;

5.5.11. active drug substance, excipient and component supplier agreements, including audits/inspections of related manufacturing facilities;

5.5.12. procedures for determining and monitoring the marginal unit variable element of Manufacturing Cost for purposes of Clause 9.5.1;

5.5.13. such other matters relating to the manufacturing and supply of Product, including any amendments to any of the terms of this Agreement, any matters that this Agreement refers to be included in the Technical Agreement or any other matters that the Parties may mutually agree to or as may be required by the NDA or any NDA Equivalent.

CLAUSE 6 DISPUTES AS TO SPECIFICATION

6.1. All claims for failure of any delivery of the Product to conform to the Specifications must be made by Acorda in writing within sixty (60) days following delivery of Product to Acorda or its Designee except in the case of latent defects. Acorda shall promptly upon Elan's request provide reasonable details of the alleged non-conformance and supporting evidence, and shall upon request permit Elan to re-test the Product. If Elan does not agree with Acorda's determination of non-conformance, then Elan shall provide Acorda with a written notice of such disagreement within twenty (20) days of receipt of the non-conformance notice (adjusted for any delay in providing appropriate details or permitting re-testing), responding to Acorda's claim. The Parties shall use commercially reasonable efforts to resolve such disagreement within ten (10) Business Days of Acorda's receipt of Elan's notice of disagreement.

6.2. Claims for latent defects, not discovered during the routine testing protocol (to be agreed in the Technical Agreement) shall be made in accordance with the Technical Agreement in writing within thirty (30) days of discovery. Failure to make timely claims in the manner to be prescribed in the Technical Agreement shall constitute acceptance of the delivery.

6.3. In the event that the Product supplied by Elan is not in compliance with the Specifications, or is otherwise adulterated, misbranded or defective, Elan shall, in addition to any other applicable remedies:

6.3.1. be responsible, at the sole cost and expense of Elan, for re-analysis, sampling, processing, return, disposal or destruction, including certification of destruction, of such non-conforming Product; and

6.3.2. at its cost, replace the nonconforming Product with Product meeting the Specifications as soon as reasonably practicable.

6.4. In the event that the nonconformity was due to a fault of Acorda, then, according to Elan's orders, the Product shall either be destroyed by Acorda, or returned to Elan for

destruction by Elan, at Acorda's expense. In such an event Acorda will not be entitled to any credit as to the non-conforming Product.

6.5. In the event of an unresolved dispute as to:

6.5.1. conformity of the Product with Specifications; or

6.5.2. whether defects in the Product are attributable to the negligent acts or omissions of Elan, the parties shall within 30 days after expiration of the ten (10) Business Day period referred to in Clause 6.1 appoint an independent laboratory to undertake the relevant testing and its findings shall be conclusive and binding upon the parties.

All costs relating to this process shall be borne solely by the party whose testing was in error.
If the parties are unable to agree as to the independent laboratory to be used, the matter shall be referred to arbitration in accordance with Article 12.14 of the License Agreement.

CLAUSE 7 SECOND SOURCE

7.1. Process Transfer to Second Source:

Acorda shall be entitled to qualify the facility of Patheon Inc. at 2100 Syntex Court, Mississauga, Ontario as a second source of the Product ("**Second Source**"), subject to Patheon, Inc. (the "**Manufacturer**") undertaking to Elan to protect the confidentiality of Elan's manufacturing processes related to Product and not use them for any other purpose, in terms reasonably satisfactory to Elan provided that Elan hereby acknowledges that the Manufacturer is in the process of being qualified as a Second Source Manufacturer.

At Acorda's request, Elan shall use commercially reasonable efforts to assist in qualifying the Second Source as an alternative site of manufacture of the Product. Pursuant to this obligation, Elan shall:

7.1.1. provide Acorda or the Manufacturer (at Acorda's request) with any information necessary to manufacture the Product;

7.1.2. provide to Acorda or the Manufacturer (at Acorda's request) the documentation constituting the required material support, more particularly practical performance advice, shop practice, specifications as to materials to be used and control methods;

7.1.3. assist Acorda and/or the Manufacturer (at Acorda's request) with the working up and use of the technology and with the training of Manufacturer's personnel to

the extent which may reasonably be necessary in relation to the manufacture of the Product by the Manufacturer. In this regard, Elan will receive the Acorda's and/or Manufacturer's scientific staff, as applicable, in its premises for certain periods, the term of which will be agreed by the parties; and

7.1.4. comply with the other obligations and responsibilities of Elan relating to technology transfer to Patheon, as set forth in the Technology Transfer Responsibilities Schedule.

Acorda shall comply with its obligations and responsibilities relating to technology transfer to Patheon, as set forth in the Technology Transfer Responsibilities Schedule.

7.2. Supply of Product from Second Source:

Acorda may purchase the following quantities of Product from the Second Source and, accordingly, if so purchased, Acorda shall have no obligation to purchase such quantities from Elan and Elan shall have no obligation to supply such quantities to Acorda:

7.2.1. In any Year, up to twenty five percent (25%) of Acorda's total requirements of Product for such Year, subject to Clauses 7.3.2 and 9.5 (the "**Second Source Quantity**");

7.2.2. quantities of the Product which Elan is not obligated to, and declines to, supply pursuant to Clause 2.3;

7.2.3. quantities of Product in addition to the Second Source Quantity required to make up any portion of a valid purchase order which is either (i) not delivered by Elan by its due date for delivery (regardless of the cause of late or short delivery), except for Minor Deficiencies, or (ii) by reason of Force Majeure, to the extent not capable of being delivered by its due date for delivery, for so long as the Force Majeure continues;

7.2.4. where there is a Serious Failure To Supply, its entire requirements of the Product, subject to Clause 7.6.

7.3. Notification of Supply from Second Source; Equitable Purchase of Samples:

7.3.1. If Acorda purchases Product from the Second Source, the amount of the same, together with the quantity so purchased as samples, shall be notified to Elan in the applicable Statement.

7.3.2. Acorda shall purchase from the Second Source at least the same proportion of samples of the Product to commercial supply of Product as the proportion of samples to commercial supply purchased by Acorda from Elan.

7.4. No Supply Restrictions On Second Source:

Acorda shall not place or attempt to place any restriction on supply from the Second Source to Elan or its licensees for sale in the Elan Territory, except to the extent of the restrictions on supply by Elan under Clause 2.2. In particular, Acorda shall not place or attempt to place any restriction on supplies from the Second Source to Elan for sale in the Elan Territory or its licensees after the end of the Term.

7.5. Responsibility for Second Source:

Assuming compliance by Elan with Clause 7.1, Acorda shall be solely responsible for:

7.5.1. all process and equipment validation in the Second Source required by applicable law or regulations and shall take all steps reasonably necessary to pass inspection by the Governmental Authority;

7.5.2. Product supplied to Acorda or its Designees by the Second Source.

7.6. Resumption of Elan Supply:

7.6.1. In the event that Product is being purchased from a Second Source as a result of Serious Failure To Supply, at such time as Elan has remedied the situation that caused it and is once again able to fulfil its obligations to supply Product pursuant to the terms and conditions of this Agreement, Elan shall so notify Acorda. Commencing on the first calendar quarter beginning after the date of such notice (the "**Resumption Quarter**"), Acorda shall resume purchasing and Elan shall resume its obligations to supply the Minimum Elan Quantities from Elan, subject to the provisions of Clause 7.6.2.

7.6.2. Acorda shall be entitled to:

7.6.2.1. honor its binding purchase commitments from the Second Source, incurred reasonably and consistently with its practice of ordering from Elan and for delivery within three (3) months of the date of such commitments, prior to the notice referred to in Clause 7.6.1; and

7.6.2.2. subsequent to the commencement of the Resumption Quarter, in addition to the Second Source Quantity, purchase from the Second Source up to twenty five percent (25%) of Minimum Elan Requirements, to the exclusion of Elan, for two consecutive calendar quarters in order to be satisfied of Elan's ability to fulfil its obligations in respect of the supply of Product pursuant to the terms and conditions of this Agreement.

7.6.3. The Technical Agreement shall contain terms applicable to the resumption of supply where the cessation is by reason of Force Majeure, which shall be not less favourable to Elan than the provisions of Clauses 7.6.1 and 7.6.2 applicable to resumption following Serious Failure to Supply.

7.7. No Termination Right:

Absent Elan's failure to use commercially reasonable efforts to supply Product in accordance with the terms of this Agreement, Acorda shall have no right to terminate this Agreement by reason of failure to supply, except as otherwise expressly provided herein.

7.8. Have Made License:

The Parties acknowledge and confirm that:

(a) to the extent that Acorda is permitted hereunder to purchase the Product from Patheon; and
(b) following termination of this Agreement, and until termination of the License Agreement —

Acorda is regarded for the purposes of Article 2.1 of the License Agreement as being permitted to have the Product made by Patheon at the Second Source (subject always to the terms and conditions of this Agreement) and that the license grant under such Article 2.1 to make and have made Product extends accordingly.

CLAUSE 8 ADVERSE EVENTS AND PRODUCT RECALL

8.1. Each party shall give the other prompt notice, which shall be promptly confirmed in writing, of any occurrence that involves:

8.1.1. any material complaint about the safety or effectiveness of a Product, including a claim for death or injury following administration of such Product (that is plausibly related to the administration of such Product); and

8.1.2. any other matter arising out of this Agreement that must be reported to a Governmental Authority.

In the case of Acorda reporting to Elan matters described in Clause 8.1.2, reporting quarterly, or in such other timescale as may be agreed in the Technical Agreement, shall be considered "prompt".

For the avoidance of doubt, Acorda shall have overall responsibility for adverse event reporting and medical complaints.

8.2. If a party:

8.2.1. is notified by a Governmental Authority that a Recall of a Product is required, requested or otherwise advisable as being probably needed; or

8.2.2. establishes a need to Recall a Product for non-conformities with the Specifications —

it shall promptly give to the other party written notice of the same with full details.

8.3. Unless otherwise agreed, after consultation with Elan, Acorda shall take the lead role in any Recall, market withdrawal, stock recovery or any other corrective action related to Product in a commercially reasonable manner and Elan shall afford all reasonable assistance. A final report shall be completed by Acorda and delivered promptly to Elan.

8.4. If the Recall, market withdrawal, stock recovery or other corrective action relating to a Product arises from Elan's negligent acts or omissions in manufacturing the Product, or failure of the Product to conform to Specifications, the costs, including the cost of replacement quantities of Products, of such Recall, market withdrawal, stock recovery or other corrective action relating to a Product shall be borne by Elan provided that Acorda could not have discovered the said act(s) or omission(s) prior to the sale of the Product by exercising reasonable diligence. In all other circumstances, such costs shall be borne by Acorda. For purposes of this Agreement, such costs shall include the expenses of notification and destruction or return of the Recalled Product and all other documented out-of-pocket costs incurred in connection with such Recall, market withdrawal, stock recovery or other corrective action relating to a Product, but shall not include lost profits or opportunity costs of either Party.

In the event that Elan should bear the costs of any recall hereunder, Elan shall be entitled but not obliged to take over and perform the recall of the Product and Acorda shall provide Elan at no cost with all such reasonable assistance as may be required by Elan.

CLAUSE 9 FINANCIAL PROVISIONS

9.1. Price of Launch Stocks:

Elan shall invoice Acorda for Launch Stocks at a price equivalent to Manufacturing Cost plus [**], subject to reconciliation pursuant to Clause 9.3.3.

9.2. Price of Samples:

The price to be charged to Acorda for Product intended for distribution as free-of-charge promotional samples in its marketing and promotion of the Product shall be equivalent to Manufacturing Cost plus [**] which price shall apply to Product supplied EXW Elan's Facility to Acorda. For the avoidance of doubt, the Parties confirm that if Acorda requires the samples to be supplied in sample packaging, Manufacturing Cost shall include all costs referable to such packaging.

9.3. Price of Product (General):

9.3.1. Except for Product referred to in Clauses 9.1 and 9.2, the price of the Product manufactured by Elan to be charged to Acorda under this Agreement shall be equivalent to eight per cent (8%) of the NSP as determined by the provisions of Clause 9.3.3 (the "**Supply Price**"), less the Discount to the extent applicable, and

subject to Clause 2.5. The foregoing price shall apply to Product supplied EXW Elan's Facility packaged and labelled in final market form and consistent with the NDA.

9.3.2. For the avoidance of doubt the Parties agree that if for whatever reason the Product supplied by Elan to Acorda which meets the Specifications and the applicable law and regulatory requirements is not sold by Acorda, payment to Elan for such Product shall nonetheless be effected and the price of the Product shall be determined by reference to the NSP calculated pursuant to the provisions of Clause 9.3.3.

9.3.3. Upon supply, Elan shall render an invoice in respect of the quantities of Product delivered to Acorda for a sum calculated by reference to eight per cent (8%) of then-applicable Notional NSP. The Parties shall adjust their account as of the end of each calendar quarter during such calendar year by Acorda paying to Elan, or by Elan crediting Acorda (as the case may be), the difference between the sum paid pursuant to the previous sentence and the actual Supply Price calculated each calendar quarter pursuant by reference to actual NSP in such quarter, within the period specified in Clause 9.6.

9.4. Discount:

Where Acorda purchases from Elan for delivery in any Year more than [**] tablets of the Product, Acorda shall be entitled to a discount (the "**Discount**") in respect of the excess equal to [**] of Elan's Manufacturing Cost for such excess tablets.

The Discount is without prejudice to Clause 2.3.

9.5. Compensating Payment:

9.5.1. In respect of all Product purchased from the Second Source pursuant to Clause 7.2.1 and **7.6.2.2**, Acorda shall make a compensating payment to Elan calculated per unit as X — Y, where "X" is the unit price that would have applied if the Product were purchased from Elan, under Clause 9.2 or 9.3 as applicable; and "Y" is the marginal unit variable element of Elan's Manufacturing Cost applicable to such Product.

9.5.2. Such compensating payment shall be made in respect of a particular quarter at the time of provision of the Statement, based on the then Notional NSP and estimated Manufacturing Cost. The Parties shall adjust their account as of the end of each calendar year by Acorda paying to Elan, or by Elan crediting Acorda (as the case may be), the difference between the sum paid pursuant to Clause 9.5.1 and the actual payment calculated on the basis of actual applicable NSP and actual Manufacturing Cost calculated at the end of the calendar year, or such other period as may be specified in the Technical Agreement within sixty (60) days after the end of the calendar year.

9.6. Time For Payment:

For the first two years following First Commercial Sale of the Product in any country of the Territory, payment for the Product supplied to Acorda shall be effected in $ within sixty (60) days of the date of the relevant invoice issued on supply by Elan pursuant to Clause 9.3.3. Thereafter, payment shall be effected by Acorda in $ within thirty (30) days of the date of the relevant invoice issued on supply by Elan pursuant to Clause 9.3.3.

The adjusting payments referred to in Clause 9.3.3 shall be made on provision of the relevant Statement.
For the avoidance of doubt, in respect of Product ordered for a particular country prior to Regulatory Approval in that country, Acorda shall be responsible for the price of such Product as from its readiness for delivery, notwithstanding that applicable law or regulations may prevent such Product from being supplied before Regulatory Approval.

9.7. Process Transfer Costs:

Except as otherwise set forth in this Agreement, in respect of the establishment, qualification and operation of the Second Source, Acorda shall be solely responsible for:

9.7.1. Acorda's own costs and expenses;

9.7.2. all third party costs and expenses, including out of pocket expenses incurred by Elan, for products or services previously approved by the Committee; and

9.7.3. work conducted by Elan, its Affiliates, and their employees and consultants, under the Technology Transfer Responsibilities schedule, or as may otherwise be agreed to by the Parties, at the rate of FTE plus 45%.

9.8. VAT:

All prices for the Product and other amounts in this Agreement are exclusive of any applicable value added or any other sales tax, for which Acorda will be additionally liable, if payable, subject to Clause 10.

CLAUSE 10 PAYMENTS, REPORTS AND AUDITS

Article 5.9 of the Licence Agreement is hereby incorporated by reference herein as if restated in its entirety herein.

CLAUSE 11 DURATION AND TERMINATION

11.1. This Agreement shall be deemed to have come into force on the Effective Date and will expire upon expiry or termination of the Licence Agreement, howsoever arising.

11.2. In addition to the rights of termination provided for elsewhere in this Agreement, either party will be entitled forthwith to terminate this Agreement by written notice to the other party if:

11.2.1. that other party commits any breach of any of the provisions of this Agreement or the Licence Agreement, and in the case of a breach capable of cure, fails to cure the same within 60 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied; provided, that if the breaching party has proposed a course of action to cure the breach and is acting in good faith to cure same but has not cured the breach by the 60th day, such period shall be extended by such period as is reasonably necessary to permit the breach to be cured, provided that such period shall not be extended by more than 90 days, unless otherwise agreed in writing by the parties;

11.2.2. that other party goes into liquidation (except for the purposes of amalgamation or reconstruction and in such manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on that other party under this Agreement);

11.2.3. an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other party;

11.2.4. any proceedings are filed or commenced by that other party under bankruptcy, insolvency or debtor relief laws or anything analogous to any of the foregoing under the laws of any jurisdiction occurs in relation to that other party.

11.3. For the purposes of Clause 11.2, a breach will be considered capable of cure if the party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).

11.4. Elan may terminate this Agreement by giving twelve (12) months' written notice to do so to Acorda.

CLAUSE 12 CONSEQUENCES OF TERMINATION

12.1. Upon exercise of those rights of termination specified in Clause 11 or elsewhere in this Agreement, this Agreement shall, subject to the provisions of the Agreement which survive the termination of the Agreement and Clause 12.2 automatically terminate forthwith and be of no further legal force or effect, provided, however, that if the Agreement is terminated by Elan under Clause 11.4 such termination shall not be effective until the expiration of such twelve (12) month period

12.2. Upon termination of this Agreement by either party, the following shall be the consequences:

12.2.1. any sums that were due from Acorda to Elan under the provisions of Clause 9 or otherwise prior to the exercise of the right to terminate this Agreement as set forth herein shall be paid in full forthwith provided , that Elan has delivered Product in accordance with the Specifications and cGMP; and Elan shall not be liable to repay to Acorda any amount of money paid or payable by Acorda to Elan up to the date of the termination of this Agreement;

12.2.2. all confidentiality provisions set out herein shall remain in full force and effect for a period of 7 years from the date of termination of this Agreement;

12.2.3. all representations and warranties shall insofar are appropriate remain in full force and effect;

12.2.4. the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement; and

12.2.5. if Elan terminates the Agreement under Clause 11.4, Acorda shall be entitled to purchase all of Acorda's requirements of Product from the Second Source as from termination becoming effective.

CLAUSE 13 REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

13.1. The following clauses of the License Agreement are hereby incorporated by reference herein as if stated herein in their entirety, except that for purposes of this Agreement, all references in such clauses to "the Agreement" or "this Agreement" shall be deemed to mean this Supply Agreement: Articles 8.2, 8.3, 8.4, 8.5, and 8.7.

13.2. Elan represents and warrants that the Product supplied to Acorda by Elan under this Agreement shall be free of any lien, security, interest or other encumbrance on title, conform to the Specifications and all applicable laws and regulations and requirements of the FDA and other Governmental Authorities including, without limitation, the cGMP regulations which apply to the manufacture, storage, packaging and supply of the Product. Elan represents and warrants that the Product supplied to Acorda under this Agreement shall be free of defects in material and workmanship, shall not be adulterated or mis-branded as defined by the Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce and shall be fit for use as a pharmaceutical product. Acorda agrees not to assert its right to rescind this Agreement in the event of a breach of the representations of Elan contained in this Clause 13.2.

13.3. Elan shall indemnify, defend and hold harmless Acorda and its officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to Third Party claims to which Acorda is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Elan of any of its obligations under this Agreement, (ii) any breach of a representation or warranty of Elan made in this Agreement, (iii) any failure of

the Product provided under this Agreement to meet the Specifications, or (iv) the manufacture or shipment of the Product provided under this Agreement by Elan, except in each case to the extent due to the negligence or wilful misconduct of Acorda.

13.4. Acorda shall indemnify, defend and hold harmless Elan and its officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to Third Party claims to which Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Acorda of any of its obligations under this Agreement, (ii) any breach of any representation or warranty of Acorda made in this Agreement, (iii) damages for personal injury (including death) and/or for costs of medical treatment, caused by or attributed to the Product, or (iv) the acts or omissions of any sub-licensee appointed pursuant to the Licence Agreement, except in each case to the extent due to the negligence or wilful misconduct of Elan or to the relative extent that Elan is obliged to indemnify Acorda pursuant to Clause 13.3.

13.5. The party seeking an indemnity shall:

13.5.1. fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;

13.5.2. permit the indemnifying party to take full control of such claim or proceedings, with counsel of the indemnifying party's choice, provided that the indemnifying party shall reasonably and regularly consult with the indemnified party in relation to the progress and status of such claim or proceedings;

13.5.3. co-operate in the investigation and defence of such claim or proceedings; and

13.5.4. take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings.

The indemnifying party may settle a Claim on terms which provide only for monetary relief and do not include any admission of liability. Save as aforesaid, neither the indemnifying party nor the party to be indemnified shall acknowledge the validity of, compromise or otherwise settle any Claim or proceedings without the prior written consent of the other, which shall not be unreasonably withheld.

13.6. TO THE FULLEST EXTENT PERMITTED BY LAW, APART FROM THE FOREGOING REPRESENTATIONS, WARRANTIES, COVENANTS AND INDEMNITIES, AND THOSE SET FORTH IN THE LICENSE AGREEMENT ELAN MAKES NO ADDITIONAL REPRESENTATIONS OR WARRANTIES AND HEREBY DISCLAIMS ALL WARRANTIES, REPRESENTATIONS, AND LIABILITIES, WHETHER EXPRESS OR IMPLIED, ARISING FROM CONTRACT OR TORT (EXCEPT FRAUD), IMPOSED BY STATUTE OR OTHERWISE, RELATING TO THE PRODUCTS AND/OR ANY PATENTS OR TECHNOLOGY USED OR INCLUDED IN THE PRODUCTS, INCLUDING ANY WARRANTIES AS

TO MERCHANTABILITY, FITNESS FOR PURPOSE, CORRESPONDENCE WITH DESCRIPTION, OR NON-INFRINGEMENT.

13.7. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND ACORDA SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

13.8. Elan and Acorda shall each maintain comprehensive general liability insurance, insuring against all liability, including product liability, personal injury, physical injury and property damage in respective amounts deemed reasonable in the industry for companies of their respective size and engaged in their respective activities under this Agreement for the duration of this Agreement and for a period of 5 years thereafter.

Each party shall provide the other party with a certificate from the insurance company verifying the above and shall notify the other party in writing at least 30 days prior to the expiration or termination of such coverage.

CLAUSE 14 MISCELLANEOUS PROVISIONS

14.1. Secrecy and Confidentiality. Article 12.1 of the License Agreement is hereby incorporated by reference herein as if stated herein in its entirety.

14.2. Licence to Elan:

Acorda hereby grants to Elan and Elan hereby accepts for the Term a non-exclusive royalty-free license to use such Acorda Patent Rights and Acorda Know-How as are necessary or useful for the purpose of manufacturing the Product. Such rights shall be sub-licensable by Elan to its Affiliates and sub-contractors, for the sole purpose of manufacturing the Product in accordance with this Agreement.

14.3. Assignment:

14.3.1. Subject to the provisions of this Clause 14.3, each party be entitled without the consent of the other:

14.3.1.1. to subcontract or delegate the whole or any part of its duties hereunder to its Affiliate(s) (but shall remain responsible for its obligations under this Agreement); and/or

14.3.1.2. to assign this Agreement to its Affiliate, provided that such assignment has no material adverse tax implications for the other Party or Parties hereto, and provided further that the assigning Party shall remain liable and responsible with such assignee to the other Party for the performance of any obligations, representations or warranties delegated, contracted, assigned or otherwise transferred to any such assignee.

14.3.2. In the event that Elan agrees to sell all or substantially all of the assets of Elan's Facility, Elan shall so notify Acorda. In such event, Elan may (a) terminate this Agreement by ninety (90) days' written notice to Acorda; or (b) assign all (but not, subject to the following sentences, a portion) of its rights and obligations under this Agreement to a Permitted Elan Assignee, provided that such transfer or assignment has no adverse tax implications for Acorda.

14.3.3. Each Party may assign all (but not a portion) of its rights and obligations under this Agreement to an entity that acquires all or substantially all of its business or assets to which this Agreement pertains, whether by merger, reorganisation, acquisition, sale or otherwise, provided, that in the case of an assignment by Elan, the assignee is a Permitted Elan Assignee.

14.3.4. Except as provided for in this Clause 14.3, this Agreement may not be assigned by a party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

14.3.5. Any permitted assignee of a Party under this Clause 14.3 shall assume all related obligations of its assignor under this Agreement.

14.4. Parties bound:

This Agreement shall be binding upon and enure for the benefit of parties hereto, their successors and permitted assigns.

14.5. Severability:

If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws:

14.5.1. such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable; or

14.5.2. if it cannot be so amended without materially altering the intention of the parties, it will be deleted the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

14.6. Force Majeure:

14.6.1. Neither party to this Agreement shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure results from Force Majeure.

14.6.2. If Force Majeure prevents or delays the performance by a party of any obligation under this Agreement, then the party claiming Force Majeure shall promptly notify the other party thereof in writing. The parties shall thereafter as soon as practicable discuss how best to continue their operations in accordance with this Agreement and shall thereafter continue such discussions on a regular basis while Force Majeure continues.

14.6.3. Where a party claims Force Majeure, the other party's obligations under this Agreement shall be suspended for the period while Force Majeure continues, but only to the extent reasonably required by the Force Majeure.

14.6.4. The party claiming Force Majeure shall use all reasonable efforts to avoid, minimise or remove the cause of such non-performance and to mitigate its effects and shall continue performance with due dispatch whenever such causes are removed.

14.6.5. Where Force Majeure continues for a period of six (6) months the other party shall have the right to terminate this Agreement, provided that it has complied with its obligations under this Clause 14.6.

14.7. Relationship of the parties:

14.7.1. Nothing contained in this Agreement is intended or is to be construed to constitute any of the parties hereto as partners or members of a joint venture or any party as an employee of another party.

14.7.2. No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind another party to any contract, agreement or undertaking with any third party.

14.8. Amendments:

No amendment, modification or addition hereto shall be effective or binding on any party hereto unless set forth in writing and executed by a duly authorised representative of all parties hereto.

14.9. Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

14.10. Entire Agreement:

14.10.1. Each of the parties hereto hereby acknowledges that in entering into this Agreement it has not relied on any representation or warranty except as expressly set forth herein or in the License Agreement or in any other document referred to herein.

14.10.2. This Agreement and the Licence Agreement, together with the exhibits and schedules hereto and thereto, together set forth all of the agreements and understandings between the parties with respect to the subject matter hereof, and supersede and terminate all prior agreements and understandings between the parties with respect to the subject matter hereof, including the SCI Agreement and the MS Agreement.

14.10.3. Nothing in this Clause 14.10 shall exclude any liability which any party would otherwise have to the other party or any right which either of them may have to rescind this Agreement for fraud.

14.11. Governing law and jurisdiction:

14.11.1. This Agreement shall be governed by and construed in accordance with the laws of the State of New York**,** excluding its conflict of laws rules.

14.11.2. Article 12.14 of the License Agreement is hereby incorporated by reference herein as if stated herein in its entirety.

14.12. Notices:

14.12.1. Any notice to be given under this Agreement shall be sent in writing in English by registered or recorded delivery post, reputable overnight courier or fax to:

Elan at
c/o Elan Pharma Ltd.
Monksland
Athlone
Co. Westmeath
Ireland
Attention: General Manager
Fax: +353 906 492427

Acorda at
15 Skyline Drive
Hawthorne, New York 10532
United States of America
Attention: President
Fax: **914.347.4560**

or to such other address(es) and fax numbers as may from time to time be notified by either party to the other hereunder.

14.12.2. Any notice sent by mail shall be deemed to have been delivered within 7 working days after despatch or delivery to the relevant courier and any notice sent by fax shall be deemed to have been delivered upon confirmation of receipt. Notice of change of address shall be effective upon receipt.

14.13. Further assurances:

At the request of any of the parties, the other party or parties shall (and shall use reasonable efforts to procure that any other necessary third parties shall) execute and do all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting party the full benefit of the terms hereof.

14.14. Counterparts:

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

14.15. Set-off:

Each of the parties will be entitled but not obliged to set-off against any amount of money payable to it by the other party hereunder, any amount of money payable by it to the other party hereunder.

IN WITNESS WHEREOF the parties have executed this Agreement on the day and date appearing at the top of page 1.

SCHEDULE 1 MANUFACTURING COST

“Manufacturing Cost” shall mean fully absorbed cost of manufacture (including packaging) which shall be determined on the basis of the following elements:

(a) Direct material, labour and overhead cost; and

(b) Such indirect labour, factory, laboratory and other overhead costs properly allocable. Overhead allocations shall include, but not be limited to, expenses of plant maintenance and engineering, plant management, receiving and warehousing, disposal and treatment of waste, building occupancy, quality control, costs of services provided to manufacturing and insurance provided to manufacturing.

Such allocations shall be in a manner consistent with GAAP from time to time and in a manner consistent with expenses and overhead allocated to other products manufactured by Elan or its Affiliates.

Where some part(s) of the manufacture or packaging is/are conducted by unaffiliated third party(ies), Manufacturing Cost shall be the amount paid to such third party(ies) plus any of the aforementioned costs incurred by Elan or its Affiliates in completing the manufacture, packaging or delivery of the Product.

SIGNED
Monksland Holdings BV

By: /s/ Pieter Bosse
By: /s/ Klaas van Blanken

for and on behalf of
ELAN CORPORATION, PLC.

Name: Monksland Holdings BV
Title: Proxyholder

SIGNED

By: /s/ Ron Cohen

for and on behalf of
ACORDA THERAPEUTICS, INC.

Name: Ron Cohen
Title: President & Chief Executive Officer

Exhibit 10.3

Portions of this exhibit (indicated by "[**]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Execution Copy

ELAN PHARMA INTERNATIONAL LIMITED

AND

ACORDA THERAPEUTICS, INC.

DEVELOPMENT AND SUPPLEMENTAL AGREEMENT
TO AMENDED AND RESTATED LICENSE
AGREEMENT
DATED 26 SEPTEMBER 2003 AS AMENDED AND
SUPPLY AGREEMENT DATED 26 SEPTEMBER 2003

Fampridine QD formulation

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This Development and Supplemental Agreement ("Agreement") is dated 14th day of January 2011 (the "Effective Date").

PARTIES:

(1) ELAN PHARMA INTERNATIONAL LIMITED, with an address at Monksland, Athlone, Co. Westmeath, Ireland ("Elan") and

(2) ACORDA THERAPEUTICS, INC., a Delaware corporation with an office at 15 Skyline Drive, Hawthorne, NY 10532, USA ("Acorda")

BACKGROUND:

(A) Elan Corporation, plc and Acorda are parties to (i) an Amended and Restated License Agreement dated 26 September 2003 pursuant to which, inter alia, Elan Corporation plc granted certain licenses under its intellectual property in respect of mono- and di- aminopyridines (as amended by Amendment No. 1 defined below, the "License Agreement") and (ii) a Supply Agreement dated 26 September 2003 pursuant to which Elan Corporation agreed to supply Product to Acorda (as amended by Amendment No. 1 defined below, the "Supply Agreement").

(B) Elan is the successor in interest of Elan Corporation, plc.'s rights and obligations under the above described agreements.

(C) By an Amendment No. 1 Agreement to the License Agreement and Supply Agreement and Consent to Sublicense dated 30 June 2009 ("Amendment No. 1"), Elan and Acorda made certain amendments to the said agreements. The License Agreement, Supply Agreement, and Amendment No. 1 are referred to herein as the "License and Supply Agreement."

(D) The Parties wish to pursue the development of one or more new formulations of the Compound and/or Alternate Compounds for existing and/or new indications and the commercialization of one of these additional formulations. The formulations will use Elan technologies upon the terms and conditions of the License and Supply Agreement and the terms and conditions set out below and/or third party technologies upon the terms and conditions set out below and specifically stated as applicable to a formulation developed using third party technologies. The Parties also wish to further to provide for certain clarifications in respect of the application of provisions of the license and Supply Agreement to formulations using Elan technologies.

TERMS:

The Parties agree as follows:

1. Definitions and Interpretation

1.1. Definitions:

In this Agreement the following expressions shall have the following meanings:

"Agreement"	means this agreement, including its recitals, with the attached Schedules.

"**Compound Know-How and First Product Know- How"**	means the Elan Know-How that is or will be disclosed to Acorda in relation to the Compound or to the First Product under the License or Supply Agreement. For clarity and avoidance of doubt this term shall not include any knowledge, information, trade secrets, data or expertise which is generated or created by Elan in any Further Development Plan activities.
"Compound and First Product Know-How License"	has the meaning set forth in Clause 4.7.
"Development Product"	means the Product developed by Acorda and Elan pursuant to this Agreement, the Further Development Plan and one or more Work Plans, which Product incorporates the Development Technology. "Development Product" does not include the "First Product" but is a "Product" under the License Agreement.
"Development Product Supply Agreement"	has the meaning set forth in Clause 9.
"Development Technology"	means the technology which is developed by Elan and/or Acorda pursuant to this Agreement.
"First Product"	means that specific formulation (twice daily) of the Product that is marketed as of the Effective Date in the United States under the trademark "Ampyrafl".
"Further Development	means the development plan for the Development Product, Plan" which as of the Effective Date is set out in Schedule 1, as it may be amended by Elan and Acorda from time to time and set out in any amendment to the Further Development Plan that may be generated in accordance with Clause 3.2 of this Agreement.
"Non-Elan Developer"	means any individual or entity other than Elan (including Acorda).
"Non-Elan Development	means a formulation of Compound or an Alternate **Product"** Compound developed or to be developed by a Non-Elan Developer to meet the Selection Criteria. For clarity, "Non-Elan Development Product" shall not be regarded as a "Product" for the purposes of the License and Supply Agreement or this Agreement.
"Non-Elan Development Product Supply Agreement"	has the meaning set forth in Clause 10.4.1

"Non-Elan Party Election"	has the same meaning as that set forth in Clause 10.2.
"Selection Criteria"	means the target criteria for the Development Product and for each Non-Elan Development Product, as specified to Non-Elan Developers and as may be amended from time to time, which as of the Effective Date are set forth in Schedule 3.
"Work Plan"	means each written plan for development of Product agreed upon by Acorda and Elan, which Work Plan sets forth the goals of the work, allocates the responsibilities of the parties for conducting the work, timelines, and any other terms and conditions agreed upon between the parties. All Work Plans shall be consecutively numbered and, upon execution by authorized representatives of the parties, shall be incorporated by reference into this Agreement.

1.2. Interpretation: In this Agreement:

1.2.1. capitalised expressions not specifically defined in this Agreement shall have the same meaning as in the License and Supply Agreement, as applicable;

1.2.2. references to clauses are to clauses of this Agreement unless stated otherwise; and

1.2.3. this Agreement shall otherwise be interpreted in the same manner as the License and Supply Agreement.

2. **Effect on Existing Agreements**

2.1. Except as expressly provided herein, the parties agree and acknowledge that the development, commercialization and commercial supply of the Development Product shall be governed by the License Agreement, the agreements incorporated by reference in the License Agreement, the Development Product Supply Agreement and in each case any amendments thereto (including but not limited to Amendment No 1). For clarity, the Development Plan does not apply to the Development Product or the Non-Elan Development Product.

2.2. For the purposes of clarity, the License Agreement as amended, the agreements incorporated by reference in the License Agreement, Supply Agreement and Amendment No. 1 shall continue to govern the development, commercialization and commercial supply of the First Product. For clarity and avoidance of doubt, the Parties hereby acknowledge that the consent granted by Elan to Acorda in Section 1of the Amendment No. 1 is not modified by this Agreement.

2.3. At appropriate times during the Term, Elan and Acorda agree that they will discuss in good faith any clarifications as may be required to any operational provisions in the License and Supply Agreement to support the development, commercialization and commercial supply of any Development Product. Any such clarifications shall be set forth in an amendment to this Agreement (or other written, duly executed Elan/Acorda agreements), executed by authorized representatives of Acorda and Elan. The Parties agree that to the extent this Agreement specifically states that certain provisions of the License Agreement and the Supply Agreement apply to Non-Elan Development Product, any capitalized terms used within the License Agreement and Supply Agreement as so referenced shall have the meaning set forth in the License Agreement or the Supply Agreement, as the case may be, unless this

Agreement specifically states otherwise.

3. **Development and Project Management (Development Product)**

3.1. Without prejudice to Acorda's rights to cease development of the Development Product at any time, throughout the Term and in accordance with the Further Development Plan and the applicable Work Plan(s), Elan and Acorda shall use commercially reasonable efforts to develop Development Product in accordance with the Further Development Plan(s). For the purpose of clarity, Acorda, in its sole discretion, may choose to cease development of the Development Product in the event that Acorda determines that continuing such development is no longer commensurate with the achievement of its own business aims. The decision not to further develop, if made by Acorda, shall not be subject to review by the Committee nor shall it be subject to arbitration under Section 12.14 of the License Agreement.

3.2. The Further Development Plan and the applicable Work Plan(s) set forth the agreed respective responsibilities of Elan and Acorda with respect to the development of the Development Product. Without prejudice to Acorda's right to cease development at any time during the term of the Further Development Plan, Elan and Acorda shall undertake their respective obligations under the Further Development Plan and the applicable Work Plan(s) on a collaborative basis and using commercially reasonable efforts. Changes may be made to the Further Development Plan by mutual, written agreement of the parties through the Committee referenced in Section 10 of the License Agreement, which written agreement shall be set forth in an amendment to the Further Development Plan and/or Work Plan, as applicable.

3.3. Detailed development work shall be agreed and set out by the parties in one or more Work Plans, which shall be in a form broadly similar to the Work Plan format attached hereto as Schedule 2. Each Work Plan must be mutually agreed by both parties and accepted and signed by a duly authorized representative of both parties. Executed Work Plans shall form a part of this Agreement.

3.4. Within two (2) weeks of the Effective Date of this Agreement, the parties will establish a project team **("Project Team"),** which shall convene regularly to keep the parties fully informed as to their progress with its respective tasks and obligations under the Further Development Plan and Work Plan(s). The Project Team shall monitor the progress of such activities.

3.5. Elan and Acorda shall update each other at meetings of the Committee as to the progress of their respective obligations under the Further Development Plan and the Work Plan(s).

3.6. The parties shall co-operate in good faith through the Project Team and the Committee particularly with respect to unknown problems and contingencies and shall perform their respective obligations in a commercially reasonable, diligent and workmanlike manner and in accordance with all applicable laws, regulations and guidelines.

3.7. Provided that a party uses reasonable endeavours to meet its obligations under this Agreement, it shall have no liability to the other as a result of any failure or delay of the Development Product to achieve any of the goals set out in the Further Development Plan or a Work Plan(s), nor for any failure of a Development Product to obtain NDA Approval or Regulatory Approval.

4. **Non-Elan Development Product**

4.1. Acorda shall afford Elan a reasonable opportunity to develop a formulation meeting the Selection

Criteria, and Elan and Acorda shall reasonably cooperate to enable that opportunity. The parties further agree that the entry into this Agreement and the performance of the Further Development Plan set out in Schedule 1meet this obligation in respect of Elan being afforded a reasonable opportunity and provided with the Selection Criteria for the Development Product, as they exist as of the Effective Date.

4.2. Subject to Clause 4.3, in the event that Acorda selects to commercialize the formulation of a Non-Elan Developer, Acorda shall discuss the reasons for its selection with Elan.

4.3. Elan acknowledges and agrees that the final decision on which formulation to develop and commercialize is within Acorda's sole discretion and that such decision is not subject to review or dispute by Elan through the Committee nor is subject to the arbitration provisions set out in Section 12.14 of the License Agreement. Acorda shall promptly disclose any agreed key financial terms of any commercialization agreement with the Non- Elan Developer to Elan, which Elan shall maintain as confidential under the confidentiality provisions of Section 12.1of the License Agreement.

4.4. Subject to the foregoing and to the other terms and conditions of this Agreement, Acorda shall be entitled, through itself or any sublicensees, to select and commercialize one Non- Elan Development Product meeting the Selection Criteria.

4.5. Acorda shall afford Elan a reasonable opportunity to develop any other formulations containing Compound or Alternate Compound not covered by this Agreement. For the avoidance of any doubt, nothing in this Agreement shall be deemed to constitute (i) Elan's consent to the commercialisation of any other subsequent Non-Elan Development Product nor any Non-Elan Development Product that meets different selection criteria or (ii) a limitation on Acorda's existing development rights under Section 12.15 of the License Agreement.

4.6. Where Acorda elects to commercialize a Non-Elan Development Product, Acorda and Elan shall generally coordinate and manage their business relationship relating to the commercialization of the Non-Elan Development Product through the Committee that is referred to in Article 10 of the License Agreement. The Committee shall also resolve any disputed issues (excluding any issues which may arise over Acorda's formulation selection under Clause 4.3 or ceasing to develop or not developing Development Product under Clause 3.1) that may arise between the Parties per Section 10.3 of the License Agreement including submission to arbitration under Article 12.14. Through the Committee, Acorda shall keep Elan reasonably informed of those matters relating to the Non-Elan Development Product which reasonably affect Elan's interests, including the general progress of development, objectives for and commercial performance of the Non-Elan Development Product, clinical and regulatory filings, sales performance and sales forecasts and any actual or threatened litigation or "paragraph IV certifications" pertaining to the Non-Elan Development Product.

4.7. Elan hereby grants to Acorda a non-exclusive, non-transferable (other than to a lawful assignee of the License Agreement) license (the "Compound Know-How and First Product Know-How license") under the Compound Know-How and First Product Know-How to develop, package, use, import, export, make and have made (subject to Clause 10) Non-Elan Development Product in the Territory and, in addition, to promote, distribute, market, offer for sale and sell the one particular Non-Elan Development Product (if any) that Acorda finally selects to commercialize under this Clause 4 in the Territory. The part of Compound Know-How and First Product Know-How License that enables Acorda to promote, distribute, market, offer for sale and sell any finally selected Non-Elan Development Product shall be sub-licensable to Acorda's existing sublicensee without Elan consent and to other sublicensees in accordance with the terms as set out in Section 2.3 of the License Agreement

for Product; provided that in each case such entitiy is responsible for commercializing Non-Elan Development Product. Acorda and any sublicensee it appoints to commercialize Non-Elan Development Product shall only share Compound Know-How and First Product Know-How with Non-Elan Developers other than itself on a strictly need-to know-basis. This Compound Know-How and First Product Know-How License shall commence as of the Effective Date and shall end upon the expiry of Acorda's obligations to make payments to Elan in respect of the Non-Elan Development Product, and subject to such payments being duly made shall be irrevocable during that period.

4.8. For clarity, the foregoing provisions shall not be construed as conferring any right or license to use any intellectual property arising from Further Development Plan activities developed solely by Elan or jointly with Elan in connection with the development, manufacture or sale of a Non-Elan Development Product, nor as conferring any liability or obligations on Elan with respect to a Non-Elan Development Product other than as expressly set out Clause 4.7 and in the Non-Elan Development Product Supply Agreement and/or other agreement(s) entered into relating to the supply of Non-Elan Development Product by Elan entered into pursuant to Clause 10 (if any).

5. **Manufacture and Supply of Pre-Commercial Batches of Development Product**

5.1. Elan shall use commercially reasonable efforts to manufacture and supply to Acorda such quantity of the Development Product as it may reasonably require to perform its activities under the Further Development Plan and each applicable Work Plan.

5.2. Per Section 3.4 of the License Agreement, supply of Development Product shall be EXW such facility as may be specified in the applicable Work Plan or as Elan may nominate and Acorda shall reasonably approve, [**].

5.3. Acorda's requests for Development Product shall clearly specify whether such use is for pre-clinical or clinical supply. Where Acorda requests Development Product for clinical supply, Elan shall manufacture it in accordance with phase specific cGMPs in addition to applicable laws and regulations.

5.4. Clauses 13.2 to 13.8 inclusive of the Supply Agreement (liability) shall apply *mutatis mutandis* in respect of the supply of pre-commercial supplies of Development Product.

6. **Registration ·**

6.1. Acorda shall be responsible, at its own expense, for conducting such pre-clinical and clinical studies as are required to obtain Regulatory Approval for the Development Product. Elan shall reasonably cooperate with Acorda in obtaining such approvals at Acorda's expense.

6.2. Elan will prepare and utilize a DMF (or similar structure for international filings) at Acorda's expense for the Development Product and Acorda shall have a right of reference to the extent required by any regulatory jurisdiction until such time, if any, as Acorda terminates all development programs related to Non-Elan Development Product. Upon receipt of notice of such termination, Elan will discontinue use of the DMF and promptly provide the relevant CMC information to Acorda in support of Acorda's regulatory filing(s), at Acorda's expense and otherwise in accordance with the provisions of Section 3.8 of the License Agreement.

7. **Additional Financial Provisions**

7.1. Development Fees for Development Product. Acorda shall pay to Elan fees in respect of Elan's activities under this Agreement at a rate of FTE plus [**], invoiced and payable monthly. Each invoice shall identify the particular work requested by Acorda and performed by Elan under the Work Plan(s) and Further Development Plan(s), as applicable. Further, the provisions of Sections 5.1.3 (development records) and 5.1.4 (third party development costs) of the License Agreement shall apply *mutatis mutandis;* provided, however, that in reference to third party development costs Elan shall have the right to charge Acorda for the time spent by Elan employees in administering the work conducted by such third parties at [**] as well as the third party development costs incurred by Elan.

7.2. Non-Elan Development Product Compensation. Notwithstanding any contrary provision of the License Agreement, in consideration of Elan's agreement to permit Acorda to commercialize the Non-Elan Development Product on the terms and conditions herein and in consideration of the grant of the Compound Know-How and First Product Know-How License, Acorda shall pay to Elan:

7.2.1. [**];

7.2.2. [**];

7.2.3. [**]; and

7.2.4. [**];

in each case as if (a) defined terms [**] and [**] referred to the Non-Elan Development Product instead of the Product and as if (b) the references in Section 5.3.1of the License Agreement and defined terms used therein to "Product" additionally referred to the Non-Elan Development Product.

7.3. Application of Rush Payments Agreement. For the avoidance of doubt, Acorda shall remain responsible to make payments to Elan under the Rush Payments Agreement in respect of the Development Product or the Non-Elan Development Product, as applicable, on the basis that "NSP" as used therein refers to such products respectively.

7.4. Ancillary.

7.4.1. Section 5.9 of the License Agreement (payments, reports and records) shall apply in respect of the Non-Elan Development Product *mutatis mutandis.*

7.4.2. Payments under Clause 7.2.1 shall be made upon provision of the Statement;

7.4.3. Payments under Clause 7.2.2 shall be made in accordance with the applicable supply agreement entered into pursuant to Clause 10, if applicable, and otherwise upon provision of the Statement.

7.4.4. In respect of payments under Clause 7.2.4 [**], Sections 5.3.2 to 5.3.5 (payment terms) of the license Agreement shall apply *mutatis mutandis.*

For clarity and as stated above, the manner and method of payment for Non-Elan Development Product are identical to the equivalent terms set out for Product payments in the License Agreement.

8. **Application of License Agreement**

In relation to clarifying the precise manner in which the license Agreement applies to the Development Product, in addition to specific citations to sections of the license Agreement herein, Elan and Acorda agree as follows:

8.1. Intellectual Property. At appropriate times during the Term and from time to time, Elan and Acorda shall prepare revised schedules of Elan Patent Rights and Acorda Patent Rights, reflecting such patents and patent applications as are incorporated and/or used in the Development Product.

8.2. License Provisions. For the purpose of clarification, Elan and Acorda agree that:

8.2.1. the reference in the definition of "Elan Patent Rights" to the infringement by the manufacture, use or sale of the Product is to be read as a reference to infringement by the manufacture, use or sale of the First Product or the Development Product; and

8.2.2. the references in the definition of "Elan Patent Rights" and "Elan Know How" to development "in connection with the Project" is to be read as if it additionally referred to development pursuant to this Agreement.

8.3. Regulatory Expressions. The definitions of "NDA", "NDA Approval", "Regulatory Approval", and terms referring to those defined terms shall be construed as they relate to the First Product or the Development Product, as applicable.

8.4. Diligence. Subject to Acorda's formulation selection right under Clause 4.3, Section 2.11 (Diligence) of the License Agreement shall apply in respect of the Non-Elan Development Product mutatis mutandis. In performing its obligations under Section 2.11 of the License Agreement, Acorda shall be entitled to select a commercially reasonable strategy Development Product or Non-Elan Development Product, as the case may be, on the other.

8.5. Royalties. In the event that (a) the Development Product is being commercially sold and (b) Elan is manufacturing one, but not both, of the First Product and the commercially sold Development Product, the Elan Royalty specified in Section 5.6 of the License Agreement shall be calculated separately for the First Product and the Development Product.

8.6. Committee. Article 10 (Committee) of the License Agreement shall be read as if it additionally referred to the Further Development Plan and its budget as appropriate. For clarity, nothing in this Agreement is intended to expand upon the oversight responsibility of the Committee with respect to Product as set forth in Article 10 of the License Agreement.

9. **Development Product Supply Agreement**

9.1. Not less than eighteen (18) months prior to the anticipated date of commercial launch of the Development Product, Elan and Acorda shall negotiate in good faith an amendment to the Supply Agreement or a new substantially similar supply agreement in respect of such Development Product **("Development Product Supply Agreement"),** which Development Product Supply Agreement shall contain the financial terms set out in this Agreement and any other provisions of this Agreement that pertain to the Development Product, together with one or more quality agreements as appropriate. The decision as to whether to amend the existing Supply Agreement or to create a substantially similar supply agreement for Development Product shall be decided by the Committee.

9.2. The price of the Development Product manufactured by Elan under the applicable Development Product Supply Agreement (or under the applicable amendment to the Supply Agreement) shall [**]. The foregoing shall be in lieu of the price stated in Clauses 9.3 and 9.4 of the Supply Agreement.

9.3. Elan shall enable the use of a mutually agreed independent second source for manufacture of the Development Product upon terms substantially similar set out in Clause 7 of the Supply Agreement, as agreed upon by the Committee and as set out in the Development Product Supply Agreement.

9.4. Except as set out in this Clause 9, as may be operationally necessary for the manufacture of a Development Product, or as may otherwise be agreed by Elan and Acorda in the Development Product Supply Agreement, the terms of the Development Product Supply Agreement shall be the same as those set out in the Supply Agreement.

10. **Non-Elan Development Product Supply Option**

10.1. In the event that Acorda, chooses to commercialize a Non-Elan Development Product in accordance with Clause 4.4 of this Agreement, Elan shall have the first option to manufacture or have manufactured by an Affiliate all or a portion of the selected Non-Elan Development Product.

10.2. Within forty-five (45) days of the decision to proceed to commercialization of a Non-Elan Development Product (a **"Non-Elan Party Election"),** Acorda shall notify Elan in writing, and shall procure that Elan is provided within that period with such information as would information as Elan may reasonably request for the purpose of determining whether it wishes to undertake such manufacture. To this end, Acorda shall procure that the applicable Non-Elan Developer is made available and with Acorda in attendance and shall cooperate fully to answer queries which Elan may have in this regard, subject to the terms of a three-way confidential disclosure agreement to be entered into between Acorda, Elan and the Non-Elan Developer.

10.3. Within ninety (90) days of receipt of all such requested information, Elan shall notify Acorda in writing whether it is willing to and believes that it is able to manufacture such Non-Elan Development Product, and the portion of the Non-Elan Development Product it wishes to manufacture. If Elan does not so notify Acorda within that period, and to the extent of the portion which Elan is not willing to or does not believe that it will be able to manufacture, Acorda shall be entitled (but not obliged) to have such Non-Elan Development Product manufactured elsewhere.

10.4. In the event that Elan agrees to and is able to manufacture such Non-Elan Development Product:

10.4.1. Elan and Acorda shall negotiate in good faith the terms and conditions of, and enter into, a supply agreement consistent with this Clause 10 and otherwise with (a) non-financial terms similar to those contained in the Supply Agreement, to the extent feasible, and (b) the financial terms set out in Clause 7.2.2 **("Non-Elan Development Product Supply Agreement");** and

10.4.2. Elan shall and Acorda shall procure that the Non-Elan Developer negotiates in good faith a technology transfer agreement and plan for the purposes of enabling Elan to manufacture the Non-Elan Development Product. Each party shall be responsible for its own costs of all such activities and Acorda shall be responsible for any costs or expenses that may be invoiced by the Non-Elan Developer. Acorda shall be responsible at its own cost for

obtaining for Elan all intellectual property rights and licenses required to undertake such manufacture.

10.5. Elan shall maintain the right to protect and control any confidential or proprietary data of Elan as set forth in the License Agreement or any applicable confidentiality or other agreement which may be entered into by Elan.

11. **Term and Termination**

11.1. This Agreement shall commence on the Effective Date and shall continue in force until the expiry or termination of the License Agreement, howsoever arising, unless terminated earlier as set forth herein. In the event that any of the terms or provisions hereof are incurably breached by either Party, the non-breaching Party may immediately terminate this Agreement by written notice. In the event of any other breach, the non-breaching Party may terminate this Agreement by the giving of written notice to the breaching Party that this Agreement will terminate on the sixtieth (60th) day from notice unless cure is sooner effected. If the breaching Party has proposed a course of action to rectify the breach and is acting in good faith to rectify same but has not cured the breach by the sixtieth (60th) day, the said period shall be extended, at the sole discretion of the non- breaching party, by such period as is reasonably necessary to permit the breach to be rectified.

11.2. For the avoidance of doubt, termination of this Agreement pursuant to Clause 11.3 or 11.1 shall not of itself result in termination of the License Agreement or the Supply Agreement.

11.3. Upon Acorda's notice to Elan of a Non-Elan Party Election, Elan's and Acorda's obligations in respect of those Work Plans concerning the Development Product not selected shall automatically terminate, subject to Clause 11.4 below.

11.4. Upon expiry or termination of this Agreement or upon the termination of obligations in respect of specific Work Plans, Elan shall provide Acorda with a timely estimate of any wind down costs and Acorda shall be responsible for:

11.4.1. payment in full for all work conducted by Elan under this Agreement (and authorized under the Further Development Plan and/or, as applicable, the specific Work Plans) up to the effective date of termination and the wind down costs of all terminated Work Plan and Further Development Plan activities; and

11.4.2. all uncancellable out of pocket costs reasonably incurred or committed prior to the effective date of termination by Elan in contemplation of the applicable Work Plan(s) and/or terminated Further Development Plan.

11.5. Clause 8 shall remain in force until expiry or termination of the License Agreement and Clause 3.7 shall remain in force indefinitely.

11.6. On a country by country basis, in respect of the Development Product, the following provisions shall continue in force until the latest of the following dates (the **"Development Product End Date")**:

(a) ten (10) years starting from the date of First Commercial Sale of the Development Product in that country;

(b) the expiry of the last to expire patent or patent application included in the Elan Patent Rights in that country;

(c) the date on which no Elan Know-How remains capable of enforcement against third parties;

(d) the loss of regulatory exclusivity in respect of the Development Product in that country; and

(e) the existence of Competition in that country.

the said surviving provisions being: (i) Acorda's obligations under Sections 5.3, 5.5, 5.6 and 5.9 of the License Agreement; (ii) Acorda's obligations under the Rush Payments Agreement; (iii) the equivalent provisions in the applicable Development Product Supply Agreements to Clause 9.5 of the Supply Agreement, as if that provision referred to any Development Product purchased up to and including the Development Product End Date otherwise than pursuant to such Development Product Supply Agreement; and (iv) Clauses 4, 7.2 to 7.4 inclusive,10, 13,14 and 15 of this Agreement.

11.7. On a country by country basis, in respect of the Non-Elan Development Product selected for commercialisation, the provisions referred to below shall continue in force until the latest of the following dates (the **"Non-Elan Product End Date")**:

(a) ten (10) years starting from the date of First Commercial Sale (as said term is defined in the License Agreement but in reference to Non-Elan Development Product rather the Product) of that Non-Elan Development Product in that country;

(b) the expiry of the last to expire patent or patent application covering such Non-Elan Development Product which Acorda or any Affiliate or Designee owns, licenses or controls;

(c) the date on which no knowledge, information, trade secrets, data or expertise covering such Non-Elan Development Product which Acorda or any Affiliate or Designee owns, licenses or controls remains capable of enforcement against third parties;

(d) the loss of regulatory exclusivity in respect of such Non-Elan Development Product in that country; and

(e) the existence of Competition in that country.

the said surviving provisions being Clauses 4, 7.2 to 7.4 inclusive, 10, 13, 14 and 15 of this Agreement.

11.8. Acorda and its Affiliates will not directly or indirectly market as a prescription medicine any other sustained release oral dosage form or transdermal form, containing the Compound or any other mono- or di-aminorpyridine active agent, other than Product (including a Development Product), or the one Non-Elan Development Product (if any) selected for commercialisation, during the period in which Acorda has an obligation to make payments to Elan under this Agreement and for one year thereafter. The foregoing shall be in addition to the restrictions contained in Section 2.2 of the License Agreement, but for the purposes of that Section such selected Non-Elan Development Product shall not be considered an "Acorda Competing Product". For the avoidance of doubt this Clause 11.8 shall survive termination of this Agreement.

12. **Warranties**

Elan and Acorda each represent and warrant to the other that:

12.1. it has the right to enter into this Agreement and perform its obligations under it;

12.2. there are no agreements between that party and any third party that conflict or may conflict with this Agreement; and

12.3. it does not require any consents from any third party to enter into and/or perform its obligations under this Agreement, including in the case of Acorda, from its sub-licensee.

13. **Confidentiality**

The provisions of Section 12.1 of the License Agreement shall apply to information disclosed between the parties for the purposes of this Agreement, including the terms of this Agreement, as if set out in full.

14. **Assignment**

14.1. Either party may assign this Agreement to any person or entity to whom it could properly assign its rights and obligations under the License Agreement.

14.2. Except as set out above, neither party may assign this Agreement without the prior written consent of the other party.

15. **General**

15.1. Limitation of Liability. UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF CLAUSE 13 OF THIS AGREEMENT (ARTICLE 12.1 OF THE LICENSE AGREEMENT) OR AS MAY BE EXPRESSLY SET FORTH IN THE DEVELOPMENT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT, AS APPLICABLE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS PROFITS, LOSS OF DATA, LOSS OF REVENUE OR LOSS OF USE DAMAGES, ARISING FROM OR RELATING TO THIS AGREEMENT OR THE DEVELOPMENT PRODUCT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS CLAUSE 15.1 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT, THE DEVELOPMENT PRODUCT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT.

15.2. Method of Calculation of Payments. The parties acknowledge and agree that the methods for calculating the royalties, fees, supply prices, compensating payments and other payments under this Agreement and under the license Agreement (as interpreted in accordance with this Agreement Supply Agreement, Development Product Supply Agreement (if any) and Non-Elan Development Product Supply Agreement (if any are for the convenience of the parties, are freely chosen and not coerced.

15.3. Parties Bound: This Agreement shall be binding upon and run for the benefit of the parties, their successors and permitted assigns.

15.4. Relationship of the Parties: In this Agreement, nothing shall be deemed to constitute a partnership between the parties or make either party an agent for the other, for any purpose whatsoever.

15.5. Entire Agreement: Without prejudice to the license Agreement and Supply Agreement and any other agreements incorporated by reference therein, this Agreement constitutes the entire agreement and understanding between the parties with respect to its subject matter. Except as expressly provided, this Agreement supersedes all prior representations, writings, negotiations or understandings with respect to that subject matter. The parties acknowledge that, in entering into this Agreement, they have not relied on, and shall have no right or remedy in respect of, any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set forth in this Agreement. Nothing in this clause shall limit or exclude any liability for fraud.

15.6. Severability: If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void

or unenforceable under applicable laws, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable, or if it cannot be so amended without materially altering the intention of the parties, it will be deleted, but the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way

15.7. Further Assurance: Each party shall do and execute, or arrange for the doing and executing of, each necessary act, document and thing reasonably within its power to implement this Agreement.

15.8. Counterparts: This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

15.9. Waivers: A failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies. No single or partial exercise of a right or remedy provided by this Agreement or by law prevents further exercise of the right or remedy or the exercise of another right or remedy.

15.10. Variations. No modification, amendment, or waiver of any provision of this Agreement shall be valid unless in writing and signed by a duly authorised officer or representative of each of the parties hereto.

15.11. Notices:

15.11.1. Elan and Acorda hereby acknowledge that pursuant to Section 12.12.1 of the license Agreement, the following addresses, fax numbers and contact names shall apply in lieu or those originally stated therein:

(a) in the case of Elan (which constitutes notice):

Address: Elan Pharma International limited
Monksland
Athlone, Co. Westmeath, Ireland
Fax:+(353) 9064 95402
Marked for the attention of: Vice President and General Counsel with a copy (receipt of which shall not constitute notice) to:

Address: Elan Pharma International limited
Treasury Building
Grand Canal Street Lower
Dublin 2, Ireland
Fax:+(353) 1709 4700
Marked for the attention of: Vice President, Commercial Management

(b) in the case of Acorda (which constitutes notice):

Address: Acorda Therapeutics, Inc
15 Skyline Drive
Hawthorne, New York 10532

Fax:(914) 347-4560
Marked for the attention of: Ron Cohen, President and Chief Executive Officer with a copy (receipt of which shall not constitute notice) to the attention of:
General Counsel, at the same address

15.11.2. Subject to those changes, Section 12.12 of the License Agreement shall apply to any notice required under this Agreement as if set out in full.

15.12. Governing Law and Arbitration: This Agreement is construed under and ruled by the laws of the State of New York, excluding its conflict of laws rules. For the purpose of this Agreement, the Parties submit to the jurisdiction of the United States District Court for the State of New York. Section 12.14 of the License Agreement (arbitration) is hereby incorporated as if it were set out at length herein and is applicable to Non-Elan Development Product as provided herein, and reading references in that Clause to Article 10 of the License Agreement (Committee) as interpreted in accordance with this Agreement.

***

Signatures begin on next page

EXECUTED by the parties on the date appearing at the top of page 1.
SIGNED

/s/ William F. Daniel

Duly authorised for and on behalf of

ELAN PHARMA INTERNATIONAL LIMITED
SIGNED

/s/ Ron Cohen

Duly authorised for and on behalf of

ACORDA THERAPEUTICS, INC.

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 25, 2023

/s/ Richard F. Pops

Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Iain M. Brown, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 25, 2023

/s/ Iain M. Brown

Iain M. Brown

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Alkermes plc (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Richard F. Pops, Chairman and Chief Executive Officer of the Company, and Iain M. Brown, Senior Vice President, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 25, 2023

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: October 25, 2023

/s/ Iain M. Brown
Iain M. Brown

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