UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 April 21, 2023 was 166,121,384 shares.

ALKERMES PLC AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023

Cautionary Note Concerning Forward-Looking Statements

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

- our expectations regarding our financial performance, including revenues, expenses, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including expectations related to product development; regulatory filings, approvals and timelines; therapeutic and commercial value, scope and potential; and the costs and expenses related to such activities and expectations;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive, payer, legislative, regulatory and policy landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and development programs; barriers to access or coverage of our products and potential changes in reimbursement of our products; and legislation, regulations, executive orders, guidance or other measures that may impact pricing and reimbursement of, and access to, our products;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding collaborations, licensing arrangements and other significant agreements with third parties relating to our products and our development programs;
- our expectations regarding the impact of new legislation, rules and regulations and the adoption of new accounting pronouncements;
- our expectations regarding near-term changes in the nature of our market risk exposures or in our management's objectives and strategies with respect to managing such exposures;
- our expectations regarding our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;
- our expectations regarding future capital requirements and expenditures for our operations and our ability to finance such capital requirements and expenditures;
- our expectations regarding the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our products and intellectual property ("IP"), including our patents;
- our expectations regarding the impact of the ongoing novel coronavirus ("COVID-19") pandemic on our business and operations;
- our expectations regarding the potential separation of our neuroscience business and 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 (our "Annual Report") and "Part II, Item 1A—Risk Factors" in this Form 10-Q.

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

Note Regarding Company and Product References

Alkermes plc is a fully-integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for 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: 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)

	March 31, 2023	December 31, 2022
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$321,401	$292,473
Investments—short-term	279,058	315,992
Receivables, net	269,178	287,967
Inventory	184,984	181,418
Contract assets	8,429	8,929
Prepaid expenses and other current assets	47,008	43,527
Total current assets	1,110,058	1,130,306
PROPERTY, PLANT AND EQUIPMENT, NET	321,109	325,361
DEFERRED TAX ASSETS	151,232	115,602
RIGHT-OF-USE ASSETS	111,586	115,855
INVESTMENTS—LONG-TERM	92,083	131,610
GOODWILL	92,873	92,873
INTANGIBLE ASSETS, NET	28,880	37,680
OTHER ASSETS	14,906	14,691
TOTAL ASSETS	$1,922,727	$1,963,978
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$190,149	$220,089
Accrued sales discounts, allowances and reserves	282,264	252,115
Operating lease liabilities—short-term	15,304	15,722
Contract liabilities—short-term	2,193	6,816
Current portion of long-term debt	3,000	3,000
Total current liabilities	492,910	497,742
LONG-TERM DEBT	289,635	290,270
OPERATING LEASE LIABILITIES—LONG-TERM	86,112	89,829
OTHER LONG-TERM LIABILITIES	48,494	42,384
Total liabilities	917,151	920,225
COMMITMENTS AND CONTINGENT LIABILITIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 171,518,796 and 168,951,193 shares issued; 166,058,960 and 164,377,009 shares outstanding at March 31, 2023 and December 31, 2022, respectively	1,715	1,690
Treasury shares, at cost (5,459,836 and 4,574,184 shares at March 31, 2023 and December 31, 2022, respectively)	(185,606)	(160,862)
Additional paid-in capital	2,938,726	2,913,099
Accumulated other comprehensive loss	(8,129)	(10,889)
Accumulated deficit	(1,741,130)	(1,699,285)
Total shareholders' equity	1,005,576	1,043,753
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,922,727	$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 LOSS
(unaudited)

	Three Months Ended March 31,	
	2023	2022
	(In thousands, except per share amounts)	
REVENUES:		
Product sales, net	$ 214,727	$ 171,268
Manufacturing and royalty revenues	72,862	105,170
License revenue	—	2,000
Research and development revenue	6	107
Total revenues	287,595	278,545
EXPENSES:		
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	58,175	55,159
Research and development	93,637	95,953
Selling, general and administrative	174,477	145,052
Amortization of acquired intangible assets	8,800	8,966
Total expenses	335,089	305,130
OPERATING LOSS	(47,494)	(26,585)
OTHER EXPENSE, NET:		
Interest income	4,966	573
Interest expense	(5,288)	(2,350)
Change in the fair value of contingent consideration	—	(19,067)
Other (expense) income, net	(39)	2,431
Total other expense, net	(361)	(18,413)
LOSS BEFORE INCOME TAXES	(47,855)	(44,998)
INCOME TAX BENEFIT	(6,010)	(9,095)
NET LOSS	$ (41,845)	$ (35,903)
LOSS PER ORDINARY SHARE:		
Basic and diluted	$ (0.25)	$ (0.22)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:		
Basic and diluted	165,085	162,483
COMPREHENSIVE LOSS:		
Net loss	$ (41,845)	$ (35,903)
Holding gain (loss), net of a tax provision (benefit) of $488 and $(1,382), respectively	2,760	(4,511)
COMPREHENSIVE LOSS	$ (39,085)	$ (40,414)

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

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

	Three Months Ended March 31,	
	2023	2022
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (41,845)	$ (35,903)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	18,714	19,197
Share-based compensation expense	22,643	18,343
Deferred income taxes	(36,117)	(29,301)
Change in the fair value of contingent consideration	—	19,067
Other non-cash charges	369	371
Changes in assets and liabilities:		
Receivables	18,789	63,290
Contract assets	500	(6,849)
Inventory	(2,029)	(4,285)
Prepaid expenses and other assets	(3,697)	(15,351)
Right-of-use assets	4,269	4,129
Accounts payable and accrued expenses	(30,154)	(33,414)
Accrued sales discounts, allowances and reserves	30,148	27,956
Contract liabilities	(4,287)	(2,980)
Operating lease liabilities	(4,379)	(4,411)
Other long-term liabilities	5,774	1,819
Cash flows (used in) provided by operating activities	(21,302)	21,678
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of property, plant and equipment	(6,860)	(7,791)
Proceeds from the sale of equipment	—	—
Proceeds from contingent consideration	—	501
Return of Fountain Healthcare Partners II, L.P. investment	—	485
Purchases of investments	(23,898)	(114,615)
Sales and maturities of investments	103,608	60,779
Cash flows provided by (used in) investing activities	72,850	(60,641)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	2,874	1,795
Employee taxes paid related to net share settlement of equity awards	(24,744)	(17,069)
Principal payments of long-term debt	(750)	(750)
Cash flows used in financing activities	(22,620)	(16,024)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	28,928	(54,987)
CASH AND CASH EQUIVALENTS—Beginning of period	292,473	337,544
CASH AND CASH EQUIVALENTS—End of period	$ 321,401	$ 282,557
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 1,762	$ 4,058

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 gains 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

	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

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.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company for the three months ended March 31, 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, contingent consideration and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different conditions or using different assumptions.

Segment Information

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

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board 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 months ended March 31, 2023 and 2022, the Company recorded product sales, net, as follows:

	Three Months Ended March 31,	
(In thousands)	**2023**	**2022**
VIVITROL	$ 96,659	$ 84,854
ARISTADA and ARISTADA INITIO	80,077	72,485
LYBALVI	37,991	13,929
Total product sales, net	$ 214,727	$ 171,268

Manufacturing and Royalty Revenues

During the three months ended March 31, 2023 and 2022, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

	Three Months Ended March 31, 2023		
(In thousands)	**Manufacturing Revenue**	**Royalty Revenue**	**Total**
Long-acting INVEGA products(1)	$ —	$ 13,562	$ 13,562
VUMERITY	12,649	16,225	28,874
RISPERDAL CONSTA	10,416	566	10,982
Other	15,375	4,069	19,444
	$ 38,440	$ 34,422	$ 72,862

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

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

In November 2021, the Company received notice of partial termination 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 INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen Pharmaceutica ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. Accordingly, the Company has not recognized royalty revenue related to U.S. sales of these products since 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 December 21, 2022, the Company received an interim award (the "Initial Interim Award") in these proceedings from the arbitral tribunal (the "Tribunal"), in which the Tribunal agreed with the Company's position that, while Janssen Pharmaceutica may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the terms of the agreement. On April 19, 2023, the Company received a second interim award (the "Second Interim Award") from the Tribunal. Pursuant to the Second Interim Award, back royalties related to fiscal year 2022 and interest are due to the Company under the license agreement and a separate Know-How Royalty (as defined in the license agreement) term applies for each of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, as follows: (i) the term for INVEGA SUSTENNA ends on August 20, 2024, (ii) the term for INVEGA TRINZA ends in the second quarter of 2030 (but no later than May 2030 when the license agreement expires), and (iii) the term for INVEGA HAFYERA ends in May 2030 (when the license agreement expires. The Tribunal directed the parties to confer and advise within 21 days concerning the rate of interest and proposed further proceedings, including whether any issues remain for resolution by the Tribunal prior to the Tribunal's issuance of a final award. Refer to Note 14, *Commitments and Contingencies* within the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for additional information regarding the arbitration proceedings with Janssen Pharmaceutica.

Contract Assets

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over time. 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 March 31, 2023 were as follows:

(In thousands)	Contract Assets
Contract assets at December 31, 2022	$ 8,929
Additions	10,115
Transferred to receivables, net	(10,615)
Contract assets at March 31, 2023	$ 8,429

Contract Liabilities

Contract liabilities consist of contractual obligations related to deferred revenue. At March 31, 2023 and December 31, 2022, $2.2 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 $4.2 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 March 31, 2023 were as follows:

(In thousands)	Contract Liabilities
Contract liabilities at December 31, 2022	$ 10,701
Additions	(934)
Amounts recognized into revenue	(3,354)
Contract liabilities at March 31, 2023	$ 6,413

4. INVESTMENTS

Investments consisted of the following (in thousands):

March 31, 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:					
Corporate debt securities	$ 125,254	$ 129	$ (114)	$ (1,683)	$ 123,586
U.S. government and agency debt securities	135,633	39	(87)	(1,103)	134,482
Non-U.S. government debt securities	21,444	—	—	(454)	20,990
Total short-term investments	282,331	168	(201)	(3,240)	279,058
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	47,232	—	(664)	(703)	45,865
U.S. government and agency debt securities	45,859	—	(415)	(1,046)	44,398
	93,091	—	(1,079)	(1,749)	90,263
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	94,911	—	(1,079)	(1,749)	92,083
Total investments	$ 377,242	$ 168	$ (1,280)	$ (4,989)	$ 371,141

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 March 31, 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 March 31, 2023, 207 of the Company's 239 investment securities were in an unrealized loss position and had an aggregate estimated fair value of $371.1 million. Approximately 46% and 48% of the Company's investment securities at March 31, 2023 are 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. In a rising interest rate environment, the Company expects its fixed-rate investment securities will carry unrealized losses. In making the determination whether the decline in fair value of these securities was other-than-temporary, the Company evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis. The Company has the intent and ability to hold these investments until recovery, which may be at maturity.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. As of March 31, 2023, the Company's total contribution in Fountain was equal to €7.4 million, and its commitment

represented approximately 7% of the partnership's total funding. The Company's net investment in Fountain was $7.9 million at March 31, 2023 and December 31, 2022, respectively, and was included within "Other assets" in the accompanying condensed consolidated balance sheets. During the three months ended March 31, 2023 and 2022, the Company recorded a decrease of $0.2 million and an increase of less than $0.1 million in its investment in Fountain, which represented the Company's proportional share of Fountain's net (losses) gains for the period. The Company is accounting for its investment in Fountain under the equity method.

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

	Three Months Ended March 31,	
(In thousands)	2023	2022
Proceeds from the sales and maturities of investments	$ 103,608	$ 60,779
Realized gains	$ —	$ —
Realized losses	$ —	$ —

The Company's available-for-sale and held-to-maturity securities at March 31, 2023 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$ 272,122	$ 268,811	$ 1,820	$ 1,820
After 1 year through 5 years	103,300	100,510	—	—
Total	$ 375,422	$ 369,321	$ 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)	March 31, 2023	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	$ 178,880	$ 149,681	$ 29,199	$ —
Corporate debt securities	169,451	—	169,451	—
Non-U.S. government debt securities	20,990	—	20,990	—
Total	$ 369,321	$ 149,681	$ 219,640	$ —

	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 three months ended March 31, 2023. At March 31, 2023, the Company had no investments whose fair value was 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 March 31, 2022, Baudax had only paid $0.5 million of the $6.4 million that was due to the Company in March 2022, the Company recorded a reduction in the fair value of the contingent consideration of $19.1 million within "Change in the fair value of contingent consideration" in the accompanying condensed consolidated statements of operations and comprehensive loss in the three months ended March 31, 2022. In September 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. In December 2022, Baudax announced that it would discontinue sales of ANJESO, the first approved Meloxicam Product, and on December 28, 2022, 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 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 $281.5 million and $278.9 million at March 31, 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)	March 31, 2023	December 31, 2022
Raw materials	$ 59,045	$ 61,064
Work in process	74,661	76,228
Finished goods(1)	51,278	44,126
Total inventory	$ 184,984	$ 181,418

(1) At March 31, 2023 and December 31, 2022, the Company had $32.6 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)	March 31, 2023	December 31, 2022
Land	$ 6,560	$ 6,560
Building and improvements	195,602	195,144
Furniture, fixtures and equipment	423,835	418,448
Leasehold improvements	52,820	54,152
Construction in progress	85,852	84,715
Subtotal	764,669	759,019
Less: accumulated depreciation and amortization	(443,560)	(433,658)
Total property, plant and equipment, net	$ 321,109	$ 325,361

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consisted of the following:

		March 31, 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	$ (443,255)	$ 22,335
Capitalized IP	11-13	118,160	(111,615)	6,545
Total		$ 583,750	$ (554,870)	$ 28,880

Based on the Company's most recent analysis, amortization of intangible assets included in the accompanying condensed consolidated balance sheet at March 31, 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 the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

9. LEASES

Future lease payments under non-cancelable leases at March 31, 2023 and December 31, 2022 consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
2023	$ 12,306	$ 16,665
2024	16,627	16,608
2025	16,874	16,855
2026	12,786	12,767
2027	9,506	9,506
Thereafter	69,474	69,474
Total operating lease payments	$ 137,573	$ 141,875
Less: imputed interest	(36,157)	(36,324)
Total operating lease liabilities	$ 101,416	$ 105,551

At March 31, 2023, the weighted average incremental borrowing rate and the weighted average remaining lease term for all operating leases held by the Company were 5.27% and 8.53 years, respectively. Cash paid for lease liabilities was $4.4 million during each of the three months ended March 31, 2023 and 2022. The Company recorded operating lease expense of $4.3 million and $4.1 million during the three months ended March 31, 2023 and 2022, respectively.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
Accounts payable	$ 37,147	$ 32,843
Accrued compensation	47,700	79,085
Accrued other	105,302	108,161
Total accounts payable and accrued expenses	$ 190,149	$ 220,089

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

(In thousands)	March 31, 2023	December 31, 2022
Medicaid rebates	$ 234,685	$ 208,332
Product discounts	15,397	13,204
Medicare Part D	21,337	18,409
Other	10,845	12,170
Total accrued sales discounts, allowances and reserves	$ 282,264	$ 252,115

11. LONG-TERM DEBT

Long-term debt consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
2026 Term Loans, due March 12, 2026	$ 292,635	$ 293,270
Less: current portion	(3,000)	(3,000)
Long-term debt	$ 289,635	$ 290,270

The 2026 Term Loans mature on March 12, 2026 and bear interest payable at LIBOR plus 2.50% with a LIBOR floor of 0.5%. The 2026 Term Loans include customary Alternative Reference Rate Committee hardwired benchmark replacement language to transition from LIBOR to the Secured Overnight Financing Rate ("SOFR"). The 2026 Term Loans have an incremental facility capacity in the amount of $175.0 million plus additional amounts, provided that the Company meets certain conditions, including a specified leverage ratio. The Company was in compliance with its debt covenants at March 31, 2023.

12. SHARE-BASED COMPENSATION

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

	Three Months Ended March 31,	
(In thousands)	2023	2022
Cost of goods manufactured and sold	$ 2,682	$ 2,382
Research and development	6,907	5,608
Selling, general and administrative	13,054	10,353
Total share-based compensation expense	$ 22,643	$ 18,343

At March 31, 2023 and December 31, 2022, $3.4 million and $3.3 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying condensed consolidated balance sheets.

13. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the three months ended March 31, 2023 and 2022, as the Company was in a net loss position, the diluted loss per share calculation did not assume conversion or exercise of stock options and restricted stock unit awards, as they would have had an anti-dilutive effect on loss per share.

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

	Three Months Ended March 31,	
(In thousands)	2023	2022
Stock options	13,007	13,461
Restricted stock unit awards	6,093	5,959
Total	19,100	19,420

14. COMMITMENTS AND CONTINGENT LIABILITIES

Litigation

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates, utilizing all available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At March 31, 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. The request for arbitration seeks, among other remedies, a declaration that Janssen Pharmaceutica is in breach of the license agreements and a resumption of royalty payments for sales of the relevant products in the U.S. In December 2022, the Company received the Initial Interim Award in these proceedings from the Tribunal. In the Initial Interim Award, the Tribunal agreed with the Company's position that, while Janssen Pharmaceutica may terminate the agreements, it may not continue to sell Products (as defined in the agreements) developed during the term of the agreements without paying royalties pursuant to the terms of the respective agreements. On April 19, 2023, the Company received the Second Interim Award from the Tribunal. Pursuant to the Second Interim Award, back royalties related to fiscal year 2022 of approximately $194.0 million (inclusive of interest) are due to the Company under the two agreements; a separate Know-How Royalty (as defined in the applicable license agreement) term applies for each of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, as follows: (i) the term for INVEGA SUSTENNA ends on August 20, 2024, (ii) the term for INVEGA TRINZA ends in the second quarter of 2030 (but no later than May 2030 when the applicable license agreement expires), and (iii) the term for INVEGA HAFYERA ends in May 2030 (when the applicable license agreement expires); and royalties for CABENUVA in the United States are owed until December 31, 2036. The Tribunal directed the parties to confer and advise within 21 days concerning the rate of interest and proposed further proceedings, including whether any issues remain for resolution by the Tribunal prior to the Tribunal's issuance of a final award. The arbitration is being conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration.

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 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 has been scheduled in the Tolmar Lawsuit for 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. Requested judicial remedies include recovery of litigation costs and injunctive relief. A bench trial concluded in December 2022. The Company is not a party to this proceeding.

VIVITROL ANDA Litigation

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

A bench trial was held in February 2023, and the Company anticipates a decision in the second half of 2023. The Company intends to continue to vigorously defend its IP.

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, on January 10, 2023, Acorda Therapeutics, Inc. filed a petition with the U.S. District Court for the Southern District of New York 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. The Company believes the petition is without merit and filed opposition papers asking the court to deny the petition and confirm the final arbitration award unchanged. 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 loss was $41.8 million or $0.25 per ordinary share—basic and diluted for the three months ended March 31, 2023, as compared to a net loss of $35.9 million or $0.22 per ordinary share—basic and diluted for the three months ended March 31, 2022.

The increase in net loss was primarily due to an increase in our operating expenses of $30.0 million, partially offset by a decrease in other expense, net of $18.1 million and an increase in revenues of $9.1 million. The increase in operating expenses was primarily due to an increase of $29.4 million in selling, general and administrative expense. The decrease in other expense, net was primarily due to the change in the fair value of contingent consideration. The increase in revenues was primarily due to an increase in product sales, net of $43.5 million, partially offset by a decrease in manufacturing and royalty revenues of $32.3 million.

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

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, and may continue to be, adversely impacted to varying degrees as a result of COVID-19 related closures, restrictions, labor shortages and other disruptions that have transpired, and may continue to transpire, while the pandemic persists.

The COVID-19 pandemic has caused, and may continue to cause, varying degrees of disruption to our employees and our business operations. While we have continued to operate our manufacturing facilities and supply our medicines throughout the pandemic, we have at times during the pandemic experienced labor or supply chain disruptions at our manufacturing facilities and may continue to experience such disruptions while the pandemic persists, which could impact our ability to manufacture our products and the third-party products from which we receive revenue in a timely manner or at all. In addition, while we have continued to conduct R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. We work with our internal teams, our clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on our manufacturing operations and R&D activities.

The degree to which the COVID-19 pandemic may continue to impact our employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new COVID-19 variants, and future developments in response thereto. 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 this Annual Report and specifically the section entitled "Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the ongoing COVID-19 pandemic or other similar outbreaks of contagious diseases."

Products

Marketed Products

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

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

Proprietary Products

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

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

Key Third-Party Products Using Our Proprietary Technologies

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

* Janssen partially terminated its license agreement related to these products, effective February 2022. See the section entitled "Products Using Our Proprietary Technologies" below and Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for more information with respect to this partial termination and the arbitration proceedings related to this partial termination and other matters in respect of these products.

Our Key Licensed Product

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

Proprietary Products

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

ARISTADA

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

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.

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 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the sections entitled "Patent and other IP protection for our products is key to our business and our competitive position but is uncertain," "Uncertainty over IP in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or negatively impact commercialization of our products, and could adversely affect our business" and "Litigation or arbitration filed against Alkermes, including securities litigation, or actions (such as citizens petitions) filed against regulatory agencies in respect of our products, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

Licensed Products and Products Using Our Proprietary Technologies

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

Products Using Our Proprietary Technologies

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

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 information about the arbitration proceedings related to the Long-acting INVEGA Products, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q and for information about risks relating to the partial termination of the exclusive license agreement with Janssen related to the Long-acting INVEGA Products and our collaborative arrangements more broadly, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically that section entitled "We rely heavily on our licensees in the commercialization and continued development of products from which we receive revenue and, if our licensees are not effective, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected." For a discussion of legal proceedings related to certain of the patents covering INVEGA SUSTENNA and INVEGA TRINZA, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

RISPERDAL CONSTA

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

Licensed Product

VUMERITY

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

Under our license and collaboration agreement with Biogen, Biogen holds the exclusive, worldwide license to develop and commercialize VUMERITY. For more information about the license and collaboration agreement with Biogen, see the "Collaborative Arrangements—Biogen" section in "Part I, Item 1—Business" in our Annual Report.

Key Development Program

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

Nemvaleukin alfa

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

ARTISTRY is our clinical development program evaluating nemvaleukin as a potential immunotherapy for cancer. The ARTISTRY program is comprised of multiple clinical trials evaluating intravenous ("IV") and subcutaneous ("SC") dosing of nemvaleukin, both as a monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with advanced solid tumors. ARTISTRY-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 Regulator Agency ("MHRA"), the regulatory body of the United Kingdom, granted nemvaleukin an Innovation Passport for the treatment of mucosal melanoma under the Innovative Licensing and Access Pathway ("ILAP").

Results of Operations

Product Sales, Net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO and, following its commercial launch in the U.S. in October 2021, LYBALVI, primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net, for sales of VIVITROL, ARISTADA, ARISTADA INITIO and LYBALVI during the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,			
(In millions, except for % of Sales)	**2023**	**% of Sales**	**2022**	**% of Sales**
Product sales, gross	$ 433.9	100.0 %	$ 342.4	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(97.9)	(22.6) %	(76.5)	(22.3) %
Chargebacks	(45.6)	(10.5) %	(33.8)	(9.9) %
Product discounts	(34.3)	(7.9) %	(26.9)	(7.9) %
Medicare Part D	(18.9)	(4.4) %	(16.0)	(4.7) %
Other	(22.5)	(5.1) %	(17.9)	(5.2) %
Total adjustments	(219.2)	(50.5) %	(171.1)	(50.0) %
Product sales, net	$ 214.7	49.5 %	$ 171.3	50.0 %

The following table compares product sales, net earned during the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		
(In millions)	**2023**	**2022**	**Change**
VIVITROL	$ 96.7	$ 84.9	$ 11.8
ARISTADA and ARISTADA INITIO	80.1	72.5	7.6
LYBALVI	37.9	13.9	24.0
Product sales, net	$ 214.7	$ 171.3	$ 43.4

VIVITROL product sales, gross, increased by 22% primarily due to an increase of 9% in the number of VIVITROL units sold and increases of 6% in the selling price of VIVITROL that went into effect in each of January 2023 and April 2022. ARISTADA and ARISTADA INITIO product sales, gross, increased by 14% primarily due to a 9% increase in the number of ARISTADA and ARISTADA INITIO units sold and increases of 3% in the selling price of ARISTADA and ARISTADA INITIO that went into effect in each of January 2023 and April 2022. LYBALVI product sales, gross, increased by 170%, which was due to a 183% increase in the number of LYBALVI units sold and a 6% increase in the selling price of LYBALVI that went into effect in November 2022.

Manufacturing and Royalty Revenues

The following table compares manufacturing and royalty revenues earned during the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		
(In millions)	**2023**	**2022**	**Change**
Manufacturing and royalty revenues:			
Long-acting INVEGA products	$ 13.6	$ 37.1	$ (23.5)
VUMERITY	28.9	30.6	(1.7)
RISPERDAL CONSTA	11.0	17.4	(6.4)
Other	19.4	20.1	(0.7)
Manufacturing and royalty revenues	$ 72.9	$ 105.2	$ (32.3)

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 INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. 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 in the U.S. Accordingly, we have not recognized royalty revenue related to U.S. sales of these products since 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 December 2022, we received the Initial Interim Award for these proceedings from the Tribunal, in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the term of the agreement. On April 19, 2023, we received the Second Interim Award from the Tribunal. Pursuant to the Second Interim Award, back royalties related to fiscal year 2022 and interest are due to us under this license agreement and a separate Know-How Royalty (as defined in the applicable license agreement) term applies for each of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, as follows: (i) the term for INVEGA SUSTENNA ends on August 20, 2024, (ii) the term for INVEGA TRINZA ends in the second quarter of 2030 (but no later than May 2030 when the applicable license agreement expires), and (iii) the term for INVEGA HAFYERA ends in May 2030 (when the applicable license agreement expires). The Tribunal directed the parties to confer and advise within 21 days concerning the rate of interest and proposed further proceedings, including whether any issues remain for resolution by the Tribunal prior to the Tribunal's issuance of a final award. For additional information regarding the arbitration proceedings with Janssen, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q. For information about risks relating to the notice of partial termination and our collaborative arrangements more broadly, see "Part I, Item 1A—Risk Factors" in our Annual Report and specifically the section entitled "We rely heavily on our licensees in the commercialization and continued development of products from which we receive revenue and, if our licensees are not effective, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected."

The decrease in royalty revenues from the Long-acting INVEGA products was primarily due to Janssen's partial termination of our license agreement related to such products. During the three months ended March 31, 2023, Janssen's rest of world net sales of XEPLION, TREVICTA and BYANNLI were $331.0 million, as compared to $387.0 million during the three months ended March 31, 2022. We expect royalty revenues from net sales of XEPLION, TREVICTA and BYANNLI to decrease over time. The amount, timing and duration of royalty revenues from sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA depend upon the outcome of our dispute with Janssen related to the impact of its partial termination of our license agreement on its obligations to continue to pay us know-how royalties in accordance with the terms of the agreement.

In addition, each of INVEGA SUSTENNA and INVEGA TRINZA are currently subject to Paragraph IV litigation in response to companies seeking to market generic versions of such products. Increased competition from new products or generic versions of these products may lead to reduced unit sales of such products and increased pricing pressure. For a discussion of these legal proceedings, see Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, and for information about risks relating to these legal proceedings, see "Part I, Item 1A—Risk Factors" in our Annual Report, and specifically the section entitled "We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

We recognize manufacturing revenue for RISPERDAL CONSTA at the point in time when RISPERDAL CONSTA has been fully manufactured, which is deemed to have occurred when the product is approved for shipment by both us and Janssen. We record royalty revenue, equal to 2.5% of Janssen's end-market net sales, in the period that the end-market sales of RISPERDAL CONSTA occur. The decrease in revenue from RISPERDAL CONSTA was primarily due to a decrease of $5.2 million in manufacturing revenue, which was primarily due to a 66% decrease in the average selling price, partially offset by a 17% increase in the number of units approved for shipment to Janssen. We expect revenues from RISPERDAL CONSTA to continue to decrease over time. 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 competition for RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure.

We receive a 15% royalty on worldwide net sales of VUMERITY for product manufactured and packaged by us, subject to increases for VUMERITY manufactured and/or packaged by Biogen or its designees, 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. The decrease in revenue from VUMERITY was primarily due to a $3.0 million decrease in royalty revenue, as net sales of VUMERITY decreased from $128.0 million in the three months ended March 31, 2022 to $108.2 million in the three months ended March 31, 2023.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Three Months Ended March 31,		
(In millions)	**2023**	**2022**	**Change**
Cost of goods manufactured and sold	$ 58.2	$ 55.2	$ 3.0

The increase in cost of goods manufactured and sold was primarily due to increases of $3.9 million and $2.7 million, respectively, in the cost of goods sold for VIVITROL and LYBALVI, due to increases in the number of units manufactured and sold 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 neuroscience business and oncology business.

The following table sets forth our external R&D expenses for the three months ended March 31, 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 March 31, 2023	2022	Change
External R&D expenses:			
Development programs:			
nemvaleukin	$ 17.7	$ 19.5	$ (1.8)
LYBALVI	3.3	5.8	(2.5)
ALKS 2680	1.7	1.4	0.3
Other external R&D expenses	15.6	16.0	(0.4)
Total external R&D expenses	38.3	42.7	(4.4)
Internal R&D expenses:			
Employee-related	42.0	40.1	1.9
Occupancy	4.4	4.2	0.2
Depreciation	2.7	2.8	(0.1)
Other	6.2	6.2	—
Total internal R&D expenses	55.3	53.3	2.0
Research and development expenses	$ 93.6	$ 96.0	$ (2.4)

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 was primarily due to decreased spend on the ARTISTRY-1 study, partially offset by increased spend on the ARTISTRY-7 study. For additional detail on the ARTISTRY development program for nemvaleukin, see the "Key Development Program" section of this "Part I, Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Form 10-Q. The decrease in expenses related to LYBALVI was primarily due to decreased R&D activities for the product in light of its commercial launch in October 2021, partially offset by continued spend on ongoing clinical studies. The increase in employee-related expense was primarily related to an increase in salaries, benefits and temporary labor.

Selling, General and Administrative Expense

(In millions)	Three Months Ended March 31, 2023	2022	Change
Selling and marketing expense	$ 118.5	$ 96.2	$ 22.3
General and administrative expense	56.0	48.9	7.1
Selling, general and administrative expense	$ 174.5	$ 145.1	$ 29.4

The increase in selling and marketing expense was primarily due to an increase of $13.0 million in external marketing expenses, primarily related to activities supporting the commercial launch of LYBALVI and an $8.0 million increase in employee-related expenses, primarily due to a 6% increase in sales and marketing headcount.

The increase in general and administrative expense was primarily due to a $3.9 million increase in employee-related expenses and a $3.3 million increase in professional service fees. The increase in employee-related expenses was primarily due to a $2.0 million increase in share-based compensation expense, due to an increase in the fair value of recent grants as compared to grants made in prior years. The increase in professional service fees was primarily due to increased spend on fees related to the potential separation of our oncology business.

Other Expense, Net

(In millions)	Three Months Ended March 31, 2023	2022	Change
Interest income	$ 5.0	$ 0.6	$ 4.4
Interest expense	(5.3)	(2.4)	(2.9)
Change in the fair value of contingent consideration	—	(19.1)	19.1
Other (expense) income, net	(0.1)	2.5	(2.6)
Total other expense, net	$ (0.4)	$ (18.4)	$ 18.0

The decrease in total other expense, net was primarily due to the change in the fair value of contingent consideration. During the three months ended March 31, 2022, we applied a 100% likelihood that Baudax would default on its obligations and applied a 9% recovery rate to amounts owed to us under the arrangement with Baudax, resulting in a $19.1 million decrease in the fair value of contingent consideration. In the three months ended September 30, 2022, we reduced the remaining fair value under the arrangement to zero and in December 2022, Baudax announced that it would discontinue the sale of ANJESO.

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

Income Tax Benefit

(In millions)	Three Months Ended March 31, 2023	2022	Change
Income tax benefit	$ (6.0)	$ (9.1)	$ 3.1

The income tax benefit in the three months ended March 31, 2023 and 2022 primarily related to an enhanced foreign derived intangible income deduction 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. The decrease in the income tax benefit was primarily due to a decrease in income earned in the U.S.

Liquidity and Financial Condition

Our financial condition is summarized as follows:

(In millions)	March 31, 2023 U.S.	Ireland	Total	December 31, 2022 U.S.	Ireland	Total
Cash and cash equivalents	$ 199.7	$ 121.7	$ 321.4	$ 208.4	$ 84.1	$ 292.5
Investments—short-term	179.8	99.3	279.1	207.6	108.4	316.0
Investments—long-term	45.9	46.1	92.0	70.3	61.3	131.6
Total cash and investments	$ 425.4	$ 267.1	$ 692.5	$ 486.3	$ 253.8	$ 740.1
Outstanding borrowings—short and long-term	$ 292.6	$ —	$ 292.6	$ 293.3	$ —	$ 293.3

At March 31, 2023 our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 282.3	$ 0.2	$ (3.4)	$ —	$ 279.1
Investments—long-term available-for-sale	93.1	—	(2.9)	—	90.2
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 377.2	$ 0.2	$ (6.3)	$ —	$ 371.1

Sources and Uses of Cash

We used $21.3 million and generated $21.7 million of cash from operating activities during the three months ended March 31, 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, corporate debt securities and debt securities issued and backed by non-U.S. governments. Our held-to-maturity investments consist of investments that are held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position that do not mature within twelve months as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At March 31, 2023, we performed an analysis of our investments with unrealized losses for impairment and determined that they were not impaired.

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

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
(In millions)	**2023**	**2022**
Cash and cash equivalents, beginning of period	$ 292.5	$ 337.5
Cash flows (used in) provided by operating activities	(21.3)	21.7
Cash flows provided by (used in) investing activities	72.8	(60.6)
Cash flows used in financing activities	(22.6)	(16.0)
Cash and cash equivalents, end of period	$ 321.4	$ 282.6

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

Operating Activities

Cash flows used in operating activities for the three months ended March 31, 2023 were $21.3 million and primarily consisted of a net loss of $41.8 million adjusted for non-cash items, including share-based compensation of $22.6 million, depreciation and amortization of $18.7 million and changes in working capital of $14.9 million, partially offset by deferred income taxes of $36.1 million.

Cash flows provided by operating activities for the three months ended March 31, 2022 were $21.7 million and primarily consisted of a net loss of $35.9 million, adjusted for non-cash items including share-based compensation of $18.3 million, depreciation and amortization of $19.2 million, change in the fair value of contingent consideration of $19.1 million and changes in working capital of $29.9 million, partially offset by deferred income taxes of $29.3 million.

Investing Activities

Cash flows provided by investing activities for the three months ended March 31, 2023 were primarily due to a $79.7 million increase in net sales of investments, offset by the purchase of $6.9 million of property, plant and equipment. Cash flows used in investing activities for the three months ended March 31, 2022 were primarily due to a $53.8 million increase in net purchase of investments and the purchase of $7.8 million of property, plant and equipment.

Financing Activities

Cash flows used in financing activities for the three months ended March 31, 2023 and 2022 primarily related to $24.7 million and $17.1 million of employee taxes paid related to the net share settlement of equity awards, respectively, partially offset by $2.9 million and $1.8 million of cash that we received upon exercises of employee stock options, respectively.

Debt

At March 31, 2023, the principal balance of our borrowings consisted of $294.0 million outstanding under our 2026 Term Loans. See Note 11, *Long-Term Debt*, in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for further discussion of our 2026 Term Loans.

Critical Accounting Estimates

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

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 March 31, 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 March 31, 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 period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

For information regarding legal proceedings, see the discussion of legal proceedings in Note 14, *Commitments and Contingent Liabilities* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q, which discussion is incorporated into this Part II, Item 1 by reference.

Item 1A. ***Risk Factors***

Risks Related to our Financial Condition and Tax Matters

Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank ("SVB"), and Signature Bank, respectively, after each bank was unable to continue their operations. These events exposed vulnerabilities in the banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market prices of regional bank stocks to plummet.

We do not hold, and do not expect to hold, cash deposits or securities at SVB and have not experienced any adverse impact to our current and projected business operations, financial condition or results of operations as a result of the SVB closure; however, we are unable to predict the extent or nature of the impacts of these evolving circumstances at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that the failure of SVB and Signature Bank or the high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

Although we expect to continue to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, one or more of our critical vendors, third-party manufacturers, or other third parties on which we rely, could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any third-party bankruptcy or insolvency, or any breach or default by a third party on which we rely, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

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

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

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the three months ended March 31, 2023. As of March 31, 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 March 31, 2023, we acquired 885,652 of our ordinary shares, at an average price of $27.94 per share, to satisfy withholding tax obligations related to the vesting of employee equity awards.

Item 5. ***Other Information***

Our policy governing transactions in our securities by our directors, officers and employees permits our directors, officers and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the three months ended March 31, 2023, each of Messrs. David J. Gaffin and C. Todd Nichols, executive officers of the Company, and Shane M. Cooke, Dr. Cato T. Laurencin and Ms. Nancy J. Wysenski, each a director of the Company, entered into a trading plan in accordance with Rule 10b5-1 and our policy governing transactions in our securities by our directors, officers and employees. We undertake no obligation to update or revise the information provided herein, including for any revision or termination of an established trading plan.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1 #*	License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999.
10.2 #*	Agreement Amendment No. 2, dated as of July 31, 2009, to the License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999, as amended by the First Amendment, dated as of July 31, 2003.
31.1 #	Rule 13a-14(a)/15d-14(a) Certification.
31.2 #	Rule 13a-14(a)/15d-14(a) Certification.
32.1 ‡	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.SCH #	Inline XBRL Taxonomy Extension Schema Document.
101.CAL #	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB #	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE #	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF #	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104 #	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

Filed herewith.

‡ Furnished herewith.

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

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

SIGNATURES

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

ALKERMES PLC

(Registrant)

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

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

Date: April 26, 2023

Exhibit 10.1

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

LICENSE AGREEMENT

by and among

ELAN PHARMACEUTICAL RESEARCH CORP.,
d/b/a
NANOSYSTEMS

and

ELAN PHARMA INTERNATIONAL LIMITED

and

JANSSEN PHARMACEUTICA N.V.

March 31, 1999

This document is the confidential information of both parties hereto.
It should be distributed on a need-to-know basis and kept in secure area.

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

TABLE OF CONTENTS

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

This License Agreement is made as of this 31st day of March, 1999 (the "Effective Date") by and among Elan Pharmaceutical Research Corp., a corporation organized and existing under the laws of the State of Georgia and doing business as NanoSystems ("EPRC"), and Elan Pharma International Limited, a corporation organized and existing under the laws of Ireland ("EPIL") (EPRC and EPIL collectively referred to herein as "NANO"), and Janssen Pharmaceutica N.V., a corporation organized and existing under the laws of Belgium ("JANSSEN").

WITNESSETH THAT:

WHEREAS, NANO possesses, among other things, certain proprietary information in connection with a technology for the formulation of crystalline drug substances into pharmaceutically acceptable dosage forms; and

WHEREAS, NANO owns or controls patents and patent applications, as well as know-how with respect to its technology and has the right to grant certain rights and licenses thereunder as set forth herein; and

WHEREAS, JANSSEN possesses proprietary information, as well as patents and patent applications in relation to a proprietary compound developed by it; and

WHEREAS, NANO and JANSSEN wish to engage in a development and license agreement with a view towards developing certain crystalline forms of a proprietary JANSSEN compound utilizing NANO's proprietary technology; and

WHEREAS, NANO is willing to grant such rights and licenses to JANSSEN under the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties to this Agreement mutually agree as follows:

ARTICLE 1 - DEFINITIONS

For purposes of this Agreement, the following capitalized terms in this Agreement shall have the following meanings, unless the context clearly requires otherwise:

1.1 "Affiliate" shall mean, with respect to any party hereto, any corporation, company, partnership, joint venture or any other entity which directly or indirectly controls, is controlled by, or is under common control with such party. For purposes of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors. For the purposes of this Agreement, EPRC and EPIL shall not be considered Affiliates of JANSSEN and JANSSEN shall not be considered an Affiliate of EPRC or EPIL.

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

1.2 "Agreement" shall mean this License Agreement.

1.3 "Analogue" shall mean a structural analogue of Compound falling under the claims of any Janssen Patent, which is developed and commercialized under this Agreement as a substitute for, and for the same indications as, 9 O-H risperidone palmitate (R 92670) or any salt or derivative thereof.

1.4 "Compound" shall mean (i) the active ingredient 9 O-H risperidone palmitate (R 92670), or any salt or derivative thereof, falling under the claims of any Janssen Patent, or (ii) in the event that JANSSEN ceases development of R 92670 prior to commercialization, an Analogue selected by JANSSEN, or (iii) in the event that JANSSEN ceases development of an Analogue prior to commercialization, another Analogue selected by JANSSEN.

1.5 1.5"Competition" shall mean a situation in which one or more Persons in a country are marketing a product containing Compound that competes with the Product and such Persons' sales of such product for a calendar quarter are at least fifteen percent (15%) of the total sales of all Products in such country, as measured by comparing equivalent units of products sold. Sales of a competing product in a country during any calendar quarter shall be conclusively deemed to be at least fifteen percent (15%) of the total sales of Products in such country if IMS America or IMS International makes such a determination based on its conduct of a market share study in such country during such quarter. Once a determination is made that Competition exists for the Product in any country, such determination shall be made again each calendar quarter for so long as the Product is marketed in that country.

1.6 "Control, Controlled" shall mean the legal authority or right of a party hereto to grant a license or sublicense of intellectual property rights to another party hereto, or to otherwise disclose proprietary or trade secret information to such other party, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party. Information that is generally known or available to the public shall not be deemed Controlled by a party hereto.

1.7 "Development Candidate" shall mean a Sterile, injectable pharmaceutical formulation of the Compound selected by JANSSEN for further development under the terms of this Agreement.

1.8 "Development Plan" shall mean the plan directed towards the development of a Development Candidate as more fully set forth in Article 3.

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

1.9 "Development Program" shall mean the program of activities specified in the Development Plan for a Development Candidate as further detailed in Article 3.

1.10 1.10"Development Team" shall mean a team comprised of representatives of NANO and JANSSEN monitoring the Development Program.

1.11 "Dollars" shall mean United States dollars.

1.12 "Elan-Independent" shall mean incorporating, embodying or derived from patent rights, know-how or technology owned, licensed or developed by Elan Corporation, plc or any of its Affiliates (i) prior to the date on which Elan Corporation, plc acquired NanoSystems, LLC, or (ii) thereafter but wholly independent of any patent rights, know-how or technology obtained by Elan Corporation, plc or any of its Affiliates as a result of such acquisition.

1.13 "EU" shall mean the member states of the European Union.

1.14 "FDA" shall mean the United States Food and Drug Administration and, when appropriate herein, shall also mean any corresponding regulatory agency in any other country in the Territory.

1.15 "Feasibility Agreement" shall mean the Feasibility Collaboration Agreement between JANSSEN and NanoSystems, LLC dated August 29, 1996.

1.16 "First Commercial Sale" shall mean the first sale of the Product by JANSSEN, its Affiliates or Licensees, or any of their distributors in any country following receipt of all regulatory approvals, including those relating to pricing and reimbursement, necessary to commence commercial sales of the Product in such country. Reasonably limited sales made prior to the receipt of all approvals necessary to commence commercial sales, such as so-called "named patient sales", "compassionate use" sales and the like, shall not be deemed First Commercial Sales.

1.17 "Highly Confidential Information" shall mean specific processing conditions and/or parameters included in NanoCrystal Technology (excluding specific processing conditions and/or parameters specifically described in any NANO Patent) that are reasonably necessary for specialized JANSSEN or NANO employees to become skilled in the art of making nanoparticles, including, but not limited to, information concerning (i) work-up and composition of starting materials, size reduction, harvesting and sizing of nanoparticles; (ii) stabilization of nanoparticles; and (iii) specific downstream processing to make nanoparticle formulations. "Highly Confidential Information" shall not include information that is aimed at providing JANSSEN or NANO employees with a general understanding of the methods, processes and equipment used to manufacture or

formulate nanoparticles, but that is not intended to enable JANSSEN or NANO employees to become skilled in the art of making or formulating nanoparticles. In addition, "Highly Confidential Information" shall include only information that is (A) disclosed to JANSSEN in written or other tangible form clearly labeled as "Highly Confidential" at the time of disclosure, or (B) initially disclosed to JANSSEN in non-tangible form and identified as "Highly Confidential" at the time of such disclosure and, within thirty (30) days following the initial disclosure, summarized and designated as "Highly Confidential" in written or other tangible form delivered to JANSSEN.

1.18 "Improvement" shall mean any enhancement of or improvement to NanoCrystal Technology developed, invented or acquired by, or coming under the Control of, any party hereto (i) as a consequence of activities conducted or information disclosed under this Agreement or the Feasibility Agreement, or (ii) during the period between the Effective Date and the filing of the IRF for the Product; provided, however, that "Improvements" shall not include any enhancements of or improvements to NanoCrystal Technology that (A) are made by Janssen and are useful solely with respect to Compound or Product; (B) concern a commercial scale manufacturing process developed by JANSSEN for Product, but do not utilize and are not derived from NanoCrystal Technology; or (C) are Elan-Independent inventions, discoveries or findings.

1.19 "IND" shall mean (i) an Investigational New Drug Application filed by JANSSEN**,** its Affiliates or Licensees pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R. § 312.3, as well as (ii) equivalent submissions with similar requirements to the appropriate health authorities in other countries in the Territory as herein defined.

1.20 "IRF" shall mean the International Registration File owned by JANSSEN, compiled in such a way as is:

(a) necessary to satisfy the requirements of an NDA in the United States;

(b) necessary to satisfy the requirements of the Notice to Applicants for marketing authorization for Proprietary Medicinal Products for use in the EU; and

(c) satisfactory to be submitted as such to the national health authorities in any country or to be used as a basis for a national application for marketing authorization for the Product in the specific format required by such national health authorities.

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

1.21 "Janssen Patent" shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that are or become owned or Controlled by JANSSEN. For the purpose hereof, "Janssen Patents" shall also include JANSSEN's interests, if any, in Selection Patents.

1.22 "Licensee" shall mean any person, corporation, unincorporated body, or other entity that is not an Affiliate of JANSSEN and to whom JANSSEN grants a sublicense of the rights granted to JANSSEN pursuant to Article 2.

1.23 "Major Markets" shall mean the United States, Japan, the United Kingdom, France and Germany.

1.24 "Nano Know-How" shall mean all information and materials, including, without limitation, processes, techniques, formulas, data, methods, equipment designs, know-how, show-how and trade secrets, patentable or otherwise, tangible or intangible, that are owned or Controlled by NANO as of the Effective Date and that relate to the preparation, purification, characterization, stabilization, processing, formulation or delivery of small particles of pharmaceutical compounds prepared using a wet milling process; provided, however, that "Nano Know-How" shall not include any Elan-Independent information or materials.

1.25 "Nano Patents" shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that are owned or Controlled by NANO as of the Effective Date or that claim or cover any Improvement; provided, however, that "Nano Patents" shall not include any Elan-Independent patents or patent applications. A worldwide list of the current Nano Patents (including pending patent applications) is attached hereto as Exhibit A. This list will be updated by NANO upon the reasonable request of JANSSEN.

1.26 "NanoCrystal Technology" shall mean the Nano Patents, the Nano Know-How and Improvements.

1.27 "NDA" shall mean (i) a New Drug Application and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning the Product which are necessary for or included in FDA approval to market a Product as more fully defined in 21. C.F.R. § 314.50 *et seq.*, or (ii) any other similar application for marketing authorization filed with the appropriate regulatory authorities in any other country of the Territory.

1.28 "Net Sales" shall mean, commencing with the First Commercial Sale of the Product in each country in the Territory, the aggregate of the gross invoiced sales price for such Product sold or commercially disposed of for value by JANSSEN, its Affiliates or the Licensees, or any of their distributors, to Third Parties, after deduction of the following amounts:

(a) all normal and customary trade and quantity discounts, allowances and rebates, including government rebates actually taken or allowed except that such discounts granted in consideration of a Third Party s agreement to purchase other products shall not be deducted;

(b) credits or allowances given or made for rejection, recall or return of previously sold Product to the extent actually taken or allowed;

(c) any tax or government charges, including any tax such as a value added or similar tax or government charge other than an income tax levied on the sale, transportation or delivery of the Product and borne by the seller thereof; and

(d) any charges for freight and insurance that are documented as billed to the final customer.

1.29 "Phase I" shall mean (i) that portion of the FDA submission and approval process which provides for the first introduction into humans of the Product with the purposes of determining human toxicity, metabolism, absorption, elimination and other pharmacological actions, as more fully defined in 21 C.F.R. § 312.21(a), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.

1.30 "Phase II" shall mean (i) that portion of the FDA submission and approval process which provides for the initial trials of the Product on a limited number of patients for the purposes of determining dose and evaluating safety and efficacy in the proposed therapeutic indication as more fully defined in 21 C.F.R. § 312.21(b), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.

1.31 "Phase III" shall mean (i) that portion of the FDA submission and approval process which provides for the continued trials of Product on sufficient numbers of patients to generate safety, efficacy and pharmacoeconomic data to support regulatory approval in the proposed therapeutic indication as more fully defined in 21 C.F.R. § 312.21(c), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.

1.32 "Product" shall mean a Sterile, injectable pharmaceutical product containing Compound that (i) utilizes or is prepared using Nano Know-How or any Improvement , and/or (ii) is covered by a Selection Patent and/or (iii) would infringe any of the Nano Patents but for the licenses granted hereunder.

1.33 "Selection Patents" shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that (i) claim findings or inventions made or conceived by JANSSEN or NANO (or any of their Affiliates) as a consequence of activities conducted or information disclosed under this Agreement or the Feasibility Agreement; and (ii) are directed to methods of preparing, purifying, characterizing, stabilizing, processing, formulating or delivering small particles of Compound or Product. A worldwide list of the current Selection Patents (including pending patent applications) is attached hereto as Exhibit B. This list will be updated by JANSSEN at the reasonable request of NANO.

1.34 "Sterile" shall mean meeting the criteria of sterility as defined in the current United States Pharmacopeia.

1.35 "Territory" shall mean all countries of the world.

1.36 "Third Party" shall mean any person, corporation, unincorporated body, or other entity other than JANSSEN, NANO and their respective Affiliates and/or Licensees.

1.37 "Valid Claim" shall mean a claim in a patent that has not lapsed or become abandoned and that has not been declared invalid by an unreversed or an unappealable decision of a court of competent jurisdiction.

ARTICLE 2 - LICENSE GRANT

2.1 NANO grants to JANSSEN a worldwide, exclusive license under the NanoCrystal Technology for the sole purpose of developing, having developed, making, having made, using, marketing, selling, having sold and distributing Product in the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.

2.2 The rights and licenses granted hereunder shall be sublicensable by JANSSEN to Licensees in any country in the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9; provided, however, that no Licensee shall be permitted to sublicense any license granted to such sublicensee.

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

2.3 JANSSEN may develop, make and/or sell Product through its Affiliates in any country in the Territory or grant sublicenses to its Affiliates in any country of the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.

2.4 At the request of JANSSEN, NANO will extend the rights and licenses granted herein to an Affiliate of JANSSEN on a direct basis in any country of the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.

2.5 Notwithstanding the granting of a sublicense to a Licensee or an Affiliate, or a direct license to an Affiliate, JANSSEN shall remain directly responsible to NANO for all obligations of JANSSEN, its Affiliates and Licensees.

2.6 Nothing herein shall preclude JANSSEN and/or its Affiliates from utilizing distributors to promote and distribute the Product in any country of the Territory.

2.7 In the event the JANSSEN would consider developing an oral formulation of the Product, the Parties will in good faith discuss the possibility and the terms and conditions under which NANO would grant JANSSEN a license under the NanoCrystal Technology to develop, make and sell such oral formulation and/or whether NANO would manufacture such oral formulation for JANSSEN.

2.8 Notwithstanding anything else herein to the contrary, in the event that JANSSEN's development, manufacture, use, marketing, sale or distribution of Product in the Territory would infringe any patent that would be a Nano Patent but for the fact that it is an Elan-Independent patent (an "Elan Patent"), NANO hereby grants to JANSSEN, to the extent NANO is legally able to do so, a non-exclusive, royalty-free license under such Elan Patent for the sole purpose of developing, having developed, making, having made, using, marketing, selling, having sold and distributing such Product in the Territory, which license shall be subject to the provisions of Article 9. The provisions of Article 11 shall not apply to any Elan Patents licensed hereunder, and NANO shall have no obligation to transfer or disclose to JANSSEN any processes, techniques, formulas, data, methods, equipment designs, know-how, show-how or trade secrets associated with any Elan Patents licensed hereunder. Notwithstanding the above, in the event NANO is legally not able to grant such a non-exclusive, royalty free license under any Elan Patent and is for similar reasons not able to grant a commitment not to sue under such Elan Patent in relation to the development, manufacture, use, marketing, sale or distribution of Product, then JANSSEN shall be entitled to deduct all costs incurred or payments made (including royalty payments) in relation to any alleged infringement of such Elan Patent or settlement or other final disposition thereof, in accordance with the provisions of Section 11.1

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

ARTICLE 3 - DEVELOPMENT ACTIVITIES

3.1 The selection and development of Development Candidate(s) that are suitable for development into a Product for commercialization and approval of the development and final commercial formulation and specifications for the Product will be the sole responsibility of JANSSEN and JANSSEN will bear all costs and expenses related thereto. At any stage in the Development Program, it will be JANSSEN's sole decision to evaluate whether the results generated warrant the continuation of the Development Program with respect to a Development Candidate.

3.2 NANO will disclose to JANSSEN within a reasonable period of time the Nano Know-How and any Improvements that NANO believes are necessary or useful in connection with the Development Program, based on the information, requests and reports provided to it by JANSSEN during the term of this Agreement. JANSSEN will disclose to NANO within a reasonable period of time any Improvements developed or invented during the term of this Agreement by JANSSEN or its Affiliates.

3.3 From the Effective Date hereof, JANSSEN will proceed with the development of the Development Candidate selected by JANSSEN, such development already having been initiated under the terms of the Feasibility Agreement.

3.4 The activities to be undertaken in the course of the Development Program will be monitored by the Development Team. The Development Team shall review and monitor the progress made during the Development Program and will discuss important milestone events. The Development Team will be chaired by JANSSEN.

3.5 Prior to NANO commencing supporting activities in relation to the Development Program, JANSSEN and NANO will agree on the specific activities to be undertaken by NANO, including timelines and related budget and such timelines and budget will be attached to the Development Plan. JANSSEN acknowledges that in the event it requests additional support activities from NANO that are not contemplated under this Agreement or in the Development Plan, NANO may not be in a position to readily provide such support in view of other commitments NANO may have to Third Parties. In such event, JANSSEN and NANO will in good faith discuss how and within what timeframe such additional support activities may be performed by NANO. In performing such support activities in relation to the Development Program, NANO will use reasonable efforts to comply with its commitments, including the commitment to dedicate sufficient staff with adequate skills to such Development Program, as set forth in the

Development Plan and as agreed upon prior to the start of the Development Program.

3.6 If NANO's development efforts include the use of a Third Party, NANO will, prior to appointing such Third Party, discuss with JANSSEN the activities to be undertaken by such Third Party and the terms and conditions thereof. NANO will not proceed with such Third Party without the prior written approval of JANSSEN, which approval shall not be unreasonably withheld.

3.7 NANO will provide JANSSEN with regular written reports on the progress of the support activities to be undertaken by it under the Development Program(s) and will create detailed descriptions of any methodologies, development formulations or processes directed to Development Candidates in order to enable JANSSEN to prepare and file any regulatory filings in relation to the Product.

3.8 JANSSEN will provide NANO on a quarterly basis with written reports on the progress of activities undertaken by it relating to the Development Program. JANSSEN agrees to use reasonable efforts, consistent with its normal business practices and in line with the efforts it devotes to projects of similar sales and technical potential, to carry out the development activities directed to a Development Candidate with the aim of developing the Product that can be commercialized.

ARTICLE 4 - CLINICAL AND REGULATORY ACTIVITIES

4.1 JANSSEN will be responsible for planning and conducting, at its own cost and expense, Phase I, Phase II and Phase III clinical trials in connection with a Development Candidate. The protocols of any Phase I, Phase II or Phase III clinical trial directed to the Development Candidate will be solely determined by JANSSEN. JANSSEN shall keep NANO apprised on a quarterly basis of the progress of any such trials and any results thereof. It will be JANSSEN's sole decision to evaluate whether the results of any clinical trial warrant the continuance of the Development Program with respect to a given Development Candidate.

4.2 JANSSEN shall be responsible, at its own cost and expense, for the preparation and filing of any IND or any other regulatory approvals necessary to start clinical trials with respect to a Development Candidate, and for compliance of such trials with the FDA's IND and related requirements. NANO shall give JANSSEN such support as may be reasonably requested by JANSSEN in relation thereto, provided such requests are restricted to the activities undertaken by NANO in accordance with the provisions of Section 3.5, or relate to requests raised by any regulatory

authorities in relation to the NanoCrystal Technology in general, as more fully described in Sections 4.7 and 4.8.

4.3 JANSSEN shall be responsible for and shall have exclusive authority for compiling the IRF, including the indications pursued therein, and for filing and obtaining NDA's in any country in the Territory where JANSSEN decides to commercialize the Product.

4.4 Upon compilation of the IRF for the Product, JANSSEN shall use reasonable efforts consistent with its normal business practices and its overall business strategy to apply for the necessary regulatory approvals in the Major Markets with respect to the Product, including regulatory approvals pertaining to pricing and reimbursement. JANSSEN will inform NANO promptly upon the filing of any application for regulatory approval, and any subsequent approval, in any Major Market and will furthermore keep NANO apprised on a quarterly basis of the filings and approvals outside the Major Markets.

4.5 All regulatory data pertaining to the Product and relating to any regulatory filing and/or approval, license or permit granted by a regulatory authority in connection with the Product will be owned by JANSSEN; provided, however, that all Drug Master Files and other submissions filed by NANO with respect to NanoCrystal Technology shall be owned by NANO.

4.6 NANO will provide JANSSEN with reasonable regulatory support related to NanoCrystal Technology in connection with the regulatory approvals to be filed by JANSSEN and the compilation of the IRF of the Product. Amongst other things , NANO will (i) prepare all necessary supporting documentation related to NANO's activities under the Development Plan requested by JANSSEN, such as certificates or other administrative documents required for reference in any regulatory filing, and (ii) issue a letter of authorization to the FDA permitting the FDA to reference NANO's relevant drug master files in reviewing applications for regulatory approval of Product. NANO will further assist JANSSEN with the preparation of supporting data related to the NanoCrystal Technology to allow JANSSEN to apply for and pursue the regulatory approvals in any country where JANSSEN decides to register Product. JANSSEN will keep NANO informed in connection with questions raised by regulatory authorities specifically related to the NanoCrystal Technology and NANO will assist JANSSEN whenever such regulatory questions or issues arise during the review process in any country. JANSSEN may reasonably request NANO to participate in critical meetings scheduled with the health authorities in relation to requests raised by such authorities with respect to the NanoCrystal Technology.

4.7 During the term of this Agreement NANO will promptly inform JANSSEN of any information or finding (including questions or remarks raised by regulatory

authorities) in relation to the NanoCrystal Technology that NANO believes or has reason to believe may have a regulatory bearing on the further making or commercialization of the Product in accordance with the regulatory approvals in any country in the Territory. In addition, NANO will provide JANSSEN with reasonable assistance whenever questions specifically related to the NanoCrystal Technology are raised by regulatory authorities during the review process in any country in the Territory, which assistance shall include participation in critical meetings scheduled with health authorities in any such country.

4.8 Each party shall promptly inform the other of any actions, questions or remarks raised by regulatory authorities in relation to the NanoCrystal Technology, or the use thereof with respect to the Product. In addition, JANSSEN will report and cause its Affiliates and Licensees to report to NANO, and NANO will report and cause its Affiliates to report to JANSSEN, all information concerning any known or suspected side effect, injury, toxicity, sensitivity reaction, customer complaint, alleged defect or other adverse experience (including the severity thereof) associated with exposure to or use of Compound or Product that is alleged, believed or suspected to be attributable to the application of NanoCrystal technology to Compound or Product. JANSSEN shall be responsible for reporting adverse experiences with respect to Product to the FDA in conformity with applicable laws and regulations. Each party shall promptly inform the other of any threatened or pending actions by the FDA or any other regulatory authority concerning Product or NanoCrystal Technology.

4.9 Any regulatory support provided by NANO under this Article 4 shall be provided free of charge; provided, however, that JANSSEN shall reimburse NANO for (i) all out-of-pocket expenses NANO or its Affiliates incur in relation to any activities requested by JANSSEN, and (ii) any extraordinary activities requested by JANSSEN, including, without limitation, attending any meetings with regulatory authorities concerning the Product.

ARTICLE 5 - PAYMENTS

5.1 In consideration of the rights and licenses granted to JANSSEN under Article 2 of this Agreement, JANSSEN shall pay to NANO the following amounts:

(a) the non-refundable sum of [**] due and payable upon the Effective Date of this Agreement;

(b) in connection with Development Candidates and Product the following sums:

(i) the sum of [**] payable within thirty (30) days of the date a Development Candidate is first administered to six (6) human subjects;

(ii) the sum of [**] payable within thirty (30) days of the date the first IND for a Development Candidate is filed;

(iii) the sum of [**] payable within thirty (30) days of JANSSEN's commencement of the first Phase III clinical trial of a Development Candidate;

(iv) the sum of [**] payable within thirty (30) days of the date the first NDA for the Product is submitted in a Major Market; and

(v) the sum of [**] payable within thirty (30) days following the date the first NDA for the Product is approved in a Major Market.

5.2 The milestone payments due under Section 5.1(b) shall only be paid once by JANSSEN. NANO will send valid VAT invoices to JANSSEN in relation to all milestone payments payable under this Agreement.

ARTICLE 6 - ROYALTIES

6.1 In consideration of the rights and licenses granted under the NanoCrystal Technology, JANSSEN shall pay a royalty of one and one-half percent (1 1/2%) on the Net Sales of Products in all countries of Territory where Nano Patents or Selection Patents containing Valid Claims are filed or subsist (hereinafter "Patent Royalty").

6.2 In further consideration of the rights and licenses under the NanoCrystal Technology, JANSSEN shall pay on its annual Net Sales in Territory a royalty in accordance with the following brackets (hereinafter "Know How Royalty"):

(a) three and one-half percent (3 1/2%) on aggregate Net Sales below 250,000,000 Dollars;

(b) five and one-half percent (5 1/2%) on aggregate Net Sales between 250,000,000 Dollars and 500,000,000 Dollars; and

(c) seven and one-half percent (7 1/2%) on aggregate Net Sales above 500,000,000 Dollars.

6.3 With respect to each country in the Territory, JANSSEN shall pay the Patent Royalties until expiration of the last to expire of the Nano Patents and the Selection Patents that are applicable in such country; provided, however, that any Nano Patent or Selection Patent consisting of a patent application pending for more than five (5) years after the Effective Date shall no longer be considered a Nano Patent or a Selection Patent, as applicable, until such time as the patent on such application issues.

6.4 With respect to each country in the Territory, JANSSEN shall pay the Know-How Royalties until the later of (i) fifteen (15) years following the First Commercial Sale in such country, or (ii) twenty (20) years following the Effective Date. The sales in any country where the Know-How Royalties are no longer due in accordance with the above provisions shall not be used in the computation of the aggregate Net Sales in accordance with Section 6.2.

6.5 If in a country a Third Party (other than a Person acting on behalf of or through a license from JANSSEN or any of its Affiliates) is selling a product in such a manner sufficient to achieve Competition, the Know-How Royalties for sales of the Product with respect to which Competition exists shall be reduced by fifty percent (50%) in such country (i.e., only fifty percent (50%) of the sales of such Product in such country shall be considered in calculating the aggregate Net Sales in accordance with Section 6.2), until such time as there is a discontinuance of Competition. Notwithstanding the foregoing, no such reduction of the Know-How Royalties shall apply in the event such Competition has caused any party hereto to take action under Section 11.2 against such Third Party; provided, however, that the reduction of the Know-How Royalties set forth in Section 11.2(g) shall be applied if Competition is caused by an infringement of Product and such infringement is not overcome within one hundred twenty (120) days following NANO's receipt of JANSSEN's written notice evidencing a prima facie case of infringement.

ARTICLE 7 - ROYALTY PAYMENTS, REPORTS AND RECORDS

7.1 7.1JANSSEN shall keep and shall cause its Affiliates and Licensees to keep, and to maintain for at least two years, true and accurate records of sales of Product and Net Sales and the royalties payable to NANO under Article 6 hereof and shall deliver to NANO a written statement thereof on or before the sixtieth (60th) day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. Said written statements shall set forth on a country-by-country basis, a calculation of the Net Sales from gross revenues for the Product during that calendar quarter, the applicable percentage royalty rates, and a computation of the royalties due to

NANO (the "Royalty Statement"). Upon NANO's receipt of each Royalty Statement from JANSSEN, NANO will send valid VAT invoices to JANSSEN confirming the royalties due and payable by JANSSEN under this Agreement.

7.2 All royalty payments to be made by JANSSEN to NANO shall be converted into Dollars at the average rate of exchange for the calendar quarter for which royalty payments are being remitted according to JANSSEN's normal procedures, as consistently applied by JANSSEN for its other products (which procedures shall be subject to NANO's review and approval, such approval not to be unreasonably withheld), and shall be made by wire transfer to a designated NANO account on or before the sixtieth (60th) day following the end of each JANSSEN accounting quarter. In the event that royalties are payable with respect to Net Sales in a country whose currency cannot be freely converted to Dollars, such currency shall be converted in accordance with the normal procedures consistently applied by JANSSEN (which procedures shall be subject to NANO's review and approval, such approval not to be unreasonably withheld).

7.3 Any income or other taxes which JANSSEN is required by law to pay or withhold on behalf of NANO with respect to royalties and any other monies payable to NANO under this Agreement shall be deducted from the amount of such royalties and monies due. JANSSEN shall furnish NANO with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by NANO. JANSSEN shall promptly provide NANO with a certificate or other documentary evidence to enable NANO to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by JANSSEN. The parties hereto will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable JANSSEN to make such payments to NANO without any deduction or withholding.

7.4 NANO shall have the right to nominate an independent certified public accountant acceptable to and approved by JANSSEN who shall have access, on reasonable notice, to JANSSEN and its Affiliates' or Licensees' records during reasonable business hours for the purpose of verifying the royalties payable as provided in this Agreement for the two preceding years. This right may not be exercised more than once in any calendar year, and once a calendar year is audited it may not be reaudited, and said accountant shall disclose to NANO only information relating solely to the accuracy of the Royalty Statements provided to NANO and the royalty payments made to NANO under this Agreement.

7.5 Any adjustment required as a result of an audit conducted under Section 7.4 shall be made within twenty-five (25) days after the date on which the accountant conducting the audit issues a written report to NANO and JANSSEN containing the results of the audit. Any underpayment by JANSSEN shall bear interest from

the date that such amount should have been paid to NANO as royalties to the date that the underpayment is actually paid to NANO by JANSSEN. The interest rate shall be the prime interest rate published in the Wall Street Journal at the close of business on the day prior to the date the underpayment is made, plus two percent (2%). In addition, if any underpayment by JANSSEN is greater than five percent (5%) of the amount previously paid to NANO for the relevant period, the costs and expenses of the audit shall be paid for by JANSSEN.

7.6 All payments due hereunder shall be made to the designated bank account of EPIL in accordance with such timely written instructions as NANO shall from time to time provide.

7.7 Each payment due from JANSSEN to NANO under this Agreement shall bear interest from the due date of such payment at the prime rate published in the Wall Street Journal on the due date for such payment plus two percent (2%), provided JANSSEN does not make such payment within thirty (30) days following the due date for such payment.

ARTICLE 8 - COMMERCIALIZATION

8.1 All business decisions, including, but not limited to, decisions concerning pricing, reimbursement, package design, sales and promotional activities for the Product, and the decision to launch or continue to market the Product in particular countries in the Territory, shall be within the sole discretion of JANSSEN. Notwithstanding the foregoing sentence, JANSSEN agrees to make a First Commercial Sale of the Product in each of the Major Markets within nine (9) months after obtaining the necessary regulatory approvals, including approvals concerning acceptable pricing and reimbursement, if applicable, in such Major Market. Said nine (9) month period will be extended, but not by more than six (6) months, upon JANSSEN's reasonable request for sound business reasons, including, but not limited to, the launch by JANSSEN, its Affiliates or Licensees of other products that do not directly compete with the Product in the Major Markets, or the intended simultaneous launch of the Product in several countries.

8.2 JANSSEN will promptly inform NANO of the First Commercial Sale of the Product in each of the Major Markets and will provide NANO with calendar quarterly updates on the First Commercial Sales of the Product in other countries.

8.3 All trademarks utilized by JANSSEN or its Affiliates or Licensees on Product under this Agreement shall be chosen and owned by JANSSEN or its Affiliates or Licensees. Upon termination of this Agreement under Article 14 or Article 15, all rights to said trademarks shall remain with JANSSEN or its Affiliates or Licensees. Notwithstanding the foregoing, JANSSEN shall not use the terms

"nano", "nanosystem" or "nanocrystal", or any terms derived therefrom, in any trademark used by JANSSEN for any purpose without the prior written approval of NANO.

ARTICLE 9 - MANUFACTURING AND SUPPLY

9.1 JANSSEN shall have the right to make or have made Products, but the latter subject to the provisions herein concerning JANSSEN's obligations with respect to Highly Confidential Information. In order to enable JANSSEN to so manufacture or have manufactured Products, NANO will, upon JANSSEN's reasonable request and subject to the terms and conditions herein, provide JANSSEN with all NanoCrystal Technology reasonably necessary in order to enable JANSSEN to commercially manufacture Product in accordance with the specifications for manufacture set forth in the IRF and as communicated by JANSSEN to NANO.

9.2 JANSSEN shall not sublicense or disclose any Highly Confidential Information to any party, including without limitation its Affiliates and Licensees, without the prior written consent of NANO, such consent not to be unreasonably withheld. Notwithstanding the foregoing, JANSSEN may, without such prior written consent, sublicense and disclose Highly Confidential Information (subject to the limitations set forth in Article 12) to a maximum of two of its Affiliates for the sole purpose of enabling such Affiliates to manufacture Product in accordance with the terms and conditions set forth herein.

9.3 In the event that, pursuant to the terms and conditions of this Agreement, JANSSEN or one of its Affiliates seeks to manufacture Product hereunder, NANO shall supply the polymeric grinding media, if any, required for such manufacture, in accordance with reasonable commercial terms to be negotiated in good faith between the parties.

9.4 JANSSEN hereby agrees to manufacture Product, and to cause all of its Affiliates permitted hereunder to manufacture Product, in conformity with all applicable laws, regulations and regulatory filings and in accordance with generally accepted standards and practices for such activities in the pharmaceutical industry.

ARTICLE 10 - RIGHTS IN TECHNOLOGY, INVENTIONS AND PATENTS

10.1 NANO agrees to use its good faith efforts to continue, at its sole cost and expense, the prosecution and maintenance of the Nano Patents listed in Exhibit A. Prosecution of pending patent applications, shall mean through final patent office appeal and any opposition proceedings or the like, including but not limited to, re-

issue applications and re-examination proceedings in the United States and any foreign counterparts thereto. Upon either party's request, but not more frequently than once per year, the parties shall in good faith review the patents and patent applications set forth in Exhibit A. If both parties agree, the prosecution of any patent applications and/or maintenance of any patents may be abandoned.

10.2 Whenever any findings or inventions made or discovered during the course of the Development Program, or as a consequence of activities conducted under this Agreement or the Feasibility Agreement, are deemed patentable, both Parties will promptly inform each other thereof and ownership and filing of any patent applications related thereto will be done in accordance with the following principles:

(a) NANO shall own and shall have the right to apply for and maintain patents at its own cost with respect to findings or inventions that are Improvements but that are not useful with respect to Compound and/or Product, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of NANO and/or JANSSEN.

(b) JANSSEN shall own and shall have the right to apply for and maintain patents at its own cost with respect to findings or inventions that are useful solely with respect to Compound and/or Product, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of JANSSEN and/or NANO. Each such patent shall be a Janssen Patent or a Selection Patent as the case may be.

(c) With respect to any finding or invention not covered by (a) or (b) above, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of JANSSEN and/or NANO, the parties shall in good faith evaluate the possibility of simultaneously applying for separate patent applications and of separately maintaining any patents issuing thereon. Should the parties agree that separate patent applications are feasible and appropriate, (i) the claims of any such patent applications filed by JANSSEN shall be limited to Compound or Product, and any patents issuing thereon shall be deemed Janssen Patents or Selection Patents as the case may be; and (ii) the claims of any such patent applications filed by NANO shall specifically exclude Compound or Product.

(d) In the event either party is of the reasonable opinion that the filing of separate applications is not feasible or appropriate, (i) NANO shall own and have the right to apply for and maintain patents with respect to findings or inventions that are Improvements (which shall be included within NanoCrystal Technology and covered by the license grant to

JANSSEN under Article 2); and (ii) JANSSEN shall own and have the right to apply for and maintain patents with respect to other findings and inventions, and the patents on such other findings and inventions shall be deemed Janssen Patents and/or Selection Patents as the case may be.

10.3 Each of JANSSEN and NANO shall provide prompt notice to the other of all findings and inventions covered under Section 10.2, and shall consult and cooperate with the other in good faith with respect to the filing of patent applications for findings and inventions covered under Section 10.2 and the maintenance of patents issued thereon including, without limitation, by executing and obtaining from employees and other Persons all assignments and other documents reasonably required in connection therewith. In addition, prior to filing any simultaneous patent applications under Section 10.2(c), each of JANSSEN and NANO shall provide the other with reasonable opportunity to comment on the proposed text of such applications and shall give due consideration to any comments received from the other concerning such applications; provided, however, that JANSSEN and its Affiliates shall not include any Highly Confidential Information in any patent applications they file hereunder without the prior written consent of NANO.

10.4 The parties agree to cooperate in order to avoid loss of any rights which may otherwise be available to the parties under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Community and other similar measures in any other country in the Territory. Without limiting the foregoing, each of JANSSEN and NANO agrees to provide the other with reasonable information and assistance in order to permit the timely filing of an application for patent term extension within the sixty (60) day period following NDA approval to market Product in the United States. Upon similar approvals by the health authorities in a country of the European Community or in other countries in the Territory, each party shall provide the other with reasonable information and assistance in order to permit the timely filing of a Supplementary Certificate of Protection of the Member States of the European Community and related filings.

ARTICLE 11 - INFRINGEMENT

11.1 If, as a result of the use of the NanoCrystal Technology in the manufacture, use or sale of the Product in any country of the Territory, JANSSEN and/or its Affiliate or Licensee is sued for patent infringement or threatened with such a lawsuit or other action by a Third Party, JANSSEN and NANO shall meet to analyze the infringement claim and the avoidance of same. If it is necessary in the judgment of JANSSEN to obtain a license from such Third Party with respect to such Product, and JANSSEN obtains an written opinion from outside counsel

concurring with JANSSEN's judgment that such a license is necessary, JANSSEN, with NANO's reasonable assistance, may negotiate for such a license and in such negotiations shall make every effort to minimize any license fees and/or royalties payable to such Third Party.

(a) If the settlement or other resolution of a lawsuit or threatened lawsuit or other action requires any payments for pre-settlement or pre-litigation resolution damages to a Third Party, including but not limited to royalty payments for past sales of an allegedly infringing Product in a country, then JANSSEN, its Affiliates and Licensees on the one hand and NANO on the other hand shall [**].

(b) For any required royalty payments on post-settlement or post-litigation sales of the allegedly infringing Product in a country, JANSSEN and/or its Affiliates or Licensees, but not NANO, shall [**].

(c) The [**] due and payable to NANO under this Section 11.1 shall only apply to the extent that the infringement is due to the use of NanoCrystal Technology in such Product and is not the result of (i) a modification of the nanoparticle formulation or nanoparticle manufacturing process of such Product, or (ii) refusal by JANSSEN to modify the Product to avoid infringement, unless JANSSEN shows that its manufacturing and regulatory costs to so avoid infringement would be commercially unreasonable. In the event that in connection with (ii) above, the parties fail to agree on whether such costs are commercially unreasonable, such matter shall be resolved in accordance with the provisions of Article 20.

(d) In the event that JANSSEN manufactures Product using a manufacturing process that does not utilize the NanoCrystal Technology and such manufacturing process is alleged by a Third Party to infringe certain patented technology of such Third Party, and JANSSEN demonstrates to NANO's reasonable satisfaction that JANSSEN is required to obtain a royalty-bearing license from a Third Party to use such Third Party's patented technology to manufacture Product, [**].

11.2 In the event that in any country in the Territory in which JANSSEN, its Affiliates or Licensees are marketing the Product, there is an infringement of a Nano Patent by a Third Party's product, JANSSEN or its Affiliates shall notify NANO in writing to that effect, including with said written notice evidence establishing a prima facie case of infringement by such Third Party. In the event of a potential multicountry infringement by the same Third Party with the same infringing product, the parties will promptly discuss the possible strategies to deal with such infringement on a global basis prior to deciding on a course of action in a single

country, taking into consideration the conditions set forth hereinafter as well as the potential scope of the infringement and the countries involved.

(a) NANO shall have the right at its sole discretion to take action to stop such infringement, including without limitation conducting patent infringement proceedings or starting settlement discussions. NANO shall bear all the costs and expenses of any suit brought by it. JANSSEN and/or its Affiliate or Licensee will cooperate with NANO in any such suit and shall have the right to consult with NANO and be represented by its own counsel at its own expense. NANO's failure to take action under this Article shall not be considered a breach of this Agreement and JANSSEN's sole remedy shall be to bring suit itself, subject to the terms and conditions of this Section 11.2.

(b) If, within forty (40) days after NANO's receipt of JANSSEN's written notice evidencing a prima facie case of infringement, NANO has not overcome the case of infringement, obtained a discontinuance of such infringement, brought suit against the Third Party infringer, or taken steps to initiate such a suit, JANSSEN shall have the right, in its sole discretion, but not the obligation to bring such suit against the infringer, subject to the conditions set forth below, at its own expense and in its own name, if legally permissible. If necessary and legally permissible, NANO will permit the suit to be brought in its name. JANSSEN shall bear all the costs and expenses of any suit brought by it. NANO will cooperate with JANSSEN in any such suit and shall have the right to consult with JANSSEN and be represented by its own counsel at its own expense.

(c) JANSSEN's right to bring suit in a country in accordance with the above provisions in connection with Nano Patents is subject to [**]. If the parties disagree on whether the above conditions are satisfied in any specific case of infringement, the matter will be submitted for decision to an independent patent counsel selected in common agreement by JANSSEN and NANO, and the parties agree to abide by the decision of such patent counsel with respect to such conditions.

(d) Notwithstanding the opinion of an independent patent counsel that the conditions in (c) above are satisfied, NANO shall have the right to withhold its consent to JANSSEN bringing suit against the Third Party infringer. [**]

(e) [**]

(f) Any damages, costs, awards, settlement amounts or other sums received by the party bringing suit arising out of any proceedings for infringement

of the Nano Patents shall be retained by such party. Notwithstanding the foregoing, whenever the party bringing suit is JANSSEN, the damages, costs, awards, settlement amounts and other sums shall be divided as follows:

(i) JANSSEN shall be entitled to its out of pocket expenses actually incurred by JANSSEN or its designated Affiliate in respect of the proceedings for infringement of the Nano Patents insofar as such expenses have not already been deducted from the royalties payable to NANO pursuant to (e) above;

(ii) NANO shall be entitled to a sum equal to any royalties withheld pursuant to (e) above; and

(iii) JANSSEN and NANO shall equally share the remainder.

(g) If, within one hundred twenty (120) days after NANO's receipt of JANSSEN's written notice [**], the infringement has not been overcome by either JANSSEN or NANO, and a Third Party's (other than a Person acting on behalf of or through a license from JANSSEN or any of its Affiliates) sales of the infringing product are or become sufficient to create Competition, then the Patent Royalties and the Know-How Royalties for sales of the Product being infringed shall each [**] in the country where the infringement is occurring, irrespective of whether NANO or JANSSEN taking action against such infringer in accordance with the provisions of this Section 11.2, until such time as there is a discontinuance of such Competition. The provisions of this subsection (g) shall not apply whenever the royalties due to NANO [**] in accordance with the conditions set forth in (d) above and the provisions of (d) shall apply to such reduction.

11.3 In the event of any infringement of a Janssen Patent by a Third Party, JANSSEN shall have the right at its sole discretion to take action to stop such infringement, including without limitation conducting patent infringement proceedings or starting settlement discussions. JANSSEN shall bear all the costs and expenses in connection with any such proceedings and discussions.

11.4 As of the Effective Date of this Agreement NANO declares that, according to the best of its current knowledge and belief, the application of the Nano Patents and Nano Know-How to the Compound does not infringe the patent rights of any Third Party in any country in the Territory.

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

ARTICLE 12 - CONFIDENTIALITY

12.1 During the performance of this Agreement, either party will disclose to the other party information which the disclosing party considers to be confidential. This information may include, without limitation, any data, information, know-how and materials which in the case of JANSSEN relates to Compound and/or Product and which in the case of NANO relates to NanoCrystal Technology, including information which is discovered by or brought to the attention of any party hereto during or as a result of, directly or indirectly, the performance of the Agreement ("Information").

12.2 For purposes of this Agreement, each party hereto is a "Submitter" as to Information or Highly Confidential Information disclosed or provided by it under this Agreement and each is a "Recipient" as to Information or Highly Confidential Information disclosed or provided to it under this Agreement.

12.3 The confidentiality obligations contained herein shall not apply to any portion of the Information or Highly Confidential Information which:

(a) is or becomes public or available to the general public otherwise than through the act or default of Recipient or any Authorized Party (as defined below);

(b) is obtained by Recipient from a Third Party who is lawfully in possession of such Information and is not subject to an obligation of confidentiality or non-use owed to Submitter;

(c) is previously known to Recipient prior to disclosure to Recipient by Submitter, as evidenced by the written records of Recipient;

(d) is independently developed, discovered or arrived at by Recipient without use of the Information, as evidenced by written records of Recipient; or

(e) is disclosed by Recipient pursuant to a requirement of law, including without limitation to governmental regulatory agencies, and is thereafter publicly disclosed or made available to the public by operation of law, provided that Recipient has complied with the provisions set forth in Section 12.9.

The Recipient shall have the burden of proof as to the existence of any of the conditions under (a) through (e) above. In addition, independent development, discovery or arrival at data, information, know-how or materials under (d) above must be established by clear and convincing evidence .

12.4 Recipient shall employ at least the same degree of care to keep all Information confidential as it employs with respect to its own information of like importance; and shall, in any event, take all steps reasonably necessary to maintain and preserve the confidentiality of all Information.

12.5 Information will only be submitted to Recipient's employees or employees of Recipient's Affiliates and Licensees on a need to know basis. Without the prior written consent of the Submitter, Recipient shall not disclose any Information to any Third Party, Affiliate or Licensee, except to those who need to know such Information to achieve the purpose of this Agreement. Each such Third Party, Affiliate and Licensee, being referred to herein as an "Authorized Party," and Recipient, including, without limitation, its representatives, agents and employees, shall use the Information only in accordance with the terms and conditions of this Agreement.

12.6 Recipient warrants that each Authorized Party or employee to whom any Information is revealed shall (i) previously have been informed of the confidential nature of the Information and (ii) will prior to any disclosure have agreed to be bound by terms and conditions of (A) a written secrecy agreement with Recipient to protect Recipient's information whenever it concerns an employee, or (B) a written confidentiality agreement with Recipient containing terms and conditions substantially equivalent to those in this Article 12 applicable to Recipient whenever it concerns an Authorized Party. Recipient shall ensure that the Information is not used or disclosed by such Authorized Party or employee except for the purposes of developing and manufacturing Product in accordance with this Agreement, and shall be responsible for any breach of this Agreement by such Authorized Party or employee.

12.7 All Information shall remain the property of Submitter. Upon termination of this Agreement and upon the written request of Submitter (i) all tangible Information (including without limitation all copies thereof and all unused samples), except for Information consisting of analyses, studies and other documents prepared by or for the benefit of Recipient, shall be promptly returned to Submitter, and (ii) all portions of such analyses, studies and other documents prepared by or for the benefit of Recipient (including all copies thereof) which are within the definition of Information shall be destroyed; provided that Recipient may retain one copy of Information in a secure location for purposes of identifying its obligations under this Agreement and for no other purposes.

12.8 The obligations of Recipient as to confidentiality and non-use set forth in this Agreement, including, without limitation, the provisions of Section 12.4, shall survive the expiration or termination of this Agreement and shall continue for five

(5) years thereafter, but in no event shall such confidentiality obligations terminate earlier than December 31, 2015.

12.9 If Recipient becomes legally required to disclose any Information, Recipient shall give Submitter prompt notice of such fact so that Submitter may seek to obtain a protective order or other appropriate remedy concerning any such disclosure and/or waive compliance with the non-disclosure provisions of this Agreement. Recipient shall fully cooperate with Submitter in connection with Submitter's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, or if Submitter waives compliance with the non-disclosure provisions of this Agreement, Recipient shall make such disclosure only to the extent that such disclosure is legally required. Any Information required to be provided to regulatory authorities or other governmental agencies in connection with a regulatory filing in accordance with the terms of this Agreement in any country in the Territory shall be permitted and shall be exempt from the provisions of this Section 12.9; provided, however, that Recipient will use efforts to see to it that such regulatory authorities or other governmental agencies treat such Information as confidential, which efforts shall be no less diligent than those Recipient uses to secure confidential treatment by regulatory authorities or other governmental agencies of Recipient's own, similarly confidential and/or proprietary data, information, know-how and materials. Notwithstanding anything else contained herein, any disclosure by JANSSEN of NANO Information to regulatory authorities or governmental agencies will be made in accordance with JANSSEN's normal business practices as consistently applied to its other pharmaceutical products.

12.10 With respect to data concerning Product, including data contained in Information, NANO shall have the right to use and to disclose to Third Parties, with no financial obligation to JANSSEN, data related to Nano Crystal Technology; provided, however, that in any such disclosure NANO shall not (i) disclose that such data is derived from Compound or Product, or (ii) identify, directly or indirectly, JANSSEN or the Compound.

12.11 The parties recognize the importance of publishing Information developed in clinical studies undertaken by JANSSEN or on behalf of JANSSEN under the provisions of this Agreement. Therefore, subject to NANO's prior approval, which approval shall not be unreasonably withheld, JANSSEN shall have the right to publish such studies in furtherance of the purposes of this Agreement: provided however that such studies do not contain any Highly Confidential Information.

12.12 With respect to Highly Confidential Information, JANSSEN and any Authorized Party to whom JANSSEN discloses Highly Confidential Information, in addition to complying with the obligations set forth herein for Information, shall:

(a) disclose it only to employees on a need to know basis to the extent permitted hereunder;

(b) treat it as confidential information and safeguard it against disclosure using strict standards and care as provided for in this Section 12.12 to protect it from disclosure to those not authorized to receive it hereunder;

(c) use it only in developing and manufacturing Products in accordance with the terms of this Agreement;

(d) require any employee that will receive it to sign for receipt of a numbered copy of it, acknowledging also such employee's receipt of the Statement attached hereto as Form 1;

(e) not make copies of any documents embodying or containing it without the prior written authorization from NANO unless all copies thereof are numbered, a record is maintained of the recipient of each said numbered copy, and such records are provided promptly to NANO upon request;

(f) retain all documents embodying or containing it under lock, separate from JANSSEN's other records and information and in the personal control of one employee of JANSSEN who shall be approved by NANO;

(g) immediately notify NANO in writing in the event of any loss, theft or disclosure thereof; and

(h) treat any modifications, advances, extensions, enhancements, or other changes to it made by JANSSEN or any Authorized Party to whom it is disclosed by JANSSEN as Highly Confidential Information as provided hereunder in the same manner as and in accordance with the provisions of this Agreement relating to Highly Confidential Information.

ARTICLE 13 - TERM

This Agreement shall become effective from the Effective Date and unless sooner terminated pursuant to any other provision of this Agreement continue in full force until the last to expire of the Nano Patents or Selection Patents, or for twenty (20) years from the Effective Date, whichever results in the longer period of time.

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

ARTICLE 14 - TERMINATION BY JANSSEN

Notwithstanding any other provision herein, JANSSEN may terminate this Agreement with respect to the entire Territory or with respect to one or more of the Major Markets upon three (3) months prior written notice to NANO.

ARTICLE 15 - TERMINATION FOR CAUSE

15.1 In the event JANSSEN or NANO or their respective Affiliates and Licensees are in material breach of any of the respective obligations and conditions contained in this Agreement, the other party shall be entitled to give the party in breach notice requiring it to cure such material breach. If such material breach is not cured within ninety (90) days after receipt of such notice, the notifying party shall be entitled (without prejudice to any of its other rights conferred on it by this Agreement) to terminate this Agreement by giving notice thereof to the party in breach, which notice shall take effect immediately.

15.2 If either party elects not to terminate this Agreement under Section 15.1 in the event of a material breach by the other party hereto, the non-breaching party may seek a determination of damages for the breach from the breaching party by resorting to the dispute resolution procedures set forth in Article 22. Upon a determination of such damages under Article 22, the non-breaching party may, to the extent possible, offset such damages against such party's payment obligations under this Agreement. Nothing herein shall prevent either party hereto from exercising such party's right to obtain temporary or permanent injunctive relief or other equitable relief restraining the other party from engaging in conduct that would constitute a breach of Article 12 or Article 31.

15.3 In the event that one of the parties hereto becomes bankrupt or insolvent, a receiver or a trustee is appointed for the property or estate of such party and said receiver or trustee is not removed within sixty (60) days, or the party makes an assignment for the benefit of its creditors, and whether any of the aforesaid events be the outcome of the voluntary act of that party, or otherwise, the other party shall be entitled to terminate this Agreement forthwith by giving a written notice to the first party.

ARTICLE 16 - RIGHTS AND OBLIGATIONS UPON TERMINATION

16.1 Upon the expiration of the term of this Agreement under Article 13, but not upon its earlier termination, JANSSEN's license rights under Section 2.1 shall become fully paid-up and shall thereafter remain royalty-free and irrevocable, but shall be non-exclusive. In addition, the provisions of Article 1, Sections 7.4, 7.5, 7.6 and

7.7, Sections 10.2, 10.3 and 10.4, Article 12 (as indicated in Section 12.8), and Articles 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29 and 30 shall survive such expiration, and all payment obligations accruing under this Agreement prior to its expiration, including without limitation all payment obligations accruing under Articles 5 and 6, shall survive such expiration.

16.2 In the event that this Agreement is terminated by JANSSEN in the entire Territory or in all Major Markets in accordance with Article 14, or by either party pursuant to Article 15, the provisions of Article 1, Sections 7.4, 7.5, 7.6 and 7.7, Sections 10.2, 10.3 and 10.4, Article 12 (as indicated in Section 12.8), and Articles 16, 17, 18, 19, 20, 21, 22, 23, 24, , 26, 27, 28, 29, 30 and 31 (as indicated therein) shall survive such termination, and all payment obligations accruing under this Agreement prior to the effective date of termination, including without limitation all payment obligations accruing under Articles 5 and 6, shall survive such termination.

16.3 Subject to the parties' obligations under Article 21 and to the limitation of liability in Section 18.4, termination of this Agreement by either party shall not prejudice the rights of such party under this Agreement to seek damages for any breach of this Agreement by the other party hereto.

ARTICLE 17 - REPRESENTATIONS AND WARRANTIES

17.1 NANO represents and warrants to JANSSEN that:

(a) The execution, delivery and performance of this Agreement by NANO does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it;

(b) NANO is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

(c) NANO is duly organized and validly existing under the laws of the state of its incorporation and has full legal power and authority to enter into this Agreement;

(d) To the best of NANO's knowledge, all of the Nano Patents are subsisting and are valid and enforceable;

(e) NANO has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Nano Patents or Nano Know-How as they relate to Compound or Product;

(f) NANO is the sole and exclusive owner or licensee of the Nano Patents and the Nano Know-How, all of which, to the best of NANO'S knowledge, are free and clear of any liens, charges and encumbrances, and, except for NANO's Affiliates, no other person, corporate or other private entity, or governmental entity or subdivision thereof has, or shall have, any claim of control with respect to the Nano Patents and the Nano Know-How as they relate to Compound or Product; and

(g) There are no claims, judgments or settlements against or owed by NANO pending or, to the knowledge of NANO, threatened, with respect to the Nano Patents and the Nano Know-How as they relate to Compound or Product.

17.2 JANSSEN represents and warrants to NANO that:

(a) The execution, delivery and performance of this Agreement by JANSSEN does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it;

(b) JANSSEN is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

(c) JANSSEN is duly organized and validly existing under the laws of the state of its incorporation and has full legal power and authority to enter into this Agreement;

(d) JANSSEN will not bind or purport to bind NANO to any affirmation, representation or warranty provided to any Third Party with respect to the Compound or Product; and

(e) To the best of JANSSEN's actual knowledge on the Effective Date, there is no reason to believe that the Selection Patent listed on the attached Exhibit B will not issue or will not be valid.

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

17.3 THE LIMITED WARRANTIES CONTAINED IN THIS SECTION 17 ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES.

ARTICLE 18 - INDEMNIFICATION

18.1 Each party (the "Indemnifying Party") shall indemnify, defend and hold the other party and its Affiliates, Licensees, employees, officers, directors, agents and consultants (each an "Indemnified Party") harmless from, against and in respect of any damages, claims, losses, liabilities, charges, actions, suits, proceedings, penalties and reasonable costs and expenses (including without limitation reasonable attorneys' fees) (collectively, the "Losses") imposed on, sustained, incurred or suffered by or asserted against any Indemnified Party, to the extent such Losses are incurred in the defense or settlement of a Third Party lawsuit or in a satisfaction of a Third Party judgment arising out of :

(a) any injuries to person and/or damage to property resulting from negligent acts that the Indemnifying Party or its Affiliates, Licensees, employees, officers, directors, agents or consultants, performed or failed to perform in carrying out activities contemplated under this Agreement or any Development Program conducted hereunder, including the negligent failure by the Indemnifying Party to provide the Indemnified Party with any Information known by Indemnifying Party that, if timely received, would have enabled the Indemnified Party to avoid such injuries or damage; and

(b) personal injury to the Indemnified Party or damage to the Indemnified Party's property resulting from negligence or intentional misconduct on the part of the Indemnifying Party or its Affiliates, Licensees, employees, officers, directors, agents and consultants in carrying out the activities contemplated by this Agreement;

provided, however, that an Indemnified Party shall not be indemnified under this Section 18.1 to the extent that such party's own negligence or intentional misconduct caused or contributed to the events giving rise to the claim for indemnification.

18.2 JANSSEN shall indemnify, defend and hold NANO and its Affiliates, and each of their officers, directors, employees, agents and consultants (each a "NANO Indemnitee") harmless from and against all Losses (other than those that are the subject of Section 18.1 hereof) arising out of or resulting from the use by or administration to any person of any Product sold or otherwise distributed by JANSSEN, its Affiliates or Licensees or any of their distributors, except to the extent such Losses arose or resulted from negligence or intentional misconduct on the part of NANO or its Affiliates, Licensees, employees, officers, directors, agents or consultants in carrying out the activities contemplated by this Agreement, so long as (i) the NANO Indemnitee allows JANSSEN to participate in or, at JANSSEN's sole option but without any obligation, to conduct at JANSSEN's expense the defense of the claim or action for which indemnification is sought under this Section 18.2, and (ii) the NANO Indemnitee does not compromise or settle such claim or action without JANSSEN's prior written consent, which shall not be unreasonably withheld.

18.3 NANO shall indemnify, defend and hold JANSSEN, its Affiliates and Licensees and each of their officers, directors, employees, agents and consultants (each a "JANSSEN Indemnitee") harmless from and against all Losses (other than those that are the subject of Section 18.1 hereof) arising out of or resulting from negligence or intentional misconduct on the part of NANO or its Affiliates, Licensees, employees, officers, directors, agents or consultants in carrying out the activities contemplated by this Agreement, so long as (i) the JANSSEN Indemnitee allows NANO to participate in or, at NANO's sole option but without the obligation, to conduct at NANO's expense the defense of the claim or action for which indemnification is sought under this Section 18.3, and (ii) the JANSSEN Indemnitee does not compromise or settle such claim or action without NANO's prior written consent, which shall not be unreasonably withheld.

18.4 IN NO EVENT SHALL ANY PARTY, OR SUCH PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES, BE LIABLE TO THE OTHER PARTY OR PARTIES HERETO FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES, COSTS OR EXPENSES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS), WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, ARISING FROM A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, EVEN IF SUCH OTHER PARTY OR PARTIES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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

ARTICLE 19 - CHOICE OF LAW

The construction, validity and performance of this Agreement shall be governed in all respects by the laws of the State of New Jersey, without giving effect to principles of conflict of laws.

ARTICLE 20 - FORCE MAJEURE

No failure or omission by the parties hereto in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement nor create any liability if the same shall arise from any cause or causes beyond the control of the parties, including but not limited to the following which, for the purposes of this Agreement, shall be regarded as beyond the control of the party in question; act of God, acts or omissions of any government or any rules, regulations or orders of any governmental authority or any officer, department, agency or instrument thereof; fire, storm, flood, earthquake, accident, acts of the public enemy, war, rebellion, insurrection, riot, invasion, strikes or lockouts.

ARTICLE 21 - DISPUTE RESOLUTION

21.1 Any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to an alleged breach or to termination of this Agreement (hereinafter "Disputes"), but excluding (i) any dispute, controversy or claim arising out of or relating to the validity, enforceability, or infringement of any Janssen Patent or any Nano Patent and (ii) other disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by arbitration in the manner described below:

(a) Before either party institutes arbitration proceedings in accordance with Section 21.2 with respect to any Dispute, executive officers of both parties shall meet in order to attempt to resolve such Dispute in a mutual acceptable manner.

(b) In the event the negotiations do not result in a mutually acceptable resolution within a reasonably short period of time (not to exceed 30 days) or no meeting between the executive officers has occurred within 30 days following the notification of such Dispute, either party shall have the right to institute arbitration proceedings.

(c) If a party intends to begin an arbitration procedure to resolve a Dispute, such party shall provide written notice (the "Arbitration Request") to the other party informing the other party of such intention and the issues to be resolved. From the date of the Arbitration Request and

until such time as any matter has been finally settled by Arbitration, the time periods provided for in Section 15.1 as to which a party must cure a breach of this Agreement shall be suspended as to the subject matter of the Dispute.

(d) Within fifteen (15) business days after receipt of the Arbitration Request, the other party may, by written notice to the party initiating the Arbitration, add additional issues to be resolved.

(e) Nothing herein shall prohibit either party hereto from seeking or obtaining temporary injunctive relief pending resolution of any Dispute in accordance with the provisions of this Article 21. In addition, nothing herein shall prohibit (i) a party hereto that is sued by a third party from filing a third party complaint against the other party hereto, or (ii) a party hereto from preserving its rights as a creditor of the other party hereto in the event that such other party becomes insolvent, voluntary or involuntary bankruptcy proceedings are instituted by or against such other party, a receiver or custodian is appointed for such other party, such other party makes an assignment for the benefit of its creditors, substantially all of the assets of such other party are seized or attached, such other party files for reorganization or dissolution, or such other person otherwise generally ceases to pay its debts when they become due.

21.2 The Arbitration shall be conducted in accordance with the Center For Public Resources Rules For Non-Administered Arbitration of Business Disputes, the arbitration proceeding shall be conducted in New York, New York. Notwithstanding those rules, the following provisions shall in any event apply to any issue submitted for arbitration hereunder.

(a) The arbitration shall be conducted by a panel of three neutral arbitrators ("Panel"). One member shall be appointed by each party and the third member shall be appointed by the two arbitrators appointed by the parties. The parties will select an arbitrator within fifteen (15) business days following the Arbitration request. The two arbitrators selected by the parties will appoint the third member within ten (10) days following their appointment.

Notwithstanding the above and in the interest of obtaining a judgment within the shortest possible period in connection with (i) certain technical or developmental matters that require referral to independent experts or (ii) Disputes where the aggregate damages sought by the claimant are stated to be less than [**] and neither party seeks equitable relief, the parties will appoint only one single neutral selected in agreement by both parties and

the provisions hereof shall apply *mutatis mutandis* to such single arbitrator.

(b) The language to be used in the arbitration shall be English.

(c) Any arbitrator selected by the parties may be of any nationality, and need not be a lawyer or hold any other professional status or membership but will be selected on the basis of his or her qualifications and expertise with respect to the matter under Dispute.

(d) The Panel shall resolve the Dispute on the basis of a written record consisting of an initial and rebuttal submission by each party (together with documentary evidence (including affidavits) supporting the positions taken in such submissions); provided that the Panel shall have the right to require the parties to make or participate in such other written or oral submissions, presentations, or examinations as the Panel shall deem necessary for the proper resolution of the matter under arbitration, all of which shall be made or submitted directly to the Panel and shall become part of the record in the proceeding.

(e) The specific pleading schedule for each proceeding shall be determined by the parties in consultation with the Panel within fifteen (15) business days following the selection of the arbitrators.

(f) Unless the parties otherwise agree at the time a particular issue is submitted for arbitration, the Panel shall be required as a condition to their engagement to agree to render a decision within thirty (30) days of the date on which the record in the proceeding is completed, but in no case more than one hundred and twenty (120) days after the date of their engagement.

(g) The parties shall use their best efforts to schedule and make their submissions, and to take all other necessary actions in connection with the proceeding, at a time and in a manner which will permit the Panel to render their decision in accordance with the schedule set forth herein.

(h) All communications with the arbitrator(s) during the proceeding shall be made in writing, with a copy thereof delivered simultaneously to the other party to the proceeding, or if made orally, made only in the presence of the other party to the proceeding or its representative.

(i) All decisions by the Panel shall be rendered by majority vote. The arbitration award or order shall be rendered in writing and shall be final and binding upon the parties. The arbitrator(s) hereunder (i) shall have no power or authority to grant or award punitive damages and (ii) shall

establish and enforce appropriate rules to ensure that the arbitration proceedings, including the decisions, are kept confidential and that all confidential and/or proprietary information of the parties is kept confidential and is used for no purpose other than for such arbitration proceedings.

(j) Judgment on any order or award shall be entered by any court of competent jurisdiction.

(k) Each party shall bear its own expenses and attorney's fees in connection with the arbitration. The fees and expenses of the arbitrator(s) shall be equally shared except that if, in the opinion of the arbitrators, any claim by a party hereto or any defense or objection thereto by the other party was unreasonable and frivolous, the arbitrators may in their discretion assess as part of the award all or any part of the arbitration expenses of the other party (including reasonable attorney's fees) and expenses of the arbitrators against the party raising such unreasonable and frivolous claim, defense or objection.

ARTICLE 22 - NOTICES

Any notice required or permitted to be given under this Agreement shall be mailed by registered or certified air mail, postage prepaid, addressed to the party to be notified at its address stated below, or at such other address as may hereafter be furnished in writing to the notifying party or by telefax to the numbers set forth below or to such changed telefax numbers as may thereafter be furnished.

If to NANO, EPIL and/or EPRC:
Elan Pharma International Limited
Lincoln House, Lincoln Place
Dublin 2, Ireland
Attention: Colin Sainsbury, Esq.
Telefax: 353-1-709-4124

With a copy to:
NanoSystems
3000 Horizon Drive
King of Prussia, PA 19406
Attention: President
Telefax: 610-313-5180

If to JANSSEN:
Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beerse Belgium
Attention: Managing Director
Telefax: 32-14-60-2841

Any notice sent under this Article 22 shall be deemed to have been received on the date actually received, or (i) five (5) business days after being mailed in the case of a notice mailed by registered or certified mail, postage prepaid; and (ii) one (1) business day after being transmitted in the case of a notice transmitted via telefax. The business days referred to in this Section 23.2 shall be business days of the recipient of the notice.

ARTICLE 23 - WAIVER

The failure on the part of NANO or JANSSEN to exercise or enforce any rights conferred upon it hereunder (including any right to terminate this Agreement under Article 15) shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter. The observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) by the party entitled to enforce such term, but any such waiver shall be effective only if in a writing signed by the party against whom such waiver is to be asserted.

ARTICLE 24 - ENTIRE AGREEMENT

24.1 Agreement constitutes the entire agreement between the parties hereto concerning the subject matter hereof and any representation, promise or condition in connection therewith, not incorporated herein, shall not be binding upon either party. This Agreement, including without limitation the exhibits attached hereto, are intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise or representation, written or oral, which is not set forth explicitly herein is intended by either party to be legally binding.

24.2 This Agreement shall expressly supersede and replace the Feasibility Agreement as the same is related to Compound and, as of the Effective Date, the Feasibility Agreement as it relates to Compound shall be of no further force or effect and shall hereby be replaced in its entirety with the terms and conditions of this Agreement.

ARTICLE 25 - ASSIGNMENT

25.1 Subject to the provisions of Section 9.2 in connection with Highly Confidential Information, JANSSEN may assign any or part of its rights under this Agreement

to any of its Affiliates. Prior to any such assignment becoming effective, such Affiliate will undertake in writing to abide by all terms and conditions of this Agreement.

25.2 JANSSEN and NANO will discuss any assignment by JANSSEN to an Affiliate prior to its implementation in order to avoid or reduce any additional tax liability to NANO resulting solely from different tax law provisions applying after such assignment to an Affiliate. For the purpose hereof, an additional tax liability to NANO means that NANO would be subject to a higher net tax on payments made hereunder after taking into account any applicable tax treaty and available tax credits, than NANO was subject to before the proposed assignment. In case no reasonable solution can be found in order to reduce or eliminate the above referred additional tax liability to NANO and NANO can demonstrate by means of written documentation, certified by an independent external auditor, that NANO cannot take a full credit against such tax liability, then NANO shall be made whole by JANSSEN or the assignee as the case may be, whenever JANSSEN wants to proceed with such assignment to such Affiliate. To the extent that NANO is not a taxable entity, any references to NANO shall, solely for the purposes of this Article, deem to refer to its members.

25.3 JANSSEN and NANO will discuss any assignment by NANO to an Affiliate prior to its implementation in order to avoid or reduce any additional tax liability to JANSSEN resulting solely from different tax law provisions applying after such assignment to an Affiliate. For the purpose hereof, an additional tax liability to JANSSEN means that JANSSEN would be subject to a higher net tax on payments made hereunder after taking into account any applicable tax treaty and available tax credits, than JANSSEN was subject to before the proposed assignment. In case no reasonable solution can be found in order to reduce or eliminate the above referred additional tax liability to JANSSEN and JANSSEN can demonstrate by means of written documentation, certified by an independent external auditor, that JANSSEN cannot take a full credit against such tax liability, then JANSSEN shall be made whole by NANO or the assignee as the case may be, whenever NANO wants to proceed with such assignment to such Affiliate. To the extent that JANSSEN is not a taxable entity, any references to JANSSEN shall, solely for the purposes of this Article, deem to refer to its members.

25.4 NANO will be entitled to assign all or a portion of its rights and obligations under this Agreement to an Affiliate or to a Third Party that acquires all or substantially all of NANO's rights in the NanoCrystal Technology from NANO. Prior to any such assignment becoming effective, such Affiliate or Third Party assignee will undertake in writing to abide by all terms and conditions of this Agreement.

ARTICLE 26 - TITLES

It is agreed that the marginal headings appearing at the beginning of the numbered Articles hereof have been inserted for convenience only and do not constitute any part of this Agreement.

ARTICLE 27 - PUBLICITY

Neither party shall originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it or any of its terms, to any amendment hereto or performances hereunder without the prior written consent of the other party, provided however, that this Article 27 shall not be applicable where either party hereto is legally required to make public, a summary or details of this Agreement, in any country. If a party believes that it has a legal requirement to make public the existence of or any details of or any events related in any way to this Agreement, it shall provide a copy of any such announcement to the other party for review and approval at least five (5) days prior to making said announcement. Nothing herein shall limit the parties' obligations under Article 12 with respect to Information and Highly Confidential Information.

ARTICLE 28 - UNENFORCEABLE PROVISIONS

The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any person or entity or any circumstance, is invalid or unenforceable, (i) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid and unenforceable provision and (ii) the remainder of this Agreement and the application of such provision to other persons, entities or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect such provision, or the application thereof, in any other jurisdiction.

ARTICLE 29 - CONSTRUCTION

As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by fact or context.

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

ARTICLE 30 - EXECUTION

This Agreement shall be executed in two (2) counterparts, each of which shall for all purposes be deemed an original.

ARTICLE 31 - NON-SOLICITATION

From the Effective Date until two (2) years following the First Commercial Sale in any of the Major Markets, JANSSEN shall not, directly or indirectly, induce, encourage, or solicit any technical personnel employed by EPRC to (i) leave such employment or (ii) accept any other position or employment, nor shall JANSSEN assist any other entity to induce, encourage, or solicit any technical personnel employed by EPRC to (i) leave such employment or (ii) accept any other position or employment.

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

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers or representatives as of the day and year first above written.

ELAN PHARMACEUTICAL
RESEARCH CORP., d/b/a
NANOSYSTEMS

By: /s/ Seamus Mulligan
Name: S. Mulligan
Title: President 31/3/99

ELAN PHARMA INTERNATIONAL LIMITED

By: /s/ Seamus Mulligan
Name: S. Mulligan
Title: President 31/3/99

JANSSEN PHARMACEUTICA N.V.

By: /s/ G. Van Reet
Name: Managing Director
Title:

By: /s/ G. Vercauteren
Name: International Vice President
Business Development

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

EXHIBIT A: NANO PATENTS

[**]

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

EXHIBIT B: SELECTION PATENTS

[**]

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

FORM 1: STATEMENT

The information contained in this document is strictly confidential information and shall be treated accordingly by the receiver. In no event shall any copies be made or shall the information be disclosed to a third party. Any disclosure to an employee of JANSSEN or of a JANSSEN Affiliate shall be on a strict need to know basis. The receiver shall keep the document under lock in a safe place. The information shall be used only as authorized by JANSSEN in the development and/or manufacturing of a nanoparticle product.

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

"Agreement Amendment No. 2"

[17 March, 2011]

Janssen Pharmaceutica N.V.
Turnhoutseweg 30
B-2340 Beerse
Belgium

Elan Drug Delivery, Inc.
3500 Horizon Drive
King of Prussia, PA 19046
USA

Dear Sirs

*RE: License Agreement dated March 31, 1999 (the "**Agreement**"), as amended by letter amendment of July 31, 2003, between Elan Drug Delivery, Inc. (successor in interest in and to Elan Pharmaceutical Research Corp., d/b/a Nanosystems ("**EDDI**") and Elan Pharma International Limited ("**EPIL**") (EDDI and EPIL collectively hereinafter referred to as "**Elan**") and Janssen Pharmaceutica N.V. ("**Janssen**")*

Elan and Janssen hereby agree that with effect from July 31, 2009 this Agreement Amendment No. 2 ("**Agreement Amendment No. 2 Effective Date**") the Agreement shall be amended as follows:

1. All references in the Agreement to EPRC shall read EDDI. All references to NANO shall read Elan**.**

2. **Article 22** Elan contact details only **-** shall be deleted and replaced with the following:

If to Elan: Elan Pharma International Limited

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

Monksland, Athlone, County Westmeath, Ireland

Attention: Vice President & Legal Counsel
Telefax: 00 353 90 64 95402

With a copy to: Elan Drug Delivery, Inc.
3500 Horizon Drive, King of Prussia, PA 19406,
USA

Attention: President
Telefax: 001 610-313-5182

3. Patent Schedules

3.1 **Exhibit A: Nano Patents** shall be deleted and replaced with Exhibit A: Nano Patents — Updated January, 2011, attached hereto.

Exhibit B: Selection Patents shall be deleted and replaced with Exhibit B Selection Patents — Updated January 2011, attached hereto.

4. Defined texts used in this Agreement Amendment No. 2 shall have the meaning assigned to them in the Agreement unless such terms are expressly defined in this Agreement Amendment No. 2. All other provisions of the Agreement not amended herein shall remain unchanged and in full force and effect.

Yours faithfully,

Signed on behalf of:
Elan Pharma International Limited

/s/ William Daniel
Name: William Daniel
Title: Director
Date: 1 April 2011

Agreed and accepted for and on behalf of
Elan Drug Delivery, Inc. successor in interest in and to Elan Pharmaceutical Research Corp., d/b/a Nanosystems

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

/s/ David Czekai

Name: David Czekai
Title: VP and GM
Date: 18 Apr 2011

Accepted for and on behalf of:
Janssen Pharamceutica N.V.

/s/ Ludo Lauwers

Name: Ludo Lauwers
Title: Senior Vice President, Site Management
Date: 17 March 2011

/s/ Dirk Collier

Member of the Board

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

Exhibit A: Nano Patents—Updated January, 2011

[**]

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

[**Exhibit B: Selection Patents—Updated July 31, 2009**]

[**]

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: April 26, 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: April 26, 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 March 31, 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: April 26, 2023

/s/ Richard F. Pops
Richard F. Pops

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: April 26, 2023

/s/ Iain M. Brown
Iain M. Brown

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