Recro Pharma, Inc.
Form 424B3
August 14, 2015
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Filed Pursuant to Rule 424(b)(3)

Registration Statement No. 333-201841

Prospectus Supplement No. 14

to Prospectus dated February 26, 2015

2,500,000 Shares

Common Stock

This Prospectus Supplement No. 14 supplements and amends our prospectus dated February 26, 2015 (the Prospectus), relating to the sale, from time to time, of up to 2,500,000 shares of our common stock by Aspire Capital Fund, LLC.

This prospectus supplement is being filed to include the information set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2015. This prospectus supplement should be read in conjunction with the Prospectus and any amendments or supplements thereto, which are to be delivered with this prospectus supplement, and is qualified by reference to the Prospectus, except to the extent that the information in this prospectus supplement updates or supersedes the information contained in the Prospectus, including any amendments or supplements thereto.

Our common stock trades on the NASDAQ Capital Market under the ticker symbol REPH. On August 13, 2015, the last reported sale price per share of our common stock was $13.24 per share.

Investing in our common stock involves risk. Please read carefully the section entitled Risk Factors beginning on page 8 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 14 is August 14, 2015.

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Quarterly Period Ended: June 30, 2015

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number: 001-36329

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**26-1523233**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

490 Lapp Road, Malvern, Pennsylvania **19355**
(Address of principal executive offices) **(Zip Code)**

(484) 395-2470

(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 x 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 x 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 ¨ (Do not check if a smaller reporting company) Smaller reporting company x

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

As of August 14, 2015, there were 9,221,374 shares of common stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(unaudited)

(amounts in thousands, except share and per share data)	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 15,687	$ 19,682
Accounts receivable	15,024	
Other receivables	22	90
Inventory	9,610	
Prepaid expenses	1,478	602
Deferred equity costs	589	
Total current assets	42,410	20,374
Property, plant and equipment, net	39,352	
Intangible assets, net	41,308	
Goodwill	6,744	
Total assets	$ 129,814	$ 20,374
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 767	$ 871
Accrued expenses	5,888	575
Current portion of long-term debt	9,123	
Total current liabilities	15,778	1,446
Long-term debt	36,495	
Warrants	6,213	
Contingent consideration	56,600	
Total liabilities	115,086	1,446
Shareholders equity		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		

Common stock, $0.01 par value. Authorized, 50,000,000 shares, issued and outstanding, 7,842,063 shares at June 30, 2015 and 7,707,600 shares at December 31, 2014		78		77
Additional paid-in capital		54,196		52,947
Accumulated deficit		(39,546)		(34,096)
Total shareholders equity		14,728		18,928
Total liabilities and shareholders equity	$	129,814	$	20,374

See accompanying notes to unaudited consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

(amounts in thousands, except share and per share data)	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 16,704	$	$ 16,704	$
Research and development revenue	1,956		1,956	
Total revenue	18,660		18,660	
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	9,395		9,395	
Research and development	2,821	1,837	4,575	2,064
General and administrative	2,597	959	4,986	1,606
Amortization of intangible assets	592		592	
Change in warrant valuation	882		882	
Change in contingent consideration valuation	2,000		2,000	
Total operating expenses	18,287	2,796	22,430	3,670
Operating income (loss)	373	(2,796)	(3,770)	(3,670)
Other income (expense):				
Interest income	4	2	8	3
Interest expense	(1,688)		(1,688)	(4,273)
Net loss	(1,311)	(2,794)	(5,450)	(7,940)
Accretion of redeemable convertible preferred stock and deemed dividend				(1,270)
Net loss applicable to common shareholders	$ (1,311)	$ (2,794)	$ (5,450)	$ (9,210)
Basic and diluted net loss per common share	$ (0.17)	$ (0.36)	$ (0.70)	$ (1.94)
Weighted average basic and diluted common shares outstanding	7,829,536	7,707,600	7,799,282	4,745,213

See accompanying notes to unaudited consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Shareholders Equity

Six Months Ended June 30, 2015

(unaudited)

(amounts in thousands, except share and per share data)	Common stock Shares	Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2014	7,707,600	$ 77	$ 52,947	$ (34,096)	$ 18,928
Shares issued in equity financing facility	96,463	1	284		285
Stock option exercise	38,000		228		228
Stock-based compensation expense			737		737
Net loss				(5,450)	(5,450)
Balance, June 30, 2015	7,842,063	$ 78	$ 54,196	$ (39,546)	$ 14,728

See accompanying notes to unaudited consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(amounts in thousands, except share and per share data)	Six Months Ended June 30, 2015	2014
Cash flows from operating activities:		
Net loss	$ (5,450)	$ (7,940)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	737	175
Depreciation expense	1,269	
Noncash interest expense	211	4,273
Amortization	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	345	
Prepaid expenses	(496)	(254)
Accounts receivables and other receivables	(2,436)	38
Accounts payable and accrued expenses	4,046	988
Net cash provided by (used in) operating activities	1,700	(2,720)
Cash flows from investing activities:		
Acquisition of Gainesville, net of cash acquired	(52,690)	
Purchase of property and equipment	(1,197)	
Net cash used in investing activities	(53,887)	
Cash flows from financing activities:		
Proceeds from initial public offering		30,364
Proceeds from long-term debt	50,000	175
Payment of debt issuance costs	(1,732)	
Payment of deferred equity costs	(304)	
Proceeds from option exercise	228	
Net cash provided by financing activities	48,192	30,539
Net increase (decrease) in cash and cash equivalents	(3,995)	27,819
Cash and cash equivalents, beginning of period	19,682	13
Cash and cash equivalents, end of period	$ 15,687	$ 27,832

Supplemental disclosure of cash flow information:		
Common stock issued in connection with equity facility	$ 285	
Conversion of notes payable and accrued interest into common stock		$ 12,274
Conversion of Series A and accrued dividends into common stock		$ 5,969

See accompanying notes to unaudited consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

(1) Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007 (inception). The Company is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post operative pain. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to IV/IM meloxicam, a proprietary, Phase III-ready, long-acting preferential COX-2 inhibitor for the treatment of moderate to severe acute pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia operating through the Company s subsidiary, Recro Gainesville, LLC or Gainesville. The acquisition is referred to herein as the Gainesville Transaction. Gainesville develops and manufactures innovative pharmaceutical products that deliver clinically meaningful benefits to patients, using its proprietary delivery technologies in collaboration with pharmaceutical companies.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses since inception and has an accumulated deficit of $39,546 as of June 30, 2015. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

The Company s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the revenue generated by its contract manufacturing business; (iii) the Company s ability to complete revenue-generating partnerships with pharmaceutical companies; (iv) the success of its research and development; (v) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately; (vi) regulatory approval and commercial success of the Company s proposed future products.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, for interim financial information. The Company s consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. In the opinion of management, the accompanying financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company s financial position as of June 30, 2015 and its results of operations and cash flows for the three and six months ended June 30, 2015 and 2014. Operating results for the six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The consolidated interim financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements.

The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2014 included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, or the Form 10-K.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Inventory

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory are raw materials used in production of commercial products. Also included in inventory are raw materials used in the production of clinical products, which do not have alternative future uses and are charged to research and development expenses when consumed.

(d) Revenue Recognition

The Company generates revenues from manufacturing and packaging services for multiple pharmaceutical companies. The agreements that the Company has with its commercial partners provide for manufacturing revenues, royalties and/or profit sharing components.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

Manufacturing and packaging service revenue is recognized upon shipment of the product in accordance with the terms of the contract, which specify when transfer of title and risk of loss occurs. After the Company has evidence of an arrangement, the price is determinable and there is a reasonable expectation regarding payment, the Company recognizes revenue.

In addition to manufacturing and packaging revenue, the customer agreements have royalties and/or profit sharing payments, computed on the net product sales of the partner. Royalty and profit sharing revenues are generally recognized when a partner sells the product to its customers, which could be in a different accounting period than the period in which the Company sold that product to the partner, and are based on a percentage of the partner s net sales or gross profits on sales of the product as specified in the underlying agreement.

Revenues related to research and development are generally recognized as the related services or activities are performed, in accordance with the contract terms. To the extent that the agreements specify services are to be performed on a fixed basis, revenues are recognized consistent with the pattern of the work performed.

(e) Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average common shares outstanding during the period. For all periods presented, the outstanding common stock options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2015 and December 31, 2014, as they would be anti-dilutive:

	June 30, 2015	December 31, 2014
Options outstanding	1,501,500	1,033,300
Warrants	794,928	150,000

Amounts in the table above reflect the common stock equivalents of the noted instruments.

(f) Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or FASB, issued updated guidance on the presentation requirements for debt issuance costs and debt discount and premium. The update requires 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 recognition and measurement guidance for debt issuance costs are not affected by the updated guidance. The updated guidance is effective for annual and interim periods beginning after December 15, 2015 and early adoption is permitted for financial statements that have not been previously issued. The Company adopted this guidance during the three and six month period ended June 30, 2015.

In May 2014, the FASB issued updated guidance regarding the accounting for and disclosures of revenue recognition, with an effective date for annual and interim periods beginning after December 15, 2016. The update provides a single comprehensive model for accounting for revenue from contracts with customers. The model requires that revenue recognized reflect the actual consideration to which the entity expects to be entitled in exchange for the goods or services defined in the contract, including in situations with multiple performance obligations. In July 2015, the FASB deferred the effective date by one year. The guidance will be effective for annual and interim periods beginning after December 15, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

(4) Acquisition of Gainesville and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Acquisition consisted of $50.0 million at closing, a $4.0 working capital adjustment and a seven-year warrant to purchase 350,000 shares of the Company s common stock at an exercise price of $19.46 per share. In addition, the Company may be required to pay up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales related to IV/IM meloxicam. Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties are allocated to the fair value of the assets acquired and liabilities assumed. The contingent consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see note 6 for further information regarding fair value).

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

The following is a preliminary estimate of the purchase price for the Gainesville Transaction:

	Estimated Fair Value
Purchase price agreement	$ 50,000
Fair value of warrants	2,470
Fair value of contingent consideration	54,600
Working capital adjustment	4,010
	$ 111,080

The contingent consideration consists of three separate components. The first component consists of two potential payments, which will be payable upon the submission of the new drug application (NDA) for meloxicam, and the related regulatory approval, respectively. The second component consists of three potential payments, based on the achievement of specified annual revenue targets. The third component consists of a royalty payment for a defined term on future meloxicam net sales.

The fair value of the first contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the probability adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates. The fair value of the third contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and the defined royalty percentage.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration components are classified as liabilities and are subject to the recognition of subsequent changes in fair value through the results of operations.

The Gainesville results of operations have been included in the consolidated statement of operations beginning April 10, 2015.

The following is a preliminary estimate of the assets acquired and the liabilities assumed in connection with the Gainesville Transaction, reconciled to the estimated purchase price:

	Amount
Accounts receivable	$ 12,519
Inventory	9,955
Prepaid expenses	380
Property, plant and equipment	39,424
Intangible assets	41,900
Goodwill	6,744
Total assets acquired	110,922
Accounts payable and accrued expenses	1,162
Warrants	2,470
Contingent consideration	54,600
Total liabilities assumed	58,232
Cash paid, net of $1,320 of cash acquired	$ 52,690

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

The fair value of the property, plant and equipment and their weighted-average useful lives are as follows:

	Estimated Fair Value	Estimated Useful Life
Buildings and improvements	$ 16,371	35 years
Land	3,263	N/A
Furniture, office & computer equipment	2,510	4-5 years
Vehicles	30	2 years
Manufacturing equipment	17,250	6-7 years
	$ 39,424	

The estimated fair value of property, plant and equipment was determined using the cost and sales approaches.

The fair value of the identifiable intangible assets and their weighted-average useful lives are as follows:

	Estimated Fair Value	Weighted Average Estimated Useful Life
Royalties and contract manufacturing relationships	15,500	6
In-process research and development	26,400	N/A
Total intangible assets	41,900	

The in-process research and development asset and customer relationships were valued using the multi-period excess earnings method, which is an income approach in which excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each quarter of a multi-quarter projection period discounted to a present value utilizing an appropriate discount rate for the subject asset. Amortization expense was $592 for the three and six months ended June 30, 2015.

(5) Unaudited Pro Forma Results of Operations

The unaudited pro forma combined results of operations for the three and six months ended June 30, 2015 (assuming the closing of the Gainesville Transaction had occurred on January 1, 2015) are as follows:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Net revenue	$ 20,339	$ 39,705
Net loss	(2,056)	(2,119)

(6) Fair Value of Financial Instruments

The Company follows FASB accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements to maximize the use of observable inputs. The three-level hierarchy of inputs to measure fair value are as follows:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity)

The Company has classified assets and liabilities measured at fair value on a recurring basis as follows:

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
($ in thousands)			
At December 31, 2014:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 10,922		
Government and agency bonds	8,663		
Cash equivalents	$ 19,585		
At June 30, 2015:			
Assets:			
Money market accounts (included in cash and cash equivalents)	$ 4,468		
Government and agency bonds	4,257		
Cash equivalents	$ 8,725		

Liabilities:	
Warrants	$ 6,213
Contingent consideration	56,600
	$ 62,813

The reconciliation of the contingent consideration and warrants measured at fair value on a recurring basis significant using unobservable inputs (Level 3) is as follows:

	Warrants	Contingent Consideration
Balance at December 31, 2014	$	$
Additions	5,331	54,600
Remeasurement	882	2,000
Balance at June 30, 2015	$ 6,213	$ 56,600

(7) Inventory

Inventory consists of the following:

	June 30, 2015
Raw materials	$ 2,974
Work in process	2,447
Finished goods	4,189
	$ 9,610

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

(8) Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2015	December 31, 2014
Clinical trial and related costs	$ 429	$ 112
Professional and consulting fees	1,180	394
Payroll and related costs	1,740	25
Interest on notes payable	1,688	
Other	851	44
	$ 5,888	$ 575

(9) Convertible Notes Payable

Upon the closing of the Company s initial public offering, or IPO, on March 12, 2014, $9,576 of 8% Convertible Promissory Notes, or Bridge Notes, outstanding plus $2,699 of accrued interest were converted into 2,045,738 shares of common stock. After the IPO, there are no Bridge Notes outstanding.

The Bridge Notes, including accrued interest, were converted upon consummation of the IPO at seventy-five percent (75%) of the initial offering price per share. The Company determined that the Bridge Notes contained a contingent beneficial conversion feature, or BCF. The contingent BCF existed at the date of issuance of the Bridge Notes, which allowed the holders to purchase equity at a 25% discount to the offering price. In accordance with the accounting guidance on convertible instruments, the contingent BCF of $4,081 was recognized as additional interest expense when the Bridge Notes, including accrued interest, were converted into shares of common stock.

(10) Long-Term Debt

The Company financed the Gainesville Transaction via a $50,000 five-year senior secured term loan, entered into on April 10, 2015, with OrbiMed Royalty Opportunities II, LP, or OrbiMed, which carries interest at LIBOR plus 14.0% with a 1.0% floor. Our obligations under the senior term loan are secured by substantially all of the Company s assets.

There are certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to fulfill on a monthly and quarterly basis. As of June 30, 2015, the Company was in compliance with the covenants.

The Company issued to OrbiMed warrants to purchase 294,928 shares of common stock, with an exercise price of $3.28 per share. The warrants are exercisable through April 10, 2022. The initial fair value of the warrants of $2,861 was recorded as debt issuance costs.

Debt issuance costs related to the term loan of $4,593, including the initial warrant fair value of $2,861, are being amortized to interest expense over the five year term of the loan and netted with the loan principal amount. The unamortized balance of debt issuance costs is $4,382 as of June 30, 2015.

As of June 30, 2015, the long-term debt balance is comprised of the following:

Principal balance outstanding	$50,000
Deferred issuance costs	(4,382)
	$ 45,618
Current portion	(9,123)
	$ 36,495

The credit agreement contains a provision that allows OrbiMed, at its option, the right to require the Company to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows, of Gainesville, as defined in the credit agreement. The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2015 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

(11) Capital Structure

(a) Common Stock

The Company is authorized to issue 50,000,000 shares of common stock, with a par value of $0.01 per share.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

On March 12, 2014 the Company completed an IPO in which the Company sold 4,312,500 shares of common stock at $8.00 per share resulting in gross proceeds of $34,500. In connection with the IPO, the Company paid $4,244 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,256. Also in connection with the IPO, all of the outstanding shares of the Company s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

(b) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of June 30, 2015, no preferred stock was issued or outstanding.

(c) Series A Redeemable Convertible Preferred Stock

The Company previously had outstanding 2,000,000 shares of Series A Stock. Each share of Series A Stock was automatically converted into 0.4 shares of common stock upon closing of the Company s IPO. The holders of Series A Stock were entitled to receive cumulative dividends of 8%, compounded annually. Upon conversion of the Series A Stock into common stock, cumulative undeclared dividends were convertible into a number of shares of common stock equal to the total amount of cumulative dividends divided by $2.00 (the Series A Stock issuance price) multiplied by 0.4 (the Series A Stock conversion ratio). Based on the IPO price of $8.00 per share of common stock, the Company recorded a non-cash deemed dividend of $1,181 upon closing of the IPO which represents the fair value of the common stock issued for such dividends in excess of the amounts previously recognized as accretion on the Series A Stock.

(d) Warrants

As of June 30, 2015, the Company had the following warrants outstanding to purchase shares of the Company s common stock:

Number of Shares	Exercise Price per Share	Expiration Date
150,000	$12.00	March 2018
350,000	$19.46	April 2022
294,928	$ 3.28	April 2022

The warrant to purchase 350,000 shares is liability classified since it contains a contingent net cash settlement feature. The warrant to purchase 294,928 shares is liability classified since it contains an anti-dilution provision. The fair value of both warrants will be remeasured through settlement or expiration with changes in fair value recognized as a period

charge within the statement of operations.

(e) Common Stock Purchase Agreement

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase, at the Company s election, up to an aggregate of $10,000 of shares of the Company s common stock over the 24 month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company issued 96,463 shares of common stock to Aspire Capital with a fair value of $285, as consideration for entering in the Purchase Agreement. In addition, the Company incurred $229 of costs in connection with the Aspire Capital facility, which, along with the fair value of the common stock has been recorded as deferred equity costs.

(12) Stock-Based Compensation

The Company established the 2008 Stock Option Plan, or the 2008 Plan, which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company s common stock to designated employees, nonemployee directors, and consultants and advisors. As of June 30, 2015, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, the Company s shareholders approved the Amended and Restated Equity Incentive Plan which increased the aggregate amount of shares available for issuance to 2,000,000.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(amounts in thousands, except share and per share data)

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2015, 904,326 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

Stock-based compensation expense for the six months ended June 30, 2015 and 2014 was $737 and $175, respectively, and for the three months ended June 30, 2015 and 2014 was $504 and $155, respectively.

The following table summarizes stock option activity during the six months ended June 30, 2015:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2014	1,033,300	$ 5.77	
Granted	506,200	6.92	
Exercised	(38,000)	6.00	
Canceled			
Balance, June 30, 2015	1,501,500	$ 5.79	8.18 years
Options exercisable, June 30, 2015	464,671	$ 6.43	5.62 years

Included in the table above are 194,000 performance-based options granted in December 2014 with an exercise price of $2.47 per share, 30% of these stock options vested in July 2015 based upon the achievement of positive topline results from the Company s completed Dex Phase II clinical trial was met. The remaining portion of the performance-based options vest monthly over a three-year period beginning on July 24, 2015.

As of June 30, 2015, there was $6,818, of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 3.4 years, which includes $1,495 of unrecognized compensation related to performance-based options.

(13) Related Party Transactions

In July 2008, the Company entered into an agreement with Malvern Consulting Group, Inc., or MCG, a consulting company affiliated with the Company s President and Chief Executive Officer. A new agreement was signed in October 2013 under which MCG continues to provide consulting services to the Company, principally in the fields of clinical development, regulatory affairs, and quality assurance. MCG consulting fees for services are based on a flat fee and time worked at hourly rates for consultants. The Company recorded MCG consulting fees for research and

development and general and administrative expenses of $129 and $123 for the three months ended June 30, 2015 and 2014, respectively and $237 and $208 for the six months ended June 30, 2015 and 2014, respectively. As of June 30, 2015, $47 and $53 are recorded in accounts payable and accrued expenses, respectively, as amounts due to MCG. In addition to fees for services, employees of MCG, certain of whom are related to the Company s President and Chief Executive Officer, received options to purchase 246,800 shares of common stock during 2009. The Company also paid $57 in rental fees to MCG for a month to month lease for facilities space for the six months ended June 30, 2015 and $44 for facilities space for the six months ended June 30, 2014.

(14) Subsequent Event

On July 1, 2015, the Company entered into a Securities Purchase Agreement, or Purchase Agreement, with certain accredited investors, or the Investors, pursuant to which the Company agreed to issue and sell to the Investors in a private placement, or Private Placement, an aggregate of 1,379,311 shares of common stock, at a price per share of $11.60, for net proceeds of approximately $14,956. The Private Placement closed on July 7, 2015. The Company agreed to pay the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the Private Placement, plus reimbursement of certain expenses. The Company intends to use the net proceeds from the Private Placement to further fund the clinical development of the Company s product candidates and for general corporate purposes. The Purchase Agreement requires the Company to file a registration statement with the Securities and Exchange Commission to register the resale of the shares within 45 days of the closing.

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

The following Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited financial statements contained in Part I, Item 1 of this quarterly report, and the audited financial statements and notes thereto for the year ended December 31, 2014 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 25, 2015. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Recro refer to Recro Pharma, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements. We may in some cases, use terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplates, believ potential or continue or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

- the results and timing of our clinical trials of Dex-IN, IV/IM meloxicam or our other product candidates, and any future clinical and preclinical studies;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval that we may obtain;
- regulatory developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- our ability to raise future financing for continued development;
- the performance of our third-party suppliers and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights;
- our ability to successfully implement our strategy;

our ability to successfully integrate our acquisition of certain assets acquired in the Gainesville Transaction (as defined below); and

our ability to meet required debt payments and operate under increased leverage and associated lending covenants.

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the Risk Factors in this Quarterly Report and in our annual report on Form 10-K filed with the SEC on March 25, 2015, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain, initially for acute post operative pain. We have two product candidates in mid to late stage clinical trials for the management of acute post operative pain. Intravenous and intramuscular, or IV/IM, meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for moderate to severe acute pain has successfully completed multiple Phase II clinical trials and we are ready to begin pivotal Phase III clinical trials. We believe IV/IM meloxicam compares favorably to competitive therapies in onset of pain relief,

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duration of pain relief and time to peak analgesic effect. Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, successfully completed a Phase II clinical trial and is also ready to begin Phase III clinical trials. Dex is a selective alpha-2 adrenergic agonist that has demonstrated analgesic properties in multiple studies. If approved, Dex-IN would also be the first and only approved acute post operative pain drug in its class of drugs. As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory distress, and constipation while maintaining analgesic, or pain relieving, effect.

We currently own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®.

We have a limited operating history. We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $30.4 million. We have incurred losses and generated negative cash flows from operations since inception. As of June 30, 2015, we had an accumulated deficit of $39.5 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing and clinical trials. We expect to incur increasing expenses over the next several years to develop IV/IM meloxicam and Dex-IN, including planned Phase III pivotal and safety trials for Dex-IN and IV/IM meloxicam. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of meloxicam and Dex.

We expect that annual operating results of operations will fluctuate for the foreseeable future due to several factors. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

On April 10, 2015, we completed our acquisition from Alkermes plc, or Alkermes, of certain assets, including the worldwide rights to IV/IM meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and increase in our workforce as a result of the addition of the Gainesville employees.

Under the terms of the purchase and sale agreement with Alkermes, we paid Alkermes $52.0 million at closing, as adjusted for working capital. Alkermes is entitled to receive up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales, in each case, related to IV/IM meloxicam. Upon closing, we issued to Alkermes a warrant to purchase an aggregate of 350,000 shares of our common stock at an exercise price of $19.46 per share. The $52.0 million up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with OrbiMed Royalty Opportunities II, LP, or OrbiMed, and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

Financial Overview

Revenues

During the three and six months ended June 30, 2015 and 2014, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue.

Manufacturing revenues We recognize manufacturing revenues from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

Royalty revenues We recognize royalty revenues related to the sale of products by our commercial partners that incorporate our technologies. Royalties are earned under the terms of a license agreement in the period the products are sold by a commercial partner and collectability is reasonably assured.

Profit sharing revenue We recognize revenue from profit sharing related to the sale of certain of our manufactured products by our commercial partners. Profit sharing revenue is earned under the terms of a license agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

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Research and development revenue Research and development revenue consists of funding that compensates us for formulation, pre-clinical and clinical testing under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent, or FTE, or hourly rate, plus direct external costs, if any.

Research and Development Expenses

Research and development expenses currently consist of costs incurred in connection with the development of Dex and IV/IM meloxicam in different delivery forms. These expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- the cost of manufacturing validation tests, if these materials are manufactured prior to obtaining regulatory approval;
- costs related to facilities, depreciation and other allocated expenses;
- costs related to on-going process development and analytical controls associated with commercial manufacturing;
- costs associated with non-clinical activities and regulatory approvals; and
- salaries and related costs for personnel in research and development functions.

We expense research and development costs as incurred. Advanced payments for goods and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received.

Since inception, we have developed and evaluated a series of Dex product candidates through Phase I pharmacokinetic and efficacy trials and placebo controlled Phase II efficacy trial. Our current clinical priorities are the development of Dex-IN and IV/IM meloxicam for acute pain following surgery. Dex-IN recently completed a Phase II bunionectomy study and is ready to begin Phase III clinical trials. IV/IM meloxicam has also successfully completed multiple Phase II clinical trials for and is ready to begin pivotal Phase III clinical trials. In addition to the development of Dex-IN and IV/IM meloxicam, we intend to strategically invest in our product pipeline, including Fadolmidine, or Fado, a second alpha-2 agonist candidate that we believe shows promise in neuropathic pain . The commitment of funding for each subsequent stage of our development programs is dependent upon, among other things, the receipt of successful clinical data.

The majority of our external research and development costs relate to clinical trials, analysis and testing of the product and patent costs. We currently rely on MCG, a related party, for a portion of our research and development activities. Costs related to facilities, depreciation, and support are not charged to specific programs.

The successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;

- the imposition by the United States Food and Drug Administration, or FDA, and comparable agencies in foreign countries of substantial requirements on the introduction of therapeutic pharmaceutical products, which may require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;

- the possibility that data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;

- the costs, timing and outcome of regulatory review of a product candidate;

- the emergence of competing technologies and products and other adverse market developments which could impede our commercial efforts; and

- the risks disclosed in the section titled Risk Factors of this quarterly report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate s commercial potential. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will be required to expend in the future on our product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, any of our other product candidates will generate revenues and cash flows.

We expect our research and development costs related to IV/IM meloxicam and Dex-IN to be substantial for the foreseeable future as we advance these product candidates through clinical trials, manufacturing scale-up and other pre-approval activities. We may elect to seek out collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. General and administrative expenses also include professional fees for legal, including patent related expenses, consulting, auditing and tax services, and stock compensation expense.

Our general and administrative expenses in 2015 will be higher than in 2014. We expect to continue to have greater expenses relating to our operations as a public company, including increased payroll and increased consulting, legal and compliance, accounting, insurance and investor relations costs. We also expect that our patent costs will increase due to the acquisition of new patents through the Gainesville Transaction and, in addition, due to the higher annuity fees that will be due on patents that are issued. In addition, if additional formulation technology is developed for our product candidates, patent expenses could increase further.

Amortization of Intangible Assets

We recognize amortization expense related to the intangible asset for our contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. The intangible asset related to IV/IM meloxicam represents in-process research and development, or IPR&D, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of IV/IM meloxicam in the Gainesville Transaction, we are required to pay milestone payments on the achievement of certain regulatory and net sales milestones and royalties on future net product sales between 10% and 12%. The estimated fair value of the initial $54.6 million payment obligation was recorded as part of the purchase price for the Gainesville Transaction. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or income.

Interest Expense

Interest expense for the three and six months ended June 30, 2015 consists of interest expense incurred on our senior secured term loan with OrbiMed. Interest expense for the three and six months ended June 30, 2014 related to our previously outstanding Bridge Notes. Upon the closing of the IPO, these Bridge Notes, including accrued interest,

were converted into shares of common stock. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Net Operating Losses and Tax Carryforwards

As of December 31, 2014, we had approximately $16.8 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $0.7 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

The closing of the IPO, together with private placements and other transactions that have occurred since our inception, may trigger, or may have already triggered, an ownership change pursuant to Section 382 of the Internal Revenue Code of 1986. If an ownership change is triggered, it will limit our ability to use some of our net operating loss carryforwards. In addition, since we will

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need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

Results of Operations

Comparison of the Three Months Ended June 30, 2015 and 2014:

	Three months ended June 30,	
	2015	**2014**
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 16,704	$
Research and development revenue	1,956	
Total revenues	18,660	
Operating expenses:		
Costs of sales (excluding amortization of intangible assets)	9,395	
Research and development	2,821	1,837
General and administrative	2,597	959
Amortization of intangible assets	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Total operating expenses	18,287	2,796
Other income (expense):		
Interest income (expense)	(1,684)	2
Net loss	$ (1,311)	$ (2,794)

Revenue and costs of sales. As a result of the Gainesville Transaction and our subsequent operation of the manufacturing business through Gainesville, revenue for the three months ended June 30, 2015 increased to $18.7 million and cost of sales increased to $9.4 million.

Research and Development. Our research and development expenses were $2.8 million and $1.8 million for the three months ended June 30, 2015 and 2014, respectively, an increase of $1.0 million and 54% from June 30, 2014, primarily due to $0.9 million of research and development costs incurred at our Gainesville facility. These incremental costs are primarily related to process development, regulatory affairs and research and development analytical work at Gainesville.

General and Administrative. Our general and administrative expenses were $2.6 million and $1.0 million for the three months ended June 30, 2015 and 2014, respectively, an increase of $1.6 million and 160% from June 30, 2014, due to

costs associated with the Gainesville Transaction, management s salaries, benefits and stock-based compensation, and increased consulting and legal fees associated with being a public company.

Amortization of Intangible Assets. Amortization expense was $0.6 million for the three months ended June 30, 2015 exclusively related to the amortization of our royalties and intangible asset over its six year estimated useful life.

Interest Expense. Interest expense was $1.7 million during the three months ended June 30, 2015. Interest expense consists of interest expense incurred on our OrbiMed senior secured term loan. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor.

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Comparison of the Six Months Ended June 30, 2015 and 2014:

	Six months ended June 30,	
	2015	**2014**
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 16,704	$
Research and development revenue	1,956	
Total revenues	18,660	
Operating expenses:		
Costs of sales (excluding amortization of intangible assets)	9,395	
Research and development	4,575	2,064
General and administrative	4,986	1,606
Amortization of intangible assets	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Total operating expenses	22,430	3,670
Other income (expense):		
Interest income (expense)	(1,680)	(4,270)
Net loss	$ (5,450)	$ (7,940)

Revenue and costs of sales. As a result of the Gainesville Transaction and our subsequent operation of the manufacturing business through Gainesville, revenue for the six months ended June 30, 2015 increased to $18.7 million and cost of sales increased to $9.4 million.

Research and Development. Our research and development expenses were $4.6 million and $2.1 million for the six months ended June 30, 2015 and 2014, respectively, an increase of $2.5 million and 122% from June 30, 2014, primarily due to an increase of $1.5 million of higher Phase 2 clinical trial costs as a result of a full quarter of trial costs compared to a trial starting in May 2014, an increase in costs in association with a work plan for the start of our IV/IM meloxicam Phase III clinical trial and an additional $0.9 million of research and development costs incurred at our Gainesville facility, which primarily related to process development, regulatory affairs and research and development analytical work at Gainesville.

General and Administrative. Our general and administrative expenses were $5.0 million and $1.6 million for the six months ended June 30, 2015 and 2014, respectively, an increase of $3.4 million and 211% from June 30, 2014, due to $1.1 million in costs associated with the Gainesville Transaction, an increase of $1.0 million in management s salaries, benefits and stock-based compensation, and $0.8 million in increased consulting and legal fees associated with being a public company.

Amortization of Intangible Assets. Amortization expense was $0.6 million for the six months ended June 30, 2015 exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six year estimated useful life.

Interest Expense. Interest expense was $1.7 million during the six months ended June 30, 2015, which consists of our interest expense incurred on our OrbiMed senior secured term loan. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. For the six months ended June 30, 2014, interest expense of $0.2 million was recorded on our Bridge Notes. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Liquidity and Capital Resources

As of June 30, 2015 and December 31, 2014, we had $15.7 million and $19.7 million, respectively, in cash and cash equivalents. On July 1, 2015, we entered into a securities purchase agreement related to a private placement of shares of our common stock in which we received net proceeds of approximately $15.0 million. Since inception through June 30, 2015, we have financed

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our product development, operations and capital expenditures primarily from private sales of $4.0 million of our Series A Stock, $9.6 million of our Bridge Notes and $30.3 million from our IPO. We also expect that revenues from the Gainesville manufacturing business will fund operations and capital expenditures at the Gainesville facility.

We will need to raise additional funds in order to continue our clinical trials of our product candidates, to commercialize any product candidates or technologies and to enhance our sales and marketing efforts for additional products we may acquire. Insufficient funds may cause us to delay, reduce the scope of, or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development. If additional funds are required, we may raise such funds through public or private sales of equity or debt securities or from bank or other loans or through strategic research and development, licensing and/or marketing arrangements from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

On February 2, 2015, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase, at our election, up to an aggregate of $10.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. The shares may be sold by us to Aspire Capital on any business day we select in two ways: (1) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a purchase at a volume weighted average price, or VWAP, of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lessor of the closing sale price or 95% of the VWAP for such purchase date. To date, we have not sold any shares to Aspire Capital under the Purchase Agreement.

On March 7, 2015, in connection with the Gainesville Transaction, we, through a wholly owned subsidiary, entered into a credit agreement with OrbiMed. Pursuant to the credit agreement, OrbiMed provided us with a term loan in the original principal amount of $50.0 million on April 10, 2015, which amount was used to fund the Gainesville Transaction. The unpaid principal amount under the credit agreement is due and payable on the five year anniversary of the loan provided thereunder by OrbiMed. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed s request. We may make voluntary prepayments in whole or in part, subject to: (i) on or prior to the 36 month anniversary of the closing of the credit agreement, payment of a Buy-Out Premium Amount (as defined in the credit agreement); and (ii) after the 36 month anniversary of the closing of the credit agreement, payment of an Exit Fee Amount (as defined in the credit agreement). In the event that there shall be Excess Cash Flow (as defined in the credit agreement) for any fiscal quarter, OrbiMed has the option to require us to prepay the unpaid principal amount of the Loan in an aggregate principal amount equal to the Excess Cash Flow, or any lesser amount requested by OrbiMed, provided that no payments under this option shall be subject to the premiums or exit fees due. The interest rate under the credit agreement is a rate per annum equal to 14.0% plus the greater of: (i) the LIBO Rate (as defined in the credit agreement) and (ii) 1.0%. In addition, the credit agreement contains certain financial and other covenants, including a minimum liquidity requirement and minimum revenue targets, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. OrbiMed has indicated an interest in retiring an estimated $7.8 million, on or before August 20, 2015, of the outstanding principal on our senior secured term loan from free cash flow generated during the second quarter of 2015 by the Gainesville contract manufacturing facility.

Sources and Uses of Cash

Cash provided by (used in) operations was $1.7 million and ($2.7) million for the six months ended June 30, 2015 and 2014, respectively, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, changes in fair value of warrants and contingent consideration, amortization of intangibles and beneficial conversion charge taken on our Bridge Notes upon the conversion of such Bridge Notes, including accrued interest, into common stock.

Cash used in investing activities was $53.9 million for the six months ended June 30, 2015 as a result of the Gainesville Transaction and purchase of property and equipment at the plant in Gainesville.

Cash provided by financing activities was $48.2 million for the six months ended June 30, 2015 primarily as a result of the credit agreement with OrbiMed for $50.0 million, net of the payment of $1.7 million of issuance costs incurred in conjunction with the agreement. Cash provided by financing activities for the six months ended June 30, 2014 was as a result of successfully raising net proceeds of $30.4 million from the IPO and the issuance of $0.2 million of Bridge Notes to SCP Vitalife.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the timing and expenses of trials prior to a New Drug Application, or NDA, for Dex-IN and IV/IM meloxicam;

- the timing and outcome of the FDA s review of an NDA for Dex-IN and IV/IM meloxicam if our trials are successful;

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- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of Dex-IN and IV/IM meloxicam;
- the costs of our commercialization activities if approved by the FDA;
- the cost of purchasing manufacturing and other capital equipment for our potential products;
- the scope, progress, results and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

We might seek additional debt or equity financing or both to fund our operations or product acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity securities. This dilution may be significant depending upon the amount of equity securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The following is a discussion of our contractual commitments as of the end of the second quarter of 2015. We are involved with in-licensing of product candidates that are generally associated with payments to the partner from whom we have licensed the product. Such payments frequently take the form of:

- an up-front payment, the size of which varies depending on the phase of the product candidate and how many other companies would like to obtain the product, which is paid very soon after signing a license agreement;
- royalties as a percentage of net sales of the product; and

milestone payments which are paid when certain parts of the overall development program and regulatory milestones (such as filing an investigational new drug application, or IND, or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

We may also out-license products, for which we hold the rights, to other companies for commercialization in other territories, or at times, for other uses. If this happens, we would expect to be paid:

an up-front payment made at or shortly after signing a partnering agreement;

royalties as a percentage of net sales of the product;

milestone payments that may be made on completion of a phase of a clinical program, or regulatory approval in a given territory; and

a payment or payments made upon achievement of a certain level of sales in a given year.

Alkermes

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes up to $120 million in milestone payments upon the achievement of certain regulatory and net sales milestones related to IV/IM meloxicam and royalties on future product sales of IV/IM meloxicam between 10% and 12%.

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In July 2015, we also entered into a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will (i) provide clinical and, if elected by us, commercial bulk supplies of IV/IM meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of a New Drug Application for IV/IM meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk IV/IM meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV/IM meloxicam, subject to a maximum of eight clinical batches in any twelve-month period unless otherwise agreed by the parties. Prior to the initiation of Phase III clinical trials for IV/IM meloxicam, we may also elect to have Alkermes supply our initial commercial requirements of bulk IV/IM meloxicam formulation. During the term of the Supply Agreement, we will purchase our clinical and, if elected, commercial supplies of bulk IV/IM meloxicam formlulation exclusively from Alkermes for a period of time.

Orion

In August 2008, we entered into a License Agreement with Orion for non-injectable Dex. Under the Dex License Agreement, we were granted an exclusive license under Orion Know-How and Cygnus/Farmos Patent to commercialize products in the territory, as defined in such agreement, and to use, research, develop, and make products worldwide solely for purposes of commercialization. We also entered into a Supply Agreement with Orion pursuant to which Orion will supply us with development quantities of Dex API at no cost. Upon receipt of regulatory approval, Orion will supply commercial quantities of bulk active pharmaceutical ingredient Dex for commercialization.

We will pay milestone payments to Orion of up to 20.5 million Euros ($22.7 million as of June 30, 2015) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through June 30, 2015, no milestones have been achieved.

We also have an active pharmaceutical ingredient, or API, agreement with Orion for the supply of Dex, which we believe provides fair pricing for the purchase of the Dex API that is produced in compliance with current good manufacturing practices, and which addresses certain circumstances related to the provision of qualified manufacturing facilities or alternatives.

In July 2010, we entered into a License Agreement with Orion for Fado. Under the Fadolmidine License Agreement, we were granted an exclusive license under Orion Know-How and Orion Patent Rights to commercialize products in the territory, as defined in such agreement, and to use, research, develop, and make products worldwide solely for purposes of commercialization.

We will pay milestone payments to Orion of up to 12.2 million Euros ($13.5 million as of June 30, 2015) based on regulatory filings and approval and on commercialized net sales levels. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through June 30, 2015, no milestones have been achieved.

Leases

We lease our Malvern facility space under an operating lease on a month-to-month basis with MCG, a related party. Our Gainesville facility leases space for additional equipment and documentation storage.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

This management s discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Other than as disclosed below, we believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 25, 2015.

Impairment of Goodwill and Indefinite-lived Intangible Assets As a result of the Gainesville Transaction, we will be required to review the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. The first

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step in the impairment analysis is to assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The two-step goodwill impairment test consists of the following steps. The first step compares a reporting unit s fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit s fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit s goodwill impairment loss, if any. Step two requires an assignment of the reporting unit s fair value to the reporting unit s assets and liabilities to determine the implied fair value of the reporting unit s goodwill. The implied fair value of the reporting unit s goodwill is then compared with the carrying amount of the reporting unit s goodwill to determine the goodwill impairment loss to be recognized, if any. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

Impairment of Long-lived Assets As a result of the Gainesville Transaction, we will be required to review the carrying value of long-lived fixed and intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

ASC 360-10-35 provides guidance with respect to the measurement of impairment. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory even has modified their estimated useful lives.

Classification of debt Under the Company s credit agreement with OrbiMed, Orbimed, at its option, has the right to require the Company to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows of Gainesville, as defined in the credit agreement. Accounting policies require that the Company estimate the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2015 upon request of OrbiMed and classify this amount as current debt in the consolidated balance sheet. Changes in estimates of future cash flows caused by items such as customer and product demand, changing operating cost structure or other unforeseen events or changes in market conditions, could cause actual future cash flows to vary from our estimates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At June 30, 2015, we had approximately $8.7 million invested in money market instruments and government agency bonds. We believe our policy of investing in highly rated securities, whose liquidities are, at June 30, 2015, all less than 90 days, minimizes such risks. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment

portfolio. We do not enter into investments for trading or speculative purposes. Our OrbiMed senior secured term loan interest expense is based on the current committed rate of LIBOR plus 14% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $62,500 of interest expense.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2015. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s, or the SEC s, rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our Annual Report on Form 10-K for the year ended December 31, 2014, which was our first Annual Report on Form 10-K, was not required to include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm under a transition period established by SEC rules applicable to new public registrants. Management will be required to provide an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2015. We are not required to comply with the independent registered public accounting firm attestation requirement of Section 404 of the Sarbanes-Oxley Act while we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

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Item 1A. Risk Factors

Except as set forth below, there have been no material changes from our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2014.

In connection with the Gainesville Transaction, we incurred significant indebtedness, which could adversely affect our business.

Prior to the Gainesville Transaction in April 2015, we had no outstanding indebtedness. Contemporaneously with the closing of the Gainesville Transaction, we entered into a $50.0 million credit agreement with OrbiMed. Accordingly, we have substantially increased indebtedness following the acquisition in comparison to a recent historical basis. Our indebtedness could have important consequences to you. For example, it:

- requires us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, reducing the availability of our cash flow to fund working capital, capital expenditures, development activity, acquisitions and other general corporate purposes.;
- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- makes us more vulnerable to increases in interest rates, as borrowings under our senior secured credit facility are at variable rates;
- limits our ability to obtain additional financing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with OrbiMed also contains certain financial and other covenants, including a minimum liquidity requirement and minimum revenue targets, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. Any failure to comply with the terms, covenants and conditions of the term loan may result in an event of default under such agreements, and could have a material adverse effect on our business, financial condition and results of operation.

Further, subject to compliance with our credit agreement with OrbiMed, we have the ability to incur additional indebtedness, which would exacerbate the risks associated with our existing debt.

The FDA or other regulatory agencies may not approve IV/IM meloxicam or may impose limitations upon any product approval.

We must obtain government approvals before marketing or selling our IV/IM meloxicam or any other product candidates in the United States and in jurisdictions outside the United States. The FDA, and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These may include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials GMP manufacturing of products tested and following these products for stability, 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 United States 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.

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 United States can be delayed, limited or not granted at all for many reasons, including:

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;

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- 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 and analytical processes or facilities;

- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;

- third-party CROs and other third-party service providers and independent clinical investigators we hire to manage and conduct the trials, may fail to perform their oversight of the trials or to meet expected deadlines;

- that our clinical investigational sites and the records kept at such sites, including the clinical trial data, may fail to be 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 as interpreted by the regulators;

- the FDA or other regulatory agencies may change their approval policies or adopt new regulations or requirements;

- 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, or that other specialized studies may be required as follow up; 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. In summary, we cannot be sure that regulatory approval will be granted for IV/IM meloxicam or any other product candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of IV/IM meloxicam or 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 IV/IM meloxicam, our share price could decline.

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/or 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, or rescinds regulatory approval as a result. 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.

We cannot predict the outcome for the remaining clinical trials for IV/IM meloxicam.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate, that our product candidates are safe and effective for use in humans. In April 2015, we acquired IV/IM meloxicam from Alkermes Plc, who has completed multiple Phase II trials. We currently expect after our meeting with the FDA and our receipt of new supplies of IV/IM meloxicam drug product which have met release specifications, we will prepare to initiate our Phase III program. There can be no assurance that the pre-clinical and clinical development efforts performed to date have been successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product candidate. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

the potential delay by a collaborative partner or investigators in beginning a clinical trial;

the inability to recruit clinical trial participants at the expected rate;

the failure of clinical trials to demonstrate a product candidate s safety or efficacy;

the inability to follow patients adequately after treatment;

unforeseen safety issues;

the inability to manufacture sufficient quantities of materials that meet release specifications and have adequate shelf life stability for use in clinical trials; and

unforeseen governmental or regulatory issues, including those by the FDA and other regulatory agencies.

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If IV/IM meloxicam fails to demonstrate safety and efficacy in clinical trials, or if third parties fail to conduct clinical trials in accordance with their obligations, the development, approval and commercialization of IV/IM meloxicam may be delayed or prevented, and such events could adversely affect our business, financial condition, cash flows and results of operations.

We rely on Alkermes and a contract manufacturer to supply us with clinical and commercial supplies of IV/IM meloxicam, and any disruption in the chain of supply may cause delay in developing and commercializing IV/IM meloxicam.

Alkermes is currently our sole supplier of bulk IV/IM meloxicam formulation. Additionally, we intend to enter into an agreement with a contract manufacturer for the provision of sterile fill and finish services. Although the supply agreement that we have with Alkermes allows us to qualify and purchase from an alternative supplier in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found. Currently, Alkermes is the only established supplier of bulk IV/IM meloxicam formulation.

If supply from our suppliers is interrupted, there could be a significant disruption in commercial or clinical supply of IV/IM meloxicam. The FDA, state regulatory authorities or other regulatory authorities outside of the United States may also require additional studies if any new suppliers are relied upon for commercial production.

Any interruption in the supply of IV/IM meloxicam could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required quantities of IV/IM meloxicam on a timely basis and at all, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Integrating the assets acquired in the Gainesville Transaction in April 2015 may be more difficult, costly or time consuming than expected and the anticipated benefits of the acquisition may not be realized.

The success of the Gainesville Transaction, including anticipated benefits, will depend, in part, on our ability to successfully combine and integrate such assets and the associated employees with our business. It is possible that the integration process could result in the loss of key employees, higher than expected costs, diversion of management attention, the disruption of ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits and cost savings of the acquisition. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully or at all, or may take longer to realize than expected.

Revenues from our manufacturing business are dependent on a small number of commercial partners, and the loss of one of these partners, or a decline in their orders, may adversely affect our business.

Our manufacturing business is currently dependent on our relationships with our commercial partners. We have five key commercial partners: Novartis Pharma AG (Ritalin LA®, Focalin XR®), Kremers Urban Pharmaceuticals, Inc. (generic Verapamil), Watson Laboratories, Inc. (Verelan PM®), Paladin Labs Inc. (Zohydro ER®) and Pernix Therapeutics Holdings, Inc. (Zohydro ER®). Our contracts with our commercial partners are for a short term, generally of one year. If any one or more of these commercial partners fail to renew their contract or otherwise significantly reduce their purchasing volume our revenues could be adversely affected.

Manufacturing revenues also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or may reduce or fail to devote the necessary resources to provide effective sales and marketing support of the products we manufacture and supply. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users. Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume. For example, the last-to-expire patents listed in the U.S. Orange Book covering Focalin XR® all expire in December 2015. Following such date, we anticipate that orders for Focalin XR® from Novartis will decrease substantially. This and any other significant reduction, delay or cancellation of orders from our commercial partners could adversely effect our revenues.

In addition, the financial covenants in our credit agreement with OrbiMed include minimum revenue targets for Gainesville, and any significant reduction, delay or cancellation of orders from our commercial partners may cause us to fail to meet such targets, which may result in an event of default under the credit agreement with OrbiMed, which could have a material adverse effect on our business, financial condition and results of operation.

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We and our third-party suppliers must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

In connection with our research and development activities and our manufacturing business, we are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

In addition, our research and development activities and our manufacturing business involve the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by those regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations, or CROs, may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or

asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

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We are subject to risks related to large-scale commercial manufacturing.

Manufacturing pharmaceuticals, especially in large quantities, is complex. The products we manufacture for our commercial partners require several manufacturing steps, and may involve complex techniques to assure quality and sufficient quantity. Our manufactured products must be made consistently and in compliance with a clearly defined manufacturing process. Slight deviations anywhere in the manufacturing process, including obtaining materials, equipment malfunctions, filling, labeling, packaging, storage, shipping, quality control and testing, some of which all pharmaceutical manufacturing companies experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs.

In addition, we rely on a limited number of suppliers and pharmaceutical wholesalers to provide the raw materials needed for the manufacture of our commercial products. We may experience deviations in the manufacturing process or interruptions in our supply chain that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and/or cause us to fail to satisfy customer orders or contractual commitments or result in litigation or regulatory action.

Our manufacturing facility also requires specialized personnel and is expensive to operate and maintain. Any suspension of the sale of products of our commercial partners to be manufactured in our facility may cause operating losses as we continue to operate the facility and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting our contractual obligations and could damage our relationships with our commercial partners, including the loss of manufacturing and supply rights.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP, and our manufacturing facility is subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facility, there are increased risks associated with cGMP compliance. Our inability to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facility to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act and the regulations of the Drug Enforcement Agency, or DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facility is located in Gainesville, Georgia, where natural disasters or similar events, like blizzards, tornadoes, fires, floods or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville facility, that damaged critical infrastructure, such as manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our manufacturing business for a substantial period of time.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

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Product liability litigation may result in financial losses and harm our reputation.

Our manufacturing business exposes us to potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. We currently maintain product liability insurance in amounts we believe are sufficient for our manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our reputation, operating results, financial condition and liquidity and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture Ritalin LA, Focalin XR, Verelan PM, generic Verapamil and Zohydro ER for our commercial partners, or to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

We may not be able to protect the intellectual property related to Zohydro ER, which could result in new or additional generic competition to Zohydro ER or limit our ability to market Zohydro ER.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch-Waxman Act, which may provide drug candidates with either a three-year or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an ANDA application (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five year exclusivity period by alleging that one or more of the patents listed in the FDA s list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. This type of litigation is commonly known as Paragraph IV litigation in the U.S. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates by obtaining FDA approval for an ANDA, the generic company may choose to launch a generic version of a drug candidate. Any launch of a generic version of our drug candidates prior to the expiration of patent protection, will have a material adverse effect on our revenues and our results of operations.

We and our commercial partners are currently involved in Paragraph IV litigations in the United States involving our patents in respect to Zohyrdo ER. These litigations may be expensive, distracting to management and protracted and could result in new or additional generic competition to Zohydro ER. The introduction of a generic version of

Zohydro ER could cause a reduction in product revenue for our manufacturing business which could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, we are currently involved in an interference in front of the United States Patent and Trademark Office with another party, which involves a patent application relating to Zohydro ER. We intend to vigorously prosecute our application that is involved in this interference. The result of the interference could result in the issuance of a patent that could limit our freedom to operate in respect to Zohydro ER, which could also cause a reduction in product revenue for our manufacturing business and have a material adverse effect on our business, results of operations, financial condition and prospects.

Failure to raise additional capital necessary to support increased capital requirements for our manufacturing facility may adversely affect our business.

Maintaining a world class cGMP pharmaceutical manufacturing facility is expensive. If the capital requirements for operating and maintaining our manufacturing facility exceed our current expectations, we may need to seek additional financing from banks or other lenders, or through public offerings or private placements of debt or equity securities. Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and maintain customer

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relationships. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly scale back or discontinue our manufacturing business, which would have a material adverse effect on our business, operating results and prospects.

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

Unregistered Sales of Equity Securities

Other than the issuance of warrants to Alkermes and OrbiMed, as disclosed on our Form 8-K filed with the SEC on April 16, 2015, there were no unregistered sales of equity securities during the period.

Use of Proceeds

On March 6, 2014, our registration statement on Form S-1 (File No. 333-191879) was declared effective by the SEC for our IPO of common stock. Aegis Capital Corporation acted as the sole book-running manager and Brean Capital, LLC acted as co-manager for the offering. At the closing of the IPO on March 12, 2014, we sold 4,312,000 shares of common stock, which includes the full exercise of the underwriters over-allotment, at an IPO price of $8.00 per share and received gross proceeds of $34.5 million, which results in net proceeds to us of approximately $30.3 million after deducting underwriting discounts, commissions and related offering costs.

As of June 30, 2015, we have used approximately $19.8 million of the net proceeds from the IPO for our Dex-IN Phase II clinical trials, manufacturing costs, short term preclinical studies, working capital and other general corporate purposes, a portion of which was paid to MCG, an affiliate of the Company. No offering costs were paid directly or indirectly to any of our directors or officers or persons owning ten percent or more of any class of our equity securities or any other affiliates.

We cannot predict with certainty all of the particular uses for our current funds, or the amounts that we will actually spend on the uses described in our Form S-1. The amounts and timing of our actual use of these funds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs. As a result, our management will have broad discretion in the application of these funds, and investors will be relying on our judgment regarding the application of the net proceeds of the offering.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit No.	Description	Method of Filing
10.1	First Amendment to Credit Agreement, dated April 10, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on April 16, 2015.
10.2	Asset Transfer and License Agreement, dated as of April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.
10.3	Transition Services Agreement, dated as of April 10, 2015, by and among Alkermes Pharma Ireland Limited, Recro Pharma, Inc., DV Technology LLC, and Alkermes Gainesville LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.

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Exhibit No.	Description	Method of Filing
10.4	Recro Pharma, Inc. Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on June 26, 2015.
10.5	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.6	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
10.7	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
10.8	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
21.1	Subsidiaries of the Registrant.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

Portions of this exhibit have been omitted pursuant to a request for confidential treatment on file with the Securities and Exchange Commission.

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SIGNATURES

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

RECRO PHARMA, INC.

Date: August 14, 2015

By: /s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2015

By: /s/ Charles Garner
Charles Garner
Chief Financial Officer
(Principal Financial Officer)

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EXHIBIT INDEX

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21.1	Subsidiaries of the Registrant.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.

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Portions of this exhibit have been omitted pursuant to a request for confidential treatment on file with the Securities and Exchange Commission.

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Exhibit 10.5

DEVELOPMENT, MANUFACTURING AND SUPPLY AGREEMENT

BETWEEN

ALKERMES PHARMA IRELAND LIMITED

AND

RECRO PHARMA, INC.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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DEVELOPMENT, MANUFACTURING AND SUPPLY AGREEMENT

THIS DEVELOPMENT, MANUFACTURING AND SUPPLY AGREEMENT (this **Agreement**) is made and entered into as of July 10, 2015 (the **Effective Date**) by and between Alkermes Pharma Ireland Limited, a private limited company organized and existing under the laws of the Republic of Ireland (**Alkermes**), and Recro Pharma, Inc., a corporation organized and existing under the laws of Pennsylvania (**Recro**). Recro and Alkermes are sometimes hereinafter referred to each as a **Party** and collectively as the **Parties**.

RECITALS:

WHEREAS, Alkermes, Eagle Holdings USA, Inc. (**Eagle**), Daravita Limited (**Daravita**), Recro and Recro Pharma LLC (**Recro Pharma**, together with Recro, the **Purchasers**) entered into a Purchase and Sale Agreement, dated as of March 7, 2015 (the **Purchase and Sale Agreement**), pursuant to which, among other things, Eagle agreed to sell, and Purchasers agreed to buy, all of the issued and outstanding membership interests of Alkermes Gainesville LLC (now known as Recro Gainesville LLC);

WHEREAS, Exhibit B to the Purchase and Sale Agreement among Alkermes, Daravita, Eagle, DV Technology LLC and the Purchasers provided, among other things, that, after the Closing Date, Alkermes would provide the clinical supply of BC Parenteral Meloxicam and Finished Meloxicam (each as defined below), and the provision of development services with respect to the Chemistry, Manufacturing and Controls (**CMC**) section for bulk nanocrystals (in support of clinical trials related to BC Parenteral Meloxicam) of a new drug application (**NDA**) for BC Parenteral Meloxicam and, if elected by Recro, the commercial supply of BC Parenteral Meloxicam, each as more specifically set forth herein, to Recro or its Affiliates;

WHEREAS, pursuant to the Intellectual Property Transfer and License Agreement (as defined below), Alkermes granted DV Technology LLC (now known as Recro Technology LLC) certain rights with respect to meloxicam products;

WHEREAS, prior to the Closing Date, Recro, Alkermes and Alkermes, Inc. entered into a letter agreement, dated March 26, 2015 (the **Meloxicam Letter**), pursuant to which Alkermes was to provide certain services prior to the Closing Date and the Parties desire to make such services subject to the terms of this Agreement;

WHEREAS, Alkermes hereby agrees to perform certain services related to the foregoing, and Recro hereby agrees to receive such services, on the terms and conditions set forth herein.

AGREEMENT:

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Alkermes and Recro agree as follows:

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Article 1

Definitions

For the purpose of this Agreement, the following words and phrases shall have the meanings set forth below. In the event of a conflict between the definition of a term contained herein and the definition of such term in the Purchase and Sale Agreement, this Agreement shall control. In addition, the terms includes, including, include and derivative forms of them shall be deemed followed by the phrase without limitation (regardless of whether it is actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)); and the term or has the inclusive meaning represented by the phrase and/or (regardless of whether it is actually written (and drawing no implication from the actual use of the phrase and/or in some instances but not in others)). The word will shall be construed to have the same meaning and effect as the word shall.

1.1 5kg Capital Equipment is defined in Section 5.4.

1.2 Action shall mean any action, claim, suit, arbitration, litigation, proceeding, or governmental investigation.

1.3 Additional Regulatory Services means any reasonable regulatory assistance that Recro may require from Alkermes, and Alkermes has agreed in writing to provide, other than the CMC Development Services.

1.4 Affiliate of a Person means any other Person that directly, or through one or more intermediaries, controls or is controlled by or is under common control with such Person. For purposes of this Agreement, control shall mean, as to any Person, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise (and the terms controlled by and under common control with shall have correlative meanings).

1.5 Agreement has the meaning set forth in the preamble.

1.6 Alkermes has the meaning set forth in the preamble.

1.7 Alkermes Facility means that portion of the Alkermes manufacturing facility located in Athlone, Ireland in which Alkermes intends to Manufacture product as required by this Agreement, including areas such as warehouse space, quality control laboratories, or office space that may be used for BC Parenteral Meloxicam, Finished Meloxicam and other products.

1.8 Alkermes Indemnitees is defined in Section 11.1(a).

1.9 Allocable Overhead means costs incurred by Alkermes or for its account which are attributable to Alkermes costs of supervisory services, general and administrative activities, occupancy (including utilities and property taxes), registrations, permits and licenses, insurance, depreciation, payroll, non-cash compensation, information systems, human resources and purchasing, as allocated to company departments based on space occupied, headcount or activity-based methods, in all cases as applied by Alkermes in accordance with GAAP and Alkermes accounting standards on a consistent basis.

1.10 Ancillary Agreements has the meaning assigned to it in the Purchase and Sale Agreement.

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1.11 Approved Methods is defined in Section 6.4(a).

1.12 Assigned Technology is defined in Section 6.8(b).

1.13 Batch means the amount of BC Parenteral Meloxicam or Finished Meloxicam derived therefrom, as applicable, produced during one production run.

1.14 BC Meloxicam SC means BC Parenteral Meloxicam that is designed for subcutaneous administration.

1.15 BC Parenteral Meloxicam means any parenteral Meloxicam in bulk crystal/formulated NanoCrystal form, as further described in the applicable Specification. For clarity, BC Parenteral Meloxicam provided hereunder shall be in [***] strength, as agreed by the Parties, or in such other strength as the Parties may agree.

1.16 Business Day shall mean any day that is not a Saturday, a Sunday or other day on which commercial banks in the City of New York, New York or Dublin, Ireland are required or authorized by Law to be closed.

1.17 Calendar Quarter means a three-month period ending on March 31, June 30, September 30, or December 31.

1.18 Calendar Year means the twelve-month period ending on December 31.

1.19 Certificate of Analysis and Compliance means the certificate for each Batch of BC Parenteral Meloxicam or Finished Meloxicam delivered hereunder listing the tests performed, the test specifications and the test results and certifying that such Batch was Manufactured in accordance with cGMP.

1.20 cGMP means current good manufacturing practice and standards as provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations to the U.S. Code of Federal Regulations Title 21 (21 CFR 210 and 21 CFR 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7 and subject to any arrangements, additions or clarifications agreed from time to time between the Parties in this Agreement.

1.21 Claim is defined in Section 11.1(c).

1.22 Clinical Requirements means the amount of BC Parenteral Meloxicam or Finished Meloxicam to be provided by Alkermes to Recro and its Sublicensees in accordance with Section 3.4 of this Agreement for the conduct of clinical studies of Finished Meloxicam.

1.23 Closing Date has the meaning assigned to it in the Purchase and Sale Agreement.

1.24 CMC means Chemistry, Manufacturing and Controls.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.25 CMC Development Services means (i) reasonable support with respect to the CMC section for bulk nanocrystals (in support of clinical trials related to BC Parenteral Meloxicam) of the NDA(s) for BC Parenteral Meloxicam sufficient to allow Recro to complete and file such CMC sections to the same standard as Alkermes would apply in submission of an NDA for its own similar products, (ii) information and expertise, including advisory, related to BC Parenteral Meloxicam and (iii) CMC regulatory assistance during the clinical work for BC Parenteral Meloxicam.

1.26 Confidential Information has the meaning set forth in Section 12.1.

1.27 Daravita has the meaning set forth in the Recitals.

1.28 DMF means the drug master file for BC Parenteral Meloxicam, and any amendments and supplements thereto, submitted to the FDA by or on behalf of Alkermes, which will contain all necessary information concerning BC Parenteral Meloxicam, the composition of the foregoing, and the Manufacture of the foregoing. All information in the DMF will be deemed to be the Confidential Information of Alkermes; provided that, the foregoing shall not limit Recro s right under Section 10.4(b) to use any information in the DMF which is included in the Technology Transfer Information.

1.29 Documentary Evidence has the meaning set forth in Section 4.5(c).

1.30 Eagle has the meaning set forth in the Recitals.

1.31 Effective Date has the meaning set forth in the preamble.

1.32 Extension Periods is defined in Section 10.1(b).

1.33 External Demand is defined in Section 12.1(b).

1.34 Ex-Works shall have the meaning accorded to that term in the ICC Incoterms 2010, International Rules for the Interpretation of Trade Terms, ICC Publication No. 715.

1.35 Existing Batches means batches of Finished Meloxicam in existence prior to the Closing Date in which batches all right, title and ownership passed to Recro as a result of the Purchase and Sale Agreement.

1.36 FDA means the United States Food and Drug Administration or any successor agency thereto.

1.37 Finished Meloxicam means BC Parenteral Meloxicam in appropriate sealed injectable filled vials without labels.

1.38 Finished Meloxicam SC means Finished Meloxicam that is designed for subcutaneous administration.

1.39 Firm PO is defined in Section 4.3(a).

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1.40 Firm Zone is defined in Section 4.2(d).

1.41 First Approval means receipt of the first Regulatory Approval for marketing and sale of Finished Meloxicam.

1.42 First-Sale Term is defined in Section 10.1(a).

1.43 Flexible Zone is defined in Section 4.2(d).

1.44 [***]

1.45 Force Majeure Event is defined in Section 13.12(a).

1.46 Fully Burdened Costs means 100% of Alkermes costs for performing the Services, which shall include Alkermes costs of materials, direct labor, warehousing, quality assurance/control, delivery and storage costs, and Allocable Overhead, in each case, to the extent allocable to such activities. The Fully Burdened Cost shall in all cases be applied by Alkermes in accordance with GAAP.

1.47 GAAP means United States generally accepted accounting principles.

1.48 Governmental Entity shall mean any court, administrative agency, commission or other governmental authority, body or instrumentality, federal, state, local, domestic or foreign governmental or Regulatory Authority.

1.49 Indemnitee is defined in Section 11.1(c).

1.50 Indemnitor is defined in Section 11.1(c).

1.51 Initial Period is defined in Section 10.1(a).

1.52 Intellectual Property Transfer and License Agreement has the meaning assigned to it in the Purchase and Sale Agreement.

1.53 Interest Rate means an interest rate of [***] per month or the maximum applicable legal rate, if less.

1.54 IP License Agreement has the meaning assigned to it in the Purchase and Sale Agreement.

1.55 Latent Defect means a defect that causes a Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, to fail to conform to the Specifications, which defect is not discoverable upon testing performed pursuant to Section 6.4(a) but is discovered at a later time.

1.56 Launch Stock means any supply of BC Parenteral Meloxicam that is ultimately intended, in Finished Meloxicam form, for commercial marketing and sale which is Manufactured by Alkermes prior to First Approval.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.57 Law shall mean any United States federal, state or local, or any non-United States law, statute, ordinance, rule, regulation, judgment, order, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Entity.

1.58 Lookback Period is defined in Section 11.3(b).

1.59 Losses is defined in Section 11.1(a).

1.60 Manufacture (including variations such as **Manufacturing**) means the performance of all operations involved in the manufacture, quality control testing (including in process, release and stability testing, if applicable), release, shipment and storage (if applicable) of BC Parenteral Meloxicam or Finished Meloxicam, as applicable.

1.61 Meloxicam means an aqueous extended-release formulation of the selective COX-2 inhibitor non-steroidal anti-inflammatory drug meloxicam that has been developed by Alkermes using NanoCrystal Technology, including an intravenous or intramuscular form existing as of the Closing Date.

1.62 Meloxicam Letter has the meaning set forth in the Recitals.

1.63 NanoCrystal Technology means Alkermes proprietary technology, known as NanoCrystal® Technology , and comprising: (a) nanoparticulate dispersions of compounds stabilized against particle growth or agglomeration, and materials, methods and equipment used for making such dispersions; and (b) formulations, including finished formulations incorporating or derived from such dispersions, and materials, methods and equipment used for making such dispersions, provided such formulations, materials, methods and equipment are for the maintenance and control of (i) nanoparticulate size of the nanoparticulate component; (ii) redispersability of the nanoparticle nanoparticulate component in biological fluids; (iii) the rate of release or delivery of the nanoparticle nanoparticulate component in vivo; or (iv) the anatomical site of release of the nanoparticle nanoparticulate component from the finished dosage form of a pharmaceutical product.

1.64 NanoMill System means the milling systems known as NanoMill® System that are part of, or embody, Alkermes intellectual property and which were designed and developed by or on behalf of Alkermes, its Affiliates and predecessers in title, for preparing nanoparticulate dispersions for pharmaceutical formulations, including the milling equipment, related vessels, components, parts, associated manuals, and protocols.

1.65 NDA has the meaning set forth in the Recitals.

1.66 Party and **Parties** has the meaning set forth in the preamble.

1.67 Patent means patents and patent applications (which for purposes of this Agreement shall include certificates of invention and applications for such certificates), including any divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, revalidations, patent term extensions, pediatric exclusivity extensions, registrations, supplementary protection certificates and renewals of any such patents or patent applications, together with foreign equivalents of any of the foregoing.

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

1.69 Phase III Clinical Trial means a human clinical trial that is prospectively designed to (a) demonstrate statistically whether a product is safe and effective for use in humans in the indication being studied in a manner sufficient to obtain Regulatory Approval to market such product in patients having the disease or condition being studied as described in 21 CFR 312.21(c), (b) be or becomes a registration trial sufficient for filing an application for a Regulatory Approval for such product in the United States or (c) an equivalent clinical trial in a country other than the United States.

1.70 Project Team defined in Section 2.1(a).

1.71 Purchase and Sale Agreement has the meaning set forth in the Recitals.

1.72 Purchasers has the meaning set forth in the Recitals.

1.73 Quality Agreement means each of the documents entered into by the Parties specifying certain quality assurance and quality control requirements relating to the Manufacture of BC Parenteral Meloxicam and Finished Meloxicam, which will be developed, agreed upon and updated by the Parties in accordance with Section 6.4(a).

1.74 Quality Signature is defined in Section 6.1.

1.75 Recall/Recovery means any action by Recro or any of its Sublicensees to detain or destroy product or recover title to or possession of, or to prevent the distribution, prescription, consumption or release of BC Parenteral Meloxicam or Finished Meloxicam sold or shipped to Third Parties. The term **Recall/Recovery** also includes the failure by Recro or any of its Sublicensees to ship BC Parenteral Meloxicam or Finished Meloxicam to Third Parties that would have been subject to recall or recovery if it had been sold or shipped.

1.76 Recro has the meaning set forth in the preamble.

1.77 Recro Indemnitees is defined in Section 11.1(b).

1.78 Regulatory Approval means, with respect to a country or region, approvals, licenses, registrations or authorizations from the relevant Regulatory Authority necessary in order to import, distribute, market and sell a pharmaceutical product in such country or region, but not including any pricing or reimbursement approvals.

1.79 Regulatory Authority means the FDA and any other analogous government regulatory authority or agency involved in granting approvals (including any required pricing or reimbursement approvals) for the development, manufacture or commercialization of pharmaceutical products in the applicable country or region.

1.80 Representatives means a Person s officers, directors. consultants, advisors, employees, stockholders, agents and other advisors or representatives.

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1.81 Requirements means the amount of BC Parenteral Meloxicam needed by Recro and its Sublicensees for marketing and sale of Finished Meloxicam.

1.82 Rolling Forecast means a forecast including (i) a rolling [***] Calendar Quarter forecast specifying the Requirements for each of the next [***] Calendar Quarters of such forecast, and each month within such Calendar Quarter, starting with the Calendar Quarter following the due date of such forecast, and (ii) for each of the [***] Calendar Years following the Calendar Year which includes the [***] Calendar Quarter covered by the Calendar Quarter forecasts provided pursuant to clause (i), an annual forecast of the Requirements for such Calendar Year, which annual forecast shall only be updated upon the inclusion of a new Calendar Year in the period covered by the annual forecasts.

1.83 SEC means the United States Securities and Exchange Commission.

1.84 Services means all services provided by Alkermes pursuant to this Agreement, including (a) all services related to clinical supply of BC Parenteral Meloxicam and Finished Meloxicam; (b) all services related to the commercial supply of BC Parenteral Meloxicam; (c) CMC Development Services; and (d) Additional Regulatory Services.

1.85 Shortage is defined in Section 5.7.

1.86 Specifications means the specifications for the Manufacture of BC Parenteral Meloxicam and Finished Meloxicam, as such specifications may be amended from time to time by agreement of the Parties. The initial Specifications are attached hereto as **Exhibit A**.

1.87 Sublicensee means an Affiliate of Recro, or a Third Party, to which Recro Technology LLC or Recro has granted rights to BC Parenteral Meloxicam or Finished Meloxicam within the scope of the licenses thereto granted to Recro Technology LLC pursuant to the IP Asset Transfer and License Agreement.

1.88 Technology means know-how, trade secrets, chemical materials, formulations, compounds, compositions, information, documents, studies, results, data, processes, methods, procedures, protocols, designs, regulatory authorizations and approvals (including investigational new drug applications), filings and correspondence, including chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, apparatuses, devices, screens, databases, database structures and data analysis methods, whether or not patentable. For the avoidance of doubt Technology does not include Patents.

1.89 Technology Transfer Information is defined in Section 10.4(b).

1.90 Term means the Initial Period plus any and all Extension Periods.

1.91 Third Party(ies) means any Person other than Alkermes or Recro and their respective Affiliates.

1.92 Third Party Reviewer is defined in Section6.3.

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1.93 Work Plans is defined in Section 3.1.

1.94 Yield Band is defined in Section 4.3(a)(b).

Article 2

Oversight/Governance/Scope

2.1 Project Team.

(a) Formation. Promptly after the Effective Date, the Parties shall appoint a team, consisting of Alkermes representatives and Recro representatives, who are appropriately skilled and knowledgeable in relation to, and who are deemed necessary to accomplish, the CMC Development Services and the supply of the Clinical Requirements, and, if elected by Recro pursuant to Section 4.1(a), the Requirements (the **Project Team**). Unless otherwise agreed, the Project Team shall consist of six (6) representatives, with three (3) represent appointed by each of Alkermes and Recro. Either Party may replace any of its representatives on the Project Team by written notice of such change to the other Party. Alkermes and Recro shall each appoint a Project Team leader, and the initial Project Team leaders, as of the Effective Date, shall be for Recro, Randy Mack and for Alkermes, Damon Warnock. All members of the Project Team shall be subject to written confidentiality obligations, or professional obligations of confidentiality, at least as restrictive as those set forth herein.

(b) Role. The Parties shall agree upon a work-scope for the Project Team which shall include the following: (i) developing a strategy for delivery of the CMC Development Services and the Clinical Requirements, (ii) monitoring of CMC Development Services performance and supply of the Clinical Requirements and Requirements, and (iii) tracking the expenditure of funds related to the CMC Development Services and the supply of the Clinical Requirements and Requirements.

(c) Meetings. The Project Team leader shall call meetings as reasonably requested during the Term by one of the Parties; provided, however, that the Project Team shall meet as frequently as necessary to fulfill its responsibilities. Unless otherwise agreed, meetings will be held at least twice per month, or at such intervals as may be agreed between the Parties at various stages of development. The Project Team leader shall establish the timing and agenda of all Project Team meetings and shall transmit notice of such meetings, including the agenda therefor, to all Project Team members; provided, however, either Party may request that specific items be included on the applicable agenda and may request that additional meetings be scheduled as needed. Meetings may be held in person, by telephone or by video conference call and the location of each meeting shall be mutually agreed upon by the Parties. A quorum of at least one Project Team representative appointed by each Party shall be present at or shall otherwise participate in each Project Team meeting. On advance written notice to the other Party, each Party may invite additional participants to attend meetings where appropriate and all such additional participants shall be subject to written confidentiality obligations or professional obligations of confidentiality, at least as restrictive as those set forth herein. Each Party shall be responsible for all travel and related costs and expenses for its representatives to participate in or attend meetings of the Project Team.

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(d) Minutes. Minutes of the meeting of the Project Team shall be transcribed and issued by Alkermes within five (5) Business Days after each meeting (or in any event at least five (5) days prior to the date of the next scheduled meeting of the Project Team). Such minutes shall include only key discussion points and decisions made and provide a list of any identified issues yet to be resolved, either within the Project Team or through the relevant resolution process. The Parties shall agree on the minutes of each meeting promptly, but in no event later than five (5) Business Days after receipt of such minutes from the Project Team leader.

(e) Decisions/Dispute Resolution. The Project Team may make decisions with respect to any subject matter that is subject to the Project Team s decision-making authority and responsibilities as set forth in this Section 2.1. Regardless of the number of individuals attending any Project Team meeting, Alkermes and Recro will have a single vote each. The Project Team shall attempt in good faith to reach unanimity with respect to matters that come before it for decision and shall give consideration to the views, positions and recommendations of each Party on such matters. If, despite such good faith efforts, the Project Team is unable to reach unanimity upon any issue or matter that is brought before it for decision, the item shall be referred for discussion to the following officers, their successors or appropriate designees (i) for Recro, its General Manager or Head of Manufacturing and (ii) for Alkermes, Declan O Connor, VP Manufacturing, who shall work together to reach an agreement within [***] of the Project Team referring such unresolved item to them. If such representatives are unable to reach a decision during such period, the item shall be referred to the following officers, their successors or appropriate designees (i) for Recro, Gerri Henwood, Chief Executive Officer and (ii) for Alkermes, Shane Cooke, President, who shall work together to reach an agreement as soon as is practicable, but within [***] of the item being referred to them. If such representatives are unable to reach a decision during such period, Recro shall have final decision making authority with respect to any issue or matter with respect to which the Project Team is unable to reach unanimity; provided, that Alkermes shall have final decision making authority with respect to any issue that relates to the Alkermes Facility, including as it relates to the Manufacture, acknowledging that Recro shall have the final decision making authority in respect of the Existing Batches and final release of BC Parenteral Meloxicam, or any Finished Meloxicam derived therefrom, to the extent applicable, in each case, for clinical trial purposes and for commercial sale.

(f) Authority. The Project Team shall have only the powers assigned to it in this Section 2.1. All activities conducted by and decisions taken by the Project Team shall be consistent with and subject to the provisions of this Agreement, and the Project Team shall not have any power to (i) take any action that conflicts with the terms of this Agreement, (ii) amend, modify or waive compliance with any of the terms of this Agreement, or (iii) create any new obligations on either of the Parties. For clarity, any disputes regarding the interpretation, breach, termination or invalidity of this Agreement will be resolved in accordance with Section 13.2

(g) Participation. The Parties shall have the right to disband the Project Team upon mutual agreement. If the Project Team is not disbanded pursuant to the preceding sentence, the Project Team shall be automatically disbanded effective upon the expiration or termination of this Agreement

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2.2 Operations During Dispute Resolution. Unless Recro directs otherwise, the provision of the CMC Development Services, and the supply of the Clinical Requirements and the Requirements will continue until such time as the Parties reach agreement on any issue subject to resolution pursuant to Section 2.1(e); provided, however, that neither Party will have any obligation to incur any costs, or to perform any related activities, if such costs would be in dispute if incurred. In addition, the Parties agree that neither Party will be liable to the other, nor be deemed to be in breach of this Agreement, either if that Party is acting in accordance with the express direction of the other Party or if that Party s ability to perform its obligations hereunder could reasonably be deemed to be impaired by a decision of the other Party.

2.3 Additional Information Sharing. Notwithstanding anything to the contrary in the Purchase and Sale Agreement or this Article 2, on a semi-annual basis, a discussion shall occur between senior representatives of Recro and Alkermes relating to development activities as set forth in Section 3.2(a) of Exhibit E of the Purchase and Sale Agreement. Further, and without prejudice to the Purchase and Sale Agreement, at least [***] months prior to the launch of any Meloxicam product and continuing thereafter for [***] months after the launch, on a Calendar Quarter basis, a senior representative of Recro shall provide a presentation to Alkermes (either in person or via agreed means of electronic communication) in respect of ongoing and projected performance of the Meloxicam product. After the [***] month period referenced above has elapsed, such a presentation shall be provided to Alkermes on a semi-annual basis for so long as any Meloxicam product is being sold or otherwise commercialized.

2.4 Scope of Agreement. This Agreement shall apply only to the supply of BC Parenteral Meloxicam and Finished Meloxicam. Alkermes shall not provide any services hereunder related to the supply or development of BC Meloxicam SC or Finished Meloxicam SC. Services related to supply or development of BC Meloxicam SC or Finished Meloxicam SC, if any, will be governed by an amendment to this Agreement or a separate Agreement. In addition, as set forth in the Quality Agreements and unless otherwise elected by Recro, Alkermes will only provide Finished Meloxicam for the first Batch that is part of the Clinical Requirements.

Article 3

CMC Development and Clinical Supply

3.1 Subject to approval by the Project Team, and as part of the Services to be performed hereunder, Alkermes shall provide CMC Development Services and all other services necessary to deliver the Clinical Requirements to Recro (or such Sublicensees as Recro shall designate in writing). All such services shall be set forth in work plans, as mutually agreed to in writing by the Parties, and subsequently attached hereto as **Exhibit B** (**Work Plans**). For clarity, the Work Plans attached hereto as of the Effective Date were previously agreed upon by the Parties and governed by the Meloxicam Letter. As of the Effective Date, all Work Plans, including the Work Plans previously governed by the Meloxicam Letter, shall be governed by this Agreement.

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3.2 Subject to the remainder of this Article 3, each Party shall use reasonable efforts, as would be deemed commensurate with the achievement of its own business aims for a similar product of its own to conduct such activities under the Work Plans as the Parties mutually agree. Further, Alkermes and Recro each undertake that they shall carry out their respective activities set forth in each Work Plan in good faith, diligently, as a collaborative effort, in a commercially reasonable and workmanlike manner, and in accordance with this Agreement, the applicable Quality Agreement, and all applicable Laws, regulations and professional standards. Each Party shall co-operate with the other in good faith particularly with respect to unknown problems or contingencies. Each Party will update the other Party on the progress of the Work Plans at meetings of the Project Team. Alkermes will use reasonable efforts to start and complete all CMC Development Services and all other services necessary to deliver the Clinical Requirements in a timely fashion in accordance with the timelines set forth in the applicable Work Plans and will promptly notify Recro in the event of any changes to such timelines. Any reports and updates shall be provided to Recro as described in the relevant Work Plan and the applicable Quality Agreement.

3.3 Alkermes shall have no liability to Recro as a result of any failure or delay of either BC Parenteral Meloxicam, or any Finished Meloxicam derived therefrom, to obtain Regulatory Approval, except to the extent that such failure or delay is the result of Alkermes material breach of this Agreement. Recro shall have no liability to Alkermes as a result of any failure or delay of BC Parenteral Meloxicam, or any Finished Meloxicam derived therefrom, to obtain Regulatory Approval or the approval of the appropriate Regulatory Authorities in any country, except to the extent that such failure or delay is the result of Recro s material breach of this Agreement.

3.4 During the Term, and subject to the terms and conditions hereof, Alkermes agrees to supply to Recro, and Recro agrees to purchase exclusively from Alkermes, the Clinical Requirements. Alkermes and Recro shall discuss in good faith forecasting and ordering requirements for supply of the Clinical Requirements. Pursuant to mutually agreeable Work Plans, Alkermes and Recro shall agree upon the quantities, dates for supply of the Clinical Requirements (to be delivered Ex Works the Alkermes Facility) and other details related to the Clinical Requirements. For clarity, the Clinical Requirements shall be (a) no less than Recro or its Sublicensees reasonably require for the completion of clinical work related to BC Parenteral Meloxicam, and the Finished Meloxicam derived therefrom, and (b) subject to Section 3.2, shall not exceed eight (8) released Batches of BC Parenteral Meloxicam and the Finished Meloxicam derived therefrom for each twelve (12) month period beginning on the Effective Date without the prior written agreement of the Parties. Prior to increasing the maximum amount of Clinical Requirements, the Parties shall consider updates to Recro s development plan for Finished Meloxicam, clinical trial results related to Finished Meloxicam, the implications of such results, and feedback from Regulatory Authorities.

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Article 4

Commercial Supply

4.1 Requirements.

(a) Requirements. Prior to the initiation of the first Phase III Clinical Trial for Finished Meloxicam, Recro shall notify Alkermes in writing as to whether Alkermes shall be required to supply Recro (and such Sublicensees or distributors as Recro may nominate) with the Requirements. Contingent upon Recro so nominating Alkermes to supply the Requirements, during the Term and subject to the terms and conditions hereof, Alkermes agrees to supply to Recro (and such Sublicensees or distributors as Recro may nominate), and Recro agrees to purchase, and shall cause (such Sublicensees or distributors as Recro may nominate) to purchase, exclusively from Alkermes, the Requirements; provided, that Recro may purchase the Requirements from another source in the event of a Shortage pursuant to Section 5.7.

(b) Launch Stock Quantities. Not less than [***] months in advance of the anticipated launch date for Finished Meloxicam, the Parties shall discuss and agree upon the Manufacture and purchase of specific quantities of Launch Stocks for launch of Finished Meloxicam. For the avoidance of doubt, any Launch Stock order shall be Manufactured in accordance with the Specifications and Recro shall be required to purchase the same even if said Specifications are subsequently not approved by the applicable Regulatory Authority.

4.2 Forecasts.

(a) Initial Forecast. Within [***] days of the delivery of the written notification required by Section 4.1(a), Recro will provide to Alkermes a Rolling Forecast of expected Requirements.

(b) Forecasts Due Periodically. Thereafter during the Term, Recro will provide to Alkermes a Rolling Forecast, no later than the [***]. Recro agrees to use commercially reasonable efforts in preparing all forecasts provided hereunder to minimize variances between forecasts. All forecasts provided by Recro will be good faith estimates of the Requirements. In the event of significant variances between forecasts the matter will be referred to the Project Team for discussion.

(c) Forecast Breakdowns. All of the forecasts provided under this Agreement will break down the amount of BC Parenteral Meloxicam by weight and strength.

(d) Firm Zone and Flexible Zone; Volume Limitations. Recro will be obligated to purchase the amount of BC Parenteral Meloxicam specified for the [***] (each such [***] will be referred to as the **Firm Zone**), and Recro will be obligated to purchase the amount of BC Parenteral Meloxicam specified for the [***] of each Rolling Forecast (each such [***] will be referred to as the **Flexible Zone**), but may, subject to Section 4.3 (b), increase or decrease the Flexible Zone forecast by [***] of the number of Batches of BC Parenteral Meloxicam. In the event that Recro wishes to increase the Flexible

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Zone forecast by more than said [***], Alkermes shall not be obliged to supply such additional amounts but shall use commercially reasonable efforts to do so. For clarity and the avoidance of doubt, the Firm Zone shall constitute the [***] day period prior to Manufacture, and the Flexible Zone shall constitute the period of [***] days prior to Manufacture. The Parties agree that except with respect to the Firm Zone and the Flexible Zone thereof no Rolling Forecast provided by Recro will be binding upon Recro.

4.3 Firm Purchase Orders.

(a) Delivery of POs. Recro will submit purchase orders (each, a **Firm PO**) for the Requirements to Alkermes at least [***] days prior to the requested delivery date. The details of a Firm PO will be consistent with the amount of BC Parenteral Meloxicam forecast for the Firm Zone . Alkermes shall have no obligation to supply BC Parenteral Meloxicam to Recro to the extent that the Firm PO does not conform to the provisions of this Section 4.3.

(b) Batch Amounts. Notwithstanding Recro s delivery of Firm POs for BC Parenteral Meloxicam, Alkermes will be obligated to Manufacture and ship BC Parenteral Meloxicam only in full Batch amounts; provided, however, that Alkermes may Manufacture BC Parenteral Meloxicam within [***] (the **Yield Band**) of the quantity specified in a Firm PO as a result of the Manufacture and shipment of such full Batch quantities. For the avoidance of doubt, in the event that any Batch yield is outside the Yield Band, but the relevant Batch is nonetheless conforming to the applicable Specifications, Alkermes shall be entitled to ship such Batch.

(c) Terms. Each Firm PO shall specify (i) the amount of BC Parenteral Meloxicam by weight and strength ordered to meet the Requirements; (ii) the month of delivery Ex Works the Alkermes Facility; (iii) the carrier; and (iv) the destination, subject to the limitations set forth in Section 4.5. The only terms of a Firm PO that shall be binding on the Parties shall be those identified in this Section 4.3(c) that are set forth on the face of such Firm PO. The terms of this Agreement are hereby incorporated by reference into each Firm PO submitted by Recro to Alkermes. No modification or amendment to this Agreement shall be effected by or result from the receipt, acceptance, signing or acknowledgment of a Party s purchase orders, quotations, invoices, shipping documents or other business forms containing terms or conditions in addition to or different from the terms and conditions set forth in this Agreement, and the terms of this Agreement shall supersede any provision in any purchase order, specification or other document that is in addition to or inconsistent with the terms of this Agreement. No other terms and conditions shall apply to the supply of the Requirements hereunder, except pursuant to the applicable Quality Agreement or pursuant to a modification of this Agreement by written agreement of the Parties.

(d) Acknowledgement. Within [***] Business Days of receiving a Firm PO, Alkermes shall give written notice to Recro specifying the acceptance of such Firm PO unless the terms of such Firm PO are not in accordance with the provisions of this Agreement. In the event that Alkermes does not accept a Firm PO, the Parties shall promptly consult with each other to resolve the underlying issues as promptly as possible, and such Firm PO shall be modified accordingly. Firm POs may neither be canceled nor modified by either Party, except as expressly provided in this Agreement.

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4.4 Delivery Dates. Alkermes shall ship BC Parenteral Meloxicam in accordance with Firm POs, as such Firm POs may have been modified, solely in accordance with the provisions of this Agreement. If Alkermes reasonably expects any delay in shipment to Recro or its designee, Alkermes shall promptly inform Recro of such expected delay, shall promptly update the delivery schedule and shall use its commercially reasonable efforts to minimize the delay, except in the case of a delay resulting solely from the action or inaction of Recro or its Affiliates, in which case Alkermes shall use reasonable efforts to minimize the delay.

4.5 Shipment.

(a) Terms. Alkermes shall make BC Parenteral Meloxicam available for collection by the carrier specified by Recro in the applicable Firm PO, Ex Works the Alkermes Facility. To the extent that Alkermes is required to supply Finished Meloxicam to Recro hereunder, said Finished Meloxicam shall be made available for collection by the carrier specified by Recro in the applicable Firm PO, Ex Works the facility of [***]. Notwithstanding anything to the contrary, Recro will be the importer of record of each shipment of BC Parenteral Meloxicam and Finished Meloxicam. Alkermes will pack and address the BC Parenteral Meloxicam in accordance with the Firm POs, and in the case of Finished Meloxicam will require it to be packed and addressed in accordance with the instructions provided in the Firm POs. For clarity, title to each shipment of BC Parenteral Meloxicam and Finished Meloxicam shall not pass until full payment has been made by Recro for said shipments.

(b) Shipping Documents. Alkermes shall send with each shipment of BC Parenteral Meloxicam, or cause to be sent with each shipment of Finished Meloxicam, a packing list containing the Recro material description/code, purchase order number, Batch number, Manufacturing date, and total amount delivered by weight and strength.

(c) Export. It is the intention of Recro to export BC Parenteral Meloxicam, from Ireland without unreasonable delay after such product has been made available for collection in accordance with Sections 3.4 and 4.5(a) (the consequence of which, it is understood by the Parties, is that the sale of such BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, shall be [***]), and Recro will provide the following documentary evidence of dispatch and such other documents as Alkermes reasonably requests (**Documentary Evidence**) to Alkermes before the 15th day of the month following the month in which each relevant sale of the BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, occurs (or fifteen (15) days following Alkermes request). Where Recro uses a carrier to export the BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, by sea on behalf of Recro, Recro should ensure that it obtains from the shipping company a copy bill of lading or certificate of shipment or shipping advice, as Documentary Evidence. Where Recro uses a carrier to export the BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, by air on behalf of Recro, Recro should ensure that it obtains from the airline concerned a signed copy of the waybill, with flight details added, as Documentary Evidence. Recro shall promptly notify Alkermes (not

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later than the due delivery date in respect of the BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom) if it does not intend to export the BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, from Ireland.

Article 5

Supplies; Capital Equipment; Manufacturing Process Changes

5.1 Subject to the other provision of this Article 5, Alkermes shall be responsible for procuring all components and materials, including active pharmaceutical product, required to Manufacture BC Parenteral Meloxicam and Finished Meloxicam (to the extent requested by Recro), prior to final clinical or commercial labeling and packaging.

5.2 No Supply to Third Parties. During the Term, Alkermes shall supply BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, solely to Recro and Recro s designated Sublicensees; Alkermes shall not supply BC Parenteral Meloxicam or Finished Meloxicam to any other Third Party.

5.3 Labeling, Packaging and Distribution. Recro shall be responsible for all labeling, packaging, and clinical and commercial distribution of BC Parenteral Meloxicam and any Finished Meloxicam derived therefrom.

5.4 Alkermes will be responsible for purchasing and installing at the Alkermes Facility any capital equipment required to support the commercial supply of BC Parenteral Meloxicam at a 5-kilogram scale (**5kg Capital Equipment**). Subject to Section 10.4(c)(ii), the 5kg Capital Equipment will be the property of Alkermes. The costs of purchasing 5kg Capital Equipment and the installation labor for the 5kg Capital Equipment and the maintenance and repair costs for the 5kg Capital Equipment will be borne by Alkermes. For clarity, and subject to Section 10.4(c)(ii), Alkermes will have the right to utilize the 5kg Capital Equipment to produce products other than BC Parenteral Meloxicam.

5.5 Alkermes shall not be required to purchase any capital equipment, other than the 5kg Capital Equipment, to support the commercial supply of BC Parenteral Meloxicam, unless and until Alkermes and Recro have entered into a written agreement setting forth the financial obligations with respect thereto, the ownership thereof and the disposition thereof upon the termination or expiration of this Agreement.

5.6 Notwithstanding Section 5.5,

(a) In the event that Recro or any applicable Regulatory Authority desires or requires any change to be made to the Manufacturing process or DMF, including the Specifications, Recro shall pay [***] for all work performed by Alkermes personnel in implementing such changes. Recro shall also reimburse Alkermes for [***]. At the end of each [***] during the period such work is being performed by Alkermes or any Third Party, Alkermes shall invoice Recro in U.S. dollars for any such work that has been performed during such [***] and [***], and Recro shall pay all such invoices within [***] days of the invoice date. Invoices shall set forth the number of hours worked by Alkermes personnel

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during such [***] and the [***], and shall contain an appropriate description of such [***]. Invoices shall be emailed to dnichols@recropharma.com.

(b) In the event that Alkermes efforts to scale up commercial supply of BC Parenteral Meloxicam to a 10-kilogram scale requires capital expenditures, which may include the purchase of a Nanomill System or components thereof, Alkermes shall obtain Recro s prior written consent prior to incurring such costs and Recro shall reimburse Alkermes Fully Burdened Costs and Third Party expenses with respect thereto within [***] days of receipt of the relevant Alkermes invoice(s). Upon payment of Alkermes Fully Burdened Costs and Third Party expenses in accordance with this Section 5.6(b), title to capital equipment purchased pursuant to this Section 5.6(b) shall automatically vest in Recro.

5.7 Shortages. Alkermes agrees that it will use commercially reasonable efforts to prevent an interruption of supply hereunder and shall immediately notify Recro of any problems or unusual production situations which may adversely affect the supply of the Clinical Requirements or the Requirements, or quality or timely delivery of BC Parenteral Meloxicam or Finished Meloxicam. If, at any time during the Term, with respect to the supply of the Requirements, Alkermes either fails to deliver at least [***] of the Requirements ordered in a given Firm PO (which quantity is in compliance with the terms of this Agreement and the applicable Quality Agreement) for more than either (a) [***] consecutive months after the delivery date therefor, or (b) in the event of a Force Majeure Event, [***] consecutive months after the delivery date therefor (a **Shortage**), then Alkermes shall: (i) give Recro prompt notice thereof, (ii) take commercially reasonable steps to enable Recro to procure adequate quantities of BC Parenteral Meloxicam or Finished Meloxicam with respect to the Requirements, as applicable, only for so long as such Shortage exists from a Third Party source in accordance with the applicable provisions of Section 10.4(b) and (iii) if such inability is partial, Alkermes shall fulfill Firm POs with such quantities of BC Parenteral Meloxicam or Finished Meloxicam, as applicable, as are available, and shall continue to use its commercially reasonable efforts to fulfill orders on a timely basis. At such time as Alkermes is able to supply Recro its Requirements and the Shortage no longer exists, Alkermes shall fulfill Firm POs and Recro shall no longer procure quantities of BC Parenteral Meloxicam or Finished Meloxicam, as applicable, from any Third Party source; provided, that once a Third Party source is qualified to supply BC Parenteral Meloxicam, Recro may continue to procure from such Third Party source the minimum amount of BC Parenteral Meloxicam required to allow such Third Party source to continue to be qualified to supply BC Parenteral Meloxicam.

Article 6

Quality

6.1 Certificate of Analysis and Compliance. Alkermes shall obtain representative samples from each Batch of BC Parenteral Meloxicam and Finished Meloxicam, as applicable, supplied by Alkermes. Alkermes shall assay and analyze such samples in accordance with the Specifications and shall prepare a Certificate of Analysis and Compliance that shall be delivered to Recro prior to the release of the corresponding Batch. The Certificate of Analysis and Compliance provided by Alkermes shall include the following: Batch number, Quality Signature (name, title, signature, and date signature applied, the **Quality Signature**), test, test specification and test result. Each Batch will be released in compliance with the release procedures set forth in the Quality Agreement.

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6.2 Quality Control and Quality Assurance; Regulatory.

(a) Quality Agreements. Each Party shall comply with the provisions of the Quality Agreements. The Quality Agreements shall be reviewed annually by the quality department of each Party and, upon mutual agreement, revised and updated in writing as necessary. In the event of a conflict between a Quality Agreement and this Agreement, this Agreement shall govern and control.

(b) Audits by Recro. With respect to BC Parenteral Meloxicam and Finished Meloxicam Manufactured and supplied to Recro hereunder, Recro shall have the right, [***] prior written request at a mutually agreeable time and at its own expense, to review and audit Alkermes quality control and assurance procedures and records, and to visit those sections of the Alkermes Facility used in such Manufacture and supply in order to assure compliance with this Agreement, the Specifications, cGMP and other applicable Laws and the Quality Agreements. All such audits shall be conducted in accordance with the provisions of this Agreement. Recro agrees that Confidential Information of Alkermes will include any documents (including any made available in electronic form) and data provided to Recro or its Sublicensees for the purpose of any such audits and any other information received by Recro or its Sublicensees, whether in writing, orally or by observation, while on-site at the Alkermes Facility to perform such audits or during the course of discussions related thereto. In addition during such audit, Alkermes may withhold certain Confidential Information contained in the DMF which Alkermes reasonably believes is highly sensitive information, provided that, Alkermes shall permit a Third Party Reviewer to access the entire DMF pursuant to Section 6.7(b). While on-site at the Alkermes Facility, Recro and its Sublicensees agree to follow all of Alkermes rules, regulations and procedures made available to them with respect to conduct at the Alkermes Facility. Further, Recro shall not have access during such audits to Alkermes Confidential Information related to other customers. Recro and its Sublicensees will cooperate with Alkermes in taking reasonable precautions to avoid exposure of the Recro and Sublicensees representatives to information regarding activities of Alkermes unrelated to BC Parenteral Meloxicam and Finished Meloxicam.

(c) Regulatory Cooperation and Support.

(i) The Parties rights and obligations with respect to any inspections of the Alkermes Facility by the FDA or other Regulatory Authorities shall be defined by the provisions of the Quality Agreements and this Section 6.2(c). All notices or other communications (whether in written, electronic or oral form) related to such inspections will be deemed to be the Confidential Information of Alkermes.

(ii) Alkermes agrees to cooperate with any inspection by any Regulatory Authority, and notwithstanding the expiration or termination of this Agreement, Alkermes shall retain all relevant documentation in relation to the

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Services and facilitate, including, without limitation, making its personnel reasonably available for, necessary regulatory inspections (e.g., pre-approval inspections supporting the regulatory filings of BC Parenteral Meloxicam in various jurisdictions) and filing of regulatory letters of authorization (e.g., cGMP statements, material statements) for the manufacture of BC Parenteral Meloxicam until the approval of BC Parenteral Meloxicam by Regulatory Authorities, subject to Recro reimbursing Alkermes for [***] with respect thereto.

6.3 cGMP Records. Alkermes shall retain original cGMP records, including any Batch records, related to the BC Parenteral Meloxicam and Finished Meloxicam, to the extent applicable, shipped to Recro. Alkermes shall retain such originals as long as required by applicable Law. From time to time, upon Recro s request, Alkermes shall disclose to Recro such cGMP records that do not include any Confidential Information which Alkermes reasonably believes is highly sensitive. In addition, Alkermes shall permit a qualified Third Party, reasonably acceptable to both Parties (such reviewer, the **Third Party Reviewer**), selected by Recro and reasonably acceptable to Alkermes, to enter the Alkermes Facility during normal business hours to review and inspect all cGMP records, including any portions of the cGMP records that contain Confidential Information which Alkermes reasonably believes is highly sensitive. Alkermes may require the Third Party Reviewer to sign a standard non-disclosure agreement with terms that are not inconsistent with the terms of this Agreement before providing the Third Party Reviewer access to the Alkermes Facility or cGMP records. Any reports generated by such Third Party Reviewer with respect to his/her review of the cGMP records shall be deemed the Confidential Information of Alkermes.

6.4 Quality.

(a) Analysis of BC Parenteral Meloxicam and Finished Meloxicam. Within [***] days from the date of shipment of a Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, in connection with the Clinical Requirements and/or the Requirements, by Alkermes, Recro may analyze said BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, to determine whether it meets the applicable Specifications and shall report any adverse findings to Alkermes within such [***] period, except for Latent Defects, which shall be reported to Alkermes pursuant to Section 6.4(c). In testing such BC Parenteral Meloxicam or the Finished Meloxicam derived therefrom, Recro shall use (i) the analytical testing methods agreed upon by the Parties, and (ii) technology transferred from Alkermes to Recro or a Third Party agreed upon by the Parties (and such Third Party subject to obligations of confidentiality reasonably acceptable to Alkermes), in each case of (i) and (ii), approved by Regulatory Authorities for batch release (the **Approved Methods**). To reject such a Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, Recro must give written notice to Alkermes within this [***] period specifying the deviation of such BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, from the applicable Specifications; if no such notice of rejection is given, Recro shall be deemed to have accepted such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom. Recro agrees to keep, true, accurate and complete records of all such sampling and analyses in accordance with its record retention policies; copies of such records shall be promptly provided to Alkermes and its representatives upon request.

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(b) Investigation of Non-Conforming BC Parenteral Meloxicam and Finished Meloxicam. Alkermes shall cooperate with Recro, in accordance with the Quality Agreement, in investigating any potential non-conforming Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, provided to Recro in connection with the Clinical Requirements and/or the Requirements. If Alkermes and Recro disagree as to whether any such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, meets the applicable Specifications, the matter shall be submitted to an independent testing laboratory, acceptable to both Parties, to determine whether the Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, conformed or did not conform to the applicable Specifications and the test results obtained from such laboratory shall be final and binding upon both Parties. Alkermes shall promptly send a portion of its retained sample of any alleged non-conforming Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, to both (i) Recro for its internal testing and review purposes; and (ii) the independent testing laboratory solely for use in accordance with this Section 6.4(b). In all events, Alkermes may reduce the portions of the retained samples to be sent to Recro and the independent testing laboratory in accordance with the previous sentence as necessary for Alkermes to retain a sufficient amount of each such retained sample for Alkermes to conduct its own testing. In testing the quality control sample, the independent testing laboratory shall use the Approved Methods , which methods shall have been transferred from Alkermes to such independent testing laboratory at Recro s cost in accordance with a transfer protocol agreed upon by the Parties. The fees and expenses of such testing shall be borne by the Party whose judgment of whether the Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, met the applicable Specifications differs from that of the independent testing laboratory. Alkermes agrees to keep, true, accurate and complete records of all retained samples of BC Parenteral Meloxicam, and the Finished Meloxicam derived therefrom, in accordance with its record retention policies; copies of such records shall be promptly provided to Recro and its representatives upon request.

(c) Latent Defects. If, within [***] after Recro s acceptance of a Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, for the Clinical Requirements and/or the Requirements, Recro discovers a Latent Defect that existed in such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, on or before Recro s acceptance of such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, Recro shall notify Alkermes immediately of such discovery, and Recro shall have the right to reject such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, by giving written notice to Alkermes specifying the deviation of such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, from the applicable Specifications; provided, however, that if Alkermes disagrees with Recro s determination that a Latent Defect exists or that the Latent Defect existed in such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, on or before Recro s acceptance of the same, then Alkermes shall so notify Recro within [***] after receiving Recro s notification about the Latent Defect, and in such case, a portion of Alkermes retained samples of such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, will be submitted for

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testing to an independent testing laboratory, acceptable to both Parties, whose determination of compliance or non-compliance of the Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, with the applicable Specifications, and the cause thereof, if non-compliant, shall be binding upon the Parties. In all events, Alkermes may reduce the portions of the retained samples to be sent to the independent testing laboratory in accordance with the previous sentence as necessary for Alkermes to retain a sufficient amount of each such retained sample for Alkermes to conduct its own testing. In testing the samples of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, the independent testing laboratory shall use the Approved Methods, which methods shall have been transferred from Recro, at Recro s cost, to such independent testing laboratory in accordance with a transfer protocol agreed upon by the Parties. Recro shall bear the fees and expenses of such testing, unless the independent testing laboratory determines that the non-compliance is due solely to the negligence or willful misconduct of Alkermes in which case Alkermes shall bear such fees and expenses. Alkermes agrees to keep, true, accurate and complete records of all retained samples of BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, in accordance with its record retention policies; copies of such records shall be promptly provided to Recro and its representatives upon request.

(d) Replacement of BC Parenteral Meloxicam and Finished Meloxicam. Regardless of whether Alkermes agrees or disagrees with Recro s determination that any Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, does not meet the applicable Specifications, Alkermes shall, at Recro s request, use commercially reasonable efforts to Manufacture replacement BC Parenteral Meloxicam, or Finished Meloxicam, as applicable, in substitution for the potentially non-conforming BC Parenteral Meloxicam, or Finished Meloxicam. Such replacement of BC Parenteral Meloxicam, or Finished Meloxicam, shall be sold by Alkermes and purchased by Recro in accordance with the terms of this Agreement, as Recro may direct, as soon as reasonably possible. In the event that any Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, does not meet the applicable Specifications, including in the case of a Latent Defect determined by the Parties and in the case of the independent testing laboratory determines that the original Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, did not comply with the applicable Specifications, then Alkermes shall render a credit to Recro for such original Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, [***] (but only if Recro has already paid for the original Batch). In the case of a Latent Defect, if the Parties determine or the independent testing laboratory determines that the original Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, did comply with the applicable Specifications at the time of shipment or that any non-compliance was discoverable upon testing permitted by Section 6.4(a), then Recro will pay [***], if it has not done so already. Notwithstanding anything in this Agreement in the contrary, (i) this Section 6.4(d) sets forth Recro s sole remedies in the event that any Batch of BC Parenteral Meloxicam, or Finished Meloxicam, as applicable, does not meet the applicable Specifications and (ii) failure of BC Parenteral Meloxicam or Finished Meloxicam to meet the applicable Specifications shall not be grounds for termination pursuant to Section 10.3(a).

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(e) Rejected BC Parenteral Meloxicam or Finished Meloxicam. Recro may not destroy any Batch of potentially non-conforming BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, until it receives written notification from Alkermes that Alkermes does not dispute that the Batch, or Finished Meloxicam derived therefrom, fails to meet the applicable Specifications and that Alkermes does not request return of such BC Parenteral Meloxicam, or Finished Meloxicam. Alkermes shall be deemed to have accepted Recro s determination that the Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, failed to meet the applicable Specifications if Alkermes does not inform Recro in writing of a dispute with respect to such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, within [***] of receipt of notice from Recro that such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, failed to meet the applicable Specifications. Upon authorization from Alkermes to do so, Recro shall destroy or have destroyed such non-conforming Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, promptly at Alkermes reasonable expense and provide Alkermes with certification of such destruction. Recro shall, upon receipt of Alkermes request for return, promptly return such non-conforming BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, to Alkermes, at Alkermes reasonable expense, for destruction by or on behalf of Alkermes and provide Recro with certification of such destruction. If Alkermes does not instruct Recro as to the return or destruction of such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, within [***] following the determination that such Batch of BC Parenteral Meloxicam, or the Finished Meloxicam derived therefrom, failed to meet the applicable Specifications, or acceptance of Recro s determination with respect thereto, Recro may choose whether to return or destroy such Batch and Alkermes shall reimburse Recro for all expenses with respect thereto.

6.5 Recalls/Recoveries of BC Parenteral Meloxicam and Finished Meloxicam.

(a) Procedure. Each Party shall comply with this Section 6.5 and the applicable Quality Agreement with respect to Recall/Recoveries of BC Parenteral Meloxicam and Finished Meloxicam.

(b) Replacement of BC Parenteral Meloxicam and Finished Meloxicam and Related Costs. If a Recall/Recovery of BC Parenteral Meloxicam or Finished Meloxicam results solely from Alkermes bad faith, gross negligence, willful misconduct, material breach of its obligations under this Agreement, or its failure to comply with applicable Law, Alkermes shall either, at Recro s discretion, [***].

6.6 Complaints and Adverse Event Reporting Regarding BC Parenteral Meloxicam and Finished Meloxicam. Each Party shall comply with the procedures for handling product complaints and reporting adverse events set forth in the applicable Quality Agreement.

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6.7 DMF.

(a) Notwithstanding anything in this Agreement to the contrary, Alkermes will maintain, [***], the DMF and hereby grants Recro and its Sublicensees (i) the right to reference the DMF in the NDA for Finished Meloxicam and (ii) the right to access Confidential Information referenced in the DMF that Alkermes reasonably believes is not highly sensitive, until the time of the technology transfer pursuant to Section 10.4(b), after which the Technology Transfer Information will be transferred to Recro in accordance with Section 10.4(b). During the course of the FDA s review of the NDA for BC Parenteral Meloxicam, Recro and its Sublicensees will inform Alkermes of any comments it receives from the FDA (including indication of deficiencies) regarding the Manufacture of BC Parenteral Meloxicam, and Alkermes will consult with Recro in drafting responses to any such comments, subject to Alkermes right to maintain confidential any proprietary information set forth in the confidential portions of the DMF.

(b) Upon Recro s written request, Alkermes shall permit a Third Party Reviewer to review and comment on the entire DMF and its adequacy to support investigational new drug or NDA filings to be made to the FDA. In no event shall such any such review be conducted hereunder more frequently than once every [***] and all such reviews shall cease upon First Approval. Such Third Party Reviewer must have executed and delivered to Alkermes a confidentiality agreement as reasonably requested by Alkermes, which shall include provisions limiting such reviewer s disclosure to Recro to only the results of such review. Recro shall pay for all such reviews. The Third Party Reviewer shall submit its findings to Alkermes for review and redaction of Confidential Information prior to submitting its findings to Recro. The Third Party Reviewer may submit the redacted findings to Recro. Any information received by Recro pursuant to this Section 6.7, that is not Confidential Information of Recro, shall be deemed to be Confidential Information of Alkermes.

6.8 Intellectual Property.

(a) Recro hereby grants to Alkermes and its Affiliates a non-transferable, non-exclusive, fully paid-up and royalty-free license, without the right to sublicense, under Patents and know-how controlled by Recro and/or Recro s Affiliates solely to the extent necessary to provide the Services hereunder. Alkermes shall exercise such license solely at the Alkermes Facility and solely during the Term.

(b) All Technology, and all Patents and other intellectual property rights arising therefrom, created or conceived (whether solely by one Party or jointly by the Parties, in each case with their Affiliates or any licensees or sublicensees, or any other Third Parties, or any employees, contractors, consultants, representatives or agents of any of the foregoing) in connection with the Services shall be owned by Alkermes (the **Assigned Technology**), except that all Technology, and all Patents and other intellectual property rights arising therefrom, created or conceived (whether solely by one Party or jointly by the Parties, in each

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case with their Affiliates or any licensees or sublicensees, or any other Third Parties, or any employees, contractors, consultants, representatives or agents of any of the foregoing) solely related to BC Parenteral Meloxicam, Finished Meloxicam or Recro s Confidential Information shall be owned by Recro (the **Meloxicam Technology**). Alkermes agrees to assign and hereby assigns to Recro, without further consideration, all right, title and interest Alkermes may have in any Meloxicam Technology. Recro agrees to assign and hereby assigns to Alkermes, without further consideration, all right, title and interest Recro may have in any Assigned Technology. Alkermes hereby grants Recro a license to any Assigned Technology on the terms and conditions of the Nanotechnology License set forth in the Asset Transfer and License Agreement dated April 10, 2015.

6.9 Manufacturing Process Changes. Without limiting Section 5.6(a), each Party shall comply with the applicable Quality Agreement with respect to the change control process to be followed if either Alkermes or Recro desires to change the Manufacturing process or DMF, including the Specifications, or if any applicable Regulatory Authority requires that the Manufacturing process, DMF or the Specifications be changed.

6.10 Licenses and Permits. Alkermes shall secure and maintain in good order such current registrations, permits and licenses as are required by Regulatory Authorities to permit Alkermes to provide the Services, for so long as is necessary to permit Alkermes to perform its obligations under this Agreement.

6.11 Manufacturing Records. Alkermes shall, to the extent such records are available to Alkermes, with respect to each Batch of BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, as applicable, Manufactured by it hereunder, for a period equal to the longer of (i) two (2) years after the expiry of the expiration dating of such Batch of BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, as applicable; (ii) five (5) years after Manufacture of such Batch of BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, as applicable; or (iii) such other period as is required by applicable Laws, rules or regulations of the European Union, United States and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, keep accurate records of the Manufacture of such Batch of BC Parenteral Meloxicam, and Finished Meloxicam derived therefrom, as applicable, including all such records which are required to be maintained under applicable Laws, rules and regulations.

Article 7

Payments

7.1 Payment.

(a) Recro shall pay Alkermes (i) [***] plus (ii) all Third Party expenses incurred by Alkermes with respect to such Services.

(b) For all Services performed with respect to the Clinical Requirements, including such Services performed pursuant to a Work Plan, Recro shall pay Alkermes an

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amount equal to (i) [***].

(c) For all Services performed with respect to the Requirements, including such Services performed pursuant to a Work Plan, Recro shall pay Alkermes an amount equal to (i) Alkermes Fully Burdened Costs with respect thereto plus (ii) [***].

(d) [***].

(e) For clarity, the Existing Batches, together with stability work completed prior to the Closing Date shall be made available by Alkermes to Recro, Ex Works the Alkermes Facility or the relevant Third Party facility, as appropriate, [***].

(f) All invoices under this Agreement shall be delivered in arrears and, subject to Section 7.1(g), Recro will pay such invoices within [***] of receipt of the applicable invoice. Invoices shall be emailed to dnichols@recropharma.com. Invoices shall be itemized and contain information on units of Fully Burdened Costs, relevant Third Party expenses to be reimbursed, time dedicated to performing Services under the Work Plans, time dedicated to performing CMC Development Services, labeling and packaging components, and batch and lot numbers for BC Parenteral Meloxicam produced and Finished Meloxicam derived therefrom.

(g) In the event of a payment dispute, Recro shall notify Alkermes of the same and pay the undisputed portion of the relevant invoice. For the [***] period following receipt of notice from Recro of the payment dispute, the Parties shall seek to resolve such dispute informally. If the Parties are unable to resolve the dispute during such [***] period, Alkermes representative, Noeleen Kenny, Vice President Alliance Management, and Recro s representative, its Chief Financial Officer, shall work together to resolve such dispute. If the aforementioned representatives are unable to resolve the dispute during a further [***] period, then the dispute shall be referred to (i) for Recro, Gerri Henwood, Chief Executive Officer and (ii) for Alkermes, Shane Cooke, President, who shall work together to reach an agreement.

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7.2 Method of Payment. Recro will make all payments when due. Recro shall make all payments hereunder in U.S. dollars by bank wire transfer in immediately available funds to such account as Alkermes may designate before such payment is due, free and clear of any taxes, duties, levies, fees or charges. Any invoice payable pursuant to Section 7.1 or Article 5 that is not paid on or before the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable Law, at the Interest Rate calculated on the number of days such payment is delinquent.

7.3 Taxes. Payments made by Recro for Services provided by Alkermes, or procured by Alkermes from a Third Party, in connection with this Agreement are exclusive of any federal, state, county or municipal sales or use tax, value added tax, excise or similar charge, or other Tax (as defined in the Purchase and Sale Agreement) assessment (other than Income Tax (as defined in the Purchase and Sale Agreement)), which will be additionally payable by Recro in the event that such Tax applies to any of these payments, provided that Alkermes will issue an appropriate invoice to support any such charge. If Recro is required by applicable Law to pay or withhold any Income Tax on behalf of Alkermes with respect to any amounts payable to Alkermes under this Agreement, then (a) Recro shall notify Alkermes of its intention to withhold no later than fifteen (15) days before the payment is due (and such notice shall be sent to the persons designated in Section 13.4); (b) Recro shall deduct the Income Taxes from the amount of such monies due; (c) any such Income Tax required to be paid or withheld shall be an expense of and borne solely by Alkermes; and (d) Recro shall promptly provide Alkermes with a certificate or other documentary evidence to enable Alkermes to support a claim for a refund or a foreign tax credit. Alkermes and Recro agree to cooperate in all respects to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available in order to enable Recro to make such payments to Alkermes without any deduction or withholding of Income Tax. It is understood and agreed that, so long as Alkermes has provided Recro with (i) a properly completed Form W-8BEN-E establishing itself as beneficial owner for purposes of the U.S.-Ireland Treaty of the payments made to Alkermes hereunder and its claim to treaty benefits under Article 7 of the U.S.-Ireland Treaty (relating to Business Profits), and such W-8BEN-E has not expired, Recro shall treat all payments to Alkermes for Services as exempt from withholding of U.S. federal Income Taxes, and (ii) a Form W-8BEN-E upon which Recro may rely to show that the payments made to Alkermes are not subject to FATCA withholding, Recro shall not withhold any amounts under FATCA from payments made to Alkermes hereunder.

Article 8

Financial Record Keeping and Audits

8.1 Record Retention. Alkermes shall keep accurate and complete books and records of accounting pertaining to the Services performed, in sufficient detail to permit Recro to confirm the accuracy of the invoices submitted hereunder. Such records shall be maintained at Alkermes principal place of business for a seven (7) year period following the year in which any such invoices were submitted.

8.2 Audit Request. For the [***] period following the close of each Calendar Year of the Term, Alkermes will, in the event that Recro reasonably requests such access, provide Recro with access once during said period and during regular business hours to audit the records described in Section 8.1 through an independent certified

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accountant selected by Recro, and which is reasonably acceptable to Alkermes, for the sole purposes of confirming the accuracy of the invoices submitted under this Agreement, and assisting in the determination of any payment dispute, in respect of Services provided in the Calendar Year then ended. Such accountant must have executed and delivered to Alkermes a confidentiality agreement as reasonably requested by Alkermes, which shall include provisions limiting such accountant s disclosure to Recro to only the results of such inspection. The results of such inspection, if any, shall be binding on both Parties. Recro shall pay for such inspections, except that in the event that an error in favor of Alkermes of more than [***] of the amounts invoiced for the period covered by the audit is discovered, then Alkermes shall reimburse Recro for any reasonable out-of-pocket costs of such accountant. Further, Alkermes shall make its employees reasonably available to Recro and its accountant for assistance in confirming the accuracy of the invoices submitted under this Agreement and assisting in the determination of any payment dispute. Any information received by Recro pursuant to this Section 8.2, that is not Confidential Information of Recro, shall be deemed to be Confidential Information of Alkermes.

8.3 Survival. This Article 8 shall survive any termination of this Agreement for a period of two (2) years.

Article 9

Representations, Warranties and Covenants

9.1 Mutual Representations and Warranties. Each Party represents, warrants and covenants to the other as follows:

(a) this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against that Party in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other applicable Laws relating to or affecting creditors rights generally and by general equitable principles;

(b) such Party has the right, power and authority to execute, deliver and perform this Agreement;

(c) the execution, delivery and performance of this Agreement does not breach, violate, contravene or constitute a default under any contracts, arrangements or commitments to which such Party is a party or by which it is bound nor do the execution, delivery and performance of this Agreement by such Party violate any applicable Laws or any order or regulation of any court, governmental body or administrative or other agency having authority over it; and

(d) such Party will not enter into any contract, arrangement or commitment in the future which conflicts with or violates any term or provision of this Agreement.

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9.2 Alkermes Representations, Warranties and Covenants. Alkermes represents, warrants and covenants to Recro as follows:

(a) all Services shall (i) to the extent applicable, be in compliance with applicable cGMP; (ii) conform in all material respects to the requirements set forth in this Agreement; and (iii) be performed in a good, professional and workmanlike manner;

(b) Alkermes shall ensure that its personnel adhere to the provisions of this Agreement and have the requisite knowledge, training and ability to perform Services competently and in accordance with the terms of this Agreement;

(c) all BC Parenteral Meloxicam and all Finished Meloxicam shall: (i) not, at the time of shipment hereunder, to the extent applicable, be adulterated or misbranded within the meaning of the U.S. Food, Drug and Cosmetic Act of 1938, as amended from time to time; (ii) conform to the Certificate of Analysis and Compliance supplied with such shipment; (iii) meet the applicable Specifications; (iv) be free of materials that have not been used or stored in accordance with the applicable specifications and/or Law; and (v) be free from liens, claims and encumbrances which affect title;

(d) Alkermes shall comply in all material respects with all (i) Laws and regulations applicable to its activities hereunder; and (ii) requirements of Regulatory Authorities applicable to its activities hereunder; and

(e) (i) none of Alkermes employees performing any Services have been debarred under 21 USC 335(a) (as amended) or 21 USC 335(b) (as amended); and (ii) Alkermes shall promptly notify Recro if Alkermes learns that any person or entity providing Services hereunder has become debarred under 21 USC 335(a) (as amended) or 21 USC 335(b) (as amended) and shall immediately replace such person or entity.

9.3 Recro Representations, Warranties and Covenants. Recro represents, warrants and covenants to Alkermes as follows: Recro shall comply in all material respects with all (a) Laws and regulations applicable to its activities hereunder and (b) requirements of Regulatory Authorities applicable to its activities hereunder.

9.4 No Implied Representations, Warranties, Covenants or Conditions. **EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS, WARRANTIES OR COVENANTS AND THERE ARE NO CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SERVICES, BC PARENTERAL MELOXICAM OR FINISHED MELOXICAM SUPPLIED HEREUNDER, INCLUDING ANY SUCH REPRESENTATIONS, WARRANTIES, COVENANTS OR CONDITIONS WITH RESPECT TO THE NON-INFRINGEMENT OF THIRD PARTY RIGHTS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF SUCH SERVICES, BC PARENTERAL MELOXICAM OR FINISHED MELOXICAM.**

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Article 10

Term; Termination

10.1 Term.

(a) Unless sooner terminated as provided in this Article 10, the term of this Agreement shall begin on the Effective Date and continue until: (a) ten (10) years from the date of the first commercial sale of Finished Meloxicam to a Third Party (the **First-Sale Term**), if the first commercial sale of Finished Meloxicam to a Third Party occurs on or before December 31, 2020 or (b) December 31, 2020, if the first commercial sale of Finished Meloxicam to a Third Party does not occur on or before December 31, 2020 (the foregoing (i) and (ii), collectively, (the **Initial Period**)).

(b) After the First-Sale Term, this Agreement shall automatically renew for successive one (1) year periods (the **Extension Periods**).

10.2 Early Termination not for Material Breach.

(a) During the Initial Period, Recro may terminate this Agreement on one hundred eighty (180) days prior written notice to Alkermes at any time subsequent to the first day on which a product is marketed by a Third Party pursuant to an abbreviated NDA referencing Finished Meloxicam (*i.e.* the date of first generic entry).

(b) Either Party may terminate this Agreement on one hundred (180) days prior written notice during an Extension Period.

(c) At any time following the one (1) year anniversary of the NDA approval for Finished Meloxicam, either Party may terminate this Agreement upon twelve (12) months written notice.

(d) This Agreement shall automatically terminate as of the Reversion Date (as defined in the IP License Agreement).

10.3 Termination upon Material Breach.

(a) Except as otherwise provided herein, if either Party commits a breach of any material provision of this Agreement and the other Party has given the breaching Party written notice of such breach, then the breaching Party shall have thirty (30) days to cure such breach. If such breach is not cured in all material respects within such thirty (30) day period, then the non-breaching Party shall have the right, upon written notice to the breaching Party and without prejudice to any other rights the non-breaching Party may have, to terminate this Agreement, unless the breaching Party is in the process of attempting in good faith to cure such breach, in which case the thirty (30) day cure period shall be extended by an additional thirty (30) days.

(b) Notwithstanding Section 10.3(a), in the event that Recro has failed to pay a material amount to Alkermes for more than sixty (60) days following the date on which such payment was due, and Alkermes provides Recro with written notice of such failure, Recro shall have thirty (30) days to pay such amount, or the undisputed portion thereof. If Recro does not pay such amount within thirty (30) days following written notice from Alkermes, Alkermes may terminate this Agreement upon written notice to Recro.

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10.4 Effects of Termination or Expiration.

(a) BC Parenteral Meloxicam and Finished Meloxicam. Upon expiration or termination of this Agreement, Alkermes will Manufacture and ship to Recro, and Recro will purchase in accordance with the provisions hereof, all BC Parenteral Meloxicam and Finished Meloxicam ordered pursuant to Firm POs issued hereunder prior to the date on which notice of such termination was given, or prior to the expiration date of the Agreement, as applicable.

(b) Technology Transfer. [***].

(c) Capital Equipment.

(i) In the event that during the Term, Alkermes obtained capital equipment pursuant to Section 5.6(b), then upon a technology transfer pursuant to Section 10.4(b), if and only if Recro has paid all expenses with respect to such capital equipment in accordance with Section 5.6(b), then, if Recro so elects by written notice, Alkermes shall ship such capital equipment to Recro or its designated Third Party manufacturer at Recro s expense, including reimbursing Alkermes Fully Burdened Costs and Third Party expenses with respect thereto.

(ii) In the event that during the Term, Alkermes obtained 5kg Capital Equipment pursuant to Section 5.4, then upon Alkermes election by written notice to Recro following a technology transfer pursuant to Section 10.4(b), Recro shall reimburse Alkermes Fully Burdened Costs and Third Party expenses with respect to such 5kg Capital Equipment to the extent such costs have not already

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

been recouped through Recro s payment of Fully Burdened Costs for the BC Parenteral Meloxicam hereunder, and Alkermes shall ship such capital equipment to Recro or its designated Third Party manufacturer, at Recro s expense.

(iii) The disposition of all other capital equipment purchased in connection with providing Services hereunder shall be determined in accordance with the applicable written agreement contemplated by Section 5.5.

(d) Additional Costs. In the event that Recro terminates this Agreement pursuant to Section 10.2 or Alkermes terminates this Agreement pursuant to Section 10.3, Recro shall promptly reimburse Alkermes for any Third Party cancellation fees and other expenses payable by Alkermes that are related to such early termination of this Agreement and are not otherwise recoverable under this Section 10.4.

(e) Accrued Rights and Obligations. Except as otherwise expressly provided in this Agreement, any expiration or termination of this Agreement shall be without prejudice to any rights accrued to the benefit of either Party, and shall not relieve either Party of any obligations accrued, prior to such expiration or termination.

(f) Surviving Provisions. The rights and obligations under Sections 6.2, 6.3, 6.4, 6.5, 6.7, 6.8, 6.11, 9.4, 10.4 and Articles 7, 8, 11, 12 and 13 shall survive any expiration or termination of this Agreement, in each case only in the event and to the extent applicable and subject to the terms and conditions stated therein. In addition, any other provision required to interpret or to enforce the Parties rights and obligations under this Agreement shall also survive, but only to the extent required for the full performance of this Agreement. Any right to terminate this Agreement, and any rights a Party has under this Article 10, as applicable, shall be in addition to and not in lieu of all other rights or remedies that the Party giving notice of termination may have at law or in equity or otherwise.

Article 11

Indemnification / Limitation of Liability

11.1 Indemnification.

(a) Recro Indemnification. Recro hereby agrees to indemnify and hold Alkermes and its Affiliates and their respective employees, directors, agents and contractors, and their respective successors, heirs and assigns and representatives (the **Alkermes Indemnitees**) harmless from and against any and all liabilities, damages, costs, expenses (including reasonable attorneys fees and other expenses of litigation), losses and judgments relating to a Third Party claim, suit, action or demand (collectively, **Losses**) to the extent arising out of or resulting from (i) any material breach of this Agreement by Recro, or (ii) use, manufacture, sale, offer for sale, import or development or commercialization of BC Parenteral Meloxicam or Finished Meloxicam (in each case, Manufactured in accordance with the applicable Specifications) by or for Recro or any of its Sublicensees, including Losses relating to death, personal injury, illness, product liability or property damage or the failure to comply with applicable Law. Third Party claims, suits, actions and demands subject to this Section 11.1(a) shall not include any claims, suits, actions or demands asserted by any Affiliate of Alkermes.

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(b) Alkermes Indemnification. Alkermes hereby agrees to indemnify and hold Recro, its Sublicensees, and their respective employees, directors, agents and contractors, and their respective successors, heirs and assigns and representatives (the **Recro Indemnitees**) harmless from and against all Losses to the extent arising out of or resulting from any material breach of this Agreement by Alkermes. Third Party claims, suits, actions and demands subject to this Section 11.1(b) shall not include any claims, suits, actions or demands asserted by any Affiliate or Sublicensee of Recro.

(c) Procedure. If any Person (each, an **Indemnitee**) intends to claim indemnification under this Section 11.1, the Indemnitee shall notify the other Party (the **Indemnitor**) in writing promptly upon becoming aware of any demand, claim, action or proceeding that may result in Losses (each, a **Claim**) (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall be entitled, by delivery of written notice to the Indemnitee within twenty (20) Business Days of the receipt of notice of a Claim, to assume and control the defense of such Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; *provided that* the Indemnitor shall only be entitled to undertake, conduct and control such settlement or defense if it acknowledges, in writing, to the Indemnitee, its obligation to indemnify the Indemnitee pursuant to the terms and subject to the limitations of this Article 11. An Indemnitee may participate in the defense of such Claim through counsel of its choice, but the cost of such counsel shall be borne solely by the Indemnitee. If the Indemnitor does not assume the defense and control of any Claim pursuant to this Section 11.1(c), the Indemnitee shall be entitled to assume and control such defense through counsel of its own choice, and the reasonable fees and expenses incurred in connection with such defense shall be considered Losses hereunder with respect to the subject matter of such claim, indemnifiable to the extent provided in this Article 11. Notwithstanding any other provision of this Section 11.1(c) to the contrary, no Indemnitee shall be required to waive a conflict of interest under any applicable rules of professional ethics or responsibility if such waiver would be required for a single law firm to defend both the Indemnitor and one or more Indemnitees. In such case, the Indemnitor shall provide a defense of the affected Indemnitees through a separate law firm reasonably acceptable to the affected Indemnitees at the Indemnitor s expense. The Indemnitee shall not settle or compromise any Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise any Claim in any manner which would have an adverse effect on the Indemnitee s interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor s expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be the Confidential Information of the Indemnitee.

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11.2 Insurance.

(a) Coverage. Each Party shall procure and maintain insurance policies for the following coverages with respect to personal injury, bodily injury and property damage arising out of its performance under this Agreement: (i) during the Term, comprehensive general liability, including broad form and contractual liability, in a minimum amount of [***] combined single limit per occurrence and in the aggregate; (ii) during the conduct of clinical trials of BC Parenteral Meloxicam, clinical trials coverage in a minimum amount of [***] combined single limit per occurrence and in the aggregate; and (iii) prior to the first commercial sale of Finished Meloxicam, product liability coverage, in a minimum amount of [***] combined single limit per occurrence and in the aggregate, with the coverage provided for in clause (ii) and clause (iii) to remain in force during the Term and for at least [***] thereafter. Upon request, each Party shall provide the other Party with insurance certificates evidencing the required coverage within thirty (30) days after the Effective Date and the commencement of each policy period and any renewal periods. In the event that any of these policies are written on a claims made basis, then such policies shall be maintained during the Term and for a period of not less than [***] following the termination or expiration of this Agreement. It is understood and agreed that this insurance shall not be construed to limit either Party s liability with respect to its indemnification obligations hereunder.

(b) Rating. The policies of insurance required by this Section 11.2 shall be issued by an insurance carrier with an A.M. Best rating of A or better.

11.3 Limitation of Liability.

(a) No Alkermes Indemnitee or Recro Indemnitee shall be entitled to indemnification pursuant to Section 11.1(a) or 11.1(b), respectively, to the extent that Losses resulted from such Alkermes Indemnitee s or such Recro Indemnitee s (as applicable) bad faith, gross negligence, willful misconduct or failure to comply with applicable Law.

(b) Alkermes liability under this Agreement howsoever arising shall not exceed the amount actually paid for the Services provided hereunder during the [***] period immediately preceding the date of the action or omission alleged to have caused such liability (**Lookback Period**). In no event shall Alkermes cumulative liability under this Agreement at any time exceed the amount actually paid as of such time for the Services provided hereunder. In all cases, for purposes of calculating the limit of liability for purposes of this Section 11.3(b), amounts paid for Services provided hereunder shall exclude any amounts paid by Alkermes to Third Parties in connection with such Services.

(c) Except with respect to liability arising from a breach of Article 12 or indemnification obligations pursuant to Article 11, notwithstanding anything to the contrary contained in this Agreement, neither Party shall have any liability under any provision of this Agreement for any punitive, incidental, consequential, special or indirect damages, including loss of future profits, revenue or income, diminution in value or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement, regardless of whether such damages were foreseeable.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Article 12

Confidential Information

12.1 Confidentiality

(a) The Parties shall refrain from, either alone or in conjunction with any other Person, or directly or indirectly through their Affiliates or Representatives, disclosing to any other Person, or using in any manner, any confidential, proprietary or secret information (**Confidential Information**) of any other Party or such Party s Affiliates; provided that the foregoing obligations of confidentiality and non-use will not apply to any Confidential Information that (i) is or becomes generally available to the public or otherwise part of the public domain and other than through any act or omission of the foregoing Persons or their Affiliates in breach of this Agreement, the Purchase and Sale Agreement, the Ancillary Agreements, the Intellectual Property Transfer and License Agreement or the IP License Agreement, (ii) is disclosed after the date hereof to the foregoing Persons or their Affiliates or Representatives on a non-confidential basis by a Third Party that is not subject to an obligation of confidentiality with respect to such Confidential Information, and (iii) is independently discovered or developed by the foregoing Persons or their Affiliates without the aid, application, or use of such Confidential Information. For clarity, the Parties agrees that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Sections 12.1(b) and 12.1(c) below.

(b) Notwithstanding Section 12.1(a), a Party may disclose the Confidential Information of the other Party in order to comply with (i) applicable non-patent Law (including any securities law or regulation or the rules of a securities exchange); (ii) a request or requirement by deposition, interrogatory, request for documents, subpoena, civil investigation demand or similar process or a formal request from a regulatory examiner, if in the reasonable opinion of counsel, such disclosure is necessary for such compliance (an **External Demand**); and (iii) to its Affiliates, and potential and actual acquirers, merger partners, investors, investment bankers or lenders and their respective counsels and advisors; *provided that*, (A) with regard to disclosure under clause (ii), prior to making such disclosure, the Party subject to such demand or request shall (x) immediately notify the other Party of the existence, terms and circumstances surrounding such External Demand, (y) consult with the other Party on the availability of taking legally available steps to resist or narrow such request or disclosure, and (z) assist the other Party, at the other Party s expense, in seeking a protective order or other appropriate remedy to the extent available under the circumstances and (B) with regard to disclosure under clause (iii), prior to making such disclosure, such entities are bound by commercially reasonable obligations of confidentiality with respect to the use and disclosure of such Confidential Information.

(c) The Parties acknowledge that either or both Parties may be obligated to make filings (including, but not limited to, the filing of a copy of this Agreement) with the SEC or other Governmental Entity. Each Party shall be entitled to make such required filings, provided that it requests confidential treatment of at least the financial terms and sensitive technical terms of this Agreement to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing of this Agreement, the Party making such filing shall provide notice to the other Party with a copy of such disclosure and, if

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applicable, a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment not less than five (5) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), and shall give good faith consideration to the other Party s comments thereon to the extent consistent with the legal requirements. No such notice shall be required under this Section 12.1(c) if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by either Party or otherwise approved by the other Party

(d) The Parties acknowledge that the obligations of confidentiality set forth in this Section 12.1 shall be in addition to, and shall not amend, modify or otherwise limit, any obligations of confidentiality or non-disclosure as set forth in the Purchase and Sale Agreement.

Article 13

Miscellaneous

13.1 Counterparts. This Agreement may be executed in two (2) or more counterparts, all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Parties. This Agreement may be executed and delivered by facsimile or as an attachment to an e-mail and upon such delivery the signature shall be deemed to have the same effect as if the original signature had been delivered to the other Parties.

13.2 Governing Law; Jurisdiction and Forum; Waiver of Jury Trial.

(a) This Agreement, and all claims or causes of action (whether based on contract, tort or any other theory) that may be based upon, arise out of or related to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware applicable to contracts negotiated, made and performed in such State without giving effect to the choice of law principles of such State or other jurisdiction that would require or permit the application of the laws of another jurisdiction.

(b) Each of the Parties hereto irrevocably consents to the exclusive jurisdiction and venue of any court within the State of Delaware in connection with any matter based upon or arising out of this Agreement or the matters contemplated herein, agrees that process may be served upon them in any manner authorized by the laws of the State of Delaware for such Persons and waives and covenants not to assert or plead any objection which they might otherwise have to such jurisdiction, venue and such process.

(c) Each Party knowingly, intentionally and voluntarily waives to the fullest extent permitted by applicable Law trial by jury in any Action brought by any of them against any other arising out of or in any way connected with this Agreement, or any other agreements executed in connection herewith or the administration thereof or any of the transactions contemplated herein or therein. Neither Party shall seek a jury trial in any Action based upon, or arising out of, this Agreement. Neither Party shall seek to consolidate any

such Action in which a jury trial has been waived with any other Action in which a jury trial cannot be or has not been waived. Each Party certifies that it has been induced to enter into this Agreement or instrument by, among other things, the mutual waivers and certifications set forth in this Section 13.2. No Party has in any way agreed with or represented to any other Party that the provisions of this Section 13.2 shall not be fully enforced in all instances.

13.3 Entire Agreement. This Agreement (including the Exhibits to this Agreement), together with the Quality Agreements, contains the entire agreement and understanding among the Parties with respect to the subject matter hereof and supersedes any prior discussion, correspondence, negotiation, proposed term sheet, agreement, understanding or arrangement, and there are no agreements, understandings, representations or warranties among the Parties other than those set forth or referred to in these documents. Neither of the Parties shall be liable or bound to the other Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth in this Agreement (including the Exhibits to this Agreement).

13.4 Notices. All notices and other communications to be given to a Party shall be sufficiently given for all purposes hereunder if in writing and delivered by hand, courier or overnight delivery service or three (3) days after being mailed by certified or registered mail, return receipt requested, with appropriate postage prepaid, or when received in the form of telegram, facsimile or e-mail and shall be directed to the address set forth below (or at such other address or facsimile number as such Party shall designate by like notice):

(a) If to Alkermes:

Alkermes Pharma Ireland Limited

Connaught House

1 Burlington Road

Dublin 4, Ireland

Attn: Noeleen Kenny, Vice President Alliance Management

F: +353 1 7728001

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP

53 State Street

Boston, MA 02109

Attn: Mitchell S. Bloom, Esq.

Robert E. Puopolo, Esq.

Fax No.: (617) 523-1231

and with a copy (which shall not constitute notice) to:

Arthur Cox

Earlsfort Centre

Earlsfort Terrace

Dublin 2, Ireland

Attn: Christopher P.J. McLaughlin

Fax No.: + 353 1 616 3901

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(b) If to Recro:

Recro Pharma, Inc.

490 Lapp Road

Malvern, PA 19355

Attn: Chris Sharr
Gerri Henwood
Email: csharr@recropharma.com
ghenwood@recropharma.com

with a copy (which shall not constitute notice) to:

Pepper Hamilton LLP

Two Logan Square

Eighteenth and Arch Streets

Philadelphia, PA 19103

Attn: Rachael M. Bushey, Esq.

Email: busheyr@pepperlaw.com

13.5 Assignment. This Agreement may not be assigned by a Party, by operation of law or otherwise, without the express written consent of the other Party (which consent may not be unreasonably delayed, conditioned or withheld); provided, however, that (a) a Party may assign, mortgage, charge or dispose of any of its rights or obligations under this Agreement without the prior written consent of the other Party in the event of a merger, sale or similar transaction involving all or substantially all of its assets, provided that doing so does not add any obligations hereunder and (b) either Party may assign this Agreement to an Affiliate.

13.6 Third Party Beneficiaries. This Agreement is not intended to confer upon any Person not a party to this Agreement (and their successors and assigns) any rights or remedies hereunder.

13.7 Amendments and Waivers. This Agreement may not be modified or amended except by an instrument or instruments in writing signed by the Party against whom enforcement of any such modification or amendment is sought. Each Party may, only by an instrument in writing, waive compliance by the other Party with any term or provision of this Agreement on the part of such other Party to be performed or complied with. The waiver by a Party of a breach of any term or provision of this Agreement shall not be construed as a waiver of any subsequent breach.

13.8 Specific Performance. The Parties agree that irreparable damage, for which monetary damages (even if available) would not be an adequate remedy, may occur in the event that Alkermes does not perform any provision of this Agreement with respect to supply of Clinical Requirements in accordance with its specified terms or otherwise breach such provisions. Accordingly, the Parties acknowledge and agree that, to prevent breaches or threatened breaches by Alkemres of any of its covenants or obligations set forth in this

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Agreement with respet to the supply of Clinical Requirements and to enforce specifically the terms and provisions of this Agreement with respect thereto, Recro shall be entitled to seek an injunction, specific performance and other equitable relief to prevent breaches of this Agreement by Alkermes with respect to the supply of Clinical Requirements and to enforce specifically the terms and provisions hereof with respect thereto, in addition to any other remedy to which Recro is entitled in law or in equity; but, in each case, only for so long as is necessary for the Parties to transfer the supply of Clinical Requirements to a Third Party that is reasonably satisfactory to Recro in accordance with Section 10.4(b). Alkermes shall not oppose the granting of an injunction, specific performance and other equitable relief sought by Recro in accordance with this Section 13.8 on the basis that Recro has an adequate remedy at law or that any award of specific performance is not an appropriate remedy for any reason at law or in equity.

13.9 Interpretation; Absence of Presumption. For the purposes of this Agreement, (i) words in the singular shall be held to include the plural and vice versa, and words of one gender shall be held to include the other gender as the context requires; (ii) references to the terms Article, Section, and Exhibit are references to the Articles, Sections and Exhibits to this Agreement unless otherwise specified; (iii) the terms hereof, herein, hereby, hereto, and derivative or similar words refer to this entire Agreement, including the Exhibits hereto; (iv) references to $ or cash shall mean U.S. dollars; (v) the word including and words of similar import when used in this Agreement shall mean including without limitation, unless otherwise specified; (vi) the word or shall not be exclusive; (vii) references to written or in writing include in electronic form; (viii) provisions shall apply, when appropriate, to successive events and transactions; (ix) each Party has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement shall be construed as if drafted jointly by the Parties hereto and no presumption or burden of proof shall arise favoring or burdening a Party by virtue of the authorship of any of the provisions in this Agreement; (x) a reference to any Person includes such Person s successors and permitted assigns; (xi) any reference to days shall mean calendar days unless Business Days are expressly specified; and (xii) when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded and if the last day of such period is not a Business Day, the period shall end at the close of business on the next succeeding Business Day.

13.10 Headings; Definitions. The Section and Article headings contained in this Agreement are inserted for convenience of reference only and shall not affect the meaning or interpretation of this Agreement.

13.11 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement (or portions thereof) shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to a Party. If any provision of this Agreement (or any portion thereof) shall be held to be so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable. Upon a determination that any term, provision, covenant or restriction of this Agreement is invalid, void or unenforceable, the Parties shall

negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

13.12 Force Majeure.

(a) Alkermes shall notify Recro of any circumstances beyond the reasonable control of Alkermes including, but not limited to, war, insurrection, riot, civil commotion, acts of terrorism, act of God, market closure (which is not in the ordinary course of business), fire, water damage, explosion, mechanical breakdown, any law, decree, regulation or order of any government or governmental body (including any court or tribunal), any material interruption in telecommunications, Internet or utilities services that prevents, hinder or delays Alkermes from performing its obligations under this Agreement (a **Force Majeure Event**).

(b) In the event that Alkermes is prevented, hindered or delayed from performing its obligations under this Agreement, in whole or in part, due to a Force Majeure Event, then (i) the affected provisions and/or other requirements of this Agreement shall be suspended to the extent necessary during the period of such disability, and (ii) Alkermes shall have no liability to Recro or any other party in connection with such suspension. Alkermes shall use its commercially reasonable best efforts to resume full performance of this Agreement as soon as reasonably practicable following the conclusion of the Force Majeure Event. From the commencement and during the continuance of a Force Majeure Event, Recro may replace, at its sole expense, any affected Service by providing such Service internally or engaging a Third Party to provide such Service and Alkermes shall reasonably cooperate with such efforts**.**

13.13 Further Assurances. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary, or that the other Party may deem advisable, in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

13.14 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute the Parties as partners, agents or joint venturers. Neither Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied Third Party beneficiaries hereunder (except for purposes of Section 11.1, the Alkermes Indemnitees and the Recro Indemnitees).

13.15 Performance by Affiliates and Subcontractors. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates, provided that notice is given to the other Party in advance. Each Party hereby guarantees the performance by its Affiliates of such Party s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party s Affiliate of any of such Party s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any

obligation to first proceed against such Party s Affiliate. In addition, Alkermes reserves the right to employ subcontractors from time-to-time to undertake certain activities related to the Services as approved by Recro, such approval not to be unreasonably withheld, delayed or conditioned. Recro hereby acknowledges and agrees that Patheon Italy is an approved subcontractor. All subcontractors will be qualified by Alkermes in a manner consistent with the Quality Agreement. All subcontractors will be held under obligations of confidentiality consistent with those set forth in Article 12. Any breach by a subcontractor of Alkermes of any of such Alkermes obligations under this Agreement shall be deemed a breach by Alkermes, and Recro may proceed directly against Alkermes without any obligation to first proceed against Alkermes subcontractor.

[*Remainder of this Page Intentionally Left Blank*]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Richie Paul
(Signature)

Name: Richie Paul

Title: Director

RECRO PHARMA, INC.

By: /s/ Gerri Henwood
(Signature)

Name: Gerri Henwood

Title: President and Chief Executive Officer

[Signature Page to Development, Manufacturing and Supply Agreement]

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Exhibit A

Specifications

Meloxicam NCD Specifications - Bulk

TEST	**SPECIFICATIONS**
	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Meloxicam IV Finished Product Specifications - Vial

TEST	SPECIFICATIONS
	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Exhibit B

Work Plans

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Exhibit C

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Exhibit 10.6

EXECUTION COPY

Date: 26 June 2003

ELAN CORPORATION, PLC.

AND

WATSON LABORATORIES, INC.

AMENDED AND RESTATED

LICENCE AND SUPPLY AGREEMENT

(VERAPAMIL)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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THIS AGREEMENT is made the 26th day of June 2003.

BETWEEN:

(1) **ELAN CORPORATION PLC,** a company incorporated in Ireland having its registered office at Lincoln House, Lincoln Place, Dublin 2, Ireland (**Elan**); and

(2) **WATSON LABORATORIES, INC.**, **as assignee of WATSON PHARMA, INC.** (formerly known as **SCHEIN PHARMACEUTICAL, INC.**), a company organized under the laws of Nevada, with offices at c/o Watson Pharma, Inc., 360 Mt. Kemble Ave., PO Box 1953, Morristown, New Jersey 07962-1953, United States of America (**Watson**).

RECITALS

(A) Elan and Watson Pharma Inc. are parties to a Development, License and Supply Agreement dated 31 March 1998.

(B) The said agreement was amended by Amendments No. 1 through 4 dated 4 September 1998, 1 December 1998, 19 May 1999 and 21 December 2000 respectively.

(C) Pursuant thereto, the Original Agreement (as defined below) relates to transdermal nicotine for prescription use and to generic verapamil and constitutes the terms upon which Elan granted to Watson Pharma, Inc. an exclusive license of the Elan Patent Rights and Elan Know-How to package, import, use, offer for sale and sell those products in the Territory and Elan agreed to supply those products to Watson Pharma, Inc.

(D) Watson Pharma, Inc., has assigned its rights under the Original Agreement to Watson and Watson has assumed all of Watson Pharma, Inc. s obligations under the Original Agreement.

(E) Elan and Watson wish to amend and restate the Original Agreement as it relates to generic verapamil, on the terms and conditions set out below. Simultaneously herewith, Elan and Watson are entering into an Amended and Restated License and Supply Agreement relating to transdermal nicotine.

NOW IT IS HEREBY AGREED AS FOLLOWS:

CLAUSE 1 PRELIMINARY

1.1. **Definitions:** In this Agreement unless the context otherwise requires:

A Rated shall have the meaning as defined and accepted by the FDA.

Affiliate shall mean any corporation or entity controlling or controlled or under common control with Elan or Watson, as the case may be. For the purposes of this Agreement, control shall mean the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors.

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Amendment Date shall mean 26 June 2003.

Biovail shall mean Biovail Corporation International of 2488 Dunwin Drive, Mississauga, Ontario, Canada.

Biovail Settlement Agreement shall mean the Settlement Agreement and Release dated 22 November 1996 between Elan and Biovail.

Biovail Suit shall mean the civil complaint which was prosecuted by Elan against Biovail in the United States District Court for the District of New Jersey captioned Marion Merrell Dow et al v. Biovail Corporation International (and which was settled by Elan and Biovail pursuant to the Biovail Settlement Agreement) whereby, inter alia,

(i) Elan alleged that Biovail had infringed certain of Elan s patents pertaining to drug products containing diltiazem; and

(ii) Biovail had sought to counterclaim that Elan s manufacturing, sale and licensing of a verapamil product under the trademark Verelan infringed patents licensed exclusively to Biovail, which allegation was denied by Elan.

Branded Verapamil shall mean a pharmaceutical product containing sustained release formulations of verapamil hydrochloride in dosage strengths of 120 milligrams, 180 milligrams, 240 milligrams and 360 milligrams which is manufactured by Elan under its NDA 19-614 and is marketed under (i) the Verelan® brand or (ii) any other brand name. Branded Verapamil shall not include Generic Verapamil (as defined below).

cGCP , cGMP , cGLP shall mean respectively current Good Clinical Practice, current Good Manufacturing Practice and current Good Laboratory Practice as defined in the US Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, as may be amended from time to time.

CFR shall mean the US Code of Federal Regulations 21, as amended from time to time.

CMC Section shall mean the chemistry, manufacturing, and controls section of the Regulatory Filing, as defined in the CFR, as may be amended from time to time, and/or its equivalent in other Regulatory Filings.

Date Of First Commercial Sale shall mean the first sale of the Product under the Original Agreement in an arm s length transaction to an independent third party, being 20 May 1999.

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DMF shall mean Drug Master File, as defined in the CFR.

Effective Date shall mean 31 March 1998.

Elan shall mean Elan Corporation, pic and any of its Affiliates.

Elan Know-How shall mean all knowledge, information, trade secrets, data and expertise which is not generally known to the public, owned by Elan, or to which Elan had rights under the terms of a license or licenses in force on the Effective Date which permit(s) disclosure of same to Watson relating to the Product, whether or not covered by any patent, copyright, design patent, trademark, trade secret or other industrial or any intellectual property rights.

In the event that Elan acquires or merges with a third party entity, Elan Know-How shall not include any know-how to the extent that such know-how relates to a product containing the same active ingredient as the DSDF which has been approved for marketing or is in development by the said third party entity at the time of such acquisition or merger. For the avoidance of doubt, the occurrence of any such acquisition or merger shall not affect the license of the Elan Know-How granted to Watson hereunder.

Elan Patent Rights shall mean all patents and patent applications listed in Schedule 2 as said schedule may be amended from time to time by mutual written agreement. Elan Patent Rights shall also include all continuations, continuations-in-part, divisionals, and any patents issuing thereon, and re-issues or re-examinations of such patents and extensions of any patents licensed hereunder. Extensions of patents shall include extensions under the U.S. Patent Term Restoration Act.

In the event that Elan acquires or merges with a third party entity, Elan Patent Rights shall not include any patent rights to the extent that such patent rights relate to a product containing the same active ingredient as the Product which has been approved for marketing or is in development by the said third party entity at the time of such acquisition or merger. For the avoidance of doubt, the occurrence of any such acquisition or merger shall not affect the license of the Elan Patent Rights granted to Watson hereunder.

FCA shall have the same meaning (Free Carrier) as in the ICC Incoterms 2000, International Rules for the Interpretation of Trade Terms, ICC Publication No. 560

FDA shall mean the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the Product in the Territory.

First Generic shall mean the first generic A Rated substitute product for Verelan in the Territory.

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Generic Verapamil shall mean the pharmaceutical product containing sustained release formulations of verapamil hydrochloride in dosage strengths of 120mg, 180mg, 240mg and 360mg manufactured for Elan under its NDA 19-614.

In Market shall mean the sale of the Product in the Territory by Watson or its Affiliates, to an unaffiliated third party, including but not limited to a wholesaler, chain store, distributor, managed care organization, hospital or pharmacy.

Mylan shall mean Mylan Pharmaceuticals, Inc. of Chestnut Ridge Road, Morgantown, Wisconsin 26504, USA.

Mylan Settlement Agreement shall mean the Settlement Agreement, dated September 1998, between Mylan and Elan.

Mylan Suit shall mean the civil action which was prosecuted by Elan and American Cyanamid Company against Mylan in the United States District Court for the Western District of Pennsylvania alleging that Mylan infringed Elan s U.S. Patent No. 4,863,742.

Normal Dosage Form shall mean one or more of strengths of the generic product set forth in Schedule 1.

Marketing Committee shall have the meaning set forth in Clause 8.1.

Net Sales Price (NSP) shall mean in the case of Product sold by Watson or an Affiliate, that sum determined by deducting from the aggregate gross In Market sales proceeds billed for the Product by Watson or its Affiliate, as the case may be, the following deductions:

(a) ordinary course trade, quantity and cash discounts, returns, credits and allowances (including inventory and price protection, chargebacks, volume reimbursements, Medicaid rebates), contract administration fees, if any incurred or granted;

(b) marketing, selling and distribution expenses prorated as to the fraction of the Product s sales relative to total generic Watson sales, subject to a cap of [***] of the sum of the aggregate gross In Market sales proceeds less the deductible items at (a) above;

(c) dedicated direct marketing expenses for the Product associated with activities to increase therapeutic substitution against other products with the same active ingredient, other than the Normal Dosage Form, in order to increase total market share/sales of the Product, limited to [***] of the sum of aggregate gross In Market sales proceeds less the deductible items in (a). Such marketing programs will be developed in consultation with the Marketing Committee.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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NSP shall be calculated on the accrual method of accounting determined in accordance with generally accepted accounting principles and on a basis consistent with Watson s customary practices.

Original Agreement shall mean the Development, License and Supply Agreement between Elan and Watson dated 31 March 1998, as amended by Amendment No. 1 dated 4 September 1998, Amendment No. 2 dated 1 December 1998, Amendment No. 3 dated 19 May 1999 and Amendment No. 4 dated 21 December 2000.

Original Agreement Date shall mean 31 March 1998.

Party shall mean Elan or Watson as the case may be. Parties shall mean Elan and Watson.

Product shall mean the Normal Dosage Strengths of Generic Verapamil, packaged and labeled for sale in the Territory.

Product Manufacturing Cost shall mean the fully allocated cost which is the sum total of all production related costs for the Product (direct labor, direct materials, facility overhead and expenses which can be allocated to the Product, QA/QC and analytical charges, packaging and regulatory compliance costs for the Product including, but not limited to, stability and FDA fees) accounted for in accordance with United States General Accepted Accounting Principles.

Product Specifications shall mean the specifications set forth in the Regulatory Filings, the specifications set forth in this Agreement, and such specifications as may from time to time be established by the applicable regulatory authorities, including without limitation, cGCPs, cGMPs and cGLPs, and such additional specifications for the Product as may be agreed by the Parties in writing.

Profit shall mean NSP less Product Manufacturing Cost.

Regulatory Filing shall include, but shall not be limited to, an abbreviated new drug application (**ANDA**), a new drug application (**NDA**) or any other application acceptable to the FDA for marketing approval for the Product, which Elan has filed in the Territory, including any supplements or amendments thereto.

Schwarz shall mean Schwarz Pharma Inc. of 6140 West Executive Drive, Mequon, Wisconsin 53092, USA.

Verelan shall mean Branded Verapamil marketed under the Verelan® brand name.

Technological Competitor shall mean a company or corporation having a substantial part of its business in the oral drug delivery, research, development and manufacturing areas of the pharmaceutical industry, with a market capitalization of at least [***], in the case of a publicly-held company, or at least [***] of annual revenues, in the case of a privately-held company.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Term shall mean the term of this Agreement, as more fully described in Clause 12.

Territory shall mean the United States of America, its territories and possessions.

$ shall mean United States Dollars.

US or **USA** shall mean the United States of America.

Watson shall mean Watson Laboratories, Inc. and its affiliate, Watson Pharma, Inc.

Watson Trademark shall mean the trademark(s) of Watson to be applied to the Product.

1.2. **Interpretation**: In this Agreement:

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

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

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

CLAUSE 2 THE LICENSE

2.1. **License to Watson**:

2.1.1 Subject to the terms of this Agreement, Elan hereby grants to Watson and Watson hereby accepts for the term of this Agreement an exclusive license of the Elan Patent Rights and the Elan Know-How to package, import, use, offer for sale and sell the Product in the Territory. For the avoidance of doubt, Watson shall have no rights (i) to sell the Product as a Branded Verapamil for prescription or over the counter non-prescription use in the Territory, or (ii) to sell the Product for over the counter non-prescription use in the Territory.

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2.1.2 Elan shall possess all rights including, without limitation, the right to research, develop, experiment with, manufacture, sell, license or otherwise market the Product outside the Territory.

2.1.3 Elan shall neither, directly or indirectly, solicit customers for the Product, or make sales of the Product, or establish or maintain in the Territory any branch or distribution depot for the sale or marketing of the Product in the Territory, or assist any party in doing so. Subject to one agreement which is in existence as of the Effective Date, in all agreements between Elan and its customers, Elan shall (i) use its reasonable endeavors to require such customers to represent, warrant and covenant that such customers shall not directly or indirectly use, market, sell or distribute the Product in the Territory, or assist any other party to do so, and (ii) at such time as Elan learns that such customer is directly or indirectly using, marketing, selling or distributing a Product in the Territory, or that such customer is assisting any other party to do so, then Elan shall immediately notify Watson in writing of such occurrence and immediately cease supplying the Product to such customer.

CLAUSE 3 INTELLECTUAL PROPERTY

3.1. **Ownership of Elan Patent Rights/Know-How**:

3.1.1 Elan shall remain the sole owner of the Elan Patent Rights and Elan Know-How.

3.1.2 Elan shall be entitled to use the Elan Patent Rights and Elan Know-How, and all technical and clinical data whether generated by Elan or Watson pursuant to this Agreement in connection with Elan s other commercial arrangements outside the Territory.

3.2. [Not used]

3.3. **Infringements**:

3.3.1 Watson and Elan shall promptly inform the other in writing of any alleged infringement of which it shall become aware by the Product of a third party s patent rights (**Defense Infringement**) or of any alleged infringement by a third party of any patents within the Elan Patent Rights (**Enforcement Infringement**). The Party with such knowledge shall provide the other Party with any available evidence of alleged infringement.

3.3.2 Subject to the provisions of Clauses 3.3.3 and 3.3.4 of this Agreement, Elan, at its option, shall be entitled to institute proceedings for any alleged Defense Infringement or Enforcement Infringement in respect of any infringements of the Elan Patent Rights with respect to the Product at its own expense and for its own benefit. In the event that Elan does

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not wish to institute such enforcement or defense proceedings, Elan has granted Schwarz the right, at its option and at its sole discretion, subject to the provisions of Clauses 3.3.3 and 3.3.4 of this Agreement, to institute enforcement or defense proceedings at its own expense and for its own benefit. In the event that Elan or Schwarz does not wish to institute such enforcement or defense proceedings, Elan shall promptly notify Watson of such decision and Watson shall, at its option and at its sole discretion, subject to the provisions of Clauses 3.3.3 and 3.3.4 of this Agreement, have the right to institute enforcement or defense proceedings at its own expense and for its own benefit. The non litigating Party shall cooperate with the other Party.

3.3.3. Biovail Settlement Agreement:

3.3.3.1 [***]

3.3.3.2 [***]

3.3.3.3 [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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3.3.3.4 [***]

3.3.3.5 [***]

3.3.4. Mylan Settlement Agreement:

3.3.4.1 [***]

3.3.4.2 [***]

3.3.4.3 [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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3.3.4.4 [***]

3.3.4.5 [***]

3.3.5. [Not used]

3.3.6. [Not used]

3.3.7. Each Party shall provide all reasonable Product technical expertise to the other Party to support any Defense Infringement litigation or Enforcement Infringement litigation (including complying with requests for orders for discovery and depositions).

3.4. **Trademarks**:

3.4.1. Watson may market, sell and/or distribute the Product under any trademark or trademarks as Watson or its customers may from time to time select. Such trademarks shall remain the sole property of Watson or its customers as the case may be, and Elan shall not use any such trademark(s) whether during the term or thereafter, without the prior written consent of Watson.

3.4.2. For the term of this Agreement Watson shall grant Elan a royalty-free license to the applicable Watson Trademarks solely to enable Elan to fulfill its obligations pursuant to the terms of this Agreement.

CLAUSE 4 COMPETING PRODUCTS

4.1. [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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4.2. [Not used]

4.3. [***]

For the avoidance of doubt, with reference to the definition of Elan Patent Rights and Elan Know-How in Clause 1, in the event that Elan acquires or merges with a third party entity, this provision shall have no application to any product containing the same active ingredient as the Product which has been approved for marketing or is in development by the said third party entity.

Elan has licensed Schwarz to sell Verelan in the Territory. The said licence excludes the right of Schwarz to provide for, market or sell a generic substitute of Verelan. Watson hereby acknowledges and confirms that Clause 4.3 of this Agreement shall in no way restrict Elan or Schwarz from selling Verelan in the Territory.

CLAUSE 5 [NOT USED]

CLAUSE 6 [NOT USED]

CLAUSE 7 REGISTRATION OF THE PRODUCT

7.1. [Not used]

7.2. [Not used]

7.3. [Not used]

7.4. [Not used]

7.5. Elan shall be responsible for maintaining all FDA and other approvals necessary for Watson to distribute the Product in the Territory and for Elan to package the Product into final marketing packaging. Watson shall be responsible for obtaining and maintaining all applicable state and local regulatory approvals for the distribution of the Product in the Territory. In the event that Watson packages the Product, Watson shall be responsible for obtaining all FDA and other approvals necessary for Watson to package the Product into final market packaging and to provide Elan with the appropriate documentation relating to the packaging relating to the packaging section of the Verelan FDA Approval. Watson and Elan shall co-operate with one another in obtaining and maintaining such approvals.

7.6. [Not used]

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CLAUSE 8 MARKETING AND PROMOTION OF THE PRODUCT

8.1. The Parties have established a Marketing Committee consisting of at least one representative from each Party who shall act as liaison between the Parties to ensure that Elan is up to date on the prevailing market conditions and Watson s efforts at marketing and selling the Product. Watson shall continue to communicate with Elan regarding its objectives for and performance of the Product in the Territory. At such meetings, Watson shall report on the ongoing sales performance of the Product in the Territory, including marketing approaches, educational campaigns, promotional and advertising materials and campaigns, sales plans and results, performance against competitors, its objectives for the Product and its plans for the next year of this Agreement. In addition the Marketing Committee shall review the quarterly royalty statements and in particular the deductible item (c) listed in the definition of NSP.

8.2. The Marketing Committee shall continue to meet on an annual basis. The Marketing Committee shall meet alternately at the offices of Elan and Watson or as otherwise agreed by the Parties. Each Party shall bear the cost of its own travel expenses.

8.3. Watson shall control and shall be responsible for all decisions regarding the pricing policies and strategies with respect to the marketing and sales of the Product. Watson shall control the format of the promotional campaign to be submitted to the FDA, but shall inform Elan thereof and provide to Elan a copy of such submissions. Watson shall use reasonable efforts to obtain approval by the FDA of the promotional campaign for the Product.

8.4. Watson shall use reasonable efforts consistent with its normal business practices to market and promote the Product throughout the Territory to all appropriate classes of trade and in doing so, shall use the same level of effort as with other similar products of similar sales potential which it markets.

8.5. To the extent permitted by law, all trade packaging, cartons and labels and other printed materials shall include due acknowledgment that the Product is developed and manufactured by Elan. Such acknowledgment shall take into consideration regulatory requirements and Watson s commercial requirements.

8.6. The Parties shall agree whether the Product is to be supplied by Elan in bulk or final market packaged form with the Watson label. If the Product is to be supplied in bulk form, Watson shall be responsible for the packaging of the Product into final market packaging. The Party responsible for packaging the Product shall mark or have marked all patent number(s) in respect of the Elan Patent Rights on all relevant packaging and labeling of the Product, subject to FDA control and regulations of all packaging copy, or otherwise reasonably communicate to the trade the existence of any Elan Patent Rights for the Territory in such a manner as to ensure compliance with, and enforceability under, applicable laws in the Territory

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8.7. [Not used]

8.8. Watson warrants that it shall not use the Product as a loss leader in its marketing programs and shall at all times use its reasonable efforts in marketing the Product.

CLAUSE 9 SUPPLY OF THE PRODUCT

9.1. Save as otherwise provided in this Agreement, Elan shall produce and supply to Watson on an exclusive basis its entire requirements of the Product for the Territory. Elan shall be the sole and exclusive supplier of the Product to Watson in the Territory. Watson shall purchase the Product exclusively from Elan in the Territory unless there is a failure on the part of Elan to supply Product as set out in Clause 9.15.

9.2. The Product to be supplied to Watson by Elan shall be packaged in the galenical form agreed by the Parties prior to the Amendment Date and complying with the Product Specifications. Elan shall deliver the Product to Watson and/or any party designated by Watson in proper packaging so as to permit safe storage and transport.

9.3. Product shall be manufactured by Elan in FDA approved manufacturing facilities containing active ingredients listed in the DMF from FDA approved facilities. Elan shall conduct stability studies to support the shipping container used in the case of bulk Product and post market stability to support Product packaged at Elan.

9.4. Except as otherwise provided herein, all forecasts made hereunder shall be made to assist Elan in planning its production and Watson in planning marketing and sales. Such forecasts shall not be binding purchase orders, and shall be without prejudice to Watson s subsequent firm purchase orders for the Product in accordance with the terms of this Agreement.

9.5. [Not used]

9.6. Elan shall deliver the Product to Watson within 120 days of the receipt of a firm purchase order therefor.

9.7. On or before the 30th day prior to the beginning of each calendar quarter hereafter, Watson shall provide a rolling 4 quarter forecast of its requirements for the Product for the period beginning on the first day of such forthcoming calendar quarter. The first calendar quarter of such 12 months forecast shall be a binding purchase commitment of Watson and shall be formalized by a firm purchase order from Watson to Elan. The remaining non-binding 3 calendar quarters are provided by Watson to Elan for planning purposes only.

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9.8. Elan shall make appropriate manufacturing arrangements in order to be able to supply Watson with between [***] and [***] of the rolling annual forecasted requirements provided by Watson for the Product.

9.9. Elan will use its reasonable efforts to fulfill Watson s requirements in excess of [***] of forecasted amounts, but shall not be obliged to meet such requirements if it is not reasonably practicable to do so provided that Elan shall supply the Product so ordered as soon thereafter as reasonably practicable.

9.10. The minimum batch size for the manufacture and supply of each dosage strength of Product is as set forth on Schedule 5.

9.11. Save as otherwise agreed between the Parties, delivery of consignments of Product shall be effected by Elan FCA Gainesville, Georgia, or such other manufacturing facility(ies) designated by Elan and all risks therein shall pass to Watson when each such consignment of the Product is loaded onto the vehicle of Watson s agent on which it is to be dispatched from the manufacturing facility designated by Elan. Watson shall fully insure or procure the insurance of all consignments of the Product from the time when risk passes as aforesaid and shall produce the supporting insurance when requested by Elan. At Watson s cost, Elan shall arrange for delivery of consignments of Product to Watson s distribution centers in Glenview, Illinois, or such other site as may be specified from time to time in writing by Watson.

9.12. After receipt of a Product shipment, Watson shall visually inspect the Product shipment and communicate rejection of all or part of such shipment as appropriate to Elan in writing. The Parties agree that Watson s visual inspection consists of (i) comparing the applicable order against the documentation accompanying the shipment to verify that the delivery date, identity, quantity and exterior shipment labeling comply with the order and (ii) visually inspecting the exterior of the Product shipment to verify that the shipment appears to be in good condition. Elan is to provide Watson with a copy of a fully executed Certificate of Analysis for each batch of Product shipped to Watson. All claims for failure of any delivery of the Product to conform to Product Specifications under Clause 13 shall be made by Watson to Elan in writing within 45 days following delivery except in the case of defects not identifiable upon visual inspection. Claims for defects not discovered during the visual inspection as set out above, shall be made by Watson to Elan in writing within 30 days of discovery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the delivery.

9.13. Product which has been delivered and which Watson notifies Elan within the period designated in Clause 9.12. does not conform to the Product Specifications shall be replaced at Elan s cost within 90 days of the receipt by Elan of the failed Product except where such non-conformity is due to the negligent acts or omissions of Watson.

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9.14. In the event of an unresolved dispute as to conformity in all material respects of the Product with Product Specifications, the Parties shall within 30 days appoint an independent laboratory to undertake the relevant testing and its findings shall be conclusive and binding upon the Parties. All costs relating to this process shall be borne solely by the unsuccessful Party. In the event that the Product is shown to have complied with the Product Specifications or that the failure to do so is attributable to the negligent acts or omissions of Watson, Watson shall promptly pay Elan for the additional Product supplied.

9.15. [Not used]

9.16. If at any time during the term, Elan is or expects that it will be unable to satisfy Watson s requirements for the Product as ordered by Watson in accordance with the terms of this Agreement, in full or in part, Elan shall promptly notify Watson, detailing the extent to which it will not meet such requirements. If there is a failure by Elan to supply Product, Elan shall (a) use its reasonable endeavors to appoint a third party to manufacture the Product or (b) at Watson s option, supplement its Regulatory Approval to permit Watson to manufacture and package the Product, and provide the information and assistance described in Clauses 12.7.7.2 and 12.7.7.3. In the event that Elan is successful in appointing such a third party, Elan shall invoice Watson at Elan s projected Product Manufacturing Cost and shall bear any additional costs payable to the third party. In the event that Elan or a third party is not in a position to supply the Product and Watson is out of stock for a period of three months Watson may at its option either terminate this Agreement in respect of the Product, or source the Product elsewhere during the period of supply interruption by Elan to ensure that market share position can be maintained. Watson shall make reasonable efforts to minimize purchases of the Product from third parties during the period of supply interruption. In such event and for the duration of third party supply, Elan shall not be entitled to any percentage of the Profit received by Watson on the Product.

9.17. When Elan has remedied the cause of its failure to satisfy Watson s requirements and is once again able to fulfill its obligations to supply the Product, Watson shall cease sourcing the Product from a third party and shall resume purchasing the Product exclusively from Elan pursuant to the terms of this Agreement. Watson shall be entitled to sell the Product on hand which has been manufactured by the third party. No profit share shall be due to Elan for Product sourced by Watson from third parties.

9.18. Elan will grant to Elan Holdings, Inc. or any other subsidiaries of Elan, as necessary or appropriate, a license to the Elan Patent Rights and Elan Know-How and other intellectual property rights necessary for such company or companies to manufacture the Product in accordance with the terms of this Agreement.

9.19. **Expiry Dating**. All Products shall have not more than three (3) months expired from the full shelf life set forth in accordance with the applicable Regulatory Filing, upon receipt by Watson; provided, however, that in the event Watson

agrees to accept Products in bulk, unpackaged form, such Products shall have not more than five (5) months expired from the full shelf life set forth in accordance with the applicable Regulatory Filing, upon receipt by Watson. Notwithstanding the foregoing, in no event shall the expiry date be less than twenty-one (21) months unless mutually agreed in writing or delivery or production is delayed due to Watson s request, or other action directly attributable to Watson.

CLAUSE 10 FINANCIAL PROVISIONS

10.1. [Not used]

10.2. **License Fees**:

In consideration of the license of the Elan Patent Rights and Elan Know-How granted to Watson under this Agreement, Watson has paid to Elan license fees of [***]. For the avoidance of doubt, Watson shall have no obligation to pay any additional license fees for the Product.

10.3. [Not used]

10.4. **Price of Product**:

10.4.1 In the event Elan shall supply the Product to Watson in bulk form, the Product shall be supplied to Watson at Product Manufacturing Cost in accordance with the terms of this Agreement, or in the event that the Product is supplied by Elan to Watson in final market packaged form, such Product shall be supplied to Watson at Product Manufacturing Cost plus [***]. For the avoidance of doubt, in the event the Product is supplied by Elan to Watson in final market packaged form, Product Manufacturing Cost shall include the fully allocated costs of packaging the Product into final market packaged form. The purchase price for the Product as of the date of this Agreement is as set forth on Schedule 6.

In the event that the Product is supplied by Elan to Watson in bulk form, any costs incurred by Watson in packaging the Product into final market packaged form shall not be a deductible expense in calculating the Profit for the Product.

10.4.2 Subject to the following paragraph, the Product Manufacturing Cost may be reviewed by Elan once per annum and may be adjusted for the following calendar year reflecting actual changes in direct manufacturing expenses. Elan shall provide Watson with written notice of any such increase in the Product Manufacturing Cost 60 days before the end of each calendar year to take effect in the following calendar year for new orders submitted by Watson in such calendar year.

10.4.3 Any increases or decreases in the cost of the active ingredient or any other components used in the Product in excess of [***] from the then current base are to be passed on in the Product

Manufacturing Cost manufactured from the effective date of use of such active ingredient or any other component.

10.4.4 Payment for all Product delivered from Elan s manufacturing facility to Watson shall be effected in U.S. Dollars ($) within thirty (30) days of the date of the delivery of the Product FCA the applicable Elan manufacturing facility.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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10.5. **Allocation**:

10.5.1 In consideration of the license of the Elan Patent Rights and the Elan Know-How to Watson hereunder, Watson shall pay royalty to Elan of [***] of Profit.

10.5.2 Within four weeks of the end of each calendar quarter, Watson shall notify Elan of the NSP of Product for that previous calendar quarter. Payments shown by each calendar quarter report to have accrued but which have not yet been paid shall be included in calculating the NSP for that quarter.

10.5.3 Payment of Profit shall be made once in each calendar quarter within 45 days after the expiry of the relevant calendar quarter.

10.5.4 All payments due hereunder shall be made in U.S. Dollars.

10.5.5 In the event that Watson or any Affiliate of Watson shall sell the Product together with other products of Watson to third parties (by the method commonly known in the pharmaceutical industry as bundling), Watson shall not conduct such bundling in such a manner as to discount one or more of the Product at a greater proportion than the other products bundled by Watson.

CLAUSE 11 PAYMENTS, REPORTS AND AUDITS

11.1. In accordance with its ordinary business practice, Watson shall keep true and accurate records of gross sales of the Product, the items deducted from the gross amount in calculating the NSP, the NSP and the royalties payable to Elan under Clause 10. Watson shall deliver to Elan a written statement (**the Statement**) thereof within 28 days following the end of each calendar quarter, (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The Statement shall outline the calculation of the NSP from gross revenues during that calendar quarter, the applicable percentage rate, the units of Product sold, marketing, selling and distribution expenses allocated to the Product and a computation of the sums due to Elan. The format of the Statement shall be as provided in Schedule 6.

11.2. Any income or other taxes which Watson is required by law to pay or withhold on behalf of Elan with respect to royalties and any other monies payable to Elan

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under this Agreement shall be deducted from the amount of such NSP payments, royalties and other monies due. Watson shall furnish Elan with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by Elan. Watson shall promptly provide Elan with a certificate or other documentary evidence to enable Elan to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by Watson. The Parties will reasonably co-operate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable Watson to make such payments to Elan without any deduction or withholding.

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

11.4. Where Elan so requests, to supplement the information available to Elan at the meetings of the Parties pursuant to Clause 8.1, Watson shall provide Elan with quarterly sales reports outlining the status of the Product in the Territory, including a summary of the market share for the Product in its market segment.

11.5. For the 90 day period following the close of each calendar year of this Agreement, Elan and Watson will, in the event that the other Party reasonably requests such access, provide each other s independent certified accountants (reasonably acceptable to the other Party) with access, during regular business hours and subject to the confidentiality provisions as contained in this Agreement, to such Party s books and records relating to the Product, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended.

11.6. In the event of a discovery of a discrepancy which exceeds 5% of the amount due or charged by a Party for any period, the cost of such audit shall be borne by the audited Party; otherwise, such cost shall be borne by the auditing Party.

11.7. If either party disagrees in any respect with the results of such verification, Watson and Elan shall meet to attempt to resolve the disagreement. If they are unable within thirty (30) days to reach a resolution, Watson and Elan shall jointly retain an independent auditor to review Elan s books and records and calculations hereunder and the verification conducted under Clause 11.5 make a final determination regarding any disputed item or items (the **Final Determination**). The decision of such independent auditor with respect to the payments, if any, to be made pursuant to this Clause 11.7 shall be final and binding on the Parties. The costs of such independent auditor shall be borne by the non-prevailing Party if the discrepancy is more than 5% (five percent), and otherwise by the party who requested the audit.

11.8. During normal business hours and provided reasonable notice has been furnished by Watson, Elan shall make (and where relevant shall procure that Elan s

subcontractor shall make) that portion of its manufacturing, testing or storage facility where Product is manufactured, tested or stored, including all record and reference samples relating to the Product available for inspection by Watson s duly qualified person or by the relevant governmental or regulatory authority. The investigation shall be limited to determining whether there is compliance with the Regulatory Filing, cGMP and other requirements of applicable law.

CLAUSE 12 DURATION AND TERMINATION

12.1. This Agreement shall be deemed to have come into force on the Effective Date and, subject to the rights of termination outlined in this Clause 12 will expire on the 5th anniversary of the Amendment Date.

12.2. Thereafter this Agreement shall continue automatically for rolling 1 year periods thereafter, unless this Agreement has been terminated by either of the Parties by serving 90 days written notice on the other immediately prior to the end of the Period set forth in Clause in 12.1 or any additional 1 year period provided for herein.

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

12.3.1 that other Party commits any material breach of any of the provisions of this Agreement, and in the case of a breach capable of remedy, fails to remedy the same within 60 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied; or

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

12.3.3 an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other Party; or

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

12.3.5 the other Party fails to promptly secure or renew any material license, registration, permit, authorization or approval for the conduct of its business in any manner contemplated by this Agreement or if any such material license, registration, permit, authorization or approval is revoked or suspended and not reinstated within sixty (60) days; or

12.3.6 an award is made against Elan and/or Watson in a patent infringement action (which is not appealed, or is unsuccessfully appealed) so that further development or marketing of the Product is prohibited or becomes economically unviable to Elan and/or Watson.

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12.4. In further addition to the rights and termination provided for elsewhere in this Agreement, Elan shall be entitled to terminate the license granted to Watson under this Agreement for the Territory in the event that:

12.4.1 [Not used]; or

12.4.2 [Not used]; or

12.4.3 a Technological Competitor of Elan or a company with a directly competing product acquires 20% or more of Watson s voting stock or where 20% or more of such company s voting stock is acquired by Watson; or

12.4.4 the net price payable to Elan (that is the price of Product and the percentage of Profit) is, or in Elan s reasonable opinion is likely to be, less than [***]; or

12.4.5 if the innovator for the Product acquires more than 20% of Watson s voting stock; or

12.4.6 in the event that Watson should market any Watson Competing Product in the Territory during the term of this Agreement.

12.5. In further addition to the rights and termination provided for elsewhere in this Agreement, Watson shall be entitled to terminate this Agreement for the Territory in the event that:

12.5.1 [Not used]; or

12.5.2 Elan has submitted fraudulent filings to the FDA or has failed to cure non-compliance notices from the FDA or maintain its Regulatory Filings; or

12.5.3 Elan is unable to ship Product for a period of more than 3 months during a given calendar year and Watson has elected not to obtain an alternative source of supply; or

12.5.4 the share of the Net Profits payable to Watson is less than [***] for the said Product for a period of one year.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

12.6. Upon exercise of those rights of termination specified in this Clause 12 or elsewhere in this Agreement, this Agreement shall, subject to the provisions of hereof which survive the termination of this Agreement, automatically terminate forthwith and be of no further legal force or effect.

12.7. Upon termination of this Agreement by either Party, or upon termination by Elan of the license for the Product, the following shall be the consequences:

12.7.1 any sums that were due from Watson to Elan under the provisions of Clause 10 or otherwise howsoever prior to the exercise of the right to terminate this Agreement as set forth herein shall be paid in full within 30 days of termination of this Agreement and Elan shall not be liable to repay to Watson any amount of money paid or payable by Watson to Elan up to the date of the termination of this Agreement;

12.7.2 all confidentiality provisions set out herein shall remain in full force and effect for a period of 5 years from the date of termination of this Agreement;

12.7.3 all responsibilities and warranties shall insofar as appropriate remain in full force and effect;

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

12.7.5 Elan shall be entitled to research, develop and commercialize the Product for its own benefit in the Territory subject to subsection (ii) of Clause 12.7.7;

12.7.6 Watson shall have an ongoing right for a period of six (6) months to sell or otherwise dispose of the stock of any Product on hand as of the date of termination of this Agreement, which such sale shall be subject to Clause 10 and the other applicable terms of this Agreement.

12.7.7 If this Agreement is terminated by Watson due to a breach or default of Elan, then (i) Elan shall covenant not to enforce the Elan Patent Rights against Watson applicable to the Product notwithstanding the termination of this Agreement for the Product or (ii) in the alternative, in consideration for a [***], Elan shall, at the option of Watson:

12.7.7.1 grant to Watson a perpetual, irrevocable and exclusive production and distribution license in the Territory so that Watson may manufacture and sell the Product without infringing any of Elan s patent and/or any other intellectual property rights and amend or supplement its Regulatory Approval for the Product in accordance with Clause 9.16 to permit Watson to manufacture and package the Product.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Watson may sub-license the said production and distribution license to one sub-licensee which is not a competitor of Elan in the drug formulation and/or product delivery business. Any such license shall apply only in regard to the Product as well as to the applications of technology derived from the Elan Patent Rights related to its use with the Product;

12.7.7.2 provide Watson with any technical data necessary for the carrying of this into effect. To this end, Elan shall impart to Watson the documentation constituting the required material support, including, without limitation, practical performance advice, shop practice, specifications as to materials to be used and control methods;

12.7.7.3 assist Watson for the working up and use of the technology necessary to manufacture the Product as well as for the training of Watson s personnel. For this purpose, Elan shall receive Watson s scientific staff in its premises for periods the term of which shall be decided by common consent; and

12.7.7.4 the provisions of Clause 10.5.2 through 10.5.4 of this Agreement regulating the payment of a portion of Profit shall apply as if they referred to the royalty payable under this Clause 12.7.

12.7A Following termination of this Agreement, Watson s right to sell the Product shall terminate, and Watson s right to market and sell the Product shall be limited to depletion of its existing inventory stock of the Product pursuant to the provisions of Clause 12.7.6. In addition, the licenses granted by Elan to Watson to sell the Product and the parties respective non-compete obligations with regard to the Product shall terminate forthwith and shall be of no further force or effect.

12.8. Elan shall be entitled to use the Elan Patent Rights and Elan Know-How, and all technical and clinical data whether generated by Elan or Watson pursuant to this Agreement in the Territory following termination of this Agreement unless termination of this Agreement is due to Elan s breach of its representations, warranties and/or obligations hereunder, and Watson elects to obtain a production license pursuant to subsection (ii) of Clause 12.7.7.

CLAUSE 13 WARRANTY AND INDEMNITY

13.1. Elan represents and warrants as of the Original Agreement Date as follows:

13.1.1. Elan has the sole, exclusive and unencumbered right to grant the license and rights granted herein to Watson, and that it has not granted any option, license or interest in or to the Elan Patent Rights or Elan Know-How to any third party which would conflict with the rights granted by this Agreement. The execution of this Agreement and the full

performance and enjoyment of the rights of Watson under this Agreement will not breach or in any way be inconsistent with the terms and conditions of any license, contract, understanding or agreement, whether express, implied, written or oral between Elan and any third party;

13.1.2. the Product supplied by Elan to Watson under this Agreement will conform to the Product Specifications and regulations governing the conduct of clinical trials and stability requirements;

13.1.3. the Product sold by Elan to Watson pursuant hereto shall be of good, merchantable and usable quality, free of defects, and shall not be adulterated or misbranded within the meaning of the US Food, Drug and Cosmetics Act;

13.1.4. Elan s manufacturing facilities conform in all material respects to applicable laws, regulations and approvals governing such facility and are adequate to produce the quantities of the Product contemplated hereby;

13.1.5. to the best of Elan s knowledge, all bulk active ingredient used in the manufacture of the Product shall be manufactured at an FDA-approved manufacturing facility in accordance with cGMP and current Bulk Drug Substances Guidelines, and shall be in compliance with the applicable specifications under the bulk product monograph.

13.2. Watson represents and warrants as of the Original Agreement Date as follows;

13.2.1. The execution of this Agreement and the full performance and enjoyment of the rights of Elan under this Agreement will not breach or in any way be inconsistent with the terms and conditions of any license, contract, understanding or agreement, whether express, implied, written or oral between Watson and any third party; and

13.2.2. Watson is cognizant in all material respects of all applicable statutes, ordinances and regulations of the Territory with respect to the handling, packaging, storage, distribution, marketing and sale of the Product including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder, including cGLP and cGMP and shall conduct such activities in a manner which complies with such statutes, ordinances, regulations and practices;

13.3. Each of Elan and Watson represents and warrants to the other as of the Original Agreement Date that:

13.3.1. it has such permits, licenses and authorizations of governmental or regulatory authorities as are necessary to own its respective properties, conduct its business and consummate the

transactions contemplated hereby; and

13.3.2. it is not currently debarred, suspended or otherwise excluded by any United States governmental agency from receiving Federal contracts.

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13.4. Except as expressly stated in this Clause 13, all other warranties, conditions and representations, express or implied, statutory or otherwise, including a warranty as to the quality or fitness for any particular purpose of the Product are hereby excluded.

13.5. **Indemnification**:

13.5.1 Elan shall indemnify and hold Watson and its Affiliates harmless from and against any claim, action, suit, proceeding, loss, liability, damage or expense (including without limitation reasonable attorneys fees) arising directly or indirectly as a result of Elan s negligent acts or omission or breach of its representations, warranties, covenants or other obligations hereunder; provided, however that Elan shall not be required to indemnify Watson with respect to any claim, action, suit, proceeding, loss, liability, damage or expense to the extent arising from or related to Watson s breach of its representations, warranties, covenants or other obligations hereunder, or from information supplied by Watson to Elan or contained in regulatory filings or correspondence prepared or delivered by Watson.

13.5.2 Watson shall indemnify and hold Elan harmless from and against any claim, action, suit, proceeding, loss, liability, damage or expense (without limitation reasonable attorneys fees) arising directly or indirectly as a result of Watson s negligent acts or omission or breach of its representations, warranties, covenants or other obligations hereunder, provided; however that Watson shall not be required to indemnify Elan with respect to any claim, action, suit, proceeding, loss, liability, damage or expense to the extent arising from or related to Elan s breach of its representations, warranties, covenants or other obligations hereunder, or from information supplied by Elan to Watson or contained in regulatory filings or correspondence prepared or delivered by Elan.

13.5.3 This Clause 13 and the obligations contained herein shall survive termination of this Agreement, whether pursuant to Clause 12 hereof, by expiration of the Term, or otherwise.

13.6. As a condition of obtaining an indemnity in the circumstances set out in Clauses 13.5, the Party seeking an indemnity shall:

13.6.1 fully and promptly notify the other Party of any claim or proceedings, or threatened claim or proceedings, provided that failure to do so shall not release the indemnifying Party of its obligations under this Clause 13 except to the extent that it is actually prejudiced;

13.6.2 permit the indemnifying Party to take full control of such claim or proceedings;

13.6.3 assist in the investigation and defense of such claim or proceedings;

13.6.4 neither the indemnifying Party or the Party to be indemnified shall compromise or otherwise settle any such claim or proceedings without the prior written consent of the other Party, which consent shall not be unreasonably withheld; and

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

13.7. Notwithstanding anything to the contrary in this Agreement, Elan and Watson shall not be liable to the other by reason of any representation or warranty, condition or other term or any duty of common law, or under the express terms of this Agreement, for any indirect, special, consequential, incidental or punitive loss or damage (whether for loss of profits or otherwise) and whether occasioned by the negligence of the respective Parties, their employees or agents or otherwise except for third party product liability claims.

CLAUSE 14 CUSTOMER COMPLAINTS, PRODUCT RECALL AND INSURANCE

14.1. **Reporting of Adverse Event**.

14.1.1 Watson shall notify Elan within three (3) business days of any complaints from third parties reported to Watson involving any serious and unexpected adverse reactions resulting from the use of the Product in the Territory. Elan shall confirm receipt by return fax to Watson. If Watson does not receive acknowledgment of the adverse event reported, Watson will re-send the report within forty-eight (48) hours and mark the report re-sent. Elan shall notify Watson promptly of any complaints from third parties reported to Elan involving any serious and unexpected adverse reactions resulting from the use of the Product outside of the Territory.

14.1.2 Contact Information. Watson contact information will be provided as follows (and updated as necessary):

Watson Laboratories, Inc.

Attn: Drug Safety (Adverse Events/Complaints)

311 Bonnie Circle

Corona, California 92880

Facsimile (909) 493 5825 OR 5815

Phone 1 800 249 5499 ext. 4399

Elan contact information will be provided as follows (and updated as necessary):

c/o Elan Drug Delivery, Inc.

Attn: Director, Labeling and Drug Safety

1300 Gould Drive

Gainesville, GA 30504

Facsimile (770) 534 8247

Phone (770) 534 8239 ext. 6351

14.1.3 Database Searches. Elan shall provide Watson with data base searches or reports at Watson s request for reconciliation or to fulfill regulatory agency reports.

14.1.4 Training of complaint handling personnel. Personnel handling complaints will be appropriately trained for both. Health care professionals will be employed for contact with reporters for adverse events.

14.1.5 SOPs. Elan will have standard operating procedures reasonably acceptable to Watson relating to handling of adverse events and complaints as agreed herein, including mechanisms for training and ensuring compliance to these and applicable FDA requirements.

14.2. Watson and Elan shall comply with the procedures for formal adverse event handling and reporting set forth in Schedule 4 to this Agreement. Watson and Elan shall keep each other informed and shall copy the other Party with all communications with the FDA and other relevant regulatory agencies with respect to the Product.

14.3. Subject to and without in any way limiting or altering Elan s statutory duties and obligations as the holder of the ANDA, Elan shall consult with Watson when reviewing whether or not to perform a recall of Product and if so, the extent and method of such recall in the Territory.

14.4. In the event of any recall of the Product, as suggested or requested by any governmental authority:

14.4.1 Watson shall perform the recall of the Product in the Territory.

14.4.2

If the recall arises from Watson s acts or omissions in the packaging (where applicable), or the transportation, storage, distribution, marketing or sale of the Product, the recall costs shall be borne by Watson.

14.4.3 If the recall arises from Elan s acts or omissions in the manufacturing and packaging of the Product, the recall costs shall be borne by Elan. In such event, Elan shall be entitled but not obliged to take over and perform the recall of the Product and Watson shall provide Elan at no cost with all such reasonable assistance as may be required by Elan.

14.4.4 If the recall arises from any other reason than set out above, the recall costs shall be borne by Elan and Watson in proportion to the percentage of Profit allocated to the Parties for such Product.

14.5. Watson and Elan shall each maintain in force, during the Term, products liability insurance coverage in minimum limits of $10,000,000 and, upon request, each Party shall furnish to the other a Certificate of Insurance; provided, however to so request such Certificate shall not be deemed a waiver to the Party s obligations hereunder

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CLAUSE 15 MISCELLANEOUS PROVISIONS

15.1. **Secrecy**:

15.1.1 Any information, whether written or oral (oral information shall be reduced to writing within one month by the Party giving the oral information and the written form shall be furnished to the other Party) pertaining to the Product that has been or will be communicated or delivered by Elan to Watson, or by Watson to Elan, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information, shall be treated by Watson and Elan, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this Clause to the extent that such confidential information:

15.1.1.1 is available to the public in public literature or otherwise, or after disclosure by one Party to the other becomes public knowledge through no default of the Party receiving such confidential information; or

15.1.1.2 was known to the Party receiving such confidential information prior to the receipt of such confidential information by such Party, whether received before or after the date of this Agreement; or

15.1.1.3 is obtained by the Party receiving such confidential information from a third party not subject to a requirement of confidentiality with respect to such confidential information; or

15.1.1.4 is required to be disclosed pursuant to: (A) any order of a court having jurisdiction and power to order such information to be released or made public; or (B) any lawful action of a

governmental or regulatory agency provided that each Party shall notify the other in writing of any disclosure of information required under this sub-Clause prior to such disclosure, or

15.1.1.5 is independently discovered by the receiving Party without the aid or application of the confidential information.

15.1.2 Each Party shall take in relation to the confidential information of the other Party all such precautions as it normally takes with its own confidential information to prevent any improper disclosure of such confidential information to any third party; provided, however, that such confidential information may be disclosed within the limits required to obtain any authorization from the applicable FDA or any governmental or regulatory agency or, with the prior written consent of the other Party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.

15.1.3 Each of the Parties agrees that it will not use, directly or indirectly, any know-how of the other Party, or other confidential information disclosed to it by the other Party or obtained by it from the other Party pursuant to this Agreement, other than as expressly provided herein.

15.1.4 Neither Party will publicize the existence of this Agreement in any way without the prior written consent of the other Party subject to the disclosure requirements of applicable laws and regulations. In the event that either Party wishes to make an announcement concerning this Agreement, that Party will seek the consent of the other Party. The terms of any such announcement shall be agreed in good faith but in any event shall refer to the Product as having been developed and manufactured by Elan.

15.2. **Assignments/ Sub-contracting**: Neither Party shall be permitted to assign or sub-license any of its rights under this Agreement without the prior written consent of the other; provided that Elan and Watson may assign this Agreement to an Affiliate without such consent provided that such assignment has no adverse tax implications for the other Party and provided further that such assigning Party is not relieved of its obligations hereunder. Any required consent shall not be unreasonably withheld or conditioned, nor delayed by more than ten (10) business days.

Elan shall also have the right to subcontract all or any portion of the manufacturing or packaging of one or more of the Product to one or more third parties. Each Party shall be responsible for the acts and/or omissions of its respective Affiliates and subcontractors.

15.3. **Parties bound**: This Agreement shall be binding upon and inure for the benefit of Parties hereto, their successors and permitted assigns.

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15.4. **Severability**: If any provision in this Agreement is agreed by the Parties to be, or is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto:-

15.4.1 such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the Parties, it will be deleted, with effect from the date of such agreement or such earlier date as the Parties may agree; and

15.4.2 the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

15.5. **Force Majeure**: Neither Party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of a government authority, non-availability of raw materials, but any such delay or failure shall be remedied by such Party as soon as practicable.

15.6. **Relationship of the Parties**: Nothing contained in this Agreement is intended or is to be construed to constitute Elan and Watson as partners or members of a joint venture or either Party as an employee of the other. Neither Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any third party.

15.7. **Amendments**: No amendment, modification or addition hereto shall be effective or binding on either Party unless set forth in writing and executed by a duly authorized representative of both Parties.

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

15.9. **No effect on other agreements**: No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the Parties unless specifically referred to, and solely to the extent provided, in any such other agreement.

Without prejudice to accrued rights and obligations under the Original Agreement as of the Amendment Date, this Agreement sets forth all of the agreements and understandings between the parties with respect to the subject matter hereof, and supersede and terminate all prior agreements and understandings between the parties with respect to the subject matter hereof, but without prejudice to any accrued rights and obligations thereunder. There are no agreements or understandings with respect to the subject matter hereof, either oral or written, between the parties other than as set forth in this Agreement.

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15.10. **Applicable Law and Jurisdiction**: This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to principles of conflicts of law. For the purpose of this Agreement the Parties agree that any dispute shall be adjudicated upon and hereby submit to the jurisdiction of the United States District Court for the Southern District of the State of New York. Each Party consents to service of process pursuant to the notice provisions of this Agreement.

15.11. **Notice**:

15.11.1 Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or fax to:

Elan at

Elan Corporation, plc.

c/o Elan International Services Ltd.

102 St. James Court

Flatts, Smiths FL04

Bermuda

Attention: Secretary

Fax: +1 441 292 2224

Watson at

c/o Watson Pharma, Inc.

360 Mt. Kemble Ave.

PO Box 1953

Morristown, New Jersey 07962-1953

United States of America

Attention: President and Chief Operating Officer

Fax: 1 973 593 5820

With a copy to:

Watson Pharmaceuticals, Inc.

311 Bonnie Circle

Corona, California 92880

Attention: General Counsel

Facsimile No.: (909) 279-8094

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

15.11.2 Any notice sent by registered air mail shall be deemed to have been delivered within 7 working days after dispatch and any notice sent by fax shall be deemed to have been delivered within 24 hours of the time of the dispatch. Notice of change of address shall be effective upon receipt.

15.12. [Not used]

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IN WITNESS of which the Parties have executed this Agreement.

SIGNED

/s/ [Illegible]

for and on behalf of
ELAN CORPORATION, PLC.

SIGNED

/s/ [Illegible]

for and on behalf of
WATSON LABORATORIES, INC.

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SCHEDULE 1 NORMAL DOSAGE FORMS

Generic Verapamil (as defined herein), limited to generic prescription use.

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SCHEDULE 2 PATENT RIGHTS

U.S. 4,863,742

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SCHEDULE 3 [NOT USED]

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SCHEDULE 4 COMPLAINT HANDLING PROCEDURES AND RECALLS

The purpose of this appendix is to establish written procedures for the communication and processing of product complaints, which includes adverse drug reactions, and recalls.

Acting in accord with this Agreement will facilitate compliance with Federal Requirements as set forth in 21 CFR 211.198 (complaint files) and 21 CFR 310.305/21 CFR 314.80 (postmarketing reporting of adverse drug reactions).

COMPLAINT COMMUNICATION AND REPORTING

All communications will be performed via facsimile within three working days of receipt of the information/complaint, except where stated otherwise.

(A) Complaints reports received by Watson will be documented using the Product Quality Report Form (attached) and followed up using Watson s existing S.O.P. A copy of the Watson complaint form will be forwarded to Elan.

(B) Complaints reported directly by Elan involving marketed batches of Product in the Territory will be documented through the use of Elan s form. A copy of Elan s complaint form will be sent to: Drug Safety (Adverse Events/Complaints) at Watson.

(C) Complaint reports which may meet Field Alert Report Criteria [21 CFR 314.81 (b)(1)] will be communicated via facsimile to the Regulatory Filing holder within one working day.

(D) Adverse drug reaction complaints will be reported by the recipient to the Regulatory Filing holder, who will be responsible for completing and submitting the adverse reaction form to the FDA in a timely manner.

COMPLAINT INVESTIGATION:

(A) Watson will investigate all Product complaints associated with labeling, handling and any other aspect under Watson s control.

(B) Elan will investigate all complaints associated with Product quality, other than the above.

(C) Elan will provide a written summary of its investigation of B above to Watson s Director of Regulatory & Professional Affairs within 30 days of either Party receiving the complaint.

COMMUNICATION WITH COMPLAINANT

Watson will be responsible for the final response to the complainant, based on the summary forwarded from Elan (for product quality problems) or on Watson s own investigations (for labeling, packaging problems, etc.).

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If a complaint involves both product quality concerns and other aspects, such as labeling problems, Elan and Watson will share information and develop a mutually acceptable final response, to be sent by Watson. Watson will forward a copy of all final complaint responses to Elan on the day the response is sent to the complainant.

PRODUCT RECALL

Any recall of Product will be agreed upon by both Parties. The Regulatory Filing holder will be responsible for initiating and ensuring that all aspects of a drug recall are carried out by the agreed upon Party, including communicating with the FDA, notifying customers, performing the recall effectiveness check, and submitting monthly reports. Both Parties will co-operate fully in recalling any Product.

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SCHEDULE 5 MINIMUM BATCH SIZES

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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SCHEDULE 6 PRICES

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SCHEDULE 7 FORM OF FINANCIAL STATEMENT

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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Exhibit 10.7

SUPPLEMENTAL AGREEMENT

Between:

(1) **ELAN CORPORATION, PLC**, a company incorporated in Ireland having its registered office at Lincoln House, Lincoln Place, Dublin 2, Ireland (**Elan**); and

(2) **WATSON LABORATORIES, INC.,** as assignee of **WATSON PHARMA, INC.** (formerly known as **SCHEIN PHARMACEUTICAL, INC.**), a company organized under the laws of Nevada, with offices at c/o Watson Pharma, Inc., 360 Mt. Kemble Ave., PO Box 1953, Morristown, New Jersey 07962-1953, United of America (hereinafter called **Watson**)

This Agreement replaces Clause 14 and Schedule 4 of the AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT (VERAPAMIL), dated 26th day of June, 2003 (hereinafter called the **Principal Agreement**).

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Elan and Watson agree as follows:

A Defined terms used in this Supplemental Agreement shall have the meaning assigned to them in the Principal Agreement unless such terms are specifically defined in this Supplemental Agreement.

B. CLAUSE 14 and SCHEDULE 4 of the Principal Agreement are hereby replaced with the following:

Supplemental Agreement

The purpose of this Supplemental Agreement is to establish written procedures for the communication and processing of customer Product complaints (i.e., technical/non-medical complaints and adverse events), and Product recalls.

This Supplemental Agreement will facilitate compliance with U.S. Federal Requirements as set forth in US Code of Federal Regulations (CFR) 21 CFR 211.198 (Complaint Files) and post marketing adverse drug experience (PADE) regulations (21 CFR 310.305, 314.80 and 314.98).

1 POLICY AND RESPONSIBILITIES

1.1. It is Elan s policy to collect and evaluate reports of adverse events that occur in relation to produces for which Elan is the application (e.g., New Drug Application (NDA), Abbreviated New Drug Application (ANDA) holder). This is performed in order to assess the validity and significance of alleged adverse event reports and to take appropriate action in order to comply with relevant ethical and/or legal obligations.

2 ADVERSE EVENTS

2.1. Adverse events will be handled in accordance with the Elan and Watson Adverse Event Processing Agreement, effective April 5, 2004, or any future updates to the Adverse Event Processing Agreement, as mutually agreed upon by both Parties.

2.2. For adverse events, including lack of efficacy reports, it will be the responsibility of Elan to assess the need for a quality investigation and to conduct such an investigation, as warranted. When an investigation is warranted, Elan will provide a written summary of their investigation to Watson s complaint operations department within thirty (30) days.

3 TECHNICAL/NON-MED1CAL PRODUCT COMPLAINTS

3.1.

Product complaints (technical, non-medical events), received by Watson will be documented and followed up using Watson s existing Standard Operating Procedure(s). Watson Corporate Quality Complaint Operations (CQCO) will forward the complaints for investigation to:

Elan Holdings, Inc.
ATTN: Director, Quality Assurance
1300 Gould Drive
Gainesville, GA 30504
Telephone No.: (770) 538-6344
Fax No.: (770) 534-1534

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3.2. Elan will be responsible for investigating all Product complaints associated with the quality of the drug specific dosage form (DSDF), labeling, packaging, handling, and any other aspects under Elan s control.

3.3. Elan will provide a written summary of their investigation to Watson s complaint operations department within thirty (30) days of either Party receiving Product complaint.

3.4. Watson will be responsible for the final response to the complainant, based on the summary forwarded from Elan.

3.5. Complaint reports received by Elan involving United States (U.S.) marketed batches of Product will be documented. Copies of complaint reports will be sent to:

Technical/Non-medical Product Complaints:

Watson Laboratories, Inc.
ATTN: Manager, Complaint Operations
311 Bonnie Circle
Corona, California 92880
Telephone No.: (951) 493-4039
Fax No.: (951) 493-5872

Adverse Events:

Watson Laboratories, Inc.
ATTN: Drug Safely- Adverse Events
311 Bonnie Circle
Corona, California 92880
Fax: (951) 493-5825

3.6. Complaint reports obtained by Watson which meet field alert report criteria [21 CFR 314.81 (b)(l)] will be communicated via facsimile within one (1) working day to:

Elan Drug Delivery, Inc.
ATTN: Sr. Director, Regulatory Affairs
1300 Gould Drive
Gainesville, GA 30504, USA
Telephone No.: (770) 534-8239
Fax No.: (770) 531-0835

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4 PRODUCT RECALL:

4.1. Both Watson and Elan will cooperate fully in recalling any Product. Costs and responsibilities associated with a recall are described as follows:

4.1.1. Subject to and without in any way limiting or altering Elan s statutory duties and obligations as the holder of the NDA. Elan shall consult with Watson when reviewing whether or not to perform a recall of Product and if so, the extent and method of such recall in the Territory.

4.1.2. In the event of any recall of the Product, as suggested or requested by any governmental authority:

4.1.2.1 Watson shall perform the recall of the Product in the Territory.

4.1.2.2 If the recall arises from Watson s acts or omissions in the packaging (where applicable), or the transportation, storage, distribution, marketing or sale of the Product, the recall costs shall be borne by Watson.

4.1.2.3 If the recall arises from Elan s acts or omissions in the manufacturing and packaging of the Product, the recall costs shall be borne by Elan. In such event, Elan shall be entitled but not obliged to take over and perform the recall of the Product and Watson shall provide Elan at no cost with all such reasonable assistance as may be required by Elan.

4.1.2.4 If the recall arises from any other reason than set out above, the recall costs shall be borne by Elan and Watson in proportion to the percentage of Profit allocated to the Parties from such Product.

4.1.3. Watson and Elan shall each maintain in force, during the Term, products liability insurance coverage in minimum amounts of $10,000,000 and, upon request, each Party shall furnish to the other a Certificate of Insurance; provided, however to so request such Certificate shall not be deemed a waiver to the Party s obligations hereunder.

4.1.4. Any recall of Product will be agreed upon by both Parties. The Regulatory Filing holder will be responsible for initiating and ensuring that all aspects of a drug recall are carried out by the agreed upon Party, including communicating with the FDA, notifying customers, performing the recall effectiveness check, and submitting monthly reports. Both Parties will co-operate fully in recalling any Product.

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5 MEETINGS

5.1. Representatives from Watson and Elan shall meet on an as needed basis or the occurrence of certain eventualities including, but not limited to:

5.1.1. a serious adverse event(s) involving actual or threatening litigation, or

5.1.2. significant modifications to the package insert.

5.2. Upon reasonable prior written notice and during normal business hours representatives from Elan may meet with Watson to annually assess Watson s Product complaint handling system. On site assessment will consist of an examination of applicable portions of Watson s Product complaint/adverse event handling procedures pertaining to the Product and to Watson s responsibilities as per this agreement.

6 MISCELLANEOUS PROVISIONS

6.1. Except as modified herein, all of the covenants, terms and conditions of the Principal Agreement remain in full force and effect and are hereby gratified and reaffirmed in all respects. In the event of any conflicts, inconsistency or incongruity between the terms and conditions of this Supplemental Agreement and the covenants, terms and conditions of the Principal Agreement, the terms and conditions of this Supplemental Agreement shall govern and control.

6.2. This Supplemental Agreement may be executed in two or more counterparts, each of which together shall contribute an original an original but which, when taken together, shall constitute but one instrument and shall become effective when copies hereof, when taken together, bear the signature of all required parties and persons.

In Witness Whereof this Supplement Agreement is executed as of the date of the last Party to sign below.

ELAN CORPORATION, PLC	WATSON LABORATORIES, INC.
BY: /s/ Paul Breen	BY: /s/ Gordon Munro
NAME: Paul Breen	NAME: Gordon Munro
TITLE: Executive Vice President	TITLE: Senior VP of [Illegible]
DATE: 8/12/2004	DATE: 11/18/2004

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Exhibit 10.8

SUPPLEMENTAL AGREEMENT NO. 2

TO THE

AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

(GENERIC VERAPAMIL)

This Supplemental Agreement No. 2 to the Amended and Restated License and Supply Agreement (Generic Verapamil) (**Supplemental Agreement No. 2**) is made the 17th day of January 2014 (**Supplemental Agreement No. 2 Effective Date**).

BETWEEN

(i) **Alkermes Pharma Ireland Limited**, as successor of Elan Corporation plc and Elan Pharma International Limited (hereinafter **Alkermes**)

and

(ii) **Watson Laboratories, Inc.**, as assignee of Watson Pharma, Inc., formerly known as Schein Pharmaceutical, Inc., a Nevada corporation (hereinafter **Watson**),

RECITALS

(A) On June 26, 2003, Elan Corporation pic and Watson entered into an Amended and Restated License and Supply Agreement relating to the license and sale of generic Verapamil in the United States. This agreement was subsequently amended by a Supplemental Agreement, which became effective on December 8, 2004. The Amended and Restated License and Supply Agreement, as amended by the Supplemental Agreement, is hereinafter referred to as the **Principal Agreement** .

(B) Since the execution of the Principal Agreement, (i) there has been the acquisition of Andrx Corporation on November 3, 2006 (the **Acquisition Date**) by the parent company of Watson, which included Anda Inc. and Valmed Pharmaceutical, Inc., both wholesale distributors of pharmaceutical products and now, along with Watson, all wholly owned subsidiaries of Actavis plc, and (ii) Elan assigned its rights, title and interest in the Principal Agreement to EDT Pharma Holdings Limited, which subsequently changed its name to Alkermes Pharma Ireland Limited. The FDA has also now imposed an annual pharmaceutical industry fee on Watson in reference to product sales, which is attributable in part to sales of Generic Verapamil.

(C) As a result of the above commercial developments, Alkermes and Watson wish to make certain changes to the Principal Agreement in accordance with the terms and conditions set out below.

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NOW IT IS HEREBY AGREED AS FOLLOWS:

1. Defined terms used in this Supplemental Agreement No 2 shall have the meaning assigned to them in the Principal Agreement unless such terms are specifically defined herein.

2. The Principal Agreement is hereby amended to add the following language, as a separate paragraph, after the definition of Affiliate in Section 1.1 entitled **Definitions:**

Notwithstanding the foregoing, for the purposes of this Principal Agreement, a Wholesaler Affiliate shall not constitute an Affiliate of Watson.

3. The Principal Agreement is hereby amended to add the following language, as a separate paragraph, after the definition of **In Market** in Section 1.1 entitled **Definitions** :

Industry Fees shall mean compulsory payments and cash rebates related to the sales of such Product paid to a government authority (or agent thereof) pursuant to the Patient Protection and Affordable Care Act as amended by the Health Care Education Affordability Reconciliation Act, to the extent allowed and taken.

4. The Principal Agreement is hereby amended to add the following additional subparagraph in the definition of **Net Sales Price** after subparagraph (c) in Section 1.1 entitled **Definitions** :

(d) The portion of the Industry Fees attributable to sales of authorized Generic Verapamil. (such Industry Fee calculated as follows: authorised Generic Verapamil sales, divided by Total branded prescription drug sales (as defined by section 9008 of the Act) for all of Watson s products, multiplied by Waton s final Industry Fees amount.)

5. The Principal Agreement is hereby amended by deleting the final subparagraph in the definition of Net Sales Price in Section 1.1 entitled **Definitions** and replacing it in its entirety with the following paragraph:

NSP shall be determined on an accrual method of accounting determined in accordance with generally accepted accounting principles and on a basis consistent with Watson s customary practices (except for the Industry Fees which is classified as an operating expense for GAAP purposes).

6. The Principal Agreement is hereby amended to add the following language, as a separate paragraph, after the definition of **Net Sales Price** in Section 1.1 entitled **Definitions** :

Notwithstanding the foregoing, for any sales by a Wholesaler Affiliate, NSP shall be calculated using the current quarters Watson Net Average Sales Price multiplied by the units shipped by Watson or its Affiliates to the Wholesaler Affiliate.

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7. The Principal Agreement is hereby amended to add the following new definition, as a separate paragraph, after the definition of Watson in Section 1.1 entitled **Definitions** :

Watson Net Average Sales Price shall mean Watson Net Sales in dollars (excluding sales by Wholesaler Affiliate) per strength divided by the number of units sold per strength. (excluding units sold by Wholesaler Affiliate)

8. The Principal Agreement is hereby amended to add the following language, as a separate paragraph, after the definition of Watson Trademark in Section 1.1 entitled **Definitions**:

Wholesaler Affiliate shall mean a subsidiary or affiliate of Watson whose primary business is wholesale distribution of pharmaceutical products, shall mean each of Anda, Inc. and Valmed Pharmaceutical, Inc., substantially all of the business of which consists of the wholesale distribution of pharmaceutical products.

9. Section 15.11 of the Principal Agreement shall be amended as follows:

The Elan contact details shall be replaced with the following Alkermes contact details:

Alkermes Pharma Ireland Limited

Connaught House

1 Burlington Road

Dublin 4

Ireland

Attention: Company Secretary

Fax: +353 (1) 772 8001

With a copy to: Vice President, Alliance Management

Fax:+353 (0)1 772 8001

10. Except as specifically amended by this Supplemental Agreement No 2, all terms and conditions of the Principal Agreement remain in full force and effect, and this Supplemental Agreement No 2 shall be deemed to be a part of the Principal Agreement.

11. This Supplemental Agreement No. 2 may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe® PDF sent by electronic mail shall be deemed to be original signatures (with actual originals for each party to follow for their permanent records).

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IN WITNESS WHEREOF, the parties hereto have caused this Supplemental Agreement No. 2 to be duly executed and delivered on the dates set forth below their signature lines, effective as of the Supplemental Agreement No. 2 Effective Date.

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Shane Cooke
Name: Shane Cooke
Title: Director
Date: 31/1/14

WATSON LABORATORIES, INC.

By: /s/ Fred Wilkinson
Name: Fred Wilkinson
Title: President, Global Brands
Date: 1/17/14

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Exhibit 21.1

LIST OF SUBSIDIARIES

Subsidiary	Ownership Percentage	Jurisdiction of Incorporation or Organization
Recro Gainesville LLC	100%	Massachusetts
Recro Enterprises, Inc.	100%	Delaware
Recro Ireland Limited	100%	Ireland
Recro Technology LLC	100%	Delaware

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Exhibit 31.1

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Quarterly Report of Recro Pharma, Inc.;

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 officers 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)) 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) 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

   (c) 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.

5. The registrant s other certifying officers 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 function):

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

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

Date: August 14, 2015

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

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Exhibit 31.2

CERTIFICATION

I, Charles Garner, certify that:

1. I have reviewed this Quarterly Report of Recro Pharma, Inc.;

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 officers 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)) 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) 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

   (c) 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.

5. The registrant s other certifying officers 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 function):

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

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

Date: August 14, 2015

/s/ Charles Garner
Charles Garner
Chief Financial Officer
(Principal Financial Officer)

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Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Recro Pharma, Inc. (the Company) on Form 10-Q for the quarter ended June 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the Report), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer s knowledge:

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

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

Date: August 14, 2015

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Charles Garner
Charles Garner
Chief Financial Officer
(Principal Financial Officer)