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# 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 June 30, 2015

OR

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

Commission File Number 001-35299

### ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

**Ireland**

(State or other jurisdiction of incorporation or organization)

**98-1007018**

(I.R.S. Employer Identification No.)

**Connaught House**

**1 Burlington Road**

**Dublin 4, Ireland**

(Address of principal executive offices)

**+ 353-1-772-8000**

(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files): Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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 July 27, 2015 was 149,398,549 shares.

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**ALKERMES PLC AND SUBSIDIARIES**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015**

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## Cautionary Note Concerning Forward-Looking Statements

This document contains and incorporates by reference “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 (“Form 10-Q”) include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products, including our development programs;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations and other significant agreements relating to our products, including our development programs;
- our expectations regarding the financial impact related to the sale of our Gainesville, GA facility and the related manufacturing and royalty revenue associated with products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam and the related contingent consideration (herein referred to as the “Gainesville Transaction”);
- our expectations regarding the impact of adoption of new accounting pronouncements;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management’s objectives and strategies with respect to managing such exposures;
- our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations; and
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

Actual results might differ materially from those expressed or implied by the forward-looking statements contained in this Form 10-Q because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements in this Form 10-Q, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Form 10-Q might not occur. For more information regarding the risks and uncertainties of our business, see “Item 1A—Risk Factors” in Part II of this Form 10-Q, “Part I, Item 1A—Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2014 (the “Annual Report”) and any subsequent reports filed with the U.S. Securities and Exchange Commission (“SEC”).

Unless otherwise indicated, information contained in this Form 10-Q concerning the disorders targeted by our products and the markets in which we operate is based on information from various third-party sources (including, without limitation, industry publications, medical and clinical journals and studies, surveys and forecasts) as well as our internal research. Our internal research involves assumptions that we have made, which we believe are reasonable, based on data from those and other similar sources and on our knowledge of the markets for our marketed and development products. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. These projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Item 1A—Risk Factors” in Part II of this

Form 10-Q and “Part I, Item 1A—Risk Factors” of our Annual Report. These and other factors could cause our results to differ materially from those expressed in the estimates included in this Form 10-Q.

### **Note Regarding Company**

Alkermes plc (as used in this report, together with our subsidiaries, “Alkermes,” “the Company,” “us,” “we” and “our”) 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 our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of commercial drug products and a clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis.

### **Note Regarding Trademarks**

We are the owner of various U.S. federal trademark registrations (“®”) and registration applications (“™”), including ARISTADA™, LinkeRx®, NanoCrystal®, SECA™ and VIVITROL®. The following are trademarks of the respective companies listed: ABILIFY®—Otsuka Pharmaceutical Co., Ltd.; AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc.; BIDIL™—Arbor Pharmaceuticals, LLC; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC; INVEGA® SUSTENNA®, INVEGA TRINZA™, XEPLION®, and RISPERDAL® CONSTA®—Johnson & Johnson Corp. (or its affiliate); MEGACE®—E.R. Squibb & Sons, LLC; RITALIN LA® and FOCALIN XR®—Novartis AG; TECFIDERA®—Biogen MA Inc.; TRICOR®—Abbvie Inc.; VERELAN®—Recro Technology, LLC; ZOHYDRO® ER—Ferrimill Limited; and ZYPREXA®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(unaudited)

	<u>June 30, 2015</u>	<u>December 31, 2014</u>
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 196,893	\$ 224,064
Investments — short-term	579,877	407,102
Receivables, net	135,782	151,551
Inventory	38,801	51,357
Prepaid expenses and other current assets	50,424	29,289
Deferred tax assets — current	15,185	13,430
Total current assets	<u>1,016,962</u>	<u>876,793</u>
PROPERTY, PLANT AND EQUIPMENT, NET	239,258	265,740
INTANGIBLE ASSETS—NET	407,599	479,412
GOODWILL	92,873	94,212
CONTINGENT CONSIDERATION	59,100	-
INVESTMENTS—LONG-TERM	55,589	170,480
OTHER ASSETS	43,295	34,635
<b>TOTAL ASSETS</b>	<b>\$ 1,914,676</b>	<b>\$ 1,921,272</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 125,722	\$ 121,258
Long-term debt—short-term	6,750	6,750
Deferred revenue—short-term	1,746	2,574
Total current liabilities	<u>134,218</u>	<u>130,582</u>
LONG-TERM DEBT	348,056	351,220
OTHER LONG-TERM LIABILITIES	12,859	11,914
DEFERRED TAX LIABILITIES, NET—LONG-TERM	12,747	18,918
DEFERRED REVENUE—LONG-TERM	7,805	11,801
Total liabilities	<u>515,685</u>	<u>524,435</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 15)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at June 30, 2015 and December 31, 2014, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 150,581,367 and 148,545,150 shares issued; 149,304,016 and 147,538,519 shares outstanding at June 30, 2015, and December 31, 2014, respectively	1,503	1,482
Treasury shares, at cost (1,277,351 and 1,006,631 shares at June 30, 2015 and December 31, 2014, respectively)	(49,384)	(32,052)
Additional paid-in capital	2,038,700	1,942,878
Accumulated other comprehensive loss	(2,725)	(3,136)
Accumulated deficit	(589,103)	(512,335)
Total shareholders' equity	<u>1,398,991</u>	<u>1,396,837</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 1,914,676</b>	<b>\$ 1,921,272</b>

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		Six Months Ended	
	June 30,	2014	June 30,	2014
	2015	2014	2015	2014
(In thousands, except per share amounts)				
<b>REVENUES:</b>				
Manufacturing and royalty revenues	\$ 113,162	\$ 130,366	\$ 241,906	\$ 241,646
Product sales, net	37,172	21,595	68,309	38,674
Research and development revenue	1,036	1,463	2,369	3,316
<b>Total revenues</b>	<b>151,370</b>	<b>153,424</b>	<b>312,584</b>	<b>283,636</b>
<b>EXPENSES:</b>				
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	30,418	43,290	70,392	82,129
Research and development	87,882	67,207	158,160	119,347
Selling, general and administrative	71,539	50,663	134,589	93,213
Amortization of acquired intangible assets	14,052	15,089	29,272	27,665
<b>Total expenses</b>	<b>203,891</b>	<b>176,249</b>	<b>392,413</b>	<b>322,354</b>
<b>OPERATING LOSS</b>	<b>(52,521)</b>	<b>(22,825)</b>	<b>(79,829)</b>	<b>(38,718)</b>
<b>OTHER INCOME, NET:</b>				
Interest income	795	323	1,455	834
Interest expense	(3,315)	(3,385)	(6,603)	(6,741)
Gain on Gainesville Transaction	9,911	—	9,911	—
Increase in the fair value of contingent consideration	1,500	—	1,500	—
Other income (expense), net	585	518	374	(1,332)
Gain on sale of property, plant and equipment	—	12,285	—	12,285
Gain on sale of investment in Acceleron Pharma Inc.	—	15,296	—	15,296
<b>Total other income, net</b>	<b>9,476</b>	<b>25,037</b>	<b>6,637</b>	<b>20,342</b>
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(43,045)</b>	<b>2,212</b>	<b>(73,192)</b>	<b>(18,376)</b>
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>	<b>3,064</b>	<b>(1,523)</b>	<b>3,574</b>	<b>2,243</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (46,109)</b>	<b>\$ 3,735</b>	<b>\$ (76,766)</b>	<b>\$ (20,619)</b>
<b>(LOSS) EARNINGS PER COMMON SHARE:</b>				
Basic	\$ (0.31)	\$ 0.03	\$ (0.52)	\$ (0.14)
Diluted	\$ (0.31)	\$ 0.02	\$ (0.52)	\$ (0.14)
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				
Basic	148,867	144,913	148,480	144,140
Diluted	148,867	154,300	148,480	144,140
<b>COMPREHENSIVE LOSS:</b>				
Net (loss) income	\$ (46,109)	\$ 3,735	\$ (76,766)	\$ (20,619)
Holding (losses) gains, net of tax of \$(39), \$6,174, \$170 and \$7,627, respectively	(80)	4,540	409	2,009
Reclassification of unrealized gains to realized gains	—	(15,296)	—	(15,296)
<b>COMPREHENSIVE LOSS</b>	<b>\$ (46,189)</b>	<b>\$ (7,021)</b>	<b>\$ (76,357)</b>	<b>\$ (33,906)</b>

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)**

	Six Months Ended	
	June 30,	
	2015	2014
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (76,766)	\$ (20,619)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	43,108	47,486
Share-based compensation expense	39,206	32,758
Deferred income taxes	(21,624)	(10,664)
Excess tax benefit from share-based compensation	(16,506)	(6,984)
Gain on Gainesville Transaction	(9,911)	—
Increase in fair value of contingent consideration	(1,500)	—
Gain on sale of property, plant and equipment	(104)	(12,160)
Gain on sale of investment of Acceleron Pharma Inc.	—	(15,296)
Other non-cash charges	(435)	9,965
Changes in assets and liabilities:		
Receivables	3,249	(5,162)
Inventory, prepaid expenses and other assets	7,012	(19,714)
Accounts payable and accrued expenses	21,138	3,693
Deferred revenue	(788)	(1,304)
Other long-term liabilities	592	3,306
Cash flows (used in) provided by operating activities	<u>(13,329)</u>	<u>5,305</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions of property, plant and equipment	(24,755)	(11,438)
Proceeds from the sale of equipment	40	14,361
Net proceeds from the Gainesville Transaction	50,241	—
Purchases of investments	(269,447)	(433,203)
Sales and maturities of investments	212,143	184,446
Cash flows used in investing activities	<u>(31,778)</u>	<u>(245,834)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of ordinary shares, net	—	248,406
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	21,837	21,821
Excess tax benefit from share-based compensation	16,506	6,984
Employee taxes paid related to net share settlement of equity awards	(17,032)	(12,546)
Principal payments of long-term debt	(3,375)	(3,376)
Cash flows provided by financing activities	<u>17,936</u>	<u>261,289</u>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<u>(27,171)</u>	<u>20,760</u>
<b>CASH AND CASH EQUIVALENTS—Beginning of period</b>	<u>224,064</u>	<u>167,562</u>
<b>CASH AND CASH EQUIVALENTS—End of period</b>	<u>\$ 196,893</u>	<u>\$ 188,322</u>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 4,480	\$ 1,491
Fair value of warrants received as part of Gainesville Transaction	\$ 2,123	\$ —
Fair value of contingent consideration received as part of Gainesville Transaction	\$ 57,600	\$ —

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

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

**1. THE COMPANY**

Alkermes 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 our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of commercial drug products and a clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes has a research and development (“R&D”) center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of Presentation*

The accompanying condensed consolidated financial statements of the Company for the three and six months ended June 30, 2015 and 2014 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended December 31, 2014. 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 United States of America (“U.S.”) (commonly referred to as “GAAP”). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to state fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto of Alkermes, which are contained in the Company’s Annual Report, which has been filed with the SEC. 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 a full fiscal year.

*Principles of Consolidation*

The condensed consolidated financial statements include the accounts of Alkermes plc and its wholly owned subsidiaries as disclosed in Note 2, *Summary of Significant Accounting Policies*, within the “Notes to Consolidated Financial Statements” accompanying its 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 management to 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 and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of contingent consideration, valuation of investments, litigation and restructuring charges. 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 assumptions or conditions.

*Segment Information*

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious diseases. The Company’s chief decision maker, the Chairman and Chief Executive Officer, reviews the Company’s operating results on an aggregate basis and manages the Company’s operations as a single operating unit.



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

*New Accounting Pronouncements*

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

In April 2014, the FASB adopted guidance that amends the requirements for reporting discontinued operations. Under the amendment, only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results will be reported as discontinued operations in the financial statements. Currently, many disposals, some of which may be routine in nature and not a change in an entity's strategy, are reported in discontinued operations. The Company adopted this guidance on January 1, 2015.

In June 2014, the FASB issued guidance that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. Existing GAAP does not contain explicit guidance on how to account for these share-based payments. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Entities have the option of prospectively applying the guidance to awards granted or modified after the effective date or retrospectively applying the guidance to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In January 2015, the FASB issued guidance that simplifies income statement presentation by eliminating the concept of extraordinary items. The guidance becomes effective for the Company in its year ending December 31, 2016 and is not expected to have an impact on the Company's consolidated financial statements.

In April 2015, the FASB issued guidance simplifying the presentation of debt issuance costs. To simplify presentation of debt issuance costs, the amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in its year ending December 31, 2018, and the Company could early adopt the standard for its year ending December 31, 2017. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

### **3. DIVESTITURE**

On March 7, 2015, the Company entered into a definitive agreement to sell the Gainesville, GA facility, the related manufacturing and royalty revenue associated with products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam to Recro Pharma, Inc. (“Recro”) and Recro Pharma LLC (together with Recro, the “Purchasers”). The sale was completed on April 10, 2015 and, under the terms of the agreement, Recro paid the Company \$54.0 million in cash and issued warrants to purchase an aggregate of 350,000 shares of Recro common stock at a per share exercise price of \$19.46, which was two times the closing price of Recro's common stock on the day prior

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

to closing. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam.

The gain on the Gainesville Transaction was determined as follows:

	<u>April 10, 2015</u> <u>(In thousands)</u>
<b>Sales Proceeds:</b>	
Cash	\$ 54,010
Fair value of warrants	2,123
Fair value of contingent consideration	57,600
Total consideration received	\$ 113,733
Less net assets sold	(101,373)
Less transaction costs	(2,449)
Gain on Gainesville Transaction	<u>\$ 9,911</u>

The Company recorded the gain on the Gainesville Transaction within the accompanying condensed consolidated statement of operations and comprehensive loss. The Company determined that the sale of assets in connection with the Gainesville Transaction did not constitute a strategic shift and that it did not and will not have a major effect on its operations and financial results. Accordingly, the operations from the Gainesville Transaction are not reported in discontinued operations.

During the three and six months ended June 30, 2015, the Gainesville, GA facility and associated intellectual property (“IP”) generated income before income taxes of \$2.4 million and \$7.6 million, respectively, and generated income before income taxes of \$7.8 million and \$16.4 million during the three and six months ended June 30, 2014, respectively.

The Company determined the value of the Gainesville Transaction’s contingent consideration using the following valuation approaches:

- The fair value of the two regulatory milestones were estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone events to occur within the next two and three years, respectively, and used a discount rate of 4.2% and 4.9%, respectively, for each of these events.
- To estimate the fair value of future royalties on net sales of the product, the Company assessed the likelihood of the product being approved for sale and expected future sales given approval and IP protection. The Company then discounted these expected payments using a discount rate of 15.9%, which the Company believes captures a market participant’s view of the risk associated with the expected payments.
- The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt plus an alpha, which ranged from 11.3% to 12.2%.

At June 30, 2015, the Company determined that the value of the Gainesville Transaction’s contingent consideration increased to \$59.1 million due primarily to a shorter time to payment on the milestones and royalties included in the contingent consideration. The \$1.5 million increase was recorded as “Change in the fair value of contingent consideration” in the three months ended June 30, 2015 in the accompanying condensed consolidated statements of operations and comprehensive loss.

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

The warrants the Company received to purchase 350,000 shares of Recro common stock were determined to have a fair value of \$2.1 million on the closing date of the transaction. At June 30, 2015, the Company determined that the value of these warrants had increased to \$3.0 million and are being recorded within other long-term assets in the accompanying condensed consolidated balance sheets. The company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at June 30, 2015:

Closing stock price at June 30, 2015	\$ 12.92
Warrant strike price	\$ 19.46
Expected term (years)	6.78
Risk-free rate	2.07 %
Volatility	80.0 %

The increase in the fair value of the warrants of \$0.9 million during the three months ended June 30, 2015 was recorded within other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss.

#### 4. INVESTMENTS

Investments consisted of the following:

	Amortized Cost	Gross Unrealized Losses		Estimated Fair Value	
		Gains	Less than One Year		Greater than One Year
<b>June 30, 2015</b>					
<b>Short-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 342,084	\$ 394	\$ (12)	\$ —	\$ 342,466
Corporate debt securities	220,406	75	(80)	—	220,401
International government agency debt securities	17,000	11	(1)	—	17,010
Total short-term investments	<u>579,490</u>	<u>480</u>	<u>(93)</u>	<u>—</u>	<u>579,877</u>
<b>Long-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	24,996	—	(32)	—	24,964
Corporate debt securities	19,068	—	(48)	—	19,020
International government agency debt securities	9,995	—	(9)	—	9,986
	<u>54,059</u>	<u>—</u>	<u>(89)</u>	<u>—</u>	<u>53,970</u>
<b>Held-to-maturity securities:</b>					
Certificates of deposit	1,619	—	—	—	1,619
Total long-term investments	<u>55,678</u>	<u>—</u>	<u>(89)</u>	<u>—</u>	<u>55,589</u>
Total investments	<u>\$ 635,168</u>	<u>\$ 480</u>	<u>\$ (182)</u>	<u>\$ —</u>	<u>\$ 635,466</u>
<b>December 31, 2014</b>					
<b>Short-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 226,387	\$ 88	\$ (15)	\$ —	\$ 226,460
Corporate debt securities	140,900	26	(66)	—	140,860
International government agency debt securities	39,774	13	(5)	—	39,782
Total short-term investments	<u>407,061</u>	<u>127</u>	<u>(86)</u>	<u>—</u>	<u>407,102</u>
<b>Long-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	100,429	—	(196)	(40)	100,193
Corporate debt securities	61,187	—	(84)	—	61,103
International government agency debt securities	7,568	—	(2)	(1)	7,565
	<u>169,184</u>	<u>—</u>	<u>(282)</u>	<u>(41)</u>	<u>168,861</u>
<b>Held-to-maturity securities:</b>					
Certificates of deposit	1,619	—	—	—	1,619
Total long-term investments	<u>170,803</u>	<u>—</u>	<u>(282)</u>	<u>(41)</u>	<u>170,480</u>
Total investments	<u>\$ 577,864</u>	<u>\$ 127</u>	<u>\$ (368)</u>	<u>\$ (41)</u>	<u>\$ 577,582</u>

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

The proceeds from the sales and maturities of marketable securities, which were primarily reinvested and resulted in realized gains and losses, were as follows:

(In thousands)	Six Months Ended June 30,	
	2015	2014
Proceeds from the sales and maturities of marketable securities	\$ 212,143	\$ 184,446
Realized gains	\$ 16	\$ 15,304
Realized losses	\$ 1	\$ 10

The Company's available-for-sale and held-to-maturity securities at June 30, 2015 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 342,340	\$ 342,368	\$ 1,619	\$ 1,619
After 1 year through 5 years	291,209	291,479	—	—
Total	<u>\$ 633,549</u>	<u>\$ 633,847</u>	<u>\$ 1,619</u>	<u>\$ 1,619</u>

At June 30, 2015, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of U.S. government and agency debt securities and corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

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 healthcare, pharmaceutical and life sciences sectors. The Company's commitment represents approximately 7% of the partnership's total funding, and the Company is accounting for its investment in Fountain under the equity method. At June 30, 2015, the Company had made payments of, and its investment is equal to, \$1.5 million (€1.2 million), which is included within "Other assets" in the accompanying condensed consolidated balance sheets. During the three and six months ended June 30, 2015, the Company recorded a reduction in its investment in Fountain of less than \$0.1 million and \$0.1 million, respectively, which represented the Company's proportional share of Fountain's net losses for these periods.

## 5. FAIR VALUE MEASUREMENTS

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 of the valuation techniques the Company utilized to determine such fair value:

(In thousands)	June 30, 2015	Level 1	Level 2	Level 3
<b>Assets:</b>				
U.S. government and agency debt securities	\$ 367,430	\$ 220,286	\$ 147,144	\$ —
Corporate debt securities	239,421	—	239,421	—
International government agency debt securities	26,995	—	26,995	—
Contingent consideration	59,100	—	—	59,100
Common stock warrants	2,999	—	—	2,999
Total	<u>\$ 695,945</u>	<u>\$ 220,286</u>	<u>\$ 413,560</u>	<u>\$ 62,099</u>

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

	December 31, 2014	Level 1	Level 2	Level 3
<b>Assets:</b>				
U.S. government and agency debt securities	\$ 326,653	\$ 189,030	\$ 137,623	\$ —
Corporate debt securities	201,963	—	201,963	—
International government agency debt securities	47,347	—	47,347	—
Total	<u>\$ 575,963</u>	<u>\$ 189,030</u>	<u>\$ 386,933</u>	<u>\$ —</u>

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period. There were no transfers of any securities between the fair value hierarchies during the six months ended June 30, 2015.

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

The following table is a rollforward of the fair value of the Company's assets whose fair value was determined using Level 3 inputs at June 30, 2015:

(In thousands)	Fair Value
Balance, January 1, 2015	\$ —
Acquisition of contingent consideration	57,600
Acquisition of common stock warrants	2,123
Increase in fair value of contingent consideration	1,500
Increase in fair value of warrants	876
Balance, June 30, 2015	<u>\$ 62,099</u>

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's condensed consolidated balance sheets consisted of the \$300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% ("Term Loan B-1") and the \$75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor ("Term Loan B-2" and together with Term Loan B-1, the "Term Loan Facility"). The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future, was as follows at June 30, 2015:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 290,167	\$ 291,569
Term Loan B-2	\$ 64,639	\$ 64,567

## 6. INVENTORY

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

(In thousands)	June 30, 2015	December 31, 2014
Raw materials	\$ 16,625	\$ 21,101
Work in process	10,410	14,824
Finished goods	11,766	15,432
Total inventory	<u>\$ 38,801</u>	<u>\$ 51,357</u>

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

**7. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Land	\$ 5,866	\$ 8,163
Building and improvements	132,936	149,158
Furniture, fixture and equipment	193,212	225,834
Leasehold improvements	13,067	12,971
Construction in progress	55,402	39,774
Subtotal	400,483	435,900
Less: accumulated depreciation	(161,225)	(170,160)
Total property, plant and equipment, net	<u>\$ 239,258</u>	<u>\$ 265,740</u>

In April 2015, as part of the Gainesville Transaction, the Company sold certain of its land, buildings, equipment and construction in progress that had a carrying value of \$38.3 million.

In April 2014, the Company sold certain of its land, buildings and equipment at its Athlone, Ireland facility that had a carrying value of \$2.2 million in exchange for \$17.5 million. \$3.0 million of the sale proceeds will remain in escrow pending the completion of certain additional services the Company is obligated to perform, and will be recognized as “Gain on sale of property, plant and equipment” in the statements of operations and comprehensive loss as the services are provided.

**8. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consisted of the following:

(In thousands)	Weighted Amortizable Life (Years)	Six Months Ended June 30, 2015		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,873	\$ —	\$ 92,873
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 465,590	\$ (144,721)	\$ 320,869
NanoCrystal technology	13	74,600	(15,758)	58,842
OCR technologies	12	42,560	(14,672)	27,888
Total		<u>\$ 582,750</u>	<u>\$ (175,151)</u>	<u>\$ 407,599</u>

In April 2015, as part of the Gainesville Transaction, the Company reduced the value of its goodwill by \$1.3 million and sold and/or licensed certain of its collaboration agreements with third-party pharmaceutical companies and Oral Controlled Release (“OCR”) technology which had a gross carrying amount of \$34.1 million and \$23.7 million, respectively.

Based on the Company’s most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at June 30, 2015 is expected to be approximately \$60.0 million, \$60.0 million, \$60.0 million, \$60.0 million and \$55.0 million in the years ending December 31, 2015 through 2019, respectively. Although the Company believes such available information and assumptions 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.

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

**9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Accounts payable	\$ 26,945	\$ 32,335
Accrued compensation	29,113	36,854
Accrued product reserves	18,261	12,607
Accrued other	51,403	39,462
Total accounts payable and accrued expenses	<u>\$ 125,722</u>	<u>\$ 121,258</u>

**10. RESTRUCTURING**

On April 4, 2013, the Company approved a restructuring plan at its Athlone, Ireland manufacturing facility consistent with the evolution of the Company's product portfolio and designed to improve operational performance for the future. The restructuring plan calls for the Company to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from its customers resulting from generic competition. The Company expects to continue to generate revenues from the manufacturing of these products through the year ending December 31, 2015.

As a result of the termination of these services, the Company also implemented a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the twelve months ended March 31, 2013, the Company recorded a restructuring charge of \$12.3 million, which consisted of severance and outplacement services. The Company has paid in cash \$11.8 million and recorded an adjustment of less than \$0.1 million due to changes in foreign currency since inception of this restructuring plan.

Restructuring activity during the six months ended June 30, 2015 was as follows:

(In thousands)	Severance and Outplacement Services
Balance, January 1, 2015	\$ 1,328
Payments	(743)
Adjustments	(116)
Balance, June 30, 2015	<u>\$ 469</u>

At June 30, 2015 and December 31, 2014, this restructuring accrual was included within "Accounts payable and accrued expenses," in the accompanying condensed consolidated balance sheets.

**11. LONG-TERM DEBT**

Long-term debt consisted of the following:

(In thousands)	June 30, 2015	December 31, 2014
Term Loan B-1, due September 25, 2019	\$ 290,167	\$ 291,476
Term Loan B-2, due September 25, 2016	64,639	66,494
Total	354,806	357,970
Less: current portion	(6,750)	(6,750)
Long-term debt	<u>\$ 348,056</u>	<u>\$ 351,220</u>

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

**12. SHARE-BASED COMPENSATION**

Share-based compensation expense consisted of the following:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Cost of goods manufactured and sold	\$ 478	\$ 1,770	\$ 2,495	\$ 4,079
Research and development	5,466	4,079	9,923	7,482
Selling, general and administrative	15,933	13,489	26,788	21,197
Total share-based compensation expense	<u>\$ 21,877</u>	<u>\$ 19,338</u>	<u>\$ 39,206</u>	<u>\$ 32,758</u>

At June 30, 2015 and December 31, 2014, \$0.7 million and \$0.8 million, respectively, of share-based compensation cost was capitalized and recorded as “Inventory” in the accompanying condensed consolidated balance sheets.

**13. (LOSS) EARNINGS PER SHARE**

Basic (loss) earnings per ordinary share is calculated based upon net (loss) income available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the calculation of diluted (loss) earnings per ordinary share, the Company uses the weighted average number of ordinary shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options and restricted stock units.

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
<b>Numerator:</b>				
Net (loss) income	<u>\$ (46,109)</u>	<u>\$ 3,735</u>	<u>\$ (76,766)</u>	<u>\$ (20,619)</u>
<b>Denominator:</b>				
Weighted average number of ordinary shares outstanding	148,867	144,913	148,480	144,140
<b>Effect of dilutive securities:</b>				
Stock options	—	8,067	—	—
Restricted stock units	—	1,320	—	—
Dilutive ordinary share equivalents	—	9,387	—	—
Shares used in calculating diluted loss per share	<u>148,867</u>	<u>154,300</u>	<u>148,480</u>	<u>144,140</u>

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Stock options	9,643	1,879	9,175	9,644
Restricted stock units	2,129	695	2,169	1,892
Total	<u>11,772</u>	<u>2,574</u>	<u>11,344</u>	<u>11,536</u>

**14. INCOME TAXES**

The Company recorded an income tax provision of \$3.1 million and \$3.6 million for the three and six months ended June 30, 2015, respectively, and an income tax benefit and income tax provision of \$1.5 million and \$2.2 million for the three and six months ended June 30, 2014, respectively. In all of these periods, the income tax provision or benefit primarily relates to U.S. Federal and state taxes on income.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of its assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. At June 30, 2015, the Company maintained a valuation allowance against certain of its U.S. and foreign deferred tax assets. The Company evaluates, at each reporting period, the need for a valuation allowance on its deferred tax assets on a jurisdiction by jurisdiction basis.



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

**15. COMMITMENTS AND CONTINGENCIES**

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. For example, the Company is currently involved in various Paragraph IV lawsuits in the U.S. and other proceedings outside of the U.S. involving its patents in respect of TRICOR, MEGACE ES and AMPYRA. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition, cash flows and results of operations.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 5 of this Form 10-Q, and Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included in our Annual Report, which has been filed with the SEC.

### Executive Summary

Net loss for the three months ended June 30, 2015 was \$46.1 million, or \$0.31 per ordinary share— basic and diluted, as compared to a net income of \$3.7 million, or \$0.03 per ordinary share— basic and \$0.02 per ordinary share— diluted for the three months ended June 30, 2014. Net loss for the six months ended June 30, 2015 was \$76.8 million, or \$0.52 per ordinary share— basic and diluted, as compared to a net loss of \$20.6 million, or \$0.14 per ordinary share— basic and diluted, for the six months ended June 30, 2014.

The increase in the net loss incurred in the three and six months ended June 30, 2015, as compared to the prior comparable periods, was primarily due to increases in R&D expense, reflecting an increased investment in our CNS development pipeline, and SG&A expense, reflecting our preparation for the anticipated launch of ARISTADA, our proposed name for aripiprazole lauroxil, later in 2015. The increase in R&D and SG&A expense were partially offset by an increase in net sales of VIVITROL in both the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014. These items are discussed in greater detail later in *Results of Operations*.

Also impacting the increase in the net loss in the three and six months ended June 30, 2015 was the sale of our facility in Gainesville, GA and the related manufacturing and royalty revenue associated with products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL. During the three and six months ended June 30, 2015, the Gainesville, GA facility generated income before income taxes of \$2.4 million and \$7.6 million, respectively, and generated income before income taxes of \$7.8 million and \$16.4 million during the three and six months ended June 30, 2014, respectively.

### Products

#### Marketed Products

Our key marketed products, which are discussed below, are expected to generate significant revenues for us. They possess long patent lives and, we believe, are singular or competitively advantaged products in their class. Refer to the "Patents and Proprietary Rights" section of our Annual Report for information with respect to the intellectual property protection for our marketed products. We expect revenues from our other marketed products, taken together, to decrease in the future due to existing and expected competition from generic manufacturers.

#### **RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA**

RISPERDAL CONSTA (risperidone long-acting injection), INVEGA SUSTENNA/XEPLION (one-month paliperidone palmitate) and INVEGA TRINZA (three-month paliperidone palmitate) are long-acting atypical antipsychotics that incorporate our proprietary technologies and are commercialized worldwide by Janssen Pharmaceutica Inc. ("Janssen, Inc."), Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International"), and Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates, "Janssen").

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

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and, as of November 2014, 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 worldwide for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA/XEPLION is manufactured by Janssen.

In May 2015, Janssen announced that the U.S. Food and Drug Administration ("FDA") approved INVEGA TRINZA, an atypical antipsychotic injection, for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. INVEGA TRINZA, the first schizophrenia treatment to be taken just four times a year, became commercially available in the U.S. in June 2015. INVEGA TRINZA uses our proprietary technology and is manufactured by Janssen.

#### **AMPYRA/FAMPYRA**

AMPYRA/FAMPYRA, to our knowledge, is the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with multiple sclerosis ("MS") who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen International GmbH ("Biogen") outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency ("EMA") conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of July 2014. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

#### **BYDUREON**

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. From August 2012 until February 2014, Bristol-Myers Squibb Company ("Bristol-Myers") and AstraZeneca plc ("AstraZeneca") co-developed and marketed BYDUREON through their diabetes collaboration. In February 2014, AstraZeneca assumed sole responsibility for the development and commercialization of BYDUREON. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca.

#### **VIVITROL**

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly injectable medication approved in the U.S. and Russia and certain of the Commonwealth of Independent States ("CIS") for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently commercialize, VIVITROL in the U.S., and Cilag GmbH International commercializes VIVITROL in Russia and certain countries of the CIS.

#### **Key Development Programs**

We also have several proprietary product candidates in various stages of development, as discussed below. Refer to the "Patents and Proprietary Rights" section of our Annual Report for information with respect to the intellectual property protection for our development products.

#### **ARISTADA**

ARISTADA is an injectable atypical antipsychotic with one-month and extended-duration formulations in development for the treatment of schizophrenia. Once in the body, ARISTADA converts into aripiprazole, which is generally available under the name ABILIFY. As a long-acting investigational medication based on our proprietary LinkeRx technology, ARISTADA is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format. In August 2014, we submitted a New Drug Application ("NDA") to the FDA for ARISTADA

for the treatment of schizophrenia. The FDA accepted our application for filing in October 2014, and granted us a Prescription Drug User Fee Act (“PDUFA”) date of August 22, 2015.

#### **ALKS 5461**

ALKS 5461 is a proprietary, oral investigational medicine in development for the treatment of major depressive disorder (“MDD”) in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan, formerly referred to as ALKS 33, is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 5461 acts as a balanced neuromodulator in the brain and represents a new approach with a novel mechanism of action for treating MDD. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies.

In January 2015, we announced topline results from FORWARD-1, one of a series of supportive clinical studies in the FORWARD phase 3 pivotal program designed to evaluate the safety and tolerability of two titration schedules of ALKS 5461. Data from FORWARD-1 confirmed the safety and tolerability of ALKS 5461 in both titration schedules evaluated—one-week and two-week dose escalation schedules. These findings were consistent with the safety and tolerability profile seen in the phase 2 study of ALKS 5461 completed in 2013. In addition, the exploratory efficacy analyses showed that ALKS 5461 reduced depressive symptoms from baseline in patients who received either of the two titration schedules. These data support the one-week titration schedule being utilized in the on-going core phase 3 efficacy studies in the FORWARD program.

#### **ALKS 3831**

ALKS 3831 is a novel, proprietary investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in the treatment of schizophrenia in patients with alcohol use.

In January 2015, we announced data from the first phase of a randomized, dose ranging, six-month phase 2 study of ALKS 3831 designed to assess the efficacy, safety and tolerability of ALKS 3831 in the treatment of schizophrenia and its attenuation of weight gain, compared to olanzapine. ALKS 3831 met the primary endpoint of the study, demonstrating equivalence to olanzapine in reduction from baseline in Positive and Negative Syndrome Scale (“PANSS”) total scores at week 12. Results showed that ALKS 3831 also met the secondary endpoint of demonstrating a lower mean percent weight gain compared to olanzapine at week 12 in the full study population, and a lower mean percent weight gain compared to olanzapine at week 12 in a pre-specified subset of patients who gained weight during the one-week olanzapine lead-in.

In April 2015, we announced data from the completed, six-month, randomized, dose-ranging phase 2 study of ALKS 3831. Patients who received ALKS 3831 during the first phase of the study, which lasted for three months, continued to receive the same dose of ALKS 3831, and patients who had received olanzapine during the first phase were switched to ALKS 3831. Data from the completed study supported and extended the initial positive results showing ALKS 3831’s favorable efficacy and mean weight gain profile and demonstrated for the first time that switching patients from olanzapine to ALKS 3831 resulted in a cessation of mean weight gain. Based on the positive results from our phase 2 study, we plan to advance ALKS 3831 into a pivotal development program in the fourth quarter of 2015.

#### **ALKS 6428**

In July 2015, we announced the initiation of a new phase 3 program called ALKS 6428. ALKS 6428 is a seven-day taper kit, designed to help physicians transition patients from opioid agonists to antagonist therapy in an outpatient setting and successfully initiate treatment with VIVITROL. We will begin the phase 3 study of ALKS 6428 in the third quarter of 2015.

**ALKS 8700**

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate ("MMF") molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In May 2015, we presented positive results from a phase 1, randomized, double-blind clinical study of ALKS 8700, designed to evaluate the safety, tolerability and single-dose pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups. Data from the study showed that ALKS 8700 was generally well tolerated and provided MMF exposures comparable to TECFIDERA, with less variability and favorable gastrointestinal tolerability. The most common adverse events were flushing and gastrointestinal-related. Based on the positive results from our phase 1 study, we requested a meeting with the FDA and plan to advance ALKS 8700 with twice-daily dosing into a pivotal development program in the fourth quarter of 2015.

**RDB 1450**

RDB 1450, formerly referred to as RDB 1419, is our selective effector cell activator ("SECA") that is designed to harness a patient's immune system to preferentially activate and increase the number of tumor killing immune cells. SECA proteins selectively target immune cells to avoid expansion of immune regulatory cells which interfere with the anti-tumor response. SECA molecules are engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic product. We filed an Investigational New Drug ("IND") application with the FDA in the second quarter of 2015 and plan to begin phase 1 clinical trials in the fall of 2015.

**ALKS 7119**

ALKS 7119 is a novel, proprietary investigational medicine that has a multivalent mechanism of action that acts on key receptors in the brain involved in several CNS diseases, including agitation in Alzheimer's disease, MDD and others. Based on correspondence with the FDA, we are conducting one additional preclinical study and now expect to initiate the first clinical study of ALKS 7119 early in the first quarter of 2016.

**Other Partnered Product Candidates**

AstraZeneca is developing line extensions for BYDUREON for the treatment of type 2 diabetes, including a weekly suspension formulation using our proprietary technology for extended-release microspheres. AstraZeneca has stated that it expects to file for approval of the BYDUREON once-weekly suspension in the U.S. and EU in 2015.

**Results of Operations**

*Manufacturing and Royalty Revenues*

Manufacturing fees are earned for the manufacture of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues earned in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014:

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
<b>Manufacturing and royalty revenues:</b>						
AMPYRA/FAMPYRA	\$ 26.9	\$ 19.5	\$ 7.4	\$ 63.5	\$ 40.1	\$ 23.4
INVEGA SUSTENNA/XEPLION	37.4	33.1	4.3	61.2	54.1	7.1
RISPERDAL CONSTA	23.4	26.9	(3.5)	46.5	55.5	(9.0)
BYDUREON	11.1	8.8	2.3	20.9	16.5	4.4
RITALIN LA/FOCALIN XR	0.7	10.9	(10.2)	9.3	20.6	(11.3)
Other	13.7	31.2	(17.5)	40.5	54.8	(14.3)
Manufacturing and royalty revenues	<u>\$ 113.2</u>	<u>\$ 130.4</u>	<u>\$ (17.2)</u>	<u>\$ 241.9</u>	<u>\$ 241.6</u>	<u>\$ 0.3</u>

The increase in AMPYRA/FAMPYRA manufacturing and royalty revenues in the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was primarily due to revenues earned on AMPYRA. The increase in AMPYRA revenue was primarily due to a 10% increase in the number of units we shipped to Acorda and a \$2.7 million increase in revenue earned from shipments of AMPYRA made to Acorda by a third-party manufacturer. Under our AMPYRA supply agreement with Acorda, we earn manufacturing and royalty revenues when AMPYRA is shipped to Acorda, either by us or a third-party manufacturer.

AMPYRA/FAMPYRA manufacturing and royalty revenues in the six months ended June 30, 2015 consisted of a \$21.2 million increase in revenues from AMPYRA and a \$2.2 million increase in revenues from FAMPYRA, as compared to the six months ended June 30, 2014. The increase in AMPYRA revenue was primarily due to a 29% increase in the number of units we shipped to Acorda and an \$8.6 million increase in revenue earned from shipments of AMPYRA made to Acorda by a third-party manufacturer. The increase in FAMPYRA revenues was primarily due to a 53% increase in the number of units we shipped to Biogen, partially offset by a 4% decrease in our estimate of end-market sales of FAMPYRA by Biogen. Under our FAMPYRA supply and license agreements with Biogen, we earn manufacturing revenue when FAMPYRA is shipped to Biogen and we earn royalties upon end-market sales of FAMPYRA by Biogen.

The increase in INVEGA SUSTENNA/XEPLION royalty revenues in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. During the three and six months ended June 30, 2015, Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$436.0 million and \$847.0 million, respectively, as compared to \$394.0 million and \$767.0 million in the three and six months ended June 30, 2014, respectively. Partially offsetting the increase in INVEGA SUSTENNA/XEPLION end-market sales by Janssen in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was a 9% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which XEPLION is sold. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalty revenues on end-market net sales of INVEGA SUSTENNA/XEPLION of: 5% on calendar-year net sales up to \$250 million; 7% on calendar-year net sales of between \$250 million and \$500 million; and 9% on calendar-year net sales exceeding \$500 million. The royalty rate resets to 5% at the beginning of each calendar year.

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was due to an 18% decrease in royalty revenues and an 11% decrease in manufacturing revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$302.0 million in the three months ended June 30, 2014 to \$247.0 million in the three months ended June 30, 2015. The decrease in manufacturing revenues was primarily due to an 18% decrease in the amount of RISPERDAL CONSTA shipped to Janssen. The decrease in RISPERDAL CONSTA manufacturing and royalty revenues in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was due to an 18% decrease in royalty revenues and a 16% decrease in manufacturing revenues. The decrease in royalty revenues was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$612.0 million in the six months ended June 30, 2014 to \$501.0 million in the six months ended June 30, 2015. The decrease in manufacturing revenues was primarily due to a 15% decrease in the amount of RISPERDAL CONSTA shipped to Janssen. Contributing to the decrease in RISPERDAL CONSTA end-market sales by Janssen in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was a 10% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which RISPERDAL CONSTA is sold. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of Janssen's end-market net sales of RISPERDAL CONSTA.

The increase in BYDUREON royalty revenues in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was due to an increase in end-market sales of BYDUREON by AstraZeneca. During the three and six months ended June 30, 2015, our estimate of AstraZeneca's end-market sales of BYDUREON was \$137.5 million and \$261.0 million, respectively, as compared to \$111.9 million and \$209.2 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the three and six months ended June 30, 2014, respectively.

The decrease in RITALIN LA/FOCALIN XR and other revenues was primarily due to the Gainesville Transaction.

In the year ending December 31, 2015, we expect that the loss of the RITALIN LA/FOCALIN XR, VERELAN and ZOHYDRO ER product franchises will result in an approximate \$40.0 million decrease in manufacturing and royalty revenue when compared to the year ended December 31, 2014.

### Product Sales, net

Our product sales, net consist of sales of VIVITROL in the U.S. to wholesalers, a specialty distributor and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the three and six months ended June 30, 2015 and 2014:

(In millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2015	% of Sales	2014	% of Sales	2015	% of Sales	2014	% of Sales
Product sales, gross	\$ 53.1	100.0 %	\$ 31.6	100.0 %	\$ 96.9	100.0 %	\$ 57.5	100.0 %
Adjustments to product sales, gross:								
Medicaid rebates	(4.7)	(8.9)%	(2.8)	(8.9)%	(8.1)	(8.4)%	(4.4)	(7.7)%
Chargebacks	(4.2)	(7.9)%	(2.1)	(6.6)%	(7.7)	(7.9)%	(3.6)	(6.3)%
Product discounts	(3.9)	(7.3)%	(2.2)	(7.0)%	(7.2)	(7.4)%	(4.1)	(7.1)%
Co-pay assistance	(1.8)	(3.4)%	(1.6)	(5.1)%	(3.2)	(3.3)%	(2.9)	(5.0)%
Product returns	(0.6)	(1.1)%	(0.9)	(2.8)%	(1.0)	(1.0)%	(1.4)	(2.4)%
Other	(0.7)	(1.3)%	(0.4)	(1.2)%	(1.4)	(1.4)%	(2.4)	(4.2)%
Total adjustments	(15.9)	(29.9)%	(10.0)	(31.6)%	(28.6)	(29.4)%	(18.8)	(32.7)%
Product sales, net	\$ 37.2	70.1 %	\$ 21.6	68.4 %	\$ 68.3	70.6 %	\$ 38.7	67.3 %

The increase in product sales, gross for the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was due to a 53% increase in the number of units sold and a 10% increase in price dating back to December 2014. The increase in product sales, gross for the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was due to a 50% increase in the number of units sold and a 13% increase in price. The increase in amount of Medicaid rebates, chargebacks and product discounts in both the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to the increase in the sales volume of VIVITROL.

### Costs and Expenses

#### Cost of Goods Manufactured and Sold

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
Cost of goods manufactured and sold	\$ 30.4	\$ 43.3	\$ 12.9	\$ 70.4	\$ 82.1	\$ 11.7

The decrease in cost of goods manufactured and sold during the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to the Gainesville Transaction in April 2015. During the three months ended June 30, 2015, the Gainesville facility had cost of goods manufactured of \$0.8 million, as compared to \$10.8 million during the three months ended June 30, 2014, primarily related to the sale of RITALIN LA/FOCALIN XR, VERELAN and ZOHYDRO ER. In the year ending December 31, 2015, we expect that the loss of these products will result in an approximate \$25.0 million decrease in cost of goods manufactured when compared to the year ended December 31, 2014.

In addition to the decrease in cost of goods manufactured and sold related to the Gainesville Transaction, the cost of goods manufactured at our Athlone facility decreased by \$3.7 million and \$4.6 million in the three and six months ended June 30, 2015, respectively, as compared to the three and six months ended June 30, 2014. This decrease is primarily due to the April 2013 restructuring plan as discussed in Note 10, *Restructuring*, in the notes to condensed consolidated statements. These decreases were partially offset by an increase in cost of goods manufactured and sold related to our Ohio manufacturing facility of \$1.2 million and \$2.4 million in the three and six months ended June 30, 2015, respectively, as compared to the corresponding prior periods, due primarily to the increase in sales of VIVITROL in 2015.

#### Research and Development Expense

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

The following table sets forth our external R&D expenses relating to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
External R&D Expenses:						
Key development programs:						
ALKS 5461	\$ 30.3	\$ 20.7	\$ (9.6)	\$ 50.4	\$ 31.7	\$ (18.7)
ARISTADA	10.2	5.8	(4.4)	19.3	13.2	(6.1)
ALKS 3831	4.9	6.0	1.1	10.0	11.1	1.1
ALKS 8700	5.0	2.3	(2.7)	6.7	3.8	(2.9)
ALKS 7106	—	2.4	2.4	—	3.6	3.6
Other development programs	7.9	4.2	(3.7)	13.0	6.7	(6.3)
Total external expenses	58.3	41.4	(16.9)	99.4	70.1	(29.3)
Internal R&D expenses:						
Employee-related	22.9	19.4	(3.5)	45.1	36.8	(8.3)
Occupancy	1.9	1.8	(0.1)	4.1	3.4	(0.7)
Depreciation	1.4	2.0	0.6	3.0	4.1	1.1
Other	3.3	2.6	(0.7)	6.6	4.9	(1.7)
Total internal R&D expenses	29.5	25.8	(3.7)	58.8	49.2	(9.6)
Research and development expenses	\$ 87.8	\$ 67.2	\$ (20.6)	\$ 158.2	\$ 119.3	\$ (38.9)

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

The increase in expenses related to ALKS 5461 was the result of the timing of three core phase 3 efficacy studies, long-term safety studies and other supporting studies related to the program. We initiated the pivotal clinical development program for ALKS 5461 in March 2014 and data from these studies is expected in 2016. The increase in expenses related to the ARISTADA program was primarily due to the initiation of the phase 1 clinical study of extended dosing intervals of ARISTADA in patients with schizophrenia in December 2014. Expenses incurred under the ALKS 6428, RDB 1450 and ALKS 7119 development programs were not material in the three months ended June 30, 2015 and 2014. The increase in employee-related expenses was primarily due to an increase in headcount as our R&D related headcount has increased by 20% since June 30, 2014 and 10% since December 31, 2014.



*Selling, General and Administrative Expense*

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
Selling, general and administrative expense	\$ 71.5	\$ 50.7	\$ (20.9)	\$ 134.6	\$ 93.2	\$ (41.4)

The increase in SG&A expense for the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014, was primarily due to a \$14.3 million and \$25.3 million increase in employee related expenses, respectively, when compared to the corresponding prior periods. This increase in employee related expenses was primarily due to us increasing the size of our commercial operations team as we near the PDUFA date for ARISTADA in August 2015 and preparing for the commercial launch of the product shortly thereafter. Our SG&A-related headcount has increased by 97% from June 30, 2014 and 81% from December 31, 2014.

In addition, as part of the pre-launch planning activities for ARISTADA, our marketing expenses increased by \$3.0 million and \$2.7 million in the three and six months ended June 30, 2015, respectively, when compared to the corresponding prior periods and we had a \$7.2 million increase in professional services in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014.

We also had a \$2.3 million and \$3.9 million increase in IT-related expenses in the three and six months ended June 30, 2015, as compared to the three and six months ended June 30, 2014. These increases were primarily due to the anticipated commercial launch of ARISTADA as we purchased hardware to support the increase in our headcount and software to enhance the infrastructure of our commercial operations team.

We expect SG&A expenses to continue to increase in 2015 as pre-launch planning activities accelerate for ARISTADA.

*Amortization of Acquired Intangible Assets*

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
Amortization of acquired intangible assets	\$ 14.1	\$ 15.1	\$ 1.0	\$ 29.3	\$ 27.7	\$ (1.6)

The intangible assets being amortized in the three and six months ended June 30, 2015 and 2014 were acquired as part of the acquisition of Elan Drug Technologies (“EDT”) in September 2011. In connection with the acquisition of EDT, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which were expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract.

As part of the Gainesville Transaction, we sold certain of the IP we acquired from EDT that had an original cost of \$57.8 million. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at June 30, 2015 is expected to be approximately \$60.0 million, \$60.0 million, \$60.0 million, \$60.0 million and \$55.0 million in the years ending December 31, 2015 through 2019, respectively.

*Other (Expense) Income, Net*

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
Interest income	\$ 0.8	\$ 0.3	\$ 0.5	\$ 1.5	\$ 0.8	\$ 0.7
Interest expense	(3.3)	(3.4)	0.1	(6.6)	(6.7)	0.1
Gain on Gainesville Transaction	9.9	—	9.9	9.9	—	9.9
Increase in the fair value of contingent consideration	1.5	—	1.5	1.5	—	1.5
Gain on sale of property, plant and equipment	—	12.3	(12.3)	—	12.3	(12.3)
Other income (expense), net	0.6	0.5	0.1	0.3	(1.4)	1.7
Gain on sale of investment in Acceleron Pharma Inc.	—	15.3	(15.3)	—	15.3	(15.3)
Total other (expense) income, net	\$ 9.5	\$ 25.0	\$ (15.5)	\$ 6.6	\$ 20.3	\$ (13.7)

In April 2015, we completed the Gainesville Transaction which included the sale of our facility in Gainesville, GA; related manufacturing and royalty revenue associated with products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL; and the IV/IM and parenteral formulations of Meloxicam, a nonsteroidal anti-inflammatory drug, which has completed multiple phase 2 trials for the management of moderate-to-severe acute pain. We acquired these assets in 2011 as part of our business combination with EDT.

The proceeds from the Gainesville Transaction consisted of \$54.0 million in cash, \$2.1 million in warrants to acquire Recro common stock and \$57.6 million in contingent consideration tied to low double digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in Note 3, *Divestiture*, in the Notes to Condensed Consolidated Statements.

We will, at each reporting date, update our assessment of the fair value of this contingent consideration and reflect any changes to the fair value within "Increase in the fair value of contingent consideration" until the milestones and/or royalties included in the contingent consideration have been settled. During the three months ended June 30, 2015, we determined that the fair value of the contingent consideration increased by \$1.5 million, due primarily to a shorter time to payment on the milestones and royalties included in the contingent consideration.

The decrease in gain on sale of property, plant and equipment in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, is due to the sale of certain of our land, buildings and equipment at our Athlone, Ireland facility. In April 2014, we sold these assets that had a carrying value of \$2.2 million, in exchange for \$17.5 million and recorded a gain of \$12.3 million, as \$3.0 million of the sales proceeds were placed in escrow pending the completion of certain additional services we are obligated to perform. The decrease in the gain on sale of investment in Acceleron Pharma Inc. was due to our selling our investment in Acceleron Pharma Inc., which consisted of equity securities, in June 2014. The Company received \$24.0 million and realized a gain of \$15.3 million from the sale of this investment.

*Income Tax Provision*

(In millions)	Three Months Ended June 30,		Change Favorable/ (Unfavorable)	Six Months Ended June 30,		Change Favorable/ (Unfavorable)
	2015	2014		2015	2014	
Provision (benefit) for income taxes	\$ 3.1	\$ (1.5)	\$ (4.6)	\$ 3.6	\$ 2.2	\$ (1.4)

The income tax provision in the three and six months ended June 30, 2015 and 2014 primarily relates to U.S. federal and state taxes on income earned in the U.S.

**Liquidity and Financial Condition**

Our financial condition is summarized as follows:

(In millions)	June 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 196.9	\$ 224.0
Investments—short-term	579.9	407.1
Investments—long-term	55.6	170.5
Total cash and investments	<u>\$ 832.4</u>	<u>\$ 801.6</u>
Outstanding borrowings—current and long-term	\$ 354.8	\$ 358.0

*Sources and Uses of Cash*

We expect that our existing cash and investment balance will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments, for at least the next twelve months. In the event business conditions were to deteriorate, we could rely on borrowings under our Term Loan Facility, which has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts, as long as we meet certain conditions, including a specified leverage ratio.

Information about our cash flows, by category, is presented in the Condensed Consolidated Statements of Cash Flows. The following table summarizes our cash flows for the six months ended June 30, 2015 and 2014:

(In millions)	Six Months Ended June 30,	
	2015	2014
Cash and cash equivalents, beginning of period	\$ 224.1	\$ 167.6
Cash (used in) provided by operating activities	(13.3)	5.3
Cash used in investing activities	(31.8)	(245.8)
Cash provided by financing activities	17.9	261.2
Cash and cash equivalents, end of period	<u>\$ 196.9</u>	<u>\$ 188.3</u>

The increase in cash flows used in operating activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to a 37% increase in cash paid to our employees and an 9% increase in cash paid to our suppliers, partially offset by a 14% increase in cash received from our customers. The increase in cash paid to our employees and suppliers are primarily due to the increase in our headcount, increased R&D activity and preparation for the launch of ARISTADA, as previously discussed. The increase in cash received from our customers is primarily due to the increase in revenues during the six months ended June 30, 2015, as compared to the six months ended June 30, 2014.

The decrease in cash flows used in investing activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to a decrease in the net purchase of investments of \$191.5 million. During the three months ended March 31, 2014, we sold approximately 5.9 million ordinary shares, through a registered direct offering to Invesco Perpetual Income Fund and Invesco Perpetual High Income Fund (the “Invesco Funds”), for gross proceeds of \$250.0 million. These proceeds were then used to purchase available-for-sale investments in accordance with our investment objectives. Our investing activity in the six months ended June 30, 2015 was centered on re-investing available-for-sale investments as they mature and investing excess cash generated from operations. We also received \$54.0 million in cash from the Gainesville Transaction, net of transaction fees of \$2.4 million we incurred as part of the sale and \$1.3 million of cash that remained in the business. These items were partially offset by a \$13.3 million increase in cash used to purchase property, plant and equipment which was primarily related to an investment in our Wilmington, Ohio manufacturing facility, where we will manufacture ARISTADA, and R&D investments in our Athlone, Ireland facility.

The decrease in cash flows provided by financing activities in the six months ended June 30, 2015, as compared to the six months ended June 30, 2014, was primarily due to the registered direct offering to the Invesco Funds mentioned above and a \$4.5 million increase in cash used to pay for employee taxes related to the net share settlement of equity

awards. These items were partially offset by a \$9.5 million increase in excess tax benefit from share-based compensation.

Our investments at June 30, 2015 consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term	\$ 579.5	\$ 0.5	\$ (0.1)	\$ 579.9
Investments—long-term available-for-sale	54.1	—	(0.1)	54.0
Investments—long-term held-to-maturity	1.6	—	—	1.6
Total	\$ 635.2	\$ 0.5	\$ (0.2)	\$ 635.5

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, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. Our held-to-maturity investments consist of investments that are restricted and 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, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At June 30, 2015, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At June 30, 2015 and December 31, 2014, none of our investments were valued using Level 3 inputs. Level 3 inputs are unobservable and are significant to the overall fair value measurement and require a significant degree of judgment.

#### *Borrowings*

At June 30, 2015, our borrowings consisted of \$356.4 million outstanding under our Term Loan Facility. Refer to Note 10, *Long-Term Debt*, within the “Notes to Consolidated Financial Statements” accompanying our Annual Report, for a discussion of our outstanding term loans.

#### *Contractual Obligations*

Refer to Part II, Item 7 of our Annual Report in the “*Contractual Obligations*” section for a discussion of our contractual obligations. Our contractual obligations as of June 30, 2015 have not materially changed from the date of that report.

#### *Off-Balance Sheet Arrangements*

At June 30, 2015, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

#### *Critical Accounting Estimates*

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

"Critical Accounting Estimates" within Part II, Item 7 of our Annual Report for a discussion of our critical accounting estimates.

#### *New Accounting Standards*

Refer to "New Accounting Pronouncements" included in Note 2, *Summary of Significant Accounting Policies* in the "Notes to Condensed Consolidated Financial Statements" in this Form 10-Q for a discussion of new accounting standards.

### **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" of 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, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks since December 31, 2014, 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 foreign currency exchange risk related to manufacturing and royalty revenues we receive on certain of our products as well as certain operating costs arising from expenses and payables at our Irish operations that are settled in euro. These foreign currency exchange rate risks are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk since December 31, 2014.

### **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 Securities Exchange Act of 1934, as amended (the "Exchange Act")), on June 30, 2015. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2015 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

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various Paragraph IV lawsuits in the U.S. and other proceedings outside of the U.S. involving our patents in respect of TRICOR, MEGACE ES and AMPYRA. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition, cash flows and results of operations.

### Item 1A. Risk Factors

#### ***The FDA or other regulatory agencies may not approve our product candidates or may impose limitations upon any product approval.***

We must obtain government approvals before marketing or selling our product candidates in the U.S. and in jurisdictions outside the U.S. The FDA, DEA, to the extent a product candidate is a controlled substance, and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the U.S. may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications. See “—Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors” in “Part I, Item 1A – Risk Factors” of our Annual Report.

This product development process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or regulatory agencies outside the U.S. can be delayed, limited or not granted at all for many reasons, including:

- the filing by a third party of a Citizen Petition with the FDA relating to our products. On July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. (“Otsuka”) submitted a Citizen Petition to the FDA requesting that the FDA refuse to approve, or delay approval of, our NDA for ARISTADA, which has a PDUFA date of August 22, 2015. On July 24, 2015, we submitted a Comment in Opposition to the Otsuka Citizen Petition to the FDA in response to Otsuka’s Citizen Petition;
- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;
- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;
- data from pre-clinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners’ manufacturing processes or facilities;

- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;
- the failure of third-party CROs and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines;
- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's GCP, or EU legislation governing GCP, including the failure to pass FDA, EMA or EU Member State inspections of clinical trials;
- the FDA or other regulatory agencies may change their approval policies or adopt new regulations;
- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful; and
- the FDA or other regulatory agencies may not agree with our or our partners' regulatory approval strategies or components of our or our partners' filings, such as clinical trial designs.

In addition, our product development timelines may be impacted by third-party patent litigation. We cannot be sure that regulatory approval will be granted for product candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of additional products will be limited by any failure to obtain these approvals. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product candidate or if the timing of FDA approval is delayed. If the FDA's or any other regulatory agency's response to any application for approval is delayed or not favorable for any of our product candidates, our share price could decline significantly.

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we would need to comply in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products. In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in the temporary or permanent withdrawal by the FDA or other regulatory agencies of our products from commercial marketing, which could seriously harm our business and cause our share price to decline. Further, even if the FDA provides regulatory approval, controlled substances will not become commercially available until after the DEA provides its final schedule designation, which may take longer and may be more restrictive than we expect or change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization.

There have been no other material changes from the risk factors disclosed in our Annual Report. For a further discussion of our Risk Factors, refer to "Part I, Item 1A – Risk Factors" of 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 six months ended June 30, 2015. As of June 30, 2015, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million.

During the three months ended June 30, 2015, we acquired, by means of net share settlements, 201,391 shares of Alkermes ordinary shares at an average price of \$61.27 per share related to the vesting of employee equity awards to satisfy withholding tax obligations. In addition, during the three months ended June 30, 2015, we acquired 4,849 shares of Alkermes ordinary shares, at an average price of \$61.84 per share, tendered by employees as payment of the exercise

price of stock options granted under our equity compensation plans.

**Item 5. Other Information**

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2015, Mr. Gordon G. Pugh, an executive officer of the Company, entered into a trading plan in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

**Item 6. Exhibits**

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Form 10-Q.



## SIGNATURES

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

ALKERMES plc

(Registrant)

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

By: /s/ James M. Frates  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: July 30, 2015

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.1 #†	Employment Agreement, dated as of September 30, 2008, by and between Iain M. Brown and Alkermes, Inc.
10.2 #†	Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.
10.3 #*	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica, Inc. (United States) (Assigned to Alkermes, Inc. in July 2006)
10.4#*	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (Assigned to Alkermes, Inc. in July 2006)
10.5#*	Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (Assigned to Alkermes, Inc. in July 2006)
10.6#*	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003. (Assigned to Alkermes, Inc. in July 2006)
10.7#	Fourth Amendment to Lease Agreement between Alkermes, Inc. and G1 TC 850 Winter Street, LLC, dated as of December 30, 2014
10.8 #†	Amendment to Employment Agreement, dated as of July 22, 2015, by and between Rebecca J. Peterson and Alkermes, Inc.
10.9 #†	Amendment to Employment Agreement, dated as of July 28, 2015, by and between Iain M. Brown and Alkermes, Inc.
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 (furnished herewith).
101 #	The following materials from Alkermes plc's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements

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#	Filed herewith.
†	Indicates a management contract or any compensatory plan, contract or arrangement.
*	Portions of such exhibit have been omitted pursuant to a request for confidential treatment submitted to the Securities and Exchange Commission.

## EMPLOYMENT AGREEMENT

This Employment Agreement (“Agreement”) is made as of the 30 day of September 2008 between Alkermes, Inc., a Pennsylvania corporation (the “Company”), and Iain M. Brown (“Vice President”).

WHEREAS, the Company has previously entered into a letter agreement with Vice President dated May 29, 2003 (the “Letter Agreement”);

WHEREAS, the Company and Vice President wish to replace the Letter Agreement with the provisions set forth herein;

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

1. Employment. The term of this Agreement shall extend from September 30, 2008 (the “Commencement Date”) until this Agreement is terminated by either the Vice President or the Company pursuant to Paragraph 4. The term of this Agreement may be referred to herein as the “Period of Employment.”

2. Position and Duties. During the Period of Employment, Vice President shall serve as Vice President, Finance of the Company, and shall have supervision and control over and responsibility for the day to day business and affairs of those functions and operations of the Company and shall have such other powers and duties as may from time to time be prescribed by the Board of Directors of the Company (the “Board”), the Chief Executive Officer of the Company (the “CEO”) or other authorized executives, provided that such duties are consistent with Vice President’s position or other positions that he may hold from time to time. Vice President shall devote his full working time and efforts to the business and affairs of the Company.

3. Compensation and Related Matters.

(a) Base Salary. Vice President’s initial annual base salary shall be his annual base salary on the Commencement Date. Vice President’s base salary shall be redetermined annually by the CEO. The base salary in effect at any given time is referred to herein as “Base Salary.” The Base Salary shall be payable in substantially equal bi-weekly installments.

(b) Incentive Compensation. Vice President shall be eligible to receive cash incentive compensation as determined by the Compensation Committee of the Board (the “Compensation Committee”) and the CEO from time to time, and shall also be eligible to participate in such incentive compensation plans as the Compensation Committee shall determine from time to time.

(c) Expenses. Vice President shall be entitled to receive prompt reimbursement for all reasonable business expenses incurred by him in performing services

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hereunder during the Period of Employment, in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Period of Employment, Vice President shall be entitled to continue to participate in or receive benefits under all of the Company's Employee Benefit Plans in effect on the date hereof, as these plans or arrangements may thereafter be amended from time to time. As used herein, the term "Employee Benefit Plans" includes, without limitation, each pension and retirement plan; supplemental pension, retirement and deferred compensation plan; savings and profit-sharing plan; stock ownership plan; stock purchase plan; stock option plan; life insurance plan; medical insurance plan; disability plan; and health and accident plan or arrangement established and maintained by the Company on the date hereof for employees of the same status within the hierarchy of the Company. Vice President shall have the right in accordance with applicable law and the Company's long-term disability plan to elect to pay the premiums for his disability coverage with after-tax dollars. During the Period of Employment, Vice President shall be entitled to participate in or receive benefits under any Employee Benefit Plan or arrangement which may, in the future, be made available by the Company to its Vice Presidents, subject to and on a basis consistent with the terms, conditions and overall administration of such plan or arrangement. Any payments or benefits payable to Vice President under a plan or arrangement referred to in this Subparagraph 3(d) in respect of any calendar year during which Vice President is employed by the Company for less than the whole of such year shall, unless otherwise provided in the applicable plan or arrangement, be prorated in accordance with the number of days in such calendar year during which he is so employed. Should any such payments or benefits accrue on a fiscal year (rather than calendar year) basis, then the proration in the preceding sentence shall be on the basis of a fiscal year rather than calendar year.

(e) Vacations. Vice President shall be entitled to the number of paid vacation days in each calendar year to which he is entitled on the Commencement Date, which vacation days shall be accrued ratably during the calendar year and the number of which may be increased in accordance with Company policies. Vice President shall also be entitled to all paid holidays given by the Company to its Vice Presidents.

4. Termination. Vice President's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. Vice President's employment hereunder shall terminate upon his death.

(b) Disability. If Vice President is prevented from performing his duties hereunder by reason of any physical or mental incapacity that results in Vice President's satisfaction of all requirements necessary to receive benefits under the Company's long-term disability plan due to a total disability, then, to the extent permitted by law, Company may terminate the employment of Vice President at or after such time. Nothing in this Subparagraph 4(b) shall be construed to waive Vice President's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 et seq. and the Americans with Disabilities Act, 42 U.S.C. §12101 et seq.

(c) Termination by Company for Cause. At any time during the Period of Employment, the Company may terminate Vice President's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by Vice President constituting a material act of willful misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by Vice President of a felony or any misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or conduct by Vice President that would reasonably be expected to result in material injury to the Company if he were retained in his position; (iii) continued, willful and deliberate non-performance by Vice President of his duties hereunder (other than by reason of Vice President's physical or mental illness, incapacity or disability) which has continued for more than thirty (30) days following written notice of such non-performance from the Company; (iv) a breach by Vice President of any of the provisions contained in Paragraph 6 of this Agreement; (v) a violation by Vice President of the Company's employment policies which has continued following written notice of such violation from the Company; or (vi) willful failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the willful inducement of others to fail to cooperate or to produce documents or other materials.

(d) Termination Without Cause. At any time during the Period of Employment, the Company may terminate Vice President's employment hereunder without Cause. Any termination by the Company of Vice President's employment under this Agreement which does not constitute a termination for Cause under Subparagraph 4(c) or result from the death or disability of Vice President under Subparagraph 4(a) or (b) shall be deemed a termination without Cause.

(e) Termination by Vice President. At any time during the Period of Employment, Vice President may terminate his employment hereunder for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that Vice President has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a substantial diminution or other substantive adverse change, not consented to by Vice President, in the nature or scope of Vice President's responsibilities, authorities, powers, functions or duties; (ii) an involuntary material reduction in Vice President's Base Salary except for across-the-board reductions similarly affecting all or substantially all management employees; (iii) a breach by the Company of any of its other material obligations under this Agreement, or (iv) a material change in the geographic location at which Vice President must perform his services. "Good Reason Process" shall mean that (A) Vice President reasonably determines in good faith that a "Good Reason" event has occurred; (B) Vice President notifies the Company in writing of the occurrence of the Good Reason event within ninety (90) days of the occurrence of such event; (C) Vice President cooperates in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice, to modify Vice President's employment situation in a manner acceptable to Vice President and Company; (D) notwithstanding such efforts, one or more of the Good

Reason events continues to exist and has not been modified in a manner acceptable to Vice President; and (E) Vice President terminates his employment no later than sixty (60) days after the end of the thirty-day cure period. If the Company cures the Good Reason event in a manner acceptable to Vice President during the thirty-day period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Subparagraph 4(a), any termination of Vice President's employment by the Company or any such termination by Vice President shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if Vice President's employment is terminated by his death, the date of his death; (ii) if Vice President's employment is terminated on account of disability under Subparagraph 4(b) or by the Company for Cause under Subparagraph 4(c), the date on which Notice of Termination is given; (iii) if Vice President's employment is terminated by the Company under Subparagraph 4(d), thirty (30) days after the date on which a Notice of Termination is given; and (iv) if Vice President's employment is terminated by Vice President under Subparagraph 4(e), thirty (30) days after the date on which a Notice of Termination is given.

5. Compensation Upon Termination.

(a) Termination Generally. If Vice President's employment with the Company is terminated for any reason during the Period of Employment, the Company shall pay or provide to Vice President (or to his authorized representative or estate) any earned but unpaid Base Salary, incentive compensation earned but not yet paid, unpaid expense reimbursements, accrued but unused vacation and any vested benefits Vice President may have under any Employee Benefit Plan of the Company, including without limitation any benefits that may accrue on Vice President's retirement from the Company, to the extent applicable (the "Accrued Benefit").

(b) Termination by the Company Without Cause or by Vice President with Good Reason. If Vice President's employment is terminated by the Company without Cause as provided in Subparagraph 4(d), or Vice President terminates his employment for Good Reason as provided in Subparagraph 4(e), then the Company shall, through the Date of Termination, pay Vice President his Accrued Benefit. The Company shall within seven (7) days of the Date of Termination provide to Vice President a general release of claims in a form and manner satisfactory to the Company (the "Release"). If Vice President signs the Release and delivers it to Company within twenty-one (21) days of Vice President's receipt of the Release and does not revoke it within seven (7) days thereafter:

(i) Company shall pay Vice President an amount equal to fifty percent (50%) of the sum of Vice President's Base Salary and his Average Incentive Compensation (the "Severance Amount"). The Severance Amount shall be paid out in substantially equal bi-weekly installments over six (6) months, in arrears beginning on the first payroll date that begins after

thirty-five (35) days from the Date of Termination. For purposes of this Agreement, "Average Incentive Compensation" shall mean the average of the annual cash incentive compensation under Subparagraph 3(b) received by Vice President for the two (2) immediately preceding fiscal years. In no event shall "Average Incentive Compensation" include any sign-on bonus, retention bonus or any other special bonus. Solely for purposes of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), each bi-weekly installment payment shall be considered a separate payment. Notwithstanding the foregoing, if Vice President breaches any of the provisions contained in Paragraph 6 of this Agreement, all payments of the Severance Amount shall immediately cease.

(ii) Subject to Vice President's copayment of premium amounts at the active employees' rate, continued participation in the Company's group health, dental and vision program for six (6) months; provided, however, that the continuation of health benefits under this Subparagraph shall reduce and count against Vice President's rights under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA").

(iii) Anything in this Agreement to the contrary notwithstanding, if at the time of Vice President's termination of employment, Vice President is considered a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, and if any payment or benefit that Vice President becomes entitled to under this Agreement is considered deferred compensation subject to interest, penalties and additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, then no such payment shall be payable or benefit shall be provided prior to the date that is the earlier of (A) six months after Vice President's separation from service, or (B) Vice President's death, and the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the first six-month period but for the application of this Subparagraph 5(b)(iii). The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

#### 6. Confidential Information, Nonsolicitation and Cooperation.

(a) Confidential Information. As used in this Agreement, "Confidential Information" means information belonging to the Company which is of value to the Company in the course of conducting its business and the disclosure of which could result in a competitive or other disadvantage to the Company. Confidential Information includes, without limitation, financial information, reports, and forecasts; inventions, improvements and other intellectual property; trade secrets; know-how; designs, processes or formulae; software; market or sales information or plans; customer lists; and business plans, prospects and opportunities (such as possible acquisitions or dispositions of businesses or facilities) which have been discussed or considered by the management of the Company. Confidential Information includes information developed by Vice President in the course of Vice President's employment by the Company, as well as other information to which Vice President may have access in connection with Vice President's employment. Confidential Information also includes the confidential information of others with which the Company has a business relationship. Notwithstanding the foregoing,

Confidential Information does not include information in the public domain, unless due to breach of Vice President's duties under Subparagraph 6(b).

(b) Confidentiality. Vice President understands and agrees that Vice President's employment creates a relationship of confidence and trust between Vice President and the Company with respect to all Confidential Information. At all times, both during Vice President's employment with the Company and after its termination, Vice President will keep in confidence and trust all such Confidential Information, and will not use or disclose any such Confidential Information without the written consent of the Company, except as may be necessary in the ordinary course of performing Vice President's duties to the Company.

(c) Documents, Records, etc. All documents, records, data, apparatus, equipment and other physical property, whether or not pertaining to Confidential Information, which are furnished to Vice President by the Company or are produced by Vice President in connection with Vice President's employment will be and remain the sole property of the Company. Vice President will return to the Company all such materials and property as and when requested by the Company. In any event, Vice President will return all such materials and property immediately upon termination of Vice President's employment for any reason. Vice President will not retain with Vice President any such material or property or any copies thereof after such termination.

(d) Nonsolicitation. During the Period of Employment and for six (6) months thereafter, Vice President (i) will refrain from directly or indirectly recruiting or otherwise soliciting, inducing or influencing any person to leave employment with the Company (other than terminations of employment of subordinate employees undertaken in the course of Vice President's employment with the Company); and (ii) will refrain from soliciting or encouraging any customer or supplier to terminate or otherwise modify adversely its business relationship with the Company. However, nothing in this Subparagraph 6(d) will prohibit Vice President from indirectly recruiting, soliciting, inducing or influencing a person to leave employment with the Company through the use of advertisements in trade journals and the like or from discussing employment opportunities with such employees to the extent such employees contact Vice President first. Vice President understands that the restrictions set forth in this Subparagraph 6(d) are intended to protect the Company's interest in its Confidential Information and established employee, customer and supplier relationships and goodwill, and agrees that such restrictions are reasonable and appropriate for this purpose.

(e) Litigation and Regulatory Cooperation. During and after Vice President's employment, Vice President shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while Vice President was employed by the Company. Vice President's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after Vice President's employment, Vice President also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or



occurrences that transpired while Vice President was employed by the Company. The Company shall reimburse Vice President for any reasonable out-of-pocket expenses incurred in connection with Vice President's performance of obligations pursuant to this Subparagraph 6(e).

(f) Injunction. Vice President agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by Vice President of the promises set forth in this Paragraph 6, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Paragraph 8 of this Agreement, Vice President agrees that if Vice President breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

7. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of Vice President's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Boston, Massachusetts in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than Vice President or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Paragraph 7 shall be specifically enforceable. Notwithstanding the foregoing, this Paragraph 7 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Paragraph 7.

8. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Paragraphs 6 or 7 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, Vice President (i) submits to the personal jurisdiction of such courts; (ii) consents to service of process; and (iii) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties with respect to any related subject matter, including without limitation the Letter Agreement. Notwithstanding the foregoing, except to the extent in conflict therewith, this Agreement does not supersede the Employee Agreement with respect to Inventions and Proprietary Information dated June 2, 2003 between Vice President and the Company.

10. Assignment; Successors and Assigns. Neither the Company nor Vice President may make any assignment of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party; provided that the Company may assign its rights under this Agreement without the consent of Vice President in the event that the Company shall effect a reorganization, consolidate with or merge into any other corporation, partnership, organization or other entity, or transfer all or substantially all of its properties or assets to any other corporation, partnership, organization or other entity. This Agreement shall inure to the benefit of and be binding upon the Company and Vice President, their respective successors, executors, administrators, heirs and permitted assigns.

11. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

12. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

13. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to Vice President at the last address Vice President has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Chief Executive Officer, and shall be effective on the date of delivery in person or by courier or three (3) days after the date mailed.

14. Amendment. This Agreement may be amended or modified only by a written instrument referencing this Agreement signed by Vice President and by a duly authorized representative of the Company.

15. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such Commonwealth. With respect to any disputes concerning Federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

16. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

ALKERMES, INC.

By: /s/ Madeline Coffin  
Madeline Coffin  
Title: VP Human Resources

/s/ Iain M. Brown  
Iain M. Brown

**AMENDMENT  
TO  
EMPLOYMENT AGREEMENT**

WHEREAS, Alkermes, Inc., a Pennsylvania corporation (the “Company”) and Mark P. Stejbach of Concord, MA (“Executive”) have previously entered into an Employment Agreement dated as of February 29, 2012 (the “Agreement”); and

WHEREAS, the Company and Executive mutually desire to amend the Agreement to address the possibility of the imposition of excise taxes under certain circumstances;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuation consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to amend the Agreement as follows:

1. The Agreement is hereby amended by adding the following Section 5(c) at the end of Section 5(b):

“(c) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the ‘Aggregate Payments’), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in Executive receiving a higher After Tax Amount (as defined below) than Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(c), the ‘After Tax Amount’ means the amount of the Aggregate Payments less all federal, state, and local

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income, excise and employment taxes imposed on Executive as a result of Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(c)(i) shall be made by a nationally recognized accounting firm selected by the Company (the 'Accounting Firm'), which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Executive. Any determination by the Accounting Firm shall be binding upon the Company and Executive."

2. This Amendment shall be binding on all successors and assigns of the parties hereof.
3. Except as amended herein, the Agreement is confirmed in all other respects.

IN WITNESS WHEREOF, the parties have executed this Amendment this 21<sup>st</sup> day of July, 2015.

ALKERMES, INC.

/s/ Madeline Coffin  
By: Madeline Coffin  
Title: VP Human Resources

/s/ Mark P. Stejbach  
Mark P. Stejbach

## LICENSE AGREEMENT

This Agreement is made as of the 13 day February of 1996, between MEDISORB TECHNOLOGIES INTERNATIONAL L.P., a Delaware limited partnership (hereinafter "Medisorb") and JANSSEN PHARMACEUTICA INC., a New Jersey corporation ("Janssen US").

WHEREAS, Medisorb and Janssen Pharmaceutica International, an affiliate of Janssen US, have entered into a certain Development Agreement, dated December 23, 1993 (the "Development Agreement"), for the development of a Product (as described below); and

WHEREAS, Janssen Pharmaceutica International has an option under the Development Agreement to enter into this License Agreement for the Medisorb technology required to make, use and sell the Product, which option Janssen Pharmaceutica International has assigned to Janssen US with the consent of Medisorb and which option Janssen US has elected to exercise; and

WHEREAS, the parties believe that it is in their mutual best interest for Medisorb to license to Janssen US on an exclusive basis in the Territory, Medisorb Patents and Technical Information within the Field, upon the terms and conditions set forth herein;

NOW, IT IS HEREBY AGREED AS FOLLOWS:

(1) Definitions: The following terms shall have the meanings ascribed to them herein, unless the context otherwise requires:

(a) "Affiliate" shall mean any company controlling, controlled by, or under common control with a party by ownership, directly or indirectly, of fifty percent (50%) or more of the total ownership or by the power to control the policies and actions of such company.

(b) "Development Program" shall mean the development activities conducted by the parties pursuant to the Development Agreement.

(c) "Field" shall mean the treatment of [

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(d) "Improvements" shall mean any improvements or developments to or of the Patents and Technical Information in the Field which Medisorb may acquire,

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discover, invent, originate, make, conceive or have a right to, in whole or in part, during the term of this Agreement, whether or not such improvement or development is patentable.

(e) "Medisorb Polymers" shall mean bioresorbable aliphatic polyesters based on glycolide, lactide, caprolactone and combinations of such polymers, which are manufactured by Medisorb and utilized in Product(s) licensed under this Agreement.

(f) "NDA" shall mean a New Drug Application and all supplements filed pursuant to the requirements of the United States Food and Drug Administration, including all documents, data and other information concerning Product which are necessary for, or included in, FDA approval to market a Product as more fully defined in 21 C.F.R. 314.5 et seq. or any other similar application for marketing authorization filed with the appropriate regulatory authorities in other countries of the Territory (as defined hereinafter).

(g) "Net Sales" shall mean the gross amounts received from sales of Products during a calendar quarter to third parties by Janssen US, its Sublicensees or any Affiliate of either, less any: (i) applicable sales taxes; (ii) cash trade or quantity discounts; (iii) amounts repaid or credited by reason of rejections or return of goods; or (iv) freight, postage and duties paid for. No deduction from the gross sales price shall be made for any item of cost incurred by the seller in its own operations incident to the manufacture, sale or shipment of the product sold. For purposes hereof, Net Sales shall not include sales of a Product from Janssen US or an Affiliate of Janssen US to any Affiliate or Sublicensee of either; it being intended that Net Sales shall only include sales to unrelated third-parties.

(h) "Patents" shall mean (i) any and all existing issued patents and patent applications or parts thereof which describe and claim a depot formulation of Risperidone, or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids and the production and use thereof; (ii) any other patents and patent applications filed by or on behalf of Medisorb, or under which Medisorb has the rights to grant licenses, which are needed to practice the inventions; and (iii) any reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part, or divisions of or to any of the foregoing which are granted hereafter or any additional protection certificate granted with respect thereto.

(i) "Product(s)" shall mean any and all depot formulations of Risperidone, or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids which are designed to deliver Risperidone, or any of its chemical analogues, over an extended period.

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(j) "Sublicensees" shall mean any company or companies, other than Janssen US's Affiliates, sublicensed by Janssen US.

(k) "Technical Information" shall mean all unpatented information, know-how, practical experience, procedures, methodology, specifications, formulae and data whether or not the same shall be patentable which have been heretofore developed or acquired by Medisorb prior to the date of this Agreement and which are necessary in order to use, manufacture or sell Products in the Field.

(l) "Territory" shall mean the United States, its Territories, Protectorates, Commonwealths, and all other political subdivisions of the United States.

## (2) License Grant

(a) Medisorb hereby grants to Janssen US in the Territory an exclusive license under the Patents and Technical Information existing prior to the effective date of this Agreement, with the right to grant sublicenses thereunder, for all purposes within the Field to practice and use the Patents and Technical Information, including the rights to manufacture and have manufactured, to use and have used, and to sell and have sold Products. Medisorb exclusively retains all rights under the Patents and Technical Information outside the Field and for use other than in Products. The right to grant sublicenses granted hereunder is exclusive to Janssen US and shall not extend to Janssen US Affiliates or Sublicensees.

(b) Medisorb shall offer to Janssen US for incorporation into this License Agreement on reasonable terms and conditions, Medisorb Improvements in the Field which, if incorporated into Janssen US's then current commercial Product(s), would: (i) result in significant changes in either the specifications for such Product(s) or the processes for producing such Product(s), and (ii) would reasonably be expected to result in enhanced market value and/or profitability of such Product(s). Examples of such Improvements would include: (i) the development by Medisorb of a non-aqueous injection vehicle which offers significant advantages with respect to ease of administration and (ii) the development by Medisorb of technology enabling [ ].

It is the parties' understanding that the effect of any such license amendment would, in general, be either an extension of the term of this Agreement for a mutually agreed period or a marginal increase in the then current royalty rate. All other Medisorb Improvements shall be made available to Janssen US for its use without further agreement. Proprietary rights to Improvements jointly developed by Medisorb and Janssen US or any of its Affiliates shall be governed by the terms of Section 5(c) of this Agreement.

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(c) In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen U.S. for use in Products, then the license granted under paragraph 2(a) above shall be expanded to include the Medisorb Technology required to make and use the Medisorb Polymers.

(3) Royalties:

(a) Janssen US shall pay or cause to be paid to Medisorb a running royalty with respect to all Products sold to customers in the Territory by Janssen US, its Affiliates and Sublicensees, payable quarter-annually in arrears within sixty (60) days following the end of Janssen US's regular fiscal quarters in any year during the term hereof, as follows: (i) 2.5% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was manufactured by Medisorb pursuant to a written contract for the supply of Product; or (ii) 5.0% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was not manufactured by Medisorb pursuant to a written contract for the supply of Product. Any withholding or other tax that Janssen US or any of its Affiliates or Sublicensees are required by statute to withhold and pay on behalf of Medisorb with respect to the royalties payable to Medisorb under this Agreement shall be deducted from said royalties and paid contemporaneously with the remittance to Medisorb; provided, however, that in regard to any tax so deducted Janssen US shall furnish Medisorb with proper evidence of the taxes paid on its behalf.

(b) In the event that Product is not claimed in a valid Patent effective in the Territory and a similar product obtains a market share greater than [ ]% of the total market revenues for Products and similar products in such country, the parties agree to meet and negotiate in good faith an appropriate reduction in the royalty rate then in effect. In no event shall a reduction in royalty rates pursuant to this section result in royalty rates [ ] of the rates specified under Section 3(a)(i) and 3(a)(ii) of this Agreement. For the purposes of this section, "similar product" shall mean a generic version of the Product(s) where: (i) the active agent is [ ], or a chemical analogue thereof and (ii) the excipient is comprised of lactic and/or glycolic acids. In the event that patent protection in the Territory for Product(s) becomes available subsequent to a royalty reduction pursuant to this section, the parties agree to (i) reinstitute the royalty otherwise applicable, and (ii) in the event that any recovery is obtained for prior infringement of the subsequently issued patent, the parties will first apply such recoveries to reimbursing Medisorb for royalties it would otherwise have received.

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(c) Janssen US shall keep complete and adequate records with respect to the proceeds of Products on which it has to pay royalties payable hereunder for at least two (2) years after expiry of the year they concern. Medisorb shall have the right to have such records of Janssen US inspected and examined, at Medisorb's expense, for the purpose of determining the correctness of royalty payments made hereunder.

Such inspection shall be made by an independent, certified public accountant to whom Janssen US shall have no reasonable objection. Such accountant shall not disclose to Medisorb any information other than that necessary to verify the accuracy of the reports and payments made pursuant to this Agreement. It is understood that such examination with respect to any quarterly accounting period shall take place not later than two (2) years following the expiration of said period. Not more than one examination per year shall take place.

Based upon the verification of such reports and whenever there is reasonable doubt about the accuracy of the sales of Product realized by an Affiliate or sublicensee, Medisorb may reasonably request Janssen US to audit the books of such Affiliate or such sublicensee in accordance with any applicable contractual provision, in order to confirm the accuracy of such reports.

(4) Production of Product/Technology Transfer:

(a) Janssen US shall use its reasonable efforts consistent with its overall business practices and strategies to commercialize and market Product, or to have the same commercialized and marketed in the Territory.

(b) In the event that Janssen US determines to manufacture Product itself or through an Affiliate or have Product manufactured by a third party, Medisorb shall transfer to Janssen US and/or Affiliate all relevant Technical Information, and provide such technical assistance, upon mutually agreed terms and conditions, as is required by Janssen US in order to enable the manufacture of Product by Janssen US, its Affiliate or its designated third party manufacturer. However, with respect to such third party manufacturers, except as limited by a written Product manufacturing agreement between Janssen US and Medisorb, Medisorb will have a right of first refusal as to the manufacture and supply to Janssen US of all Product(s), and component bioabsorbable polymers utilized in such Product(s). Medisorb will have a period of thirty (30) days following written notice from Janssen US of terms it is offering to, or prepared to accept from, a third party manufacturer to notify Janssen US of its intention to exercise its right of first refusal to supply Product and/or component bioabsorbable polymers thereof to Janssen US, its Affiliates and Licensees on terms no less favorable to Janssen US than those offered by such

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third party manufacturer. Such third party manufacturer cannot be an in-kind competitor to Medisorb and must be reasonably acceptable to Medisorb with respect to confidential protection of Medisorb's Technical Information. In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen U.S. for use in Products, then the right of first refusal under this paragraph respecting the supply of the component bioabsorbable polymers shall be eliminated. For the purposes of this section, an "in-kind" competitor shall mean any organization which regularly engages in the contract development and/or contract manufacture of injectable controlled release drug delivery systems comprising a polymeric excipient based on lactic and/or glycolic acids and/or other closely related monomers. This Section 4(b) specifically supersedes Section 7(B) of the Development Agreement, which Section 7(B) shall be of no further force or effect.

(5) Proprietary Rights

(a) Medisorb will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to absorbable polymers, controlled release of active agents, and/or manufacturing methods or processes relating to such polymers and the controlled delivery systems for active agents based on such polymers previously owned by Medisorb or developed by Medisorb as a result of the Development Program or otherwise. Medisorb will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Janssen US agrees to provide Medisorb with any necessary utility information.

Medisorb shall inform Janssen US of any patent application it wishes to file to protect proprietary rights defined in Article 5, resulting from either the Development Program or the preliminary Development Program and shall forward a copy of any such patent application to Janssen US at least one month prior to filing.

Medisorb shall consider any suggestions made by Janssen US for amplifying such application and shall accordingly amend the application where in Medisorb's opinion it is appropriate.

Medisorb shall not abandon part or whole of any of the patents or patent applications without having first consulted Janssen US, which shall have the right to further pursue any patents or patent applications which Medisorb wishes to abandon, or parts thereof, in its own name and at its own expense.

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(b) Janssen US and/or its Affiliate will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to Risperidone or any chemical analogues of Risperidone with similar physiological activity previously owned by Janssen US and/or its Affiliate or developed by Janssen US and/or affiliate as a result of this Agreement or otherwise. Janssen US and/or its Affiliate will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Medisorb agrees to provide Janssen US with any necessary utility information.

(c) Any inventions, other than those falling under either section 5(a) or 5(b) hereof, having an inventorship jointly between at least one employee of Janssen US or an Affiliate of Janssen US and one employee of Medisorb or an Affiliate of Medisorb shall be jointly-owned by Janssen US or Janssen US Affiliate as the case may be and Medisorb. Each party will cooperate fully in the filing and prosecution of such patent applications.

Janssen US and Medisorb shall agree on which of both shall be responsible for the filing, prosecution and maintenance of any such joint patent applications and patents (hereinafter referred to as the "Responsible Party") in Territory. In principle, the party having contributed the most to the invention to be protected shall be the responsible party, unless agreed upon differently. Upon mutual consent, the responsible party may select an agent for drafting, filing and prosecuting a joint application. However, both parties shall agree who shall be the agent and to what extent this agent shall be used.

The Responsible Party shall consult the other party when drafting any\ new jointly owned patent application. The final draft shall be forwarded to the other party at least one month prior to filing to give the opportunity to make final comments.

The Responsible Party shall not abandon part or whole of any of the patents or patent applications without having first consulted the other party, which shall have the right to further pursue any patents or patent applications which the responsible party wishes to abandon, or parts thereof, in its own name and at its own expense.

All out-of-pocket costs made in relation to joint patent applications and patents in the Territory shall be shared equally by Janssen US and Medisorb. A statement of costs shall be made up on a quarterly basis and invoiced to the other party.

Medisorb shall grant to Janssen US an exclusive fully-paid up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part,

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divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of Risperidone or any chemical analogues of Risperidone with similar physiological activity. However, nothing contained in this paragraph shall obviate Janssen US's obligation to pay royalties under Section 3 hereof with respect to any Products developed hereunder.

Janssen US shall grant to Medisorb an exclusive fully paid-up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of bioabsorbable polymers in the field of human and/or veterinary medicine.

(d) In addition, each party will retain exclusive title to its respective confidential information in accordance with the provisions of Article 9 below.

**(6) Patent Infringement**

(a) In the event that either party becomes aware that any third party is infringing in the Territory any patents included within the Patents, the party becoming aware of such infringement shall promptly give notice of such infringement to the other party. Any possible action against such alleged infringement of the Patents will be carried out by either or both of the parties in accordance with the provisions specified hereinafter in paragraphs (b), (c), (d) and (e).

(b) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Medisorb retains full title and ownership pursuant to Article 5 a), Medisorb shall use all reasonable efforts to take action against such infringement in its own name, at its own expense and on its own behalf.

If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen US shall be entitled at its own discretion and at its own expense, to take immediate action against such infringement in its own name, at its own expense and on its own behalf. Medisorb will give all reasonable assistance to Janssen in taking such action in accordance with Article 6(e), including giving Janssen the authority to file and prosecute such suit and, if necessary, being named a party in such action. If Janssen US commences or assumes such action, Janssen US may credit [ ] of

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any royalty otherwise due to Medisorb for sales in such country or countries against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen US. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen US as a result of such action. Except for such repayment of royalties deducted, Janssen US shall be entitled to retain all recoveries therefrom.

In no event shall Medisorb settle with such infringing third party in the Field without the prior written consent of Janssen US.

(c) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates retains full title and ownership pursuant to Article 5 B), Janssen US shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen US fails to take action against such infringement, or if Janssen US does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement. Medisorb shall be entitled to retain all recoveries, if any, therefrom.

(d) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling within the definition of the Field, Janssen US shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen US fails to take action against such infringement, or if Janssen US does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Janssen US will have a continuing right to take over any such action at its own expense and shall pay to Medisorb from any recoveries Janssen US receives (i) Medisorb's expenses and (ii) from any sums remaining after deduction of Medisorb's and Janssen US's expenses, an amount proportionate to Medisorb's expenses in relation to Janssen US's expenses.

Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the

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infringing product would be a drug product falling outside the definition of the Field, Medisorb shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen US shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Medisorb will have a continuing right to take over any such action at its own expense. If Janssen US commences or assumes such action, Janssen US may credit [ ] of any royalty otherwise payable to Medisorb payable hereunder against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen US. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen US as a result of such action. Except for such repayment of royalties deducted, Janssen US shall be entitled to retain all recoveries therefrom.

(e) Each party agrees to cooperate reasonably with the other party in such litigation, including making available to the other party records, information, and evidence relevant to the infringement of the Patent.

(7) Third Party Intellectual Property Rights

(a) Medisorb warrants that to the best of its current knowledge and belief the Products to be developed hereunder will not infringe the patent rights of any third party.

(b) In the event that the manufacture, use or sale of the Product would constitute an infringement of the rights of a third party in the Territory because of the use of the Patents or Medisorb's know how, each party shall, as soon as it becomes aware of the same, notify the other thereof in writing, giving in the same notice full details known to it of the rights of such third party and the extent of any alleged infringement. The parties shall after receipt of such notice meet to discuss the situation, and, to the extent necessary attempt to agree on a course of action in order to permit Janssen US to practice the license granted hereunder. Such course of action may include: (a) modifying the Product or its manufacture so as to be noninfringing; (b) obtaining an appropriate license from such third party; or (c) fight the claim or suit. In the event that within a short period of time, the parties fail to agree on an appropriate course of action Janssen US may decide upon the course of action in the interest of the further development, manufacturing or commercialization of the Product.

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(c) In the event that the parties cannot agree on modifying the Product or in the case that such modification would not be economically viable or regulatory feasible, Janssen US, whenever it relates to know how, whether patented or not, owned by Janssen US in accordance with the provisions of Article 5 (b) and (c), or Medisorb, whenever it relates to know how, whether patented or not, owned by Medisorb in accordance with the provisions of Article 5 (a), will have the right to negotiate with such third party for such license. Both parties hereto will in any event in good faith consult with each other with respect to such negotiations and the party negotiating such license as indicated above, will make every effort to minimize the amount of license fees and royalties payable thereunder. In no event shall either party as a result of such settlement, grant a sublicense or cross license to the third party to settle the suit, without the prior written approval of the other party. In the event that such negotiations result in a consummated agreement, any license fee and/or royalties to be paid thereunder shall be paid by the party responsible for the negotiations as indicated above, [ ] of any license fees or royalties paid by Janssen US under such license will be creditable against royalties due to Medisorb hereunder.

(d) In the event that either or both parties would further to such notification under Paragraph 7 (b) decide to defend such suit or claim in which a third party alleges that the manufacture, use or selling of the Product in the Territory infringes said third party's patent in, Janssen US shall have the right to apply [ ] of the royalties due to Medisorb on the sales of the allegedly infringing Product against its litigation expenses.

(8) Term:

(a) Except as otherwise provided herein, this Agreement and the term of the license granted to Janssen US hereunder shall commence on the date first written above and shall expire (i) upon expiration of the last to expire Patent or (ii) fifteen (15) years after the date of the first commercial sale of Product in the Territory, whichever is later; provided, that in no event shall the license granted hereunder expire later than the twentieth anniversary of the first commercial sale of Product. After expiration of the license granted to Janssen US hereunder, Janssen US shall retain a fully paid-up non-exclusive license to manufacture, use and sell Products in the Field in the Territory.

(b) Medisorb may convert the exclusive license granted under this Agreement to non-exclusive if Janssen US does not maintain the following minimum annual royalty payments to Medisorb. With respect to the entire Territory, the minimum royalty obligation will first apply to the twelve month period following the anniversary of the end of the month in which the Product was launched. During the first twelve month period and each subsequent twelve month period that such minimum royalty obligation is applicable, the

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minimum royalty amount to be paid by Janssen US will be calculated by multiplying the applicable royalty rate by [ ] percent of the actual aggregate net sales of other [ ] products in the Territory during such twelve month period.

Janssen US shall have the right to make up any shortfall in minimum royalty payments from Product sales in the Territory provided, such make-up payment is made at the same time and in the same manner as required for the underlying minimum royalty obligation.

(c) In the event that either party shall enter or be put into voluntary or compulsory liquidation or have a receiver appointed or default in the observance or performance of its obligations under this Agreement and shall fail to remedy such default within ninety (90) days after the delivery of written notice from the other party, the other party shall be entitled upon giving written notice to terminate this Agreement.

(d) Janssen US may terminate this Agreement without cause upon 30 days prior written notice. Thereafter, Janssen US shall have no further rights or privileges with respect to the use of Medisorb Technology in Products and Medisorb shall be under no further obligation of non-competition or exclusive dealing.

(e) Any early termination of the Agreement shall be without prejudice to the rights of either party against the other accrued under this Agreement prior to termination.

(f) Upon any termination of this Agreement, any remaining inventory of Product may be sold, provided all royalties otherwise due hereunder are paid with respect to such sales.

(g) All rights and licenses granted under or pursuant to this Agreement by Medisorb to Janssen U.S. are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses to "intellectual property" as defined under section 101(60) of the Bankruptcy Code. The parties agree that Janssen, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

(9) Confidentiality:

(a) Each party agrees to keep confidential and to not use for any purpose other than as set forth herein all technical information and materials supplied by the other hereunder and any information a party may acquire about the other or its activities as a result of entering into this Agreement, provided that such obligation shall not apply to

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technical information or material which: (i) was in the receiving party's possession without restriction prior to receipt from the other party or its Affiliates; (ii) was in the public domain at the time of receipt; (iii) becomes part of the public domain through no fault of the receiving party; (iv) shall be lawfully received from a third party with a right of further disclosure; (v) shall be required to be disclosed by law, by regulation or by the rules of any securities exchange.

(b) Except as may be otherwise provided herein, the confidentiality obligations as set out in this Section shall continue so long as this Agreement remains in force and thereafter for a period of seven (7) years.

(c) Janssen US shall cause its Affiliates and Sublicensees to abide by the obligations of confidentiality with respect to unpublished information within the Patents and Technical Information.

(d) Any confidential information relating to the subject matter of this Agreement imparted to the other party prior to the execution of this Agreement shall be considered to fall under the terms of this Agreement.

(10) Disclaimer of Warranty: Medisorb makes no representations or warranties, express or implied, with respect to the Medisorb Patents and Technical Information licensed to Janssen US hereunder, including without limitation any warranties of merchantability or fitness for a particular purpose.

(11) Liability.

(a) Janssen US agrees to indemnify, defend and hold harmless Medisorb from and against any liability, loss, damages and expenses (including reasonable attorney fees) Medisorb may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Medisorb by reason of personal injury or damage to property arising out or caused by Janssen US's promotion, use and sale of the Product, except where such liabilities claims, demands, costs or judgments are caused by Medisorb's failure to provide Janssen US with any information as specified in Section 12 (c) and Article 13. Medisorb will notify Janssen US as soon as it becomes aware of any such claim or action and agrees to give reasonable assistance in the investigation and defense of such claim or action it being understood that it shall allow Janssen US to control the disposition of the same.

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(b) Medisorb agrees to indemnify, defend and hold harmless Janssen US from and against any liability, loss, damages and expenses (including reasonable attorney fees) Janssen US may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Janssen US by reason of personal injury or damage to property arising out or caused by Medisorb's failure to provide Janssen US with any information as specified in Section 12(c) and Article 13.

(c) In no event shall either party be liable for loss of profits, loss of goodwill or any consequential or incidental damages of any kind of the other party.

(12) Product Information and Adverse Drug Events

(a) As Janssen US has superior knowledge of the end-use applications to which Products licensed hereunder will be put, Janssen US is responsible for providing third parties with adequate information as to the medical profile of such Products. Janssen US will provide Medisorb with copies of the product information document which is part of the NDA for the Product.

(b) Medisorb does not claim the expertise to judge whether Product(s) will perform acceptably in Janssen US's application(s). Janssen US is the sole judge as to whether Product(s) will perform acceptably in Janssen US's application(s). Janssen US represents and warrants on an on-going basis during the term of this agreement that it has the capability to assess the suitability of Product(s) in Janssen US's application(s) and agrees to conduct adequate testing to confirm the safety and efficacy of Products prior to commercialization.

(c) Medisorb will provide to Janssen US promptly after its discovery by Medisorb, any information in its possession which indicates adverse effects in humans associated with the Products, including the bioabsorbable polymeric components thereof, licensed hereunder. For the purpose of this Agreement "adverse event" shall mean an experience which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of a disease or for the modification of a physiological function and any report of an overdose.

(13) Government Approvals

Janssen US shall be responsible for conducting all necessary testing as well as determining what, if any, government approvals are required for the use and sale of Product licensed hereunder and shall comply with all such requirements prior to and following the sale or distribution of such Products.

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Medisorb shall cooperate fully with Janssen US in obtaining regulatory approvals for Product licensed hereunder and shall, at Janssen US's request, provide appropriate regulatory authorities with any and all information concerning Medisorb's technology, Medisorb polymers and Medisorb's manufacturing process for such Product.

In this respect Medisorb undertakes that it has submitted or will as soon as possible submit a type IV Drug Master File to the FDA identifying Medisorb's method of manufacture, release specifications and testing methods used in the manufacture of Medisorb Polymers and a type I Drug Master File of Medisorb's manufacturing facilities where Product may be manufactured. Medisorb will authorize Janssen U.S. at its request to cross-reference any Drug Master Files relating to the Medisorb Polymers.

(14) Force Majeure: Neither party shall be liable for its failure to perform any of its obligations hereunder if such failure is occasioned by a contingency beyond its reasonable control including, but not limited to, occurrences such as strikes or other labor disturbances, lock out, riot, war, default by a common carrier, fire, flood, storm, earthquake, other acts of God, inability to obtain raw materials, failure of plant facilities or government regulation, act or failure to act. Each party shall notify the other immediately upon occurrence or cessation of any such contingencies. If such contingency continues unabated for at least 180 consecutive days, either party shall have the right to terminate this Agreement without further obligation beyond those actually incurred prior to such termination.

(15) Press Communications: Neither party shall originate any publicity, news release or public announcement, written or oral relating to this Agreement, including its existence, without the prior written approval of the other party.

(16) Notices: Any legal notice required or permitted hereunder shall be considered properly given if in writing and sent by first class mail, certified mail or by telefacsimile to the party being notified at the respective address of such party as follows:

If to Medisorb:

Medisorb Technologies International L.P.  
6954 Cornell Road  
Cincinnati, OH 45242

Facsimile: 513-489-2348

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If to Janssen US:

Janssen U.S.  
1125 Trenton-Harbourton Road  
P.O. Box 200  
Titusville, New Jersey 08560-0200

Facsimile: 609-630-2616

with a copy to Janssen Pharmaceutica International  
Kollerstrasse 38  
6300 Zug 6  
Switzerland  
Facsimile: 00-41-42449565

Such notice shall be effective upon receipt or upon refusal to accept such notice. In any case, notice shall be presumed effective no later than five (5) days after such notice is sent.

Neither party shall originate any publicity, news release or public announcement, written or oral, relating to this Agreement, including its existence, without the written approval of the other party.

(17) Assignment: This Agreement shall not be assigned by either party without the prior written consent of the other party; provided, however, that assignment shall be permitted without such consent to any party, not less than 50% of the total interest of which owns, is owned by, or is under common control with the assigning party. In the event of any such permitted assignment the assignee shall be subject to and shall agree in writing to be bound by the terms and conditions of this Agreement.

(18) Dispute Resolution: The parties shall amicably discuss and negotiate any matters which arise under this Agreement and are not specifically set forth hereunder. If any disputes arise under this Agreement, the parties shall use their reasonable efforts to meet and resolve such disputes. In the event that the parties are unable to resolve any such disputes, then both parties hereby agree to submit said disputes to the jurisdiction of the competent courts of the State of New Jersey and agree that any litigation in any way related to this Agreement shall be submitted to such courts and that same shall be subject to the laws of the State of New Jersey without regard to its rules respecting choice of law.

(19) Severability: In the event any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or any of the parties hereto to be invalid, illegal or unenforceable such provision or provisions shall be validly reformed to as nearly approximate the intent of the

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parties as possible and, if unenforceable; shall be divisible and deleted in such jurisdiction, elsewhere this Agreement shall not be affected.

(20) Captions: The captions of this Agreement are for convenience only, and shall not be deemed of any force or effect whatsoever in construing this Agreement.

(21) Waiver: The failure on the part of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right, nor operate to bar the exercise or enforcement thereof at any time thereafter.

(22) Survival: The following Articles of this Agreement shall survive the termination or expiration of this Agreement: 5, 9, 10, 11, 15, 17, and 18.

(23) Miscellaneous: This Agreement may be executed by the parties hereto in counterparts, each of which when so executed and delivered shall be considered to be an original, but all such counterparts shall together constitute but one and the same instrument. This Agreement is the complete agreement of the parties and supersedes all previous understandings and agreements relating to the subject matter hereof. Neither this Agreement nor any of the terms hereof may be terminated, amended, supplemented, waived or modified orally, but only by an instrument in writing signed by the party against whom enforcement of the termination, amendment, supplement, waiver or modification is sought.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed this Agreement as of the day and year first above written.

JANSSEN PHARMACEUTICA INC.

By: /s/ Paula F. Costa  
Name: Paula F. Costa  
Title: President  
Date: 2/13/96

(Second Janssen Signatory.)

By: /s/ Bruce D. Given  
Name: Bruce D. Given  
Title: Group Vice President  
Date: 2/16/96

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MEDISORB TECHNOLOGIES INTERNATIONAL L.P.

by: Medisorb Technologies  
International, Inc.,  
its General Partner

By: /s/ David R. Lohr  
Name: David R. Lohr  
Title: President  
Date: January 31, 1996

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## LICENSE AGREEMENT

This Agreement is made as of the 21 day February of 1996, between MEDISORB TECHNOLOGIES INTERNATIONAL L.P., a Delaware limited partnership (hereinafter "Medisorb") and JANSSEN PHARMACEUTICA INTERNATIONAL, a division of Cilag International AG, a Swiss business corporation ("Janssen").

WHEREAS, the parties have entered into a certain Development Agreement, dated December 23, 1993 (the "Development Agreement"), for the development of a Product (as described below); and

WHEREAS, Janssen has an option under the Development Agreement to enter into this License Agreement for the Medisorb technology required to make, use and sell the Product, which option Janssen has elected to exercise; and

WHEREAS, the parties believe that it is in their mutual best interest for Medisorb to license to Janssen on an exclusive basis in the Territory, Medisorb Patents and Technical Information within the Field, upon the terms and conditions set forth herein;

NOW, IT IS HEREBY AGREED AS FOLLOWS:

(1) Definitions: The following terms shall have the meanings ascribed to them herein, unless the context otherwise requires:

(a) "Affiliate" shall mean any company controlling, controlled by, or under common control with a party by ownership, directly or indirectly, of fifty percent (50%) or more of the total ownership or by the power to control the policies and actions of such company.

(b) "Development Program" shall mean the development activities conducted by the parties pursuant to the Development Agreement.

(c) "Field" shall mean the treatment of [  
].

(d) "Improvements" shall mean any improvements or developments to or of the Patents and Technical Information in the Field which Medisorb may acquire,

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discover, invent, originate, make, conceive or have a right to, in whole or in part, during the term of this Agreement, whether or not such improvement or development is patentable.

(e) "International Registration Dossier" ("IRF") shall mean the Product registration file compiled by Janssen Pharmaceutica N.V., Beerse, Belgium on behalf of Janssen, the contents and format being such that it can be submitted as such to national health authorities or be used as a basis for a national application for marketing authorization for the Products in the specific format required by such national health authorities.

(f) "Medisorb Polymers" shall mean bioresorbable aliphatic polyesters based on glycolide, lactide, caprolactone and combinations of such polymers, which are manufactured by Medisorb and utilized in Product(s) licensed under this Agreement.

(g) "Net Sales" shall mean the gross amounts received from sales of Products during a calendar quarter to third parties by Janssen, its Sublicensees or any Affiliate of either, less any: (i) applicable sales taxes; (ii) cash trade or quantity discounts; (iii) amounts repaid or credited by reason of rejections or return of goods; or (iv) freight, postage and duties paid for. No deduction from the gross sales price shall be made for any item of cost incurred by the seller in its own operations incident to the manufacture, sale or shipment of the product sold. For purposes hereof, Net Sales shall not include sales of a Product from Janssen or an Affiliate of Janssen to any Affiliate or Sublicensee of either; it being intended that Net Sales shall only include sales to unrelated third-parties.

(h) "Patents" shall mean (i) any and all existing issued patents and patent applications or parts thereof which describe and claim a depot formulation of Risperidone, or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids and the production and use thereof; (ii) any other patents and patent applications filed by or on behalf of Medisorb, or under which Medisorb has the rights to grant licenses, which are needed to practice the inventions; and (iii) any reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part, or divisions of or to any of the foregoing which are granted hereafter or any additional protection certificate granted with respect thereto.

(i) "Product(s)" shall mean any and all depot formulations of Risperidone or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids which are designed to deliver Risperidone or any of its chemical analogues, over an extended period.

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(j) "Sublicensees" shall mean any company or companies, other than Janssen's Affiliates, sublicensed by Janssen.

(k) "Technical Information" shall mean all unpatented information, know-how, practical experience, procedures, methodology, specifications, formulae and data whether or not the same shall be patentable which have been heretofore developed or acquired by Medisorb prior to the date of this Agreement and which are necessary in order to use, manufacture or sell Products in the Field.

(l) "Territory" shall mean worldwide with the exception of the United States, its Territories, Protectorates, Commonwealths, and all other political subdivisions of the United States.

(2) License Grant

(a) Medisorb hereby grants to Janssen in the Territory an exclusive license under the Patents and Technical Information existing prior to the effective date of this Agreement, with the right to grant sublicenses thereunder, for all purposes within the Field to practice and use the Patents and Technical Information, including the rights to manufacture and have manufactured, to use and have used, and to sell and have sold Products. Medisorb exclusively retains all rights under the Patents and Technical Information outside the Field and for use other than in Products. The right to grant sublicenses granted hereunder is exclusive to Janssen and shall not extend to Janssen Affiliates or Sublicensees.

(b) Medisorb shall offer to Janssen for incorporation into this License Agreement on reasonable terms and conditions, Medisorb Improvements in the Field which, if incorporated into Janssen's then current commercial Product(s), would: (i) result in significant changes in either the specifications for such Product(s) or the processes for producing such Product(s), and (ii) would reasonably be expected to result in enhanced market value and/or profitability of such Product(s). Examples of such Improvements would include: (i) the development by Medisorb of a non-aqueous injection vehicle which offers significant advantages with respect to ease of administration and (ii) the development by Medisorb of technology enabling [ ]. It is the parties' understanding that the effect of any such license amendment would, in general, be either an extension of the term of this Agreement for a mutually agreed period or a marginal increase in the then current royalty rate. All other Medisorb Improvements shall be made available to Janssen for its use without further agreement. Proprietary rights to Improvements jointly developed by Medisorb and Janssen shall be governed by the terms of Section 5(c) of this Agreement.

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(c) In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen for use in Products, then the license granted under paragraph 2(a) above shall be expanded to include the Medisorb Technology required to make and use the Medisorb Polymers.

(3) Royalties:

(a) Janssen shall pay or cause to be paid to Medisorb a running royalty with respect to all Products sold to customers by Janssen, its Affiliates and Sublicensees, payable quarter-annually in arrears within sixty (60) days following the end of each three (3) month period ending on March 31, June 30, September 30 or December 31 in any year during the term hereof, as follows: (i) 2.5% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was manufactured by Medisorb pursuant to a written contract for the supply of Product; or (ii) 5.0% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was not manufactured by Medisorb pursuant to a written contract for the supply of Product. Any withholding or other tax that Janssen or any of its Affiliates are required by statute to withhold and pay on behalf of Medisorb with respect to the royalties payable to Medisorb under this Agreement shall be deducted from said royalties and paid contemporaneously with the remittance to Medisorb; provided, however, that in regard to any tax so deducted Janssen shall furnish Medisorb with proper evidence of the taxes paid on its behalf.

(b) In the event that, in a country where Product is not claimed in a valid Patent, a similar product obtains a market share greater than [ ]% of the total market revenues for Products and similar products in such country, the parties agree to meet and negotiate in good faith an appropriate reduction in the royalty rate then in effect. In no event shall a reduction in royalty rates pursuant to this section result in royalty rates [ ] of the rates specified under Section 3(a)(i) and 3(a)(ii) of this Agreement. For the purposes of this section, "similar product" shall mean a generic version of the Product(s) where: (i) the active agent is [ ], or a chemical analogue thereof and (ii) the excipient is comprised of lactic and/or glycolic acids. In the event that patent protection for Product(s) becomes available subsequent to a royalty reduction pursuant to this section, the parties agree to (i) reinstitute the royalty otherwise applicable, and (ii) in the event that any recovery is obtained for prior infringement of the subsequently issued patent, the parties will first apply such recoveries to reimbursing Medisorb for royalties it would otherwise have received.

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(c) Janssen shall keep complete and adequate records with respect to the proceeds of Products on which it has to pay royalties payable hereunder for at least two (2) years after expiry of the year they concern. Medisorb shall have the right to have such records of Janssen inspected and examined, at Medisorb's expense, for the purpose of determining the correctness of royalty payments made hereunder.

Such inspection shall be made by an independent, certified public accountant to whom Janssen shall have no reasonable objection. Such accountant shall not disclose to Medisorb any information other than that necessary to verify the accuracy of the reports and payments made pursuant to this Agreement. It is understood that such examination with respect to any quarterly accounting period shall take place not later than two (2) years following the expiration of said period. Not more than one examination per year shall take place.

Based upon the verification of such reports and whenever there is reasonable doubt about the accuracy of the sales of Product realized by an Affiliate or sublicensee, Medisorb may reasonably request Janssen to audit the books of such Affiliate or such sublicensee in accordance with any applicable contractual provision, in order to confirm the accuracy of such reports.

(4) Production of Product/Technology Transfer:

(a) Janssen shall use its reasonable efforts to commercialize and market Product, or to have the same commercialized and marketed.

(b) In the event that Janssen determines to manufacture Product itself or have Product manufactured by a third party, Medisorb shall transfer to Janssen all relevant Technical Information, and provide such technical assistance, upon mutually agreed terms and conditions, as is required by Janssen in order to enable the manufacture of Product by Janssen or its designated third party manufacturer. However, with respect to such third party manufacturers, except as limited by a written Product manufacturing agreement between Janssen and Medisorb, Medisorb will have a right of first refusal as to the manufacture and supply to Janssen of all Product(s), and component bioabsorbable polymers utilized in such Product(s). Medisorb will have a period of thirty (30) days following written notice from Janssen of terms it is offering to, or prepared to accept from, a third party manufacturer to notify Janssen of its intention to exercise its right of first refusal to supply Product and/or component bioabsorbable polymers thereof to Janssen, its Affiliates and Licensees on terms no less favorable to Janssen than those offered by such third party manufacturer. Such third party manufacturer cannot be an in-kind competitor to Medisorb and must be reasonably acceptable to Medisorb with respect to confidential protection of

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Medisorb's Technical Information. In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen for use in Products, then the right of first refusal under this paragraph respecting the supply of the component bioabsorbable polymers shall be eliminated. For the purposes of this section, an "in-kind" competitor shall mean any organization which regularly engages in the contract development and/or contract manufacture of injectable controlled release drug delivery systems comprising a polymeric excipient based on lactic and/or glycolic acids and/or other closely related monomers. This Section 4(b) specifically supercedes Section 7(B) of the Development Agreement, which Section 7(B) shall be of no further force or effect.

(c) The right of first refusal granted to Medisorb pursuant to Section 4(b) above shall be contingent upon: (i) Medisorb and Janssen reaching an agreement concerning the financing, scheduling and construction in Europe of a Medisorb manufacturing facility within twelve (12) months of the date first above written or the initiation of Phase III human clinical trials, whichever is later, and (ii) prior to the qualification of Medisorb's European manufacturing facility, Medisorb using reasonable efforts to supply from its United States manufacturing facilities all of Janssen's commercial requirements for Product pursuant to the Product Supply Agreement anticipated by Section 7(A) of the Development Agreement.

(5) Proprietary Rights

(a) Medisorb will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to absorbable polymers, controlled release of active agents, and/or manufacturing methods or processes relating to such polymers and the controlled delivery systems for active agents based on such polymers previously owned by Medisorb or developed by Medisorb as a result of the Development Program or otherwise. Medisorb will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Janssen agrees to provide Medisorb with any necessary utility information.

Medisorb shall inform Janssen of any patent application it wishes to file to protect proprietary rights defined in Article 5, resulting from either the Development Program or the preliminary Development Program and shall forward a copy of any such patent application to Janssen at least one month prior to filing.

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Medisorb shall consider any suggestions made by Janssen for amplifying such application and shall accordingly amend the application where in Medisorb's opinion it is appropriate.

Nine months after the first filing, Medisorb shall propose a list of countries in which it intends to file foreign equivalents. Janssen shall be given the opportunity to propose further countries to be added to the list. In case the adding of some or all of these further countries is unacceptable to Medisorb, Janssen shall have the right to file patent applications in those countries, in Medisorb's name and at Janssen expense. Medisorb shall assist in the transfer of rights for the latter patent applications and shall provide all information necessary to file and prosecute such patent applications.

Medisorb shall not abandon part or whole of any of the patents or patent applications without having first consulted Janssen, which shall have the right to further pursue any patents or patent applications which Medisorb wishes to abandon, or parts thereof, in its own name and at its own expense.

(b) Janssen and/or its Affiliate will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to Risperidone or any chemical analogues of Risperidone with similar physiological activity previously owned by Janssen and/or its Affiliate or developed by Janssen as a result of this Agreement or otherwise. Janssen and/or its Affiliate will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Medisorb agrees to provide Janssen with any necessary utility information.

(c) Any inventions, other than those falling under either section 5(a) or 5(b) hereof, having an inventorship jointly between at least one employee of Janssen or an Affiliate of Janssen and one employee of Medisorb or an Affiliate of Medisorb shall be jointly-owned by Janssen and Medisorb. Each party will cooperate fully in the filing and prosecution of such patent applications.

Janssen and Medisorb shall agree on which of both shall be responsible for the filing, prosecution and maintenance of any such joint patent applications and patents (hereinafter referred to as the "Responsible Party"). In principle, the party having contributed the most to the invention to be protected shall be the responsible party, unless agreed upon differently. Upon mutual consent, the responsible party may select an agent for drafting, filing and prosecuting a joint application. However, both parties shall agree who shall be the agent and to what extent this agent shall be used.

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The Responsible Party shall consult the other party when drafting any new jointly owned patent application. The final draft shall be forwarded to the other party at least one month prior to filing to give the opportunity to make final comments.

The Responsible Party shall propose a list of countries in which it intends to file such patent applications. The other party shall be given the opportunity to propose further countries to be added to the list. In case the adding of some or all of these further countries is unacceptable to the Responsible Party, the other party shall have the right to file patent applications in those countries, in its own name and at its own expense. The Responsible Party shall assist in the transfer of rights for the latter patent applications and shall provide all information necessary to file and prosecute such patent applications.

The Responsible Party shall not abandon part or whole of any of the patents or patent applications without having first consulted the other party, which shall have the right to further pursue any patents or patent applications which the responsible party wishes to abandon, or parts thereof, in its own name and at its own expense.

All out-of-pocket costs made in relation to joint patent applications and patents shall be shared equally by Janssen and Medisorb. A statement of costs shall be made up on a quarterly basis and invoiced to the other party.

Medisorb shall grant to Janssen an exclusive fully-paid up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of Risperidone or any chemical analogues of Risperidone with similar physiological activity. However, nothing contained in this paragraph shall obviate Janssen's obligation to pay royalties under Section 3 hereof with respect to any Products developed hereunder.

Janssen shall grant to Medisorb an exclusive fully paid-up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of bioabsorbable polymers in the field of human and/or veterinary medicine.

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(d) In addition, each party will retain exclusive title to its respective confidential information in accordance with the provisions of Article 9 below.

(6) Patent Infringement

(a) In the event that either party becomes aware that any third party is infringing any patents included within the Patents in any country or countries, the party becoming aware of such infringement shall promptly give notice of such infringement to the other party. Any possible action against such alleged infringement of the Patents will be carried out by either or both of the parties in accordance with the provisions specified hereinafter in paragraphs (b), (c), (d) and (e).

(b) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Medisorb retains full title and ownership pursuant to Article 5 a), Medisorb shall use all reasonable efforts to take action against such infringement in its own name, at its own expense and on its own behalf.

If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen shall be entitled at its own discretion and at its own expense, to take immediate action against such infringement in its own name, at its own expense and on its own behalf. If Janssen commences or assumes such action, Janssen may credit [ ] of any royalty otherwise due to Medisorb for sales in such country or countries against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen as a result of such action. Except for such repayment of royalties deducted, Janssen shall be entitled to retain all recoveries therefrom.

In no event shall Medisorb settle with such infringing third party in the Field without the prior written consent of Janssen.

(c) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen retains full title and ownership pursuant to Article 5 B), Janssen shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen fails to take action against such infringement, or if Janssen does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to

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in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement. Medisorb shall be entitled to retain all recoveries, if any, therefrom.

(d) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling within the definition of the Field, Janssen shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen fails to take action against such infringement, or if Janssen does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Janssen will have a continuing right to take over any such action at its own expense and shall pay to Medisorb from any recoveries Janssen receives (i) Medisorb's expenses and (ii) from any sums remaining after deduction of Medisorb's and Janssen's expenses, an amount proportionate to Medisorb's expenses in relation to Janssen's expenses.

Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling outside the definition of the Field, Medisorb shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Medisorb will have a continuing right to take over any such action at its own expense. If Janssen commences or assumes such action, Janssen may credit [ ] of any royalty otherwise payable to Medisorb payable hereunder against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen as a result of such action. Except for such repayment of royalties deducted, Janssen shall be entitled to retain all recoveries therefrom.

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(e) Each party agrees to cooperate reasonably with the other party in such litigation, including making available to the other party records, information, and evidence relevant to the infringement of the Patent.

(7) Third Party Intellectual Property Rights

(a) Medisorb warrants that to the best of its current knowledge and belief the Products to be developed hereunder will not infringe the patent rights of any third party.

(b) In the event that the manufacture, use or sale of the Product would constitute an infringement of the rights of a third party in a country because of the use of the Patents or Medisorb's know how, each party shall, as soon as it becomes aware of the same, notify the other thereof in writing, giving in the same notice full details known to it of the rights of such third party and the extent of any alleged infringement. The parties shall after receipt of such notice meet to discuss the situation, and, to the extent necessary attempt to agree on a course of action in order to permit Janssen to practice the license granted hereunder. Such course of action may include: (a) modifying the Product or its manufacture so as to be noninfringing; (b) obtaining an appropriate license from such third party; or (c) fight the claimor suit. In the event that within a short period of time, the parties fail to agree on an appropriate course of action Janssen may decide upon the course of action in the interest of the further development, manufacturing or commercialization of the Product.

(c) In the event that the parties cannot agree on modifying the Product or in the case that such modification would not be economically viable or regulatorily feasible, Janssen, whenever it relates to know how, whether patented or not, owned by Janssen in accordance with the provisions of Article 5 (b) and (c), or Medisorb, whenever it relates to know how, whether patented or not, owned by Medisorb in accordance with the provisions of Article 5 (a), will have the right to negotiate with such third party for such license. Both parties hereto will in any event in good faith consult with each other with respect to such negotiations and the party negotiating such license as indicated above, will make every effort to minimize the amount of license fees and royalties payable thereunder. In no event shall either party as a result of such settlement, grant a sublicense or cross license to the third party to settle the suit, without the prior written approval of the other party. In the event that such negotiations result in a consummated agreement, any license fee and/or royalties to be paid thereunder shall be paid by the party responsible for the negotiations as indicated above, [ ] of any license fees or royalties paid by Janssen under such license will be creditable against royalties due to Medisorb with respect to such country or countries.

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(d) In the event that either or both parties would further to such notification under Paragraph 7 (b) decide to defend such suit or claim in which a third party alleges that the manufacture, use or selling of the Product infringes said third party's patent in a country, Janssen shall have the right to apply [ ] of the royalties due to Medisorb on the sales of the allegedly infringing Product against its litigation expenses.

(8) Term:

(a) Except as otherwise provided herein, this Agreement and the term of the license granted to Janssen hereunder shall commence on the date first written above and shall expire (i) upon expiration of the last to expire Patent in such country or (ii) fifteen (15) years after the date of the first commercial sale of Product in such country, whichever is later; provided, that in no event shall the license granted hereunder expire later than the twentieth anniversary of the first commercial sale of Product in any country with the exception of the following countries where the fifteen (15) year minimum shall pertain regardless: Canada, France, Germany, Italy, Japan, Spain and the United Kingdom. After expiration of the license granted to Janssen hereunder, Janssen shall retain a fully paid-up non-exclusive license to manufacture, use and sell Products in the Field in the Territory.

(b) Medisorb may convert the exclusive license granted under this Agreement to non-exclusive if Janssen does not maintain the following minimum annual royalty payments to Medisorb:

(i) With respect to the entire Territory, excluding Japan, the minimum royalty obligation will first apply to the twelve month period following the anniversary of the end of the month in which the Product was launched in the third major country. For the purpose of this Article only, major country shall mean France, Germany, United Kingdom or Italy. During the first twelve month period that such minimum royalty obligation is applicable, the minimum royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by [ ] percent of the actual aggregate net sales of other [ ] products during such twelve month period in the three major countries referred to above.

As from the subsequent twelve month period the minimum annual royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by [ ]% of the aggregate net sales of other [ ] products during such period in all countries where Product has been launched and marketed for a period of minimally twelve months prior to the actual reference twelve month period; and

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(ii) In Japan the minimum royalty obligation will be first applied to the twelve month period following the anniversary of the end of the month in which the Product was launched. The minimum annual royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by an amount representing [ ]% of the aggregate net sales of other [ ] products in Japan during such period.

Janssen shall have the right to make up any shortfall in minimum royalty payments from Product sales, both in Japan and in the rest of the Territory provided, such make-up payment is made at the same time and in the same manner as required for the underlying minimum royalty obligation.

Janssen may elect to have its exclusive rights converted into non-exclusive rights on a country by country basis. As a consequence thereof, such country's other [ ] products sales will no longer be taken into account for calculating the above minimum royalty obligation.

(c) In the event that either party shall enter or be put into voluntary or compulsory liquidation or have a receiver appointed or default in the observance or performance of its obligations under this Agreement and shall fail to remedy such default within ninety (90) days after the delivery of written notice from the other party, the other party shall be entitled upon giving written notice to terminate this Agreement.

(d) Janssen may terminate this Agreement without cause upon 30 days prior written notice. Thereafter, Janssen shall have no further rights or privileges with respect to the use of Medisorb Technology in Products and Medisorb shall be under no further obligation of non-competition or exclusive dealing.

(e) Any early termination of the Agreement shall be without prejudice to the rights of either party against the other accrued under this Agreement prior to termination.

(f) Upon any termination of this Agreement, any remaining inventory of Product may be sold, provided all royalties otherwise due hereunder are paid with respect to such sales.

(9) Confidentiality:

(a) Each party agrees to keep confidential and to not use for any purpose other than as set forth herein all technical information and materials supplied by the

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other hereunder and any information a party may acquire about the other or its activities as a result of entering into this Agreement, provided that such obligation shall not apply to technical information or material which: (i) was in the receiving party's possession without restriction prior to receipt from the other party or its Affiliates; (ii) was in the public domain at the time of receipt; (iii) becomes part of the public domain through no fault of the receiving party; (iv) shall be lawfully received from a third party with a right of further disclosure; (v) shall be required to be disclosed by law, by regulation or by the rules of any securities exchange.

(b) Except as may be otherwise provided herein, the confidentiality obligations as set out in this Section shall continue so long as this Agreement remains in force and thereafter for a period of seven (7) years.

(c) Janssen shall cause its Affiliates and Sublicensees to abide by the obligations of confidentiality with respect to unpublished information within the Patents and Technical Information.

(d) Any confidential information relating to the subject matter of this Agreement imparted to the other party prior to the execution of this Agreement shall be considered to fall under the terms of this Agreement.

(10) Disclaimer of Warranty: Medisorb makes no representations or warranties, express or implied, with respect to the Medisorb Patents and Technical Information licensed to Janssen hereunder, including without limitation any warranties of merchantability or fitness for a particular purpose.

(11) Liability

(a) Janssen agrees to indemnify, defend and hold harmless Medisorb from and against any liability, loss, damages and expenses (including reasonable attorney fees) Medisorb may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Medisorb by reason of personal injury or damage to property arising out or caused by Janssen's promotion, use and sale of the Product, except where such liabilities claims, demands, costs or judgments are caused by Medisorb's failure to provide Janssen with any information as specified in Section 12 (c) and Article 13. Medisorb will notify Janssen as soon as it becomes aware of any such claim or action and agrees to give reasonable assistance in the investigation and defense of such claim or action it being understood that it shall allow Janssen to control the disposition of the same.

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(b) Medisorb agrees to indemnify, defend and hold harmless Janssen from and against any liability, loss, damages and expenses (including reasonable attorney fees) Janssen may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Janssen by reason of personal injury or damage to property arising out or caused by Medisorb's failure to provide Janssen with any information as specified in Section 12 (c) and Article 13.

(c) In no event shall either party be liable for loss of profits, loss of goodwill or any consequential or incidental damages of any kind of the other party.

(12) Product Information and Adverse Drug Events

(a) As Janssen has superior knowledge of the end-use applications to which Products licensed hereunder will be put, Janssen is responsible for providing third parties with adequate information as to the medical profile of such Products. Janssen will provide Medisorb with copies of the IPID (International Product Information Document) and the IPPI (International Patient Package Insert), which are all part of the IRF for the Product. For the purpose of this Agreement IPID refers to the document that summarizes all medically relevant features of the Product, including the instructions for use meant to inform the medical profession, whereas the IPPI is a patient-oriented document, based upon the IPID that summarizes all relevant information on the Product in lay language. Janssen will keep Medisorb informed of any revisions or amendments in the IPID and IPPI of the Product.

(b) Medisorb does not claim the expertise to judge whether Product(s) will perform acceptably in Janssen's application(s). Janssen is the sole judge as to whether Product(s) will perform acceptably in Janssen's application(s). Janssen represents and warrants on an on-going basis during the term of this agreement that it has the capability to assess the suitability of Product(s) in Janssen's application(s) and agrees to conduct adequate testing to confirm the safety and efficacy of Products prior to commercialization.

(c) Medisorb will provide to Janssen promptly after its discovery by Medisorb, any information in its possession which indicates adverse effects in humans associated with the Products, including the bioabsorbable polymeric components thereof, licensed hereunder. For the purpose of this Agreement "adverse event" shall mean an experience which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of a disease or for the modification of a physiological function and any report of an overdose.

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(13) Government Approvals

Janssen shall be responsible for conducting all necessary testing as well as determining what, if any, government approvals are required for the use and sale of Product licensed hereunder and shall comply with all such requirements prior to and following the sale or distribution of such Products.

Medisorb shall cooperate fully with Janssen in obtaining regulatory approvals for Product licensed hereunder and shall, at Janssen's request, provide appropriate regulatory authorities with any and all information concerning Medisorb's technology, Medisorb polymers and Medisorb's manufacturing process for such Product.

In this respect Medisorb undertakes that it has submitted or will as soon as possible submit a type IV Drug Master File to the FDA identifying Medisorb's method of manufacture, release specifications and testing methods used in the manufacture of its bioabsorbable polymers and a type I Drug Master File of Medisorb's manufacturing facilities where Product may be manufactured. Medisorb will authorize Janssen at its request to cross-reference any Medisorb Drug Master Files relating to the Medisorb Polymers.

(14) Force Majeure: Neither party shall be liable for its failure to perform any of its obligations hereunder if such failure is occasioned by a contingency beyond its reasonable control including, but not limited to, occurrences such as strikes or other labor disturbances, lock out, riot, war, default by a common carrier, fire, flood, storm, earthquake, other acts of God, inability to obtain raw materials, failure of plant facilities or government regulation, act or failure to act. Each party shall notify the other immediately upon occurrence or cessation of any such contingencies. If such contingency continues unabated for at least 180 consecutive days, either party shall have the right to terminate this Agreement without further obligation beyond those actually incurred prior to such termination.

(15) Press Communications: Neither party shall originate any publicity, news release or public announcement, written or oral relating to this Agreement, including its existence, without the prior written approval of the other party.

(16) Notices: Any legal notice required or permitted hereunder shall be considered properly given if in writing and sent by first class mail, certified mail or by telefacsimile to the party being notified at the respective address of such party as follows:

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If to Medisorb:

Medisorb Technologies International L.P.  
6954 Cornell Road  
Cincinnati, OH 45242  
USA  
Facsimile: 513-489-2348

If to Janssen:

Janssen Pharmaceutica  
Kollerstrasse 38  
6300 Zug 6  
Switzerland  
Facsimile: 00-41-42449565

Such notice shall be effective upon receipt or upon refusal to accept such notice. In any case, notice shall be presumed effective no later than five (5) days after such notice is sent.

Neither party shall originate any publicity, news release or public announcement, written or oral, relating to this Agreement, including its existence, without the written approval of the other party.

(17) Assignment: This Agreement shall not be assigned by either party without the prior written consent of the other party; provided, however, that assignment shall be permitted without such consent to any party, not less than 50% of the total interest of which owns, is owned by, or is under common control with the assigning party. In the event of any such permitted assignment the assignee shall be subject to and shall agree in writing to be bound by the terms and conditions of this Agreement.

(18) Dispute Resolution: The parties shall amicably discuss and negotiate any matters which arise under this Agreement and are not specifically set forth hereunder. If any disputes arise under this Agreement, the parties shall use their best efforts to meet and resolve such disputes. In the event that the parties are unable to resolve any such disputes, then both parties hereby agree to submit said disputes to the jurisdiction of the competent Courts of Zurich, Switzerland, and agree that any litigation in any way related to this Agreement shall be submitted to such Courts and that same shall be subject to Swiss law.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL  
TREATMENT REQUEST. REDACTED MATERIAL IS BRACKETED AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.



(19) Severability: In the event any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or any of the parties hereto to be invalid, illegal or unenforceable such provision or provisions shall be validly reformed to as nearly approximate the intent of the parties as possible and, if unreformable; shall be divisible and deleted in such jurisdiction, elsewhere this Agreement shall not be affected.

(20) Captions: The captions of this Agreement are for convenience only, and shall not be deemed of any force or effect whatsoever in construing this Agreement.

(21) Waiver: The failure on the part of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right, nor operate to bar the exercise or enforcement thereof at any time thereafter.

(22) Survival: The following Articles of this Agreement shall survive the termination or expiration of this Agreement: 5, 9, 10, 11, 15, 17, and 18.

(23) Miscellaneous: This Agreement may be executed by the parties hereto in counterparts, each of which when so executed and delivered shall be considered to be an original, but all such counterparts shall together constitute but one and the same instrument. This Agreement is the complete agreement of the parties and supersedes all previous understandings and agreements relating to the subject matter hereof. Neither this Agreement nor any of the terms hereof may be terminated, amended, supplemented, waived or modified orally, but only by an instrument in writing signed by the party against whom enforcement of the termination, amendment, supplement, waiver or modification is sought.

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TREATMENT REQUEST. REDACTED MATERIAL IS BRACKETED AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed this Agreement as of the day and year first above written.

JANSSEN PHARMACEUTICA INTERNATIONAL  
A division of Cilag International AG

By: /s/ Erik Rombouts  
Name: Erik Rombouts  
Title: Operations Director  
Date: February 21, 1996

[Second Janssen Signatory]

By: /s/ Heinz Schmid  
Name: Heinz Schmid  
Title: General Manager  
Date: February 21, 1996

MEDISORB TECHNOLOGIES INTERNATIONAL L.P.

by: Medisorb Technologies  
International, Inc.,  
its General Partner

By: /s/ David R. Lohr  
Name: David R. Lohr  
Title: President  
Date: January 31, 1996

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THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH "\*" AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

#### ADDENDUM TO MANUFACTURING AND SUPPLY AGREEMENT

This Addendum to Manufacturing and Supply Agreement (this "Addendum"), dated as of the 1st day of August, 2001 (the "Effective Date") is by and between JPI PHARMACEUTICA INTERNATIONAL, a division of Cilag AG International Zug, a company duly organized and existing under the laws of Switzerland, having its principal office in CH-6300 Zug, Kollerstrasse 38, Switzerland ("JPI") and JANSSEN PHARMACEUTICA Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA ("Janssen US" and, together with JPI, "Janssen") on the one hand and Alkermes Controlled Therapeutics Inc. II, a company organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal office at 64 Sidney Street, Cambridge MA 02139-4136, USA ("ACTII") on the other hand.

WHEREAS, Janssen and ACTII have been collaborating for the development of a Risperidone depot formulation incorporating ACTII's proprietary technology concerning bioabsorbable polymer technologies and have entered into a Development Agreement and two License Agreements related thereto; and

WHEREAS, Janssen and ACTII entered into that certain Manufacturing and Supply Agreement, dated August 6, 1997 (the "Supply Agreement"), with respect to the commercial manufacture and supply of such Risperidone depot formulation to Janssen; and

WHEREAS, Janssen and ACTII desire to enter into this Addendum regarding the expansion of ACTII's manufacturing facilities, and the financial responsibilities of each of the parties in connection with such expansion, in order to support the increased sales forecasts for such Risperidone depot formulation; and

WHEREAS, Janssen and ACTII further desire to enter into this Addendum to formally provide for a collaborative effort to develop the manufacturing facility and commercial supply of Product.

NOW, THEREFORE, in consideration of the mutual covenants and conditions set forth below, and intending to be legally bound hereby, the parties agree as follows:

#### ARTICLE 1 - DEFINITIONS

Section 1.1. Unless provided otherwise, any capitalized terms used in this Addendum and not defined herein or below, shall have the meaning set forth in the Supply Agreement.

1.1.1. "Regulatory Approval" shall mean either (i) the approval of a New Drug Application, or a comparable application, for the Product by the United States Food and Drug Administration ("FDA"), or (ii) regulatory approval in two (2) of the Major EU Member States (for the purpose hereof, "Major EU Member States" means Germany, UK, France, Spain and

Italy), together in each case with satisfaction of any related regulatory and notification requirements of the FDA or such other regulatory authority.

## ARTICLE 2 - EXPANSION PROJECT

Section 2.1. The Project. ACTII will retain the services of an engineering firm to develop plans to expand ACTII's manufacturing facility located in Wilmington, Ohio (the "Project"), including detailed timelines for completion of the Project. The Project shall include the following elements:

2.1.1. The expansion to the current facility will be a detached addition on the same campus as the original facility in Wilmington, Ohio (such detached addition, including the equipment to be fitted therein, are referred to herein as the "Expansion");

2.1.2. The Expansion will include the utilities for a second and third wet process line and a second filling line;

2.1.3. Only the equipment for the second wet process line will be installed as part of the Project; and

2.1.4. The Project is expected to be completed by early August 2003 and cost approximately twelve million dollars (\$12,000,000), all according to the preliminary budget and timetable set forth on Schedule A attached hereto.

2.1.5. The underlying assumption of the terms agreed in this Addendum is that the Expansion will be dedicated to the manufacturing of the Product. Notwithstanding the above, ACTII shall have the right to manufacture other products in the Expansion, [\*\*\*]. ACTII shall be entitled to proceed with such intended manufacturing activities, provided that the Global Supply Team is satisfied, in its reasonable judgment, that such activities will not affect the quality (including GMP guidelines), the supply chain or capacity requirements for the Product. In the event that ACTII proceeds with its intended manufacturing activities, ACTII and Janssen will negotiate in good faith the impact (if any) of such activities on the Minimum Revenues and/or the Guarantee provided in this Addendum and modify it accordingly.

Section 2.2. The Project Plan. Upon completion of the work by the engineering firm, which is expected to be completed prior to July 31, 2001, Janssen and ACTII shall meet to review the plans, budget and timetable for completion of the Project, determine the actions to be taken by each of the parties and to finalize the plans, budget and timetable for the Project (the "Project Plan"). The Project Plan, including the budget, must be amended by mutual agreement of the parties (after consultation with the Global Supply Team (defined in Section 5.2)) if the change impacts the timeline, capacity or budget with respect to the Product. At any time the parties amend the budget included in the Project Plan, a corresponding amendment to the Guarantee Cap (defined in Section 3.2) shall also be made.

Section 2.3. Contractors and Construction. Upon approval by both parties of the Project Plan, ACTII shall engage the services of any contractors necessary to begin and complete

actual construction of the Project and shall oversee such construction. ACTII shall cause the timetable for completion of the Project that is part of the Project Plan to be incorporated into all contracts and agreements with such contractors.

### ARTICLE 3 - FINANCIAL RESPONSIBILITY FOR THE PROJECT

Section 3.1. ACTII's Responsibility. ACTII shall be responsible for payment of all costs and expenses related to construction of the Project, including the design of and engineering services related to the Project, subject to the Guarantee and Minimum Revenues (each as defined in Sections 3.2 and 3.4, respectively).

Section 3.2. The Guarantee. In the event that Janssen terminates development of the Product prior to commercial launch or Janssen terminates the Project, Janssen will reimburse ACTII for all cumulative out-of-pocket expenses made or actually and irrevocably committed by ACTII for the Project through the date of ACTII's receipt of written notice of such termination (such reimbursement payment referred to herein as the "Guarantee"). The Guarantee shall not exceed [\*\*\*] (the "Guarantee Cap"), unless the parties have mutually agreed to amend the budget and the Guarantee Cap pursuant to Section 2.2.

Section 3.3. Refund of the Guarantee. If Janssen pays to ACTII the Guarantee due to Janssen's termination of the Project and if the Expansion is utilized by ACTII for another product with another corporate partner within [\*\*\*] of Janssen's termination of the Project, then ACTII shall refund that portion of the Guarantee that is proportional to the actual utilization of the Expansion during the [\*\*\*] period which shall be paid to Janssen in installments over the months remaining in the [\*\*\*] period and so long as the utilization continues.

Section 3.4. Minimum Revenues. For a period of ten (10) calendar years, Janssen shall guarantee a certain minimum amount of revenues to ACTII from Janssen from the purchase of Product under the Supply Agreement (the "Minimum Revenues"), unless Janssen realizes the cumulative Minimum Revenues prior to the expansion of such 10-year period, all in accordance with this Section 3.4 and the subsections below.

3.4.1. Upon completion of the work by the engineering firm, which is expected to be completed prior to July 31, 2001, Janssen and ACTII shall meet to review the Project cost. If the aggregate Project cost is [\*\*\*] or more, but less than [\*\*\*], the Minimum Revenues shall be:

Scenario 1: Detached Plant without filling line  
Capital Cost: [\*\*\*]

Calendar Year of Minimum Revenues	Minimum Revenue for Alkermes \$ million
[***]	[***]

3.4.2. If the aggregate Project cost is less than [\*\*\*] or greater than [\*\*\*], then Janssen and ACTII shall recalculate the Minimum Revenue amounts based on the Project cost and assumptions and preliminary Minimum Revenue amounts set forth below.

(a) The Minimum Revenues are intended to derive a minimum revenue that drives a net present value of [\*\*\*] using a [\*\*\*] discount rate for ACTII's manufacturing facility investment.

(b) For the purpose of calculating the Minimum Revenues under this Section 3.4, the Project cost shall not exceed [\*\*\*], unless the parties have mutually agreed to amend the budget pursuant to Section 2.2.

(c) The Minimum Revenues under this Section 3.4.2 shall be calculated in substantially the same way as the Minimum Revenues under Section 3.4.1 were calculated as shown on Schedule C.

3.4.3. First Calendar Year. The first calendar year in which Minimum Revenues shall be guaranteed, shall begin on the earlier of (a) the January 1 immediately following Regulatory Approval or (b) January 1, 2004, unless the parties agree otherwise.

3.4.4. Excess. If the aggregate amount of Product purchased by Janssen under the Supply Agreement in any one calendar year (an "Actual Purchase Amount") exceeds the Minimum Revenue amount for such calendar year, then such excess (the "Excess Credit") shall be credited against any future calendar year in which Janssen's Actual Purchase Amount is less than the Minimum Revenue amount for such calendar year.

3.4.5. Shortfall. If an Actual Purchase Amount is less than the Minimum Revenue amount for the relevant calendar year, then any available Excess Credit shall be added to the Actual Purchase Amount for such calendar year. If the sum of Actual Purchase Amount plus any such Excess Credit are less than the Minimum Revenue amount for such calendar year, then Janssen shall pay to ACTII the difference between the Minimum Revenue and the sum of the Actual Purchase Amount plus such Excess Credit (if any). A portion of an Excess Credit may be used if only a portion is necessary to bring the sum of the Actual Purchase Amount plus the Excess Credit up to the Minimum Revenue amount for the relevant calendar year, in which case the balance of the Excess Credit can be used for another future calendar year; provided, however, that the aggregate amount of Excess Credit may only be added to an Actual Purchase Amount once.

3.4.6. Reporting. Within seventy-five (75) days of the end of each calendar year after Regulatory Approval, ACTII shall prepare and deliver to Janssen a report showing (a) the Actual Purchase Amount and the Minimum Revenue amount for such calendar year, (b) any Excess Credit added to the Actual Purchase Amount, (c) any Excess Credit from a prior or the current calendar year available but not added to the Actual Purchase Amount, and (d) any amount due to ACTII under Section 3.4.5.

3.4.7. Prepayment. If (i) sales of Product are such that Janssen determines that the expanded facility will not be utilized or (ii) Janssen ceases to sell Product or terminates the Supply Agreement after Regulatory Approval but before all Minimum Revenues have been achieved, then Janssen may, in its discretion, (a) prepay the Minimum Revenues in a lump sum that is the then net present value of the Minimum Revenues not yet achieved or (b) continue to pay any shortfall under Minimum Revenues over time as provided in this Section 3.4. If Janssen prepays the Minimum Revenues in a lump sum under this Section 3.4.7 and if the Expansion is utilized by ACTII for another product incorporating its bioabsorbable polymer technology with another corporate partner within three (3) years of such prepayment, then ACTII shall refund that portion of the lump sum payment that is proportional to the actual utilization of the Expansion during the 3-year which shall be paid to Janssen in installments over the months remaining in the 3-year and so long as the utilization continues.

#### ARTICLE 4 - SECOND FILLING LINE AND FUTURE EXPANSIONS

Section 4.1. Second Filling Line. The parties may mutually determine that a second filling line needs to be added to the manufacturing facility. If such a determination is made, it is anticipated that the cost of adding a second filling line will be approximately [\*\*\*]. Janssen and ACTII shall amend the Guarantee Cap and the Minimum Revenues to take into account such additional cost, taking into consideration the assumptions set forth in Section 3.4 (including the subsections) and the subsections below.

4.1.1. Upon completion of the work by the engineering firm with regard to the Project, including the second filling line, Janssen and ACTII shall meet to review the Project cost. If the aggregate Project cost is [\*\*\*] or more, but less than [\*\*\*], the Minimum Revenues, if a second filling line is included, shall be:

	Scenario 2: Detached Plant filling line Capital Cost: [***] Minimum Revenue for Alkermes \$ million
Calendar Year of Minimum Revenues	
[***]	[***]

4.1.2. If the aggregate Project cost, including a second filling line, is less than [\*\*\*] or greater than [\*\*\*], then Janssen and ACTII shall re-calculate the Minimum Revenue amounts based on the Project cost, including the second filling line, and assumptions and preliminary Minimum Revenue amounts set forth below.

(a) The Minimum Revenues are intended to derive a minimum revenue that drives a net present value of [\*\*\*] using a [\*\*\*] discount rate for ACTII's manufacturing facility investment.

(b) For the purpose of calculating the Minimum Revenues under this Section 4.1.2, the Project cost shall not exceed [\*\*\*], unless the parties have mutually agreed to amend the budget pursuant to Section 2.2.

(c) The Minimum Revenues under this Section 4.1.2 shall be calculated in substantially the same way as the Minimum Revenues under Section 4.1.1 were calculated as shown on Schedule C.

Section 4.2. Reimbursement of Incremental Capital Cost. In the event that the parties determine to include a second filling line (the "2nd Line") in the Project, Janssen shall reimburse ACTII for the financial cost of the incremental capital associated with the 2nd Line. To that end, Janssen shall pay to ACTII, on a quarterly basis, an amount equal to the Prime Rate times the capital expenses associated with the 2nd Line in excess of the capital expenses associated with the Project excluding the 2nd Line. For purposes hereof, "Prime Rate" shall be the prime rate as reported in the eastern edition of The Wall Street Journal on the first day of the relevant calendar quarter on which The Wall Street Journal is published. Janssen's obligation under this Section 4.2 shall terminate upon the occurrence of both of the following two conditions: (a) Product delivered by ACTII to Janssen under the Supply Agreement meets or exceeds [\*\*\*] period and (b) Janssen's [\*\*\*] supply forecast for Product to be delivered by ACTII under the Supply Agreement exceeds the vial filling capacity of the existing filling line in any [\*\*\*] period in such [\*\*\*] forecast.

Section 4.3. Future Expansions. If the Global Supply Team determines that an additional process line is required, then such additional line will be included in the Project under conditions to be negotiated by Janssen and ACTII at the time of such determination.

#### ARTICLE 5 - MANAGEMENT OF PROJECT AND COMMERCIAL SUPPLY

Section 5.1. Collaborative Efforts. Both parties acknowledge and agree that the management of the commercial supply chain of Product is of critical importance, as is (i) the timely expansion of the capacity for the manufacturing of the bulk Product and the vial filling, (ii) the transition of the current activities to a continuous commercial manufacturing and supply process and (iii) the eventual commercial supply and logistics chain. Therefore, the parties shall actively collaborate with each other, including a free exchange of expertise and knowledge, with the following goals: (a) the timelines of expansion and supply are respected, (b) a robust manufacturing and supply process is developed, (c) Product will comply with all relevant quality and regulatory requirements and (d) a continued supply of Product in accordance with current forecasts is achieved.

Section 5.2. Global Supply Team. ACTII shall be responsible for the operation and management of the Project and the manufacture and supply of Product. Notwithstanding the foregoing, a Global Supply Team shall be established under this Section 5.2 whose goal will be to enhance and facilitate the collaborative effort described in Section 5.1.

5.2.1. Formation and Make-Up. Within thirty (30) days after the Effective Date, the parties shall form the Global Supply Team. The Global Supply Team shall consist of an



equal number of representatives of each party. The Global Supply Team may delegate its responsibilities and authority to one or more Sub-Teams. The members of the Global Supply Team and any Sub-Teams shall have expertise in the functional disciplines that either party believes should be represented at the team or sub-team. The representatives of a party may be changed from time to time at the discretion of that party upon written notification by the party making such change to the other.

5.2.2. Oversight of the Project and Commercial Supply. The Global Supply Team shall be responsible for recommending actions to ACTII and Alkermes management following periodic reviews of the Project and the commercial supply process. Within fifteen (15) days after the receipt of the Project Plan, or any amendment or supplement to the Project Plan, the Global Supply Team or the appropriate Sub-Team shall meet to evaluate the Project Plan, amendment or supplement and recommend actions. The Global Supply Team or the appropriate Sub-Team shall periodically review the Project Plan and the progress of the activities called for under the plan. ACTII and Alkermes management shall keep the Global Supply Team and any Sub-Teams informed on a periodic basis of issues and decisions affecting the commercial supply chain and the construction of the Project and shall consult with it on such issues before making decisions whenever possible.

5.2.3. Meetings. The Global Supply Team and any Sub-Teams shall meet from time to time as determined by the team members. It is expected that the teams shall meet in person at least once in each calendar quarter. The location of team meetings shall alternate between ACTII's and Janssen's offices unless otherwise agreed by the parties, with the first meeting being held at ACTII's Ohio office. Consultants and non-member employees of the parties may attend team meetings as required to further the team's goals. Minutes of all meetings setting forth decisions of the Global Supply Team or Sub-Team will be prepared and circulated by the party hosting the meeting within thirty (30) days of such meeting. Such minutes will become official when agreed to by all team members. Each party will bear all expenses associated with attendance of its employees and consultants at such meetings. If the team members all agree, a meeting may be held by means of telephone conference or similar communications equipment by means of which all persons participating in the meeting can hear each other.

5.2.4. Decisions. Recommendations of the Global Supply Team or Sub-Teams shall be made by unanimous vote, with the representatives of each party having one collective vote. If the Global Supply Team or a Sub-Team is unable to reach a unanimous vote on any issue, then the issue shall be referred to the President of Alkermes (or successor position) and the Senior Vice President of Manufacturing of Janssen (or successor position) for further discussion and resolution. These individuals shall, as soon as practicable, attempt in good faith to resolve the dispute and, thereby, make the recommendation on behalf of the Global Supply Team or Sub-Team. These individuals may obtain the advice of other employees as they deem necessary or advisable in order to make the recommendation. If such issue (a) is not resolved within thirty (30) days after it has been referred to such persons for resolution, (b) would cause a serious interruption of the manufacturing and supply chain and (c) is related to the Logistic Systems, Quality System, Control of Change, Validation, timelines of the Project Plan or

commercialization ramp-up, the issue shall be resolved in accordance with the views of the Senior Vice President of Manufacturing of Janssen. Any issue related to the budget for the Project shall be discussed in good faith to determine the appropriate modification or outcome and shall be agreed to by the parties in good faith. Also, in the event ACTII is reasonably of the opinion that Janssen's standpoint on any of the above issues could adversely affect its obligations under the Supply Agreement, it will raise such issue and the parties will duly consider it and its ramifications in resolving the issue at hand. In the event Janssen nevertheless decides to proceed in accordance with its standpoint, the parties will in good faith discuss the modifications that may be warranted in relation to the other obligations with respect to which ACTII had raised concerns.

Section 5.3. Janssen Representative at the Project. In order to implement the collaborative effort set forth under Section 5.1, Janssen will have the right to have one or more Janssen representatives visit the Project and/or the entire manufacturing facility in Wilmington, Ohio for short or extended periods of time. Any such visits shall be at Janssen's expense; provided that ACTII shall provide some accommodation at the site upon reasonable request and provided that there is no disruption to the course of business at the site. In the event that there is any dispute under this Section 5.3 or either party has a concern related to the Janssen representative(s) at the manufacturing facility, the Global Supply Team shall attempt to resolve such dispute or address such concern.

Section 5.4. Janssen Support. At ACTII's request, Janssen shall reasonably assist ACTII in its contacts with manufacturing and supply contractors and shall support ACTII in connection with its vendor relations.

#### ARTICLE 6 - MISCELLANEOUS

Section 6.1. [\*\*\*].

Section 6.2. Bankruptcy provisions. In the event ACTII or Alkermes, Inc. files a petition in bankruptcy, insolvency or reorganization for the benefit of its creditors or if a receiver or trustee is appointed as provided for in Section 10.2.3 of the Supply Agreement, ACTII shall, unless and until the Supply Agreement would be rejected by the bankruptcy trustee in accordance with the relevant bankruptcy codes, continue to perform all its obligations under the Supply Agreement, including this Addendum, unless and until Janssen elects to terminate the Supply Agreement in accordance with Section 10.2.3 of the Supply Agreement. By October 31, 2001, ACTII shall submit to a neutral escrow agent mutually agreeable to the parties, such as DSI Technology Escrow Services, Inc. (the "Escrow Agent"), to hold in escrow all of the standard operating procedures and batch records, which shall contain detailed descriptions of all steps and operations involved in the approved Manufacturing Process (the "Escrow Documents"). ACTII shall update the Escrow Documents annually. In the event that Janssen terminates the Agreement under Section 10.2.3 of the Supply Agreement, Janssen shall be free to access the Escrow Documents. Janssen, ACTII and the Escrow Agent shall execute an escrow agreement which will control the deposit, possession and release of the Escrow Documents and any conflict between this Addendum and such escrow agreement shall be controlled by the escrow agreement. Janssen, as a licensee of intellectual property rights granted under the

License Agreement dated February 13, 1996, by and between Janssen US and ACT II and the License dated February 21, 1996, by and between JPI and ACT II, shall in addition to any rights or remedies expressly provided herein, retain any and all of its rights under the bankruptcy code to resort to other remedies as may now or hereafter exist at law or in equity in such event.

Section 6.3. Amendments to the Supply Agreement. To the extent that the provisions of this Addendum are in conflict with Sections 2.2 and 2.9 of the Supply Agreement, Sections 2.2 and 2.9 shall be deemed to be amended by this Addendum. The provision regarding Minimum Revenues in this Addendum shall supersede the provisions for minimum number of Product to be purchased by Janssen pursuant to Section 2.11 of the Supply Agreement for the ten (10) calendar years following Regulatory Approval of Product. Except as provided in the foregoing two sentences, all of the provisions of the Supply Agreement shall remain in full force and effect.

Section 6.4. Prior Agreements. The parties hereto acknowledge that this Addendum and the Supply Agreement contain the entire agreement between the parties pertaining to the manufacture and supply of Product in Territory and terminates and supersedes all prior agreements, understandings, letters or other instruments whatsoever, whether written or oral, between the parties or any of their affiliates with respect to such matters.

IN WITNESS WHEREOF, JPI, Janssen US and ACTII have caused this Addendum to Manufacturing and Supply Agreement to be executed by their respective duly authorized officers on the date first set forth above.

JANSSEN PHARMACEUTICA INTERNATIONAL represented by  
CILAG AG INTERNATIONAL

By: /s/ Erik Rombouts  
Name: Erik Rombouts  
Title: Vice President

JANSSEN PHARMACEUTICA INC.

By: /s/ David Y. Norton  
Name: David Y. Norton  
Title: President

ALKERMES CONTROLLED THERAPEUTICS INC. II

By: /s/ Robert A. Breyer  
Name: Robert A. Breyer  
Title:

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SCHEDULE A  
PRELIMINARY TIMETABLE AND BUDGET

\*\*\*]

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SCHEDULE B  
SALES FORECASTS AS OF THE EFFECTIVE DATE  
AS OF JUNE 2001

\*\*\*

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SCHEDULE C  
CALCULATION OF MINIMUM REVENUES

\*\*\*]

## AMENDMENT TO MANUFACTURING AND SUPPLY AGREEMENT

THIS AMENDMENT (the "Amendment") is made and entered into as of December 22, 2003 to the Manufacturing and Supply Agreement entered into as of August 6, 1997 by and between JPI PHARMACEUTICA INTERNATIONAL, a division of Cilag AG International Zug ("JPI"), JANSSEN PHARMACEUTICA INC. ("JANSSEN US") and ALKERMES CONTROLLED THERAPEUTICS INC. II ("ACT II"), as amended (the "Agreement") (any terms used but not defined herein shall have the meaning set forth in the Agreement).

## RECITALS:

WHEREAS, JPI, JANSSEN US and ACT II have entered into the Agreement; and

WHEREAS, the parties now wish to enter into this Amendment to clarify the terms for payment of the Manufacturing Fee as set forth in the Agreement by amending the terms and conditions of the Agreement as set forth below;

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

1. Article 1.3 of the Agreement shall be deleted in its entirety and replaced with a new Article 1.3 which shall read as follows:

1.3 "Final Product" shall mean a Presentation Form approved and marketed by JANSSEN, their Affiliates and licensees, ready for sale to the final customer.

2. Article 1.5 of the Agreement shall be deleted in its entirety and replaced with Article 1.5(a) and Article 1.5(b) which shall read as follows:

1.5(a) "U.S. Licensed Net Selling Price" shall mean the \* offered by JANSSEN, its Affiliates or licensees in a given calendar year (or such shorter period as may be applicable) to independent third parties for each Presentation Form of the Final Product for sale in the United States, its territories and possession, less deductions for (i) trade, cash and ordinary business discounts allowed; (ii) allowances or credits to customers on account of rejection or return of Final Product; and (iii) managed care rebates or allowances and mandatory price allowances imposed by governments.

If JANSSEN, its Affiliates or licensees sell any Presentation Form of the Final Product in the United States in such a manner that the \* of the same is not readily identifiable then the \* shall be whichever is the higher of (i) the fair market value of such Final Product or (ii) the proportion of the bundled price attributed to such Final Product by JANSSEN, its Affiliates or licensees whenever the Final Product is sold as a part of a package of products or services. For the purpose hereof "fair market

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value" shall mean, without limitation, the value of such Final Product sold to similar third parties in similar quantities in the United States. If the fair market value cannot be determined in the United States, the fair market value will be negotiated by the parties in good faith.

- 1.5(b) "ROW Licensed Net Selling Price" shall mean the \* offered by JANSSEN, its Affiliates or licensees in a given calendar year (or such shorter period as may be applicable) to independent third parties for each Presentation Form of the Final Product for sale in the Territory (other than the United States, its territories and possessions), less deductions for (i) trade, cash and ordinary business discounts allowed; (ii) allowances or credits to customers on account of rejection or return of Final Product; and (iii) managed care rebates or allowances and mandatory price allowances imposed by governments.

If JANSSEN, its Affiliates or licensees sell any Presentation Form of the Final Product in a country in the Territory (other than the United States, its territories and possessions) in such a manner that the \* of the same is not readily identifiable then the \* for that country shall be whichever is the higher of (i) the fair market value of such Final Product or (ii) the proportion of the bundled price attributed to such Final Product by JANSSEN, its Affiliates or licensees whenever the Final Product is sold as part of a package of products or services. For the purpose hereof "fair market value" shall mean, without limitation, the value of such Final Product sold to similar third parties in similar quantities. If the fair market value cannot be determined in any given country, the fair market value will be determined by the value of such Final Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities.

3. Article 1.7 of the Agreement shall be deleted in its entirety and replaced with a new Article 1.7 which shall read as follows:

- 1.7 "Manufacturing Fee" shall mean the fee to be paid by JPI and JANSSEN US to ACT II for each Presentation Form of the Product in consideration for the Manufacture of Products supplied to each of them in accordance with the terms hereof and which fee will be calculated as a percentage of the U.S. Licensed Net Selling Price and/or the ROW Licensed Net Selling Price, as applicable, for each Presentation Form of the Final Product in accordance with the mechanism set forth in Article 6.

4. A new Article 1.13 shall be added to the Agreement which shall read as follows:

- 1.13 "Presentation Form" shall mean a form of the Product or the Final Product determined by the amount of the single dose (either 25 mg., 37.5 mg. or 50 mg.) of the depot formulation of Risperidone contained therein.

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5. Article 6 of the Agreement shall be deleted in its entirety and replaced with a new Article 6 which shall read as follows:

6.1 In consideration of the manufacturing activities to be performed by ACT II hereunder, JPI and JANSSEN US will pay the Manufacturing Fee for the Products supplied to each of them.

The Manufacturing Fee will be calculated as a certain percentage of the U.S. Licensed Net Selling Price and/or ROW Licensed Net Selling Price, as applicable. Subject to the terms and conditions set forth in this Agreement, the actual percentage that shall apply with respect to a given calendar year will be determined in accordance with the mechanisms set forth in this Article 6 and Exhibit D attached hereto.

6.1.1 The Manufacturing Fee for calendar year 2002 has been established pursuant to Exhibit I hereto.

6.1.2 (a) Determination of Manufacturing Fee. Subject to the terms and conditions set forth in this Article 6.1.2, the Manufacturing Fees for calendar year 2003 and any subsequent calendar year will be calculated on the basis of the (i) U.S. Licensed Net Selling Prices and/or ROW Licensed Net Selling Prices for such calendar year (expressed in USD at the exchange rates then applied by JANSSEN in accordance with its normal accounting procedures), as applicable, for each Presentation Form of the Final Product and (ii) the total amount of Product expressed in units that has been Manufactured and shipped pursuant to Article 4 by ACT II for such calendar year.

(b) Determination of a Provisional Manufacturing Fee. For the sake of administrative ease, by \*, JANSSEN and ACT II will agree in good faith on the "U.S. Provisional Manufacturing Fee" and the "ROW Provisional Manufacturing Fee" for each Presentation Form of the Product for the upcoming calendar year. The "U.S. Provisional Manufacturing Fee" for each such Presentation Form of the Product shall be calculated by taking the forecast submitted by JANSSEN in \* for the upcoming calendar year in accordance with Exhibit E (the "\* Forecast"), to determine an estimated total amount of Product to be ordered, then determining the applicable percentage from Exhibit D to the Agreement (based on the such estimated total amount of Product) (the "Applicable Percentage") and adding \* to facilitate cash flow (the "Additional Percentage") to such Applicable Percentage to determine the "Provisional Manufacturing Fee Percentage." The Provisional Manufacturing Fee Percentage shall then be applied to JANSSEN's estimated U.S. Licensed Net Selling Price for the upcoming calendar year (which shall be determined by JANSSEN in good faith and submitted to ACT II by \* of the prior calendar year) to determine the U.S. Provisional Manufacturing Fee. "ROW Provisional Manufacturing Fee " for each such Presentation Form of

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the Product shall be calculated by taking (i) the \* Forecast; and (ii) JANSSEN's estimated ROW Licensed Net Selling Price for the upcoming calendar year (which shall be determined by JANSSEN in good faith and submitted to ACT II by \* of the prior calendar year) and applying the Provisional Manufacturing Fee Percentage to the estimated ROW Licensed Selling Price to determine the ROW Provisional Manufacturing Fee. Subject to the other provisions of this Article 6.1.2, ACT II shall invoice JANSSEN US for all Product to be shipped to JANSSEN US in the subsequent calendar year at the U.S. Provisional Manufacturing Fee and shall invoice JPI for all Product to be shipped to JPI in the subsequent calendar year at the ROW Provisional Manufacturing Fee. Either the "U.S. Provisional Manufacturing Fee" and/or the "ROW Provisional Manufacturing Fee" may also be referred to as the "Provisional Manufacturing Fee."

(c) Recalculation of the Provisional Manufacturing Fee. Within \* business days after the end of each calendar quarter JANSSEN shall send to ACT II a report setting forth for each Presentation Form of the Final Product (i) its actual U.S. Licensed Net Selling Price for the calendar year to date; (ii) its actual ROW Licensed Net Selling Price for the calendar year to date; and (iii) the actual number of units of Product ordered by JANSSEN pursuant to Exhibit E for the calendar year to date plus the number of units of Product forecast to be ordered by JANSSEN during the balance of the calendar year as set forth in the most recent forecast submitted in accordance with Exhibit E (specifying such units by Presentation Form and by geographical area (US - ROW)) ("Revised Annual Total Products"). The parties shall use such Revised Annual Total Products to recalculate the Applicable Percentage from Exhibit D by substituting such number for the comparable estimated number used to determine the then current Provisional Manufacturing Fee Percentage. The parties shall add an Additional Percentage to this Applicable Percentage to create a new Provisional Manufacturing Fee Percentage. The parties shall also apply the Applicable Percentage to the actual year-to-date US Licensed Net Selling Price and ROW Licensed Net Selling Price to determine an interim US Provisional Manufacturing Fee and an interim ROW Provisional Manufacturing Fee to be used for calculation purposes. The parties shall next use such newly calculated interim Provisional Manufacturing Fees to recalculate the total amount payable for Product shipped to JANSSEN during the current calendar year to date to determine if such recalculation would result in an underpayment or overpayment for such Product (a "Payment Differential") of more than \*. The parties shall also calculate the total amount payable for Revised Annual Total Products using the newly calculated interim Provisional Manufacturing Fees as well as the prior Provisional Manufacturing Fees to determine if these amounts represent more than a \* potential overpayment or underpayment for such Product. In the event that there is either a underpayment or overpayment of more than \* or \* as described above, then the party who has overpaid or who has been underpaid may request the other party to pay the Payment Differential within \* of the end of such calendar quarter (such payment a "True Up"). In addition, in the event that there is a

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True Up, the parties shall apply the newly calculated Provisional Manufacturing Fee Percentage to the actual year-to-date US Licensed Net Selling Price and ROW Licensed Net Selling Price to determine a revised US Provisional Manufacturing Fee and ROW Provisional Manufacturing Fee which shall become the Provisional Manufacturing Fees to be used during the balance of the calendar year, unless replaced by subsequently recalculated Provisional Manufacturing Fees in accordance with this paragraph.

(d) Annual Reconciliation. Within thirty (30) days after the end of each calendar year, JANSSEN shall send to ACT II a report stating for each Presentation Form of the Final Product (i) its U.S. Licensed Net Selling Price for such calendar year; (ii) its ROW Licensed Net Selling Price for such calendar year; and (iii) the total number of units of Product shipped to JANSSEN during such calendar year (on a country-by-country basis). Any payment required by JANSSEN to ACT II or vice versa to compensate for any difference between the U.S. Provisional Manufacturing Fee and/or the ROW Provisional Manufacturing Fee (calculated in accordance with paragraphs (b) and (c) above) and the applicable Manufacturing Fees as determined by such actual prices and total number of units of Product shipped shall be made to the appropriate Party no later than February 10<sup>th</sup> of the year in which the report is delivered and in accordance with the provisions of Article 6.4.

(e) Calculation of Units During Calendar Years 2003 to 2005. In calculating the total number of units of Product shipped to JANSSEN for each of calendar years 2003-2005, whether or not such units of Product are actually shipped, the parties will deem as shipped (i) all Product ordered by JANSSEN prior to the end of August of each such calendar year and (ii) all Product ordered by JANSSEN in the August forecast for each such calendar year (the "August Forecast") submitted in accordance with the ordering procedures set forth in Exhibit E. Any Product ordered by JANSSEN other than as set forth above, even if such Product is shipped, will not, however, be deemed to be shipped when making such calculation, and will also not be deemed to be shipped when calculating the total number of units of Product shipped during any subsequent calendar year. Any units of Product ordered by JANSSEN as set forth above, but not shipped, shall be invoiced to JANSSEN when shipped at the Manufacturing Fee for the applicable calendar year, rather than at the then current Provisional Manufacturing Fee. From the calendar year 2006 onwards, the Manufacturing Fee will be calculated based on the total number of units of Product actually shipped to JANSSEN for such calendar year.

(f) Recalculation of Price if No NDA Approval Received. In the event that the New Drug Application for the Product (#21-346) filed with the FDA on August 31, 2001 (the "NDA") is not approved by the FDA, then the Manufacturing Fee for any Product that has been shipped and invoiced to JANSSEN US at the U.S. Provisional Manufacturing Fee shall be determined by utilizing the comparable ROW Licensed Net Selling Price for such Product rather than the U.S. Licensed Net Selling Price, with such determination to be made on the last day of the calendar quarter following the receipt of notice from the FDA that such NDA will not be approved.

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(g) Recalculation of Price if Delayed Product Launch. In the event that the launch of the Product does not occur following approval by the FDA of the NDA for the Product in any given calendar year when Product has been shipped and invoiced to JANSSEN US at the U.S. Provisional Manufacturing Fee, then the annual reconciliation for such Product will be performed pursuant to Article 6.1.2(d) in the calendar year in which such launch occurs, and the Manufacturing Fee for such Product shall be calculated by using the percentage determined by the total amount of Product shipped in the calendar year such Product was shipped and the U.S. Licensed Net Selling Price in the calendar year in which the Product was launched.

(h) Illustrative Examples. Exhibit J hereto provides examples for illustrative purposes only of calculations made pursuant to paragraphs (b), (c), (d) and (e) hereof. In the event of any conflict between Exhibit J and this Agreement, the provisions of this Agreement shall control.

- 6.2 JANSSEN shall keep or cause to be kept accurate records in sufficient detail to enable the Manufacturing Fees for Products sold hereunder to be determined. JANSSEN, upon the written request (including reasonable notice) and at the expense of ACT II, and in any event not more frequently than once in any calendar year, shall permit an independent public accountant of national prominence selected by ACT II, and approved by JANSSEN (with approval not unreasonably to be withheld), to have access during normal business hours to those records as may be reasonably necessary to verify the accuracy of the Manufacturing Fees for Products sold for any calendar year ending not more than three (3) years prior to the date of the aforementioned written request. If such accountant determines that the Manufacturing Fees have been overstated or understated, then one party shall make a payment to the other party as necessary to correct the amount of the Manufacturing Fees paid for Product supplied hereunder, which payment shall be based on the difference between the actual and the misstated Manufacturing Fees. In addition, if such accountant reasonably determines that the Manufacturing Fees have been understated for the audited period by more than \*, then JANSSEN shall pay the reasonable costs of such audit. ACT II agrees that all information subject to review under this Article 6.2 shall be deemed JANSSEN's Confidential Information subject to the terms and conditions of Article 7. ACT II shall retain and cause its independent accountant to retain all such information in confidence in accordance with Article 7 and such information may only be used for purposes germane to this Article 6.2.
- 6.3 ACT II shall invoice JPI or JANSSEN US for the Provisional Manufacturing Fee due with respect to each batch of Product supplied to each of them or their

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respective designee when shipped pursuant to Article 4. JPI and JANSSEN US shall pay such, invoice within forty-five (45) days after the date of the invoice.

- 6.4 All payments required to be paid hereunder shall be made in United States Dollars by wire transfer of immediately available funds to the financial institution, account number, account party's name and wire transfer information designated in writing by ACT II to JPI and JANSSEN US as the place of payment.
- 6.5 No party shall have the right to reduce, by set off, counterclaim, adjustment or otherwise, any amount owed by it to the other party pursuant to this Agreement, unless explicitly provided for otherwise.
- 6.6 JANSSEN shall bear all applicable national, federal, provincial, municipal and other governmental taxes (such as sale, use or similar taxes), duties, or import charges, except for any tax on profits or income of ACT II, that ACT II may be required to pay or collect as a result of the payments of the Manufacturing Fee or the Provisional Manufacturing Fee.
- 6.7 Within ten (10) business days after the end of each month, JANSSEN shall deliver to ACT II a report setting forth the dollar amount and the units of each Presentation Form of the Final Product sold during the prior month on a country-by-country basis. In addition, each month JANSSEN shall provide to ACT II the foreign currency exchange rates used to calculate the Final Product sales for each country.
6. Exhibit D shall be amended by deleting the words "Licensed Net Selling Price" and substituting the words "U.S. Licensed Net Selling Price and/or ROW Licensed Net Selling Price."
7. This Amendment and the Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of law provisions.
8. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall continue in full force and effect as provided therein. This Amendment and the Agreement constitute the entire agreement between the parties hereto relating to the subject matter hereof and thereof and supersede all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto.

[signature page follows]

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IN WITNESS WHEREOF, JPI, JANSSEN US and ACT II have executed and delivered this Amendment effective as of the date first set forth above.

ALKERMES CONTROLLED  
THERAPEUTICS INC. II

By: /s/ Michael Landine

Name: Michael Landine

Title: Vice President

JPI PHARMACEUTICA  
INTERNATIONAL represented by  
CILAG AG INTERNATIONAL ZUG

By: /s/ Erik Rombouts

Name: ERIK ROMBOUTS

Title: VP ALLIANCE MGMT

By: /s/ Heinz Schmid

Name: HEINZ SCHMID

Title: GENERAL MANAGER

JANSSEN PHARMACEUTICA INC.

By: /s/ Peter Miller

Name: Peter Miller

Title: President

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EXHIBIT I

[\*\*\*]

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EXHIBIT J

[\*\*\*]

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#### FOURTH AMENDMENT TO LEASE

**THIS FOURTH AMENDMENT TO LEASE** (this “**Amendment**”) is made and entered into as of December 30, 2014, by and between **GI TC 850 WINTER STREET, LLC, a Delaware limited liability company** (“**Landlord**”), and **ALKERMES, INC., a Pennsylvania corporation** (“**Tenant**”).

#### RECITALS

- A. Landlord (as successor in interest to PDM Unit 850, LLC, a Delaware limited liability company) and Tenant are parties to that certain Lease dated April 22, 2009 (the “**Original Lease**”), which Original Lease has been previously amended by that certain First Amendment to Lease dated June 15, 2009, that certain Second Amendment to Lease (the “**Second Amendment**”) dated November 12, 2013 and that certain Third Amendment to Lease (the “**Third Amendment**”) dated May 15, 2014 (collectively, the “**Lease**”). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **146,629** rentable square feet (as more particularly described in the Lease, the “**Original Premises**”) in the building located at 850 and 852 Winter Street, Waltham, Massachusetts (the “**Building**”).
- B. Tenant has requested that additional space containing approximately **13,365** rentable square feet (the “**Fourth Expansion Premises**”) and approximately **353** square feet of storage space (the “**Storage Space**”) and, together with the Fourth Expansion Premises, the “**Fourth Expansion Space**”), as shown on **Exhibit A** hereto, be added to the Original Premises and that the Lease be appropriately amended and Landlord is willing to do the same on the following terms and conditions.
- C. The Lease by its terms shall expire on February 28, 2021 (the “**Expiration Date**”), and the parties desire to extend the term of the Lease solely as to the Fourth Expansion Space, all on the following terms and conditions.

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. **Expansion.**

1.1 **Addition of Fourth Expansion Premises.** Effective as of January 1, 2015 (the “**Fourth Expansion Effective Date**”), the Original Premises is increased from approximately 146,629 rentable square feet in the Building to approximately **159,994** rentable square feet in the Building by the addition of the Fourth Expansion Premises, and from and after the Fourth Expansion Effective Date, the Original Premises and the Fourth Expansion Premises, collectively, shall be deemed the “Premises”, as defined in the Lease, and as used herein. The term for the Fourth Expansion Premises shall commence on the Fourth Expansion Effective Date and end on the Fourth Expansion Space Expiration Date (as defined in Section 2.1 below) unless sooner terminated in accordance with the terms of the Lease, as amended hereby. The Fourth Expansion Premises is subject to all the terms and conditions of the Lease except as expressly modified herein and except that Tenant shall not be entitled to receive any allowances, abatements or other financial concessions granted with respect to the Original Premises unless such concessions are expressly provided for herein with respect to the Fourth Expansion Space.

1.2 **Addition of Storage Space.**

1.2.1 Landlord leases to Tenant and Tenant accepts the Storage Space for the term (the “**Storage Term**”) commencing on the Fourth Expansion Effective Date and ending

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on the Fourth Expansion Space Expiration Date, unless the Lease or Tenant's right to possession of the Premises thereunder terminates sooner, in which case the Storage Term shall end on such earlier termination date.

- 1.2.2 The Storage Space shall be used by Tenant for the storage of equipment, inventory or other non-perishable items normally used in Tenant's business, and for no other purpose whatsoever. Tenant agrees to keep the Storage Space in a neat and orderly fashion and to keep all stored items in cartons, file cabinets or other suitable containers. All items stored in the Storage Space shall be at least eighteen (18) inches below the bottom of all sprinklers located in the ceiling of the Storage Space, if any. Tenant shall not store anything in the Storage Space which is unsafe or which otherwise may create a hazardous condition, or which may increase Landlord's insurance rates, or cause a cancellation or modification of Landlord's insurance coverage. Without limitation, Tenant shall not store any flammable, combustible or explosive fluid, chemical or substance nor any perishable food or beverage products, except with Landlord's prior written approval. Landlord reserves the right to adopt and enforce reasonable rules and regulations governing the use of the Storage Space from time to time.
- 1.2.3 All applicable terms and provisions of the Lease shall be applicable to the Storage Space, including, without limitation, Articles 4 and 12 of the Original Lease, except that Landlord need not supply air-cooling, heat, water, janitorial service, cleaning, passenger or freight elevator service or window washing to the Storage Space and Tenant shall not be entitled to any work allowances, rent credits, expansion rights or renewal rights with respect to the Storage Space unless such concessions or rights are specifically provided for herein with respect to the Storage Space. Landlord shall provide electricity for standard lighting in the Storage Space, at no additional monthly charge to Tenant. Tenant shall not, without the prior written consent of Landlord, which consent may be withheld in Landlord's sole discretion, assign, sublease, transfer or encumber the Storage Space or grant any license, concession or other right of occupancy or permit the use of the Storage Space by any party other than Tenant.
- 1.2.4 Landlord shall not be liable for any theft or damage to any items or materials stored in the Storage Space, it being understood that Tenant is using the Storage Space at its own risk. Tenant agrees to accept the Storage Space in its condition and "as-built" configuration existing on the earlier of the date Tenant takes possession of the Storage Space or the Fourth Expansion Effective Date. At any time and from time to time, but upon at least thirty (30) days prior written notice, Landlord shall have the right to relocate the Storage Space to a new location which shall be no smaller than the square footage of the Storage Space. Landlord shall pay the direct, out-of-pocket, reasonable expenses of such relocation.
- 1.2.5 Upon termination of the Storage Term or earlier termination of Tenant's rights to the Storage Space, Tenant shall vacate the Storage Space and deliver the same to Landlord in the same condition that the Storage Space was delivered to Tenant. At the expiration or earlier termination of the Storage Term, Tenant shall remove all debris and all items of Tenant's personalty from the Storage Space. Tenant shall be fully liable for all damage Tenant or any of the other Tenant Responsible Parties (as defined in Section 5.02(b) of the Original Lease) cause to the Storage Space. Tenant

shall have no right to hold over or otherwise occupy the Storage Space at any time following the expiration or earlier termination of the Storage Term, and in the event of such holdover, Landlord shall immediately be entitled to institute dispossessory proceedings to recover possession of the Storage Space, without first providing notice thereof to Tenant. In the event of holding over by Tenant after expiration or termination of the Storage Term without the written authorization of Landlord, Tenant shall pay Storage Base Rent (as defined in Section 3.2 below) for such holding over in an amount equal to \$12.75 per day for each day of holdover plus all damages, including consequential damages, that Landlord incurs as a result of the Tenant's hold over. During any such holdover, Tenant's occupancy of the Storage Space shall be deemed that of a tenant at sufferance, and in no event, either during the Storage Term or during any holdover by Tenant, shall Tenant be determined to be a tenant-at-will under applicable law. While Tenant is occupying the Storage Space, Landlord or Landlord's authorized agents shall be entitled to enter the Storage Space, upon reasonable notice, to display the Storage Space to prospective tenants. Landlord agrees that except in the event (a) Tenant is in default under the Lease, as amended hereby, beyond any applicable notice and cure period, (b) Landlord and Tenant are negotiating for or have agreed to an early termination of the Lease, or (c) Landlord and Tenant otherwise mutually agree to the contrary, Landlord shall not show the Storage Space to prospective tenants except during the last twelve (12) months of the term of the Lease (as the same may be further extended).

- 1.3 **Delay in the Fourth Expansion Effective Date.** The Fourth Expansion Effective Date shall be delayed to the extent that Landlord fails to deliver possession of the Fourth Expansion Space for any reason, including but not limited to, holding over by Prior Tenant (as defined in Section 9.7 below). Any such delay in the Fourth Expansion Effective Date shall not subject Landlord to any liability for any loss or damage resulting therefrom. If the Fourth Expansion Effective Date is delayed, the Fourth Expansion Space Expiration Date shall not be similarly extended.
2. **Extension.** The term of the Lease solely for the Fourth Expansion Space is hereby extended for a period of six (6) months and shall expire on August 31, 2021 ("**Fourth Expansion Space Expiration Date**"), unless sooner terminated in accordance with the terms of the Lease. That portion of the term commencing the day immediately following the Expiration Date ("**Fourth Expansion Space Extension Date**") and ending on the Fourth Expansion Space Expiration Date shall be referred to herein as the "**Fourth Expansion Space Extended Term**".

**Base Rent.**

- 3.1 **Base Rent for the Fourth Expansion Premises.** In addition to Tenant's obligation to pay Base Rent for the Original Premises, Tenant shall pay Landlord Base Rent for the Fourth Expansion Premises during the remainder of the current term and during the Fourth Expansion Space Extended Term as follows:

<b>Period</b>	<b>Rentable Square Footage</b>	<b>Annual Rate Per Square Foot</b>	<b>Annual Rent</b>	<b>Monthly Base Rent</b>
1/1/2015 – 8/31/2015	13,365	\$20.43	\$273,046.95	\$22,753.91
9/1/2015 – 8/31/2017	13,365	\$21.78	\$291,089.70	\$24,257.48
9/1/2017 – 8/31/2019	13,365	\$23.19	\$309,934.35	\$25,827.86
9/1/2019 – 8/31/2021	13,365	\$24.65	\$329,447.25	\$27,453.94

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease, as amended hereby.

- 3.2 **Storage Base Rent.** Tenant shall pay rent for the Storage Space ("**Storage Base Rent**") as follows:

<b>Period</b>	<b>Square Footage</b>	<b>Annual Storage Base Rent</b>	<b>Monthly Storage Base Rent</b>
1/1/2015 – 8/31/2021	353	\$3,060.00	\$255.00

All Storage Base Rent shall be payable in the same manner that Base Rent is payable under the Lease.

4. **Security Deposit.** From and after the Fourth Expansion Effective Date, the security deposit required under the Lease is increased from \$1,493,105.25 to **\$1,565,499.01** (the "**New Face Amount**"). No later than thirty (30) days following the date of this Amendment, Tenant shall deliver to Landlord an additional letter of credit (the "**Fourth Expansion Premises Letter of Credit**") with a face amount equal to \$72,393.76, which Fourth Expansion Premises Letter of Credit shall comply with the terms of Section 2.05 of the Original Lease, as amended by Section 10 of the Second Amendment and Section 4(a) of the Third Amendment, and shall otherwise be in a form and substance reasonably satisfactory to Landlord. Notwithstanding anything to the contrary contained in the Lease, as amended hereby, in the event that at any time the financial institution which issued the Letter of Credit (as defined in Section 2.05 of the Original Lease) or the Fourth Expansion Premises Letter of Credit, as applicable, is declared insolvent by the FDIC or is closed for any reason, Tenant must immediately provide a substitute Letter of Credit that satisfies the requirements of the Lease, as amended hereby, from a financial institution acceptable to Landlord, in Landlord's sole discretion.

5. **Tenant's Pro Rata Share.** For the period commencing with the Fourth Expansion Effective Date and ending on the Fourth Expansion Space Expiration Date, Tenant's Pro Rata Share for the Fourth Expansion Premises is **7.42%** of the Building. Accordingly, for the period commencing on the Fourth Expansion Effective Date and continuing through the Expiration Date, Tenant's Pro Rata Share is increased from 81.44% of the Building to **88.87%** of the Building. The Storage Space shall not be included in the determination of Tenant's Pro Rata Share under the Lease.
  
6. **Additional Rent.** For the period commencing with the Fourth Expansion Effective Date and ending on the Fourth Expansion Space Expiration Date, Tenant shall pay all Additional Rent payable under the Lease, including Tenant's Pro Rata Share of Operating Expenses and Taxes applicable to the Fourth Expansion Premises in accordance with the terms of the Lease, as amended hereby. Tenant shall not be required to pay Tenant's Pro Rata Share of Operating Expenses and Taxes in connection with the Storage Space. Any electricity for the Fourth Expansion Premises shall be payable pursuant to Section 3.01 of the Lease commencing on the Fourth Expansion Effective Date.
  
7. **Improvements to Fourth Expansion Space.**
  - 7.1 **Condition of Fourth Expansion Space.** Tenant has inspected the Fourth Expansion Space and agrees to accept the same "as is" without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements. Tenant hereby acknowledges and agrees that Landlord has fulfilled all of its obligations pursuant to Exhibit "7.02" to the Original Lease, Section 5(b) of the First Amendment and Section 6 of the First Amendment. Upon the expiration or earlier termination of the Lease, Tenant shall remove all personal property from the Fourth Expansion Space and surrender the Fourth Expansion Space in accordance with the terms of the Lease including, without limitation, Section 15.1 of the Original Lease. Tenant is in the process of purchasing certain furniture and/or equipment listed on **Exhibit B** (collectively, the "**Personal Property**") and owned by Prior Tenant. Landlord has agreed to allow the Personal Property to remain in the Fourth Expansion Space prior to the Fourth Expansion Effective Date. Landlord (i) shall not be liable for any loss of or damage to the Personal Property, (ii) disclaims any ownership of and responsibility for the Personal Property, and (iii) makes no representation as to its nature, suitability, quality or condition. Tenant acknowledges that it is relying solely on its own investigation of the Personal Property and not on any information provided by Landlord. Notwithstanding anything to the contrary contained in the Lease, as amended hereby, Tenant must, at Tenant's sole cost and expense, remove the Personal Property from the Premises upon the expiration or sooner termination of the Lease. Personal Property left in the Premises shall be deemed abandoned by Tenant and title to the same shall thereupon pass to Landlord under this Lease as by a bill of sale.
  
  - 7.2 **Responsibility for Improvements to Fourth Expansion Space.** Any construction, alterations or improvements to the Fourth Expansion Space shall be performed by Tenant at its sole cost and expense using contractors selected by Tenant and approved by Landlord and shall be governed in all respects by the terms of the Lease. In any and all events, the Fourth Expansion Effective Date shall not be postponed or delayed if the initial improvements to the Fourth Expansion Space are incomplete on the Fourth Expansion Effective Date for any reason whatsoever. Any delay in the completion of initial improvements to the Fourth Expansion Space shall not subject Landlord to any liability for any loss or damage resulting therefrom.
  
8. **Early Access to Fourth Expansion Space.** During any period that Tenant shall be permitted to enter the Fourth Expansion Space prior to the Fourth Expansion Effective Date (e.g., to perform alterations or improvements, if any), Tenant shall comply with all terms and provisions of the Lease, except those provisions requiring payment of Base Rent or Tenant's Pro Rata Share of Operating Expenses and Taxes

as to the Fourth Expansion Space. If Tenant takes possession of the Fourth Expansion Space prior to the Fourth Expansion Effective Date for any reason whatsoever (other than the performance of work in the Fourth Expansion Space with Landlord's prior approval), such possession shall be subject to all the terms and conditions of the Lease and this Amendment, and Tenant shall pay Base Rent and Tenant's Pro Rata Share of Operating Expenses and Taxes as applicable to the Fourth Expansion Space to Landlord on a per diem basis for each day of occupancy prior to the Fourth Expansion Effective Date.

9. **Extension Options.**

9.1 Tenant acknowledges and agrees that Tenant's right to extend the term of the Lease set forth in Article 22 of the Original Lease applies solely to the Original Premises, and that Tenant's right to extend the term of the Lease only with regard to the Fourth Expansion Space shall be governed by this Section 9. Provided that (i) Tenant is not in default after any applicable notice and cure periods have expired under the Lease, as amended hereby, at the time Tenant gives its Fourth Expansion Space Extension Notice (as defined below) or at the time the applicable Fourth Expansion Space Option Term would commence, or (ii) no sublets of more than 50% of the Fourth Expansion Space are then in effect that required Landlord's consent under Article 13 of the Original Lease, Tenant shall have the right, at its election, to extend the Fourth Expansion Space Term for two (2) additional periods of five (5) years each (each, a "**Fourth Expansion Space Option Term**") commencing upon the expiration of the Fourth Expansion Space Term or first Fourth Expansion Space Option Term, as applicable, provided that Tenant shall give Landlord an irrevocable (except as expressly set forth in Section 22.04 of the Original Lease) written notice (a "**Fourth Expansion Space Extension Notice**") in the manner provided in Section 18.01 of the Original Lease of the exercise of its election to so extend at least twelve (12) months, and no more than fifteen (15) months prior to the expiration of the Fourth Expansion Space Term (as the same may have been extended). Except for this Section 9 with respect to the second such Fourth Expansion Space Option Term, the provisions of the Work Letter, and as expressly otherwise provided in this Amendment, all the agreements and conditions in the Lease, as amended hereby, shall apply to the applicable Fourth Expansion Space Option Term, including without limitation the obligation to pay Additional Rent for Tenant's Pro Rata Share of Taxes and Tenant's Pro Rata Share of Operating Expenses. If Tenant shall give written notice as provided in Section 18.01 of the Original Lease of the exercise of the election in the manner and within the time provided aforesaid, the Fourth Expansion Space Term shall be extended upon the giving of the notice without the requirement of any action on the part of Landlord.

9.2 The annual Base Rent payable for each year during any Fourth Expansion Space Term shall be ninety-five percent (95%) of the market rent as determined in the manner set forth in Sections 22.03, 22.04 and 22.05 of the Original Lease, but in no event less than the annual Base Rent payable immediately prior to the commencement of the Fourth Expansion Space Option Term in question. If the annual Base Rent for any Fourth Expansion Space Option Term has not been determined by the commencement date of such Fourth Expansion Space Option Term, Tenant shall pay Base Rent at the last annual rental rate in effect for the expiring term until such time as annual Base Rent for the Fourth Expansion Space Option Term has been determined. Upon such determination, the Base Rent for the Fourth Expansion Space shall be retroactively adjusted to the commencement of such Fourth Expansion Space Option Term. If such adjustment results in an underpayment of Base Rent by Tenant, Tenant shall pay Landlord the amount of such underpayment within thirty (30) days after the determination thereof. If such adjustment results in an overpayment of Base Rent by Tenant, Landlord shall credit such overpayment against the next installment of Base Rent due under the Lease and, to the extent necessary, any subsequent installments, until the entire amount of such overpayment has been credited against Base Rent.

10. **Other Pertinent Provisions.** Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

10.1 **Parking.** Effective as of the Fourth Expansion Effective Date, Tenant shall have the right to use forty-four (44) additional non-designated parking spaces (based on a parking ratio of 3.3 parking spaces per 1,000 rentable square feet of the Fourth Expansion Premises) in the parking areas shown on Exhibit "20.10" to the Lease. Accordingly, effective as of the Fourth Expansion Effective Date, Tenant's non-designated parking spaces shall be increased from five hundred two (502) non-designated parking spaces to five hundred forty-six (546) non-designated parking spaces. Included within the foregoing five hundred forty-six (546) non-designated parking spaces are fifty-seven (57) non-designated parking spaces located in the parking garage on the lower level of the Building, with direct access to the Building lobby serving the Premises. During the period commencing as of the Fourth Expansion Effective Date and continuing through the Fourth Expansion Space Expiration Date, Tenant shall have the right to use forty-four (44) non-designated parking spaces. Included within the foregoing forty-four (44) spaces are six (6) non-designated parking spaces located in the parking garage on the lower level of the Building, with direct access to the Building lobby serving the Premises. Except as modified herein, the use of such non-designated parking spaces shall be subject to the terms of the Lease, as amended hereby.

10.2 **Landlord's Address for Notices.** Landlord's address for notices set forth in Article 18 of the Original Lease is hereby deleted in its entirety and replaced with the following:

"GI TC 850 Winter Street, LLC  
c/o GI Partners  
188 The Embarcadero, Suite 700  
San Francisco, California 94105  
Attention: TechCore Asset Management"

10.3 **Landlord's Address for Payment of Rent.** Landlord's address for the payment of Rent set forth in Section 2.03 of the Original Lease is hereby deleted in its entirety and replaced with the following:

"Instructions for Electronic Payments (Wire or ACH):  
Wells Fargo Bank, N.A.  
ABA Routing #: 121 000 248  
Account Name:  
Account #:

Lockbox Address:  
GI TC 850 Winter Street, LLC  
P.O. Box 784550  
Philadelphia, Pennsylvania 19178-4550"

10.4 **Insurance.** Tenant's insurance required under Section 4.02 of the Original Lease ("**Tenant's Insurance**") shall include the Fourth Expansion Space. Concurrent with Tenant's delivery of this Amendment, Tenant shall provide Landlord with a certificate of insurance, in form and substance satisfactory to Landlord and otherwise in compliance with Section 4.02 of the Original Lease, evidencing that Tenant's Insurance covers the Original Premises and the Fourth Expansion Space, upon delivery of this Amendment, executed by Tenant, to Landlord, and



thereafter as necessary to assure that Landlord always has current certificates evidencing Tenant's Insurance.

11.

**Miscellaneous.**

- 11.1 This Amendment, including **Exhibit A** (Outline and Location of Fourth Expansion Space) and **Exhibit B** (Personal Property) attached hereto, sets forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or other work to the Premises, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.
- 11.2 Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect. In the case of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall govern and control. The capitalized terms used in this Amendment shall have the same definitions as set forth in the Lease to the extent that such capitalized terms are defined therein and not redefined in this Amendment.
- 11.3 Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.
- 11.4 Tenant hereby represents to Landlord that Tenant has dealt with no broker in connection with this Amendment. Tenant agrees to indemnify and hold Landlord and the Indemnitees harmless from all claims of any brokers claiming to have represented Tenant in connection with this Amendment.
- 11.5 Any provision of the Lease providing for the indemnification by one party of the second party, including, without limitation, Tenant's indemnity obligations pursuant to Section 12.01 of the Original Lease, shall survive the termination of the Lease with respect to any claims or liability accruing prior to such termination.
- 11.6 At Landlord's option, this Amendment shall be of no force and effect unless and until accepted by any guarantors of the Lease, who by signing below shall agree that their guaranty shall apply to the Lease as amended herein, unless such requirement is waived by Landlord in writing.
- 11.7 Each signatory of this Amendment represents hereby that he or she has the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting. Tenant hereby represents and warrants that neither Tenant, nor any persons or entities holding any legal or beneficial interest whatsoever in Tenant, are (i) the target of any sanctions program that is established by Executive Order of the President or published by the Office of Foreign Assets Control, U.S. Department of the Treasury ("**OFAC**"); (ii) designated by the President or OFAC pursuant to the Trading with the Enemy Act, 50 U.S.C. App. § 5, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-06, the Patriot Act, Public Law 107-56, Executive Order 13224 (September 23, 2001) or any Executive Order of the President issued pursuant to such statutes; or (iii) named on the following list that is published by OFAC: "List of Specially Designated Nationals and Blocked Persons." If the foregoing representation is untrue at any time during the lease term (as extended), an Event of Default under the Lease will be deemed to have occurred, without the necessity of notice to Tenant.

- 11.8 This Amendment specifically is contingent upon the termination of that certain Lease dated October 28, 2010 (as amended, the “**Prior Tenant Lease**”), by and between Landlord (as successor in interest to PDM 850 Unit, LLC, a Delaware limited liability company) and Wilmer Cutler Pickering Hale and Dorr LLP, a Delaware limited liability partnership (“**Prior Tenant**”) relating to the Fourth Expansion Space. Landlord currently is negotiating the terms of an agreement with Prior Tenant to terminate the Prior Tenant Lease (the “**Prior Tenant Termination Agreement**”). If Landlord fails to enter into the Prior Tenant Termination Agreement with Prior Tenant on or before November 26, 2014 then Landlord may terminate this Amendment by providing written notice thereof to Tenant, whereupon, this Amendment shall be null and void and of no force or effect and the Lease shall continue in full force and effect as if this Amendment had not been executed.
- 11.9 Redress for any claim against Landlord under the Lease and this Amendment shall be limited to and enforceable only against and to the extent of Landlord’s interest in the Building. The obligations of Landlord under the Lease are not intended to and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its trustees or board of directors and officers, as the case may be, its investment manager, the general partners thereof, or any beneficiaries, stockholders, employees, or agents of Landlord or the investment manager, and in no case shall Landlord be liable to Tenant hereunder for any lost profits, damage to business, or any form of special, indirect or consequential damages.

*[Signature Page Follows]*

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

**LANDLORD:**

**GI TC 850 WINTER STREET, LLC,  
a Delaware limited liability company**

By: /s/ Tony Lin

Name: Tony Lin

Title: Authorized Person

Dated: 12/30/2014

**TENANT:**

**ALKERMES, INC.,  
a Pennsylvania corporation**

By: /s/ Michael Landine

Name: Michael Landine

Title: Senior Vice President

Dated: \_\_\_\_\_, 2014

**GUARANTOR:**

**ALKERMES PLC,  
an Irish public limited company**

By: /s/ Shane Cooke

Name: Shane Cooke

Title: President

Dated: \_\_\_\_\_, 2014

**EXHIBIT A - OUTLINE AND LOCATION OF FOURTH EXPANSION SPACE**

**attached to and made a part of the Amendment dated as of December \_\_, 2014, between  
GI TC 850 WINTER STREET, LLC, a Delaware limited liability company, as Landlord and  
ALKERMES, INC., a Pennsylvania corporation, as Tenant**

**Exhibit A** is intended only to show the general layout of the Fourth Expansion Space as of the beginning of the Fourth Expansion Effective Date. It does not in any way supersede any of Landlord's rights set forth in the Lease with respect to arrangements and/or locations of public parts of the Building and changes in such arrangements and/or locations. It is not to be scaled; any measurements or distances shown should be taken as approximate.

**EXHIBIT B – PERSONAL PROPERTY**

**attached to and made a part of the Amendment dated as of December \_\_, 2014, between  
GI TC 850 WINTER STREET, LLC, a Delaware limited liability company, as Landlord and  
ALKERMES, INC., a Pennsylvania corporation, as Tenant**

- (2) qty. Wood Conference Tables
- (16) qty. Leather Conference Chairs
- (4) qty. Receptions high back chairs
- (1) qty. Coffee table
- (80) qty. Mesh conference chairs with Racks
- (24) qty. Folding conference tables with Carts
- (1) qty. Gunlock Podium
- (2) qty. Oversized Leather Chairs
- (2) qty. Bar Height Stool
- (1) qty. Cocktail table.
- (1) qty. Refrigerator
- (2) qty. Microwaves
- (1) qty. Dishwasher
- (1) qty, 7' Orange Fabric Bench
- (4) qty. 60" Dark Wood Credenzas
- (2) qty. Office Suites of Knoll Systems furniture
- (4) qty. Knoll Systems Furniture Admin Stations
- (12) qty. Built in office Suites (Desk, Overhead shelving, Bookcase, Wardrobe)
- (6) qty. Stand-alone Desks
- (6) qty. Credenzas
- (24) qty. Task Chair
- (18) qty. Office Side Chair
- (7) qty. Shelving Units (Quik Lock)
- (18) qty. 36" 3-Drawer Lateral File Cabinets
- (10) qty. 36" 5-drawer Lateral File Cabinets

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**AMENDMENT  
TO  
EMPLOYMENT AGREEMENT**

WHEREAS, Alkermes, Inc., a Pennsylvania corporation (the “Company”) and Rebecca J. Peterson of Watertown, MA (“Executive”) have previously entered into an Employment Agreement dated as of July 30, 2012 (the “Agreement”); and

WHEREAS, the Company and Executive mutually desire to amend the Agreement to address the possibility of the imposition of excise taxes under certain circumstances;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuation consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to amend the Agreement as follows:

1. The Agreement is hereby amended by adding the following Section 5(c) at the end of Section 5(b):

“(c) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the ‘Aggregate Payments’), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in Executive receiving a higher After Tax Amount (as defined below) than Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(c), the ‘After Tax Amount’ means the amount of the Aggregate Payments less all federal, state, and local

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income, excise and employment taxes imposed on Executive as a result of Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(c)(i) shall be made by a nationally recognized accounting firm selected by the Company (the 'Accounting Firm'), which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Executive. Any determination by the Accounting Firm shall be binding upon the Company and Executive."

2. This Amendment shall be binding on all successors and assigns of the parties hereof.
3. Except as amended herein, the Agreement is confirmed in all other respects.

IN WITNESS WHEREOF, the parties have executed this Amendment this 22<sup>nd</sup> day of July, 2015.

ALKERMES, INC.

/s/ Madeline Coffin

By: Madeline Coffin  
Title: VP Human Resources

/s/ Rebecca J. Peterson

Rebecca J. Peterson

**AMENDMENT  
TO  
EMPLOYMENT AGREEMENT**

WHEREAS, Alkermes, Inc., a Pennsylvania corporation (the “Company”) and Iain Brown of Alkermes, Inc. (“Vice President”) have previously entered into an Employment Agreement dated as of the 30th day of September, 2008 (the “Agreement”); and

WHEREAS, the Company and Vice President mutually desire to amend the Agreement to address the possibility of the imposition of excise taxes under certain circumstances;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuation consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to amend the Agreement as follows:

1. The Agreement is hereby amended by adding the following Section 5(c) at the end of Section 5(b):

“(c) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of Vice President, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the ‘Aggregate Payments’), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which Vice President becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in Vice President receiving a higher After Tax Amount (as defined below) than Vice President would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(c), the ‘After Tax Amount’ means the amount of the Aggregate Payments less all federal, state, and local

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income, excise and employment taxes imposed on Vice President as a result of Vice President's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, Vice President shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(c)(i) shall be made by a nationally recognized accounting firm selected by the Company (the 'Accounting Firm'), which shall provide detailed supporting calculations both to the Company and Vice President within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Vice President. Any determination by the Accounting Firm shall be binding upon the Company and Vice President."

2. This Amendment shall be binding on all successors and assigns of the parties hereof.
3. Except as amended herein, the Agreement is confirmed in all other respects.

IN WITNESS WHEREOF, the parties have executed this Amendment this 28th day of July, 2015.

ALKERMES, INC.

Name: /s/ Madeline Coffin  
Title: VP Human Resources

VICE PRESIDENT  
Name: /s/ Iain M. Brown  
Iain M. Brown

## 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.

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

Date: July 30, 2015

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## CERTIFICATIONS

I, James M. Frates, 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.

By: /s/ James M. Frates  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: July 30, 2015

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**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 of Alkermes plc (the "Company") on Form 10-Q for the period ended June 30, 2015 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 James M. Frates, Senior Vice President and 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, to our knowledge that:

(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.

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

By: /s/ James M. Frates  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

Date: July 30, 2015

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