UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended: June 30, 2017

☐ **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 ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section13(a) of the Exchange Act. ☒

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

As of August 9, 2017, there were 19,059,604 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, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 8,728	$ 64,483
Short-term investments	41,517	—
Accounts receivable	10,102	10,411
Inventory	6,888	8,746
Prepaid expenses and other current assets	2,572	1,118
Total current assets	69,807	84,758
Property, plant and equipment, net	37,638	37,300
Deferred income taxes	19,777	17,060
Intangible assets, net	36,141	37,433
Goodwill	6,446	6,446
Total assets	$ 169,809	$ 182,997
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,421	$ 4,132
Accrued expenses and other current liabilities	6,551	9,893
Current portion of long-term debt, net	2,057	2,236
Total current liabilities	12,029	16,261
Long-term debt, net	22,657	22,152
Warrants and other long-term liabilities	2,788	3,397
Contingent consideration	75,347	69,574
Total liabilities	112,821	111,384
Commitments and contingencies (Note 13)		
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, 19,054,566 shares at June 30, 2017 and 19,043,216 shares at December 31, 2016	191	190
Additional paid-in capital	135,083	132,691
Accumulated deficit	(78,210)	(61,268)
Accumulated other comprehensive loss	(76)	—
Total shareholders' equity	56,988	71,613
Total liabilities and shareholders' equity	$ 169,809	$ 182,997

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 16,750	$ 16,933	$ 34,878	$ 34,072
Research and development revenue	184	346	798	949
Total revenues	16,934	17,279	35,676	35,021
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	10,448	9,547	20,946	19,818
Research and development	7,073	8,320	14,836	16,129
General and administrative	6,322	2,763	10,354	5,421
Amortization of intangible assets	646	646	1,292	1,291
Change in warrant valuation	(1,084)	1,240	(793)	(354)
Change in contingent consideration valuation	2,959	1,534	5,773	4,512
Total operating expenses	26,364	24,050	52,408	46,817
Operating loss	(9,430)	(6,771)	(16,732)	(11,796)
Other income (expense):				
Interest income	117	8	222	17
Interest expense	(1,207)	(1,317)	(2,390)	(2,829)
Net loss before income taxes	(10,520)	(8,080)	(18,900)	(14,608)
Income tax benefit	1,665	195	1,958	184
Net loss	$ (8,855)	$ (7,885)	$ (16,942)	$ (14,424)
Per share information:				
Net loss per share of common stock, basic	$ (0.46)	$ (0.83)	$ (0.89)	$ (1.53)
Net loss per share of common stock, diluted	$ (0.48)	$ (0.83)	$ (0.89)	$ (1.53)
Weighted average common shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Weighted average common shares outstanding, diluted	19,220,700	9,544,629	19,220,175	9,398,288
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(19)	—	(76)	—
Comprehensive loss	$ (8,874)	$ (7,885)	$ (17,018)	$ (14,424)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Shareholders' Equity
For the Six Months Ended June 30, 2017
(Unaudited)

(amounts in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2016	19,043,216	190	132,691	(61,268)	—	71,613
Stock-based compensation expense	—	—	2,370	—	—	2,370
Stock option exercise	3,600	1	22	—	—	23
Issuance of restricted stock units	7,750	—	—	—	—	—
Other comprehensive loss	—	—	—	—	(76)	(76)
Net loss	—	—		(16,942)	—	(16,942)
Balance, June 30, 2017	19,054,566	$ 191	$ 135,083	$ (78,210)	$ (76)	$ 56,988

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(Unaudited)

(amounts in thousands)	For the Six Months Ended June 30, 2017	2016
Cash flows from operating activities:		
Net loss	$ (16,942)	$ (14,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,370	1,430
Non-cash interest expense	326	449
Depreciation expense	2,424	2,511
Amortization	1,292	1,291
Acquired in-process research & development charges	766	—
Change in warrant valuation	(793)	(354)
Change in contingent consideration valuation	5,773	4,512
Deferred income taxes	(2,717)	(1,007)
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	1,858	2,254
Prepaid expenses and other current assets	(1,454)	(1,098)
Accounts receivable	309	(2,887)
Accounts payable, accrued expenses and other liabilities	(4,194)	1,928
Net cash used in operating activities	(10,982)	(5,395)
Cash flows from investing activities:		
Purchase of property and equipment	(3,185)	(1,081)
Purchase of short-term investments	(53,593)	—
Proceeds from maturity/redemption of investments	12,000	—
Acquisition of license agreement	(18)	—
Net cash used in investing activities	(44,796)	(1,081)
Cash flows from financing activities:		
Proceeds from Aspire facility	—	4,175
Payments on long-term debt	—	(2,633)
Proceeds from option exercise	23	—
Net cash provided by financing activities	23	1,542
Net decrease in cash and cash equivalents	(55,755)	(4,934)
Cash and cash equivalents, beginning of period	64,483	19,779
Cash and cash equivalents, end of period	$ 8,728	$ 14,845
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,064	$ 2,373
Cash paid for taxes	$ 467	$ 166
Unrealized loss on available-for-sale securities	$ 76	$ —
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$ 385	$ 129
Amortization of deferred equity costs	$ —	$ 224

See accompanying notes to consolidated financial statements.

(1) Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007. The Company is a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division. Each of these divisions are deemed to be reportable segments (see Note 3(m) and Note 17). The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings, and the CDMO division leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular, or injectable, meloxicam, a proprietary long-acting preferential COX-2 inhibitor being developed for the management of moderate to severe pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia. The acquisition is referred to herein as the Gainesville Transaction. In July 2017, the Company submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration for our lead investigational product candidate intravenous, or IV meloxicam 30 mg for the management of moderate to severe pain.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $78,210 as of June 30, 2017. Though its CDMO segment has been profitable, 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, including the payment of the Gainesville Transaction contingent payments, which may become due upon achievement of certain development and commercialization milestones for meloxicam (see Note 4). The Company's future operations are highly dependent on a combination of factors, including (i) the continued profitability of the CDMO segment; (ii) the timely and successful completion of additional financing and/or alternative sources of capital, debt or partnering transactions; (iii) the success of its research and development, including the results and timing of its clinical trials; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products. Management believes that the Company's existing cash, cash equivalents and short-term investments as of June 30, 2017 will be sufficient to fund its operations through mid-year 2018.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited 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 and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by the U.S. GAAP for complete annual financial statements. 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 consolidated 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 results for the interim periods. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017.

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, 2016 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

(b) Use of Estimates

The preparation of financial statements and the notes to the 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) Cash, Cash Equivalents

Cash and cash equivalents represents cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired to be cash equivalents. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to ten years for furniture and office equipment; six to ten or more years for manufacturing equipment; two to five years for vehicles; 35 to 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance cost are expensed as incurred.

(e) Business Combinations

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 805, "Business Combinations," or ASC 805, the Company allocates the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make significant estimates and assumptions, in particular with respect to intangible assets. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from management of the acquired companies and expectations of future cash flows. Transaction costs and restructuring costs associated with the transaction are expensed as incurred. In-process research and development, or IPR&D, is the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires the Company to make significant estimates. In a business combination, the Company capitalizes IPR&D as an intangible asset, and for an asset acquisition the Company expenses IPR&D in the Consolidated Statements of Operations on the acquisition date.

(f) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized, but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a two-step method for determining impairment.

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.

Intangible assets include the Company's royalties and contract manufacturing relationships intangible asset as well as an IPR&D asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and is amortized on a straight-line basis over a useful life of six years.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its consolidated statements of operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

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. The most recent tests as of November 30, 2016, indicated that goodwill and indefinite-lived intangible assets were not impaired. There were no indicators of impairment as of June 30, 2017.

(g) Revenue Recognition

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

Manufacturing and other related services revenue is recognized when persuasive evidence of an arrangement exists, shipment has occurred and the 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.

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 commercial partner. Royalty and profit sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement in the period the products are sold and when collectability is reasonably assured.

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. In agreements which specify milestones, the related revenues are recognized upon the achievement of a substantive milestone.

(h) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company manages its cash, cash equivalents and short-term investments based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

The Company's accounts receivable balances are concentrated amongst approximately five customers and if any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

(i) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist primarily of funds paid to third parties for the provision of services for pre-commercialization and manufacturing scale-up activities, drug development, clinical trials, statistical analysis and report writing and regulatory filing fees and compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expenses relating to these costs.

Upfront and milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining product technology licenses are charged to research and development expense as acquired IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use.

(j) Stock-Based Awards

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model

to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of options grants. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

Non-employee stock-based awards are revalued until an award vests and the Company recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, which is known as the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

(k) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company accrues interest, and related penalties are classified as income tax expense in the Consolidated Statements of Operations. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(l) Net Loss Per Common Share

Basic 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 unvested restricted stock units have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents for the three and six months ended June 30, 2017 include warrants using the treasury stock method. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator, net of tax, under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

The following table sets forth the computation of basic earnings per share and diluted earnings per share:

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Basic Earnings Per Share				
Net loss	$ (8,855)	$ (7,885)	$ (16,942)	$ (14,424)
Weighted average common shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Net loss per share of common stock, basic	$ (0.46)	$ (0.83)	$ (0.89)	$ (1.53)
Diluted Earnings Per Share				
Net loss	$ (8,855)	$ (7,885)	$ (16,942)	$ (14,424)
Add change in warrant valuation	(341)	—	(234)	—
Diluted net loss	$ (9,196)	$ (7,885)	$ (17,176)	$ (14,424)
Weighted average common shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Add shares from outstanding warrants	168,270	—	169,244	—
Weighted average common shares outstanding, diluted	19,220,700	9,544,629	19,220,175	9,398,288
Net loss per share of common stock, diluted	$ (0.48)	$ (0.83)	$ (0.89)	$ (1.53)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2017 and 2016, as they would be anti-dilutive:

	June 30,	
	2017	2016
Options and restricted stock units outstanding	3,680,799	2,229,343
Warrants	490,000	784,928

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

(m) Segment Information

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified CDMO and Acute Care as reportable segments. Segment disclosures are included in Note 17. Segment operating profit (loss) is defined as segment revenue less segment operating expenses (segment operating expenses consist of general and administrative expenses, research and development expenses, and the change in valuation of contingent consideration and warrants). The following items are excluded from segment operating profit (loss): interest income and expense, and income tax benefit (expense). Segment assets are those assets and liabilities that are recorded and reported by segment operations. Segment operating capital employed represents segment assets less segment liabilities.

(n) Recent Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update, or ASU, No. 2017-11 *"Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Features,"* or ASU 2017-11. ASU 2017-11 simplifies the accounting for certain financial instruments with down round features, as equity-linked instruments or embedded equity-linked features will not be accounted for as a liability solely because there is a down-round feature. The amendments are effective for public companies for annual and interim periods beginning after December 15, 2018. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation - Scope of Modification Accounting*. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to

apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04 *"Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment,"* or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15 *"Classification of Certain Cash Receipts and Cash Payments,"* or ASU 2016-15. ASU 2016-15 provides guidance in the classification of certain cash receipts and payments in the statement of cash flows where diversity in practice exists. This new guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842),*" or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, "*Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,"* or ASU 2015-16. ASU 2015-16 addresses the accounting for and disclosure of measurement-period adjustments that occur in periods after a business combination is consummated. This update requires that the acquirer recognize measurement-period adjustments in the reporting period in which they are determined. Prior period information should not be revised. This update also requires an entity to present separately on the face of the income statement or disclose in the notes the amount recorded in the current-period income statement that would have been recorded in previous reporting periods if the adjustments had been recognized as of the acquisition date. The updated guidance is effective for annual and interim periods beginning after December 15, 2016. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, "*Simplifying the Measurement of Inventory,"* or ASU 2015-11. ASU 2015-11 addresses changes in the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments in this guidance do not apply to inventory that is measured using last-in, first-out, or LIFO, or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost methods. Within the scope of this new guidance, an entity should measure inventory at the lower of cost and net realizable value; where net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The new guidance must be applied on a prospective basis. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In May 2014, the FASB issued ASU No. 2014-09, *"Revenue from Contracts with Customers,"* or ASU 2014-09. ASU 2014-09 represents 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 new standard permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company currently anticipates adopting the standard using the modified retrospective method. The Company plans to complete an analysis of existing contracts with its customers and to assess the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards by the end of the third quarter. The new standard will result in additional revenue-related disclosures in the

footnotes to the consolidated financial statements. The Company will continue to assess new customer contracts during 2017. Adoption of this standard will require changes to business processes, systems and controls to support the additional required disclosures. The Company is in the process of identifying such changes.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Gainesville Transaction consisted of $50.0 million cash at closing, a $4.0 million 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 $125.0 million in milestone payments (including, at the Company's election, either (i) $10 million upon a new drug application, or NDA, filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones related to injectable meloxicam) and a percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). 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).

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 NDA for meloxicam and the related regulatory approval or one payment upon regulatory approval. 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.

(5) NMB Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBs, and a proprietary chemical reversal agent from Cornell University, or Cornell. The NMBs and reversal agent are referred to herein as the NMB Related Compounds. The NMB Related Compounds include one novel intermediate-acting NMB that has initiated Phase I clinical trials and two other agents, a novel short-acting NMB, and a rapid-acting reversal agent proprietary to these NMB Related Compounds.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of $766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of $350 that is included within Accounts payable, as well as operational liabilities and acquisition-related costs of $416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs, each of which is reported as a component of Accrued expenses and other current liabilities and Other non-current liabilities on the Consolidated Balance Sheet as of June 30, 2017.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMB Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds.

The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considering the early clinical stage of the novel and unproven NMB Related Compounds. The Company concluded that the acquired IPR&D of Cornell did not constitute a business as defined under ASC 805 due to the incomplete nature of the inputs and the absence of processes from a market participant perspective. Substantial additional research and development will be required to develop any NMB Related Compounds into a commercially viable drug candidate, including completion of pre-clinical testing and clinical trials, and, if such clinical trials are successful, application for regulatory approvals and manufacturing repeatability and scale-up. There is risk that a marketable compound may not be well tolerated and may never be approved.

Acquired IPR&D in the asset acquisition was accounted for in accordance with FASB ASC Topic 730, "Research and Development." At the date of acquisition, the Company determined that the development of the projects underway at Cornell had not yet reached technological feasibility and that the research in process had no alternative future uses. Accordingly, the acquired IPR&D was charged to expense in the Consolidated Statements of Operations on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

(6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, warrants and the contingent consideration. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

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

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)
At December 31, 2016:			
Assets:			
Money market mutual funds (See Note 7)	$ 37,079	$ —	$ —
U.S. Treasury obligations (See Note 7)	20,517	—	—
Cash equivalents	$ 57,596	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 3,397
Contingent consideration (See Note 4)	—	—	69,574
	$ —	$ —	$ 72,971
At June 30, 2017:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$ 6,043	$ —	$ —
Total cash equivalents	$ 6,043	$ —	$ —
Short-term investments			
U.S. Treasury obligations (See Note 7)	$ 41,517	$ —	$ —
Total financial assets	$ 47,560	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 2,604
Contingent consideration (See Note 4)	—	—	75,347
	$ —	$ —	$ 77,951

The Company developed its own assumptions to determine the value of the warrants that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the contractual term of the warrants, risk free interest rates and dividend yield. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

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

	Warrants	Contingent Consideration
Balance at December 31, 2016	$ 3,397	$ 69,574
Additions	—	—
Remeasurement	(793)	5,773
Balance at June 30, 2017	$ 2,604	$ 75,347

The Company follows the disclosure provisions of FASB ASC Topic 825, "Financial Instruments" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of June 30, 2017, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable, accrued expenses and current debt obligations approximate fair value due to the short-term nature of these instruments. The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of long-term debt approximated fair value at June 30, 2017 due to the estimated amount of the Excess Cash Flow payments and terms of the debt.

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

(7) Short-term Investments

Short-term investments as of June 30, 2017 consist of government money market funds and U.S. Treasury obligations. In accordance with FASB ASC Topic 320, "Investments – Debt and Equity Securities," or ASC 320, the Company has classified its entire investment portfolio as available-for-sale securities with secondary or resale markets, and, as such, its portfolio is reported at fair value with unrealized gains and losses included in Comprehensive Income in stockholders' equity and realized gains and losses included in other income/expense. The following is a summary of available-for-sale securities as of June 30, 2017.

	June 30, 2017			
Description	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Money market mutual funds	$ 6,043	$ —	$ —	$ 6,043
U.S. Treasury obligations	41,593	—	(76)	41,517
Total Investments	$ 47,636	$ —	$ (76)	$ 47,560

As of June 30, 2017, the Company's investments had maturities ranging from one to six months. As of December 31, 2016, all of the Company's investments in US. Treasury obligations had original maturities of less than three months. The fair value of the Company's U.S. Treasury obligations is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, and other observable inputs.

Certain investment securities as of June 30, 2017 had fair values less than their amortized costs and, therefore, contained unrealized losses. The Company has evaluated these investments and has determined that the decline in value was not related to any Company or industry specific event. As of June 30, 2017, there were 23 U.S. Treasury investments with unrealized losses. The gross unrealized losses related to these investments were due to changes in interest rates. Given that the Company has no intent to sell any of these investments until a recovery of its fair value, which may be at maturity, and there are no current requirements to sell any of these investments, the Company did not consider these investments to be other-than-temporarily impaired as of June 30, 2017. The Company anticipates full recovery of amortized costs with respect to these investments at maturity or sooner in the event of a more favorable market interest rate environment. The duration of time the investments had been in a continuous unrealized loss position as of June 30, 2017 was less than 12 months.

(8) Inventory

Inventory is stated at the lower of cost and net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Cost is determined using the first-in, first-out method. Inventory was as follows as of June 30, 2017 and December 31, 2016:

	June 30, 2017	December 31, 2016
Raw materials	$ 2,371	$ 2,618
Work in process	3,151	5,219
Finished goods	1,777	1,793
	7,299	9,630
Provision for inventory obsolescence	(411)	(884)
	$ 6,888	$ 8,746

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

The provision for inventory obsolescence decreased approximately $473 during the six months ended June 30, 2017, primarily due to the disposal of the fully reserved inventory at December 31, 2016. Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Inventory is ordered to meet specific customer orders and largely reflects demand. Factors influencing inventory obsolescence include changes in demand, product life cycle, product pricing, physical deterioration and quality concerns.

(9) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	June 30, 2017	December 31, 2016
Land	$ 3,263	$ 3,263
Building and improvements	15,757	15,613
Furniture, office and computer equipment	4,031	3,811
Vehicles	30	30
Manufacturing equipment	23,454	21,508
Construction in progress	2,650	2,198
	49,185	46,423
Less: accumulated depreciation and amortization	11,547	9,123
Property, plant and equipment, net	$ 37,638	$ 37,300

Depreciation expense for the three and six months ended June 30, 2017 was $1,228 and $2,424, respectively. Depreciation expense for the three and six months ended June 30, 2016 was $1,240 and $2,511, respectively.

(10) Intangible Assets

The following represents the balance of the intangible assets at June 30, 2017:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships:	$ 15,500	$ 5,759	$ 9,741
In-process research and development	26,400	—	26,400
Total	$ 41,900	$ 5,759	$ 36,141

The following represents the balance of intangible assets at December 31, 2016:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships:	$ 15,500	$ 4,467	$ 11,033
In-process research and development	26,400	—	26,400
Total	$ 41,900	$ 4,467	$ 37,433

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

Amortization expense for each of the six months ended June 30, 2017 and 2016 was $1,292 and $1,291, respectively, and for the three months ended June 30, 2017 and 2016 was $646. As of June 30, 2017, future amortization expense is as follows:

	Amortization
July - December 2017	$ 1,291
2018	2,583
2019	2,583
2020	2,583
2021	701
Total	$ 9,741

(11) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2017	December 31, 2016
Clinical trial and related costs	$ 340	$ 2,564
Professional and consulting fees	643	360
Payroll and related costs	3,218	4,547
Property plant and equipment	383	720
Deferred revenue	518	418
Income tax payable	603	311
Other	846	973
	$ 6,551	$ 9,893

(12) Long-Term Debt

The Company financed the Gainesville Transaction with cash on hand and a $50,000 five-year senior secured term loan, pursuant to a credit agreement, entered into on April 10, 2015, with OrbiMed Royalty Opportunities II, LP, or OrbiMed. The unpaid principal amount under the credit agreement is due and payable on April 10, 2020, 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. The Company 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 equal to (A) for full prepayments of the unpaid principal amount, $75,000 less all previously prepaid principal amounts and all previously paid interest or (B) for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and (ii) after the 36-month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon the CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow calculation. No payments under this option shall be subject to the buy-out premium. As of June 30, 2017, the Company has paid $22,653 of principal payments on the senior secured loan from the Excess Cash Flow calculation. The credit agreement carries interest at three month LIBOR plus 14.0% with a 1.0% floor. The Company's obligations under the senior term loan are secured by substantially all of the Company's assets.

The credit agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis. As of June 30, 2017, the Company was in compliance with the covenants.

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

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

Debt issuance costs related to the term loan of $4,579, 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 $2,633 as of June 30, 2017. As of June 30, 2017, the long-term debt balance is comprised of the following:

Principal balance outstanding	$	27,347
Unamortized deferred issuance costs		(2,633)
	$	24,714
Current portion		(2,057)
	$	22,657

The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2017 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

(13) Commitments and Contingencies

(a) Licenses

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine, or Dex, for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. The Company is required to pay Orion lump sum payments of up to €20,500 ($23,393 as of June 30, 2017) on the achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. Through June 30, 2017, no such milestones have been achieved.

The Company is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine, or Fado, for use as a human therapeutic, in any dosage form in the Territory. The Company is required to pay Orion lump sum payments of up to €12,200 ($13,921 as of June 30, 2017) on achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 15% depending on annual sales levels. Through June 30, 2017, No such milestones have been achieved.

The Company is party to a license agreement with Cornell University for the exclusive license of the NMB Related Compounds. Under the terms of the agreement, the Company will pay Cornell an initial upfront fee and Cornell is also entitle to receive additional milestone payments, and annual license maintenance fees as well as royalties. See Note 5 for further information regarding these payment obligations.

(b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, the Company agreed to pay to Alkermes up to an additional $125.0 million in milestone payments (including, at the Company's election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). At the end of July 2017, the Company has filed the NDA and has not made the election as to which milestone payment it will make as of the 10-Q filing date.

The Company is party to 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 commercial bulk supplies of injectable meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for injectable meloxicam. Pursuant to the Supply Agreement, Alkermes will supply the Company with such quantities of bulk injectable meloxicam formulation as shall be reasonably required for the completion of clinical trials of injectable meloxicam. During the term of the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

(c) Product Manufacturing

The Company is party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), for the clinical and, if approved by the U.S. Food and Drug Administration, or FDA, commercial supply of injectable meloxicam. Pursuant to the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

The Company is also party to an active pharmaceutical ingredient, or API, supply agreement with Orion, whereby Orion provides the Company with API for the development and commercialization of its Dex product candidates. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed-upon amounts. Any amounts ordered by the Company that are greater than the planned supply will be charged at 50% of the supply price for commercial product.

(d) Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, the Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

As part of the Gainesville Transaction, the Company acquired the rights to Zohydro ER®, which the Company licenses to its commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® is subject to six paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016 by Actavis, and in December 2015 by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date of November 2019 and September 2034, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and the Company's predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and in 2015, the Company filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In addition, in April 2015, the U.S. Patent and Trademark Office, or the USPTO, declared an interference between one of the Company's patent applications relating to a dosage form of Zohydro ER® and two Purdue Pharma, LP, or Purdue, applications. On April 29, 2016, the USPTO found the Company's claims and the Purdue claims involved in the interference to be invalid. Purdue appealed this decision to the U.S. Court of Appeals for the Federal Circuit on June 28, 2016, and on June 13, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the USPTO.

Under the Company's license agreement with Pernix, the Company has the right to control the enforcement of the Company's patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse the Company for all reasonable costs of paragraph IV certification actions. On September 29, 2016, the Company entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the District Court in the Actavis case ruled in the Company's favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

(e) Leases

On January 1, 2017, the Company entered into a six-year lease for its Malvern, Pennsylvania facility that expires on December 31, 2022. In February 2017, the Company also entered into a three-year lease for office space in Dublin, Ireland that expires April 2020. The Company is also a party to operating leases for office equipment and storage. Rent expense includes rent as well as additional operating and tenant improvement expenses.

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

As of June 30, 2017, future minimum lease payments excluding operating expenses and tenant improvements for the leases, are as follows:

	Lease payments
2017	$ 281
2018	568
2019	497
2020	403
2021	362
2022	373
Total	$ 2,484

(f) Purchase Commitments

As of June 30, 2017, the Company had outstanding non-cancelable and cancelable purchase commitments in the amount of $13,612 related to inventory, capital expenditures and other goods and services.

(g) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of June 30, 2017, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $1,420, from that date through calendar year 2018.

(14) 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.

On March 12, 2014, the Company completed an initial public offering, or 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, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

On July 7, 2015, the Company closed a private placement with certain accredited investors in which the Company sold 1,379,311 shares of common stock at a price of $11.60 per share, for net proceeds of $14,812. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the private placement, plus reimbursement of certain expenses.

On August 19, 2016, the Company closed an underwritten public offering in which the company sold 1,986,666 shares of common stock at a price per share of $7.50, for net proceeds of $13,367 after deducting underwriting commissions and offering expenses.

On December 16, 2016, the Company closed an underwritten public offering in which the company sold 6,670,000 shares of common stock at a price per share of $6.00, for net proceeds of $36,888 after deducting underwriting commissions and offering expenses.

(b) 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 was 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 $253 of costs in connection with the Purchase Agreement, which, along with the fair value of the

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

common stock, has been recorded as deferred equity costs. During 2016, the Company sold 1,143,940 shares of common stock under the Purchase Agreement for $7,796. The agreement expired in February 2017.

(c) 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, 2017, no preferred stock was issued or outstanding.

(d) Warrants

As of June 30, 2017, 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
140,000	$ 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.

The following table summarizes the fair value and the assumptions used for the Black-Scholes option-pricing model for these liability classified warrants.

	Date of issuance	June 30, 2017	December 31, 2016
Fair value	$ 5,331	$ 2,604	$ 3,397
Expected dividend yield	— %	— %	— %
Expected volatility	80 %	80 %	85 %
Risk-free interest rates	1.73 %	1.89 %	1.93 %
Remaining contractual term	7 years	4.75 years	5.25 years

(15) Comprehensive Loss

The Company's comprehensive loss is shown on the Consolidated Statements of Operations as of June 30, 2017, and is comprised of net unrealized gains and losses on the Company's available-for-sale securities. The total of comprehensive loss for the three and six months ended June 30, 2017 was $8,874 and $17,018, respectively. The tax effect for the six months ended June 30, 2017 of other comprehensive loss was $26.

(16) 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, non-employee directors, and consultants and advisors. As of June 30, 2017, 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, or the A&R Plan, which amended and restated the 2013 Plan and increased the aggregate amount of shares available for issuance to 2,000,000. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the plan may be increased by the board of directors by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2016 and 2015, the number of shares available for

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

issuance under the A&R Plan was increased by 619,181 and 461,215, respectively. The total number of shares authorized for issuance under the A&R plan as of June 30, 2017 is 3,080,396.

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, 2017, 279,905 shares and 174 shares are available for future grants under the A&R Plan and 2008 Plan, respectively.

The weighted average grant-date fair value of the options awarded to employees during the six months ended June 30, 2017 and 2016 was $5.36 and $4.18, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	June 30,	
	2017	2016
Range of expected option life	6 years	6 years
Expected volatility	84.71%	74.82%
Risk-free interest rate	1.87-2.17%	1.13-1.91%
Expected dividend yield	—	—

The following table summarizes stock option activity during the six months ended June 30, 2017:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2016	2,611,929	$ 7.01	
Granted	753,570	7.46	
Exercised	(3,600)	6.00	
Expired/forfeited/cancelled	(19,393)	8.65	
Balance, June 30, 2017	3,342,506	$ 7.10	7.4 years
Vested	1,740,772	$ 6.59	6.0 years
Vested and expected to vest	3,226,304	$ 7.08	7.4 years

Included in the table above are 501,000 options granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

The following table summarizes restricted stock units activity during the six months ended June 30, 2017.

	Number of shares
Balance, December 31, 2016	7,750
Granted	339,043
Vested	(7,750)
Expired/forfeited/cancelled	(750)
Balance, June 30, 2017	338,293
Expected to vest	338,293

During 2017, the Company granted 91,150 performance-based restricted stock units, or RSUs, which vest based on attaining clinical and operational goals during 2017, as well as 247,893 time-based RSUs, which vest over four years.

Stock-based compensation expense for the six months ended June 30, 2017 and 2016 was $2,370 and $1,430, respectively.

As of June 30, 2017, there was $11,588 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.7 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2017, the aggregate intrinsic value of the vested and unvested options was $2,266 and $603, respectively.

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

(17) Segment Reporting

The Company operates through two business segments: an Acute Care segment and a revenue-generating CDMO segment. The Acute Care segment is primarily focused on developing innovative products for hospital and related settings, and the CDMO segment leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. Acute Care has no revenue, and its costs consist primarily of expenses incurred in conducting the Company's clinical and preclinical studies, acquiring clinical trial materials, regulatory activities, personnel costs and pre-commercialization of meloxicam. CDMO revenue streams are derived from manufacturing, royalty and profit-sharing revenues, as well as CDMO's research and development services performed for commercial partners.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 3). The Company evaluates performance of its reportable segments based on revenue and operating income (loss). The Company does not allocate interest income, interest expense or income taxes to its operating segments.

The following table summarizes segment information as of and for the six months ended June 30, 2017 and 2016:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
CDMO	$ 16,934	$ 17,279	$ 35,676	$ 35,021
Acute Care	—	—	—	—
Total	$ 16,934	$ 17,279	$ 35,676	$ 35,021
Operating income (loss):				
CDMO	$ 4,060	$ 5,634	$ 10,258	$ 11,277
Acute Care	(13,490)	(12,405)	(26,990)	(23,073)
Total	$ (9,430)	$ (6,771)	$ (16,732)	$ (11,796)
Depreciation and amortization:				
CDMO	$ 1,865	$ 1,917	$ 3,702	$ 3,802
Acute Care	9	—	14	—
Total	$ 1,874	$ 1,917	$ 3,716	$ 3,802
Capital expenditures:				
CDMO	$ 1,366	$ 737	$ 2,896	$ 1,081
Acute Care	75	—	289	—
Total	$ 1,441	$ 737	$ 3,185	$ 1,081

	June 30, 2017	December 31, 2016
Total assets:		
CDMO	$ 78,986	$ 77,828
Acute Care	90,823	105,169
Total	$ 169,809	$ 182,997

(18) Related Party Transactions

The Company's President and Chief Executive Officer, or CEO, owns a majority of the stock of Malvern Consulting Group, or MCG, a pharmaceutical incubator and consulting firm. The CEO's husband, who is also a shareholder of the Company, is a consultant and a shareholder of MCG. In addition, the CEO's son is the President and a shareholder of MCG. During 2016, certain immediate family members of the CEO were employees of MCG, including the CEO's brother and sister-in-law. Since formation, the Company entered into various transactions with MCG, as detailed below. However, since becoming a public

company, the Company sought to decrease its involvement with MCG, and, as of December 31, 2016, the Company no longer has any involvement or transactions with MCG.

During 2016, certain of the Company's executive officers, its CEO, its Senior Vice President, Development and its Senior Vice President, Regulatory Affairs and Quality Assurance, who is also the CEO's sister, provided minimal consulting services from time to time to MCG. Until December 31, 2016, the Company was a party to a Master Consulting Services Agreement with MCG. Pursuant to the agreement, MCG provided the Company with certain consulting services for a fee based upon hourly rates previously approved by the Company's Board of Directors. In consideration for such services, the Company recorded $89 and $190 for the three and six months ended June 30, 2016, respectively. A portion of these amounts were used during 2016 to pay a portion of the respective salaries of MCG employees that, as described above, included immediate family members of the Company's CEO.

Until December 31, 2016, the Company was party to an Office Services Agreement with MCG for the lease of an aggregate of 8,458 square feet of office and lab space located at its Malvern, Pennsylvania facility and the provision of IT services and general office support. Pursuant to the Office Services Agreement, the Company paid MCG $57 in the three and six months ended June 30, 2016. The Company terminated this agreement on December 31, 2016 and is now a party to a six-year lease directly with the landlord of the Company's Malvern, Pennsylvania facility (see Note 13).

As of December 31, 2016, the Company terminated the Master Consulting Agreement and the Office Services Agreement and MCG no longer provides any services or has any contracts with the Company.

The Company's Senior Vice President, Regulatory and Quality, who is the CEO's sister, has held that position since 2014. Effective January 1, 2017, the CEO's sister-in-law and brother, respectively, terminated their employment with MCG and were hired as the Company's Director of Human Resources and the Company's Vice President, Manufacturing. The Company's board of directors approved these hires consistent with the Company's related person transaction policy.

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, 2016 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 9, 2017. 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," "believes," "estimates," "predicts," "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:

- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to obtain and maintain regulatory approval of injectable meloxicam and our product candidates, and the labeling under any approval that we may obtain;
- the results, timing and outcome of our clinical trials of injectable meloxicam or our other product candidates, and any future clinical and preclinical studies;
- our ability to successfully commercialize injectable meloxicam or our other product candidates, upon regulatory approval;
- our ability to comply with the legal and regulatory frameworks applicable to our business and other regulatory developments in the United States and foreign countries;
- our ability to raise future financing and attain profitability for continued development of our business and our product candidates and to meet required debt payments, and any milestone payments owing to Alkermes, or our other licensing and collaboration partners;
- our ability to operate under increased leverage and associated lending covenants;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CRO's, and third-party suppliers and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights against third parties;
- our ability to maintain our relationships and contracts with our key commercial partners;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance; and
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in the tax laws.

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" included in Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 9, 2017 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 specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating CDMO division. Each of these divisions are deemed to be reportable segments for financial reporting purposes.

Our Acute Care segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed two pivotal Phase III clinical trials, a large Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, we enrolled a total of approximately 1,100 patients in our Phase III program. At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, initial pre-commercialization of meloxicam and personnel costs.

Our CDMO segment leverages our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for our CDMO segment and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care segment. We operate a 97,000 square-foot, DEA-licensed manufacturing facility in Gainesville, Georgia, and we currently develop and/or manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil sustained release and Zohydro ER®, as well as development stage products. Our CDMO segment's revenue streams are derived from manufacturing, royalty and profit sharing revenues, as well as our research and development of services performed for commercial partners.

We have incurred losses and generated negative cash flows from operations since inception, and expect to continue to incur significant and increasing operating losses for the foreseeable future. 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, clinical trials and pre-commercialization activities. We have used revenue generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO's revenue will continue to contribute cash for general corporate purposes that may, to some extent, reduce the amount of external capital needed to fund development operations. We expect to incur increasing expenses over the next several years to develop and commercialize injectable meloxicam, including continued pre-commercial activities for IV meloxicam. Based upon the availability of additional financial resources, we may also develop and commercialize our other product candidates in our pipeline, as well as other products we may in-license.

On April 10, 2015, we completed the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and the increase in our workforce as a result of the addition of the employees at our Gainesville, Georgia manufacturing facility. The consideration paid consisted of $50.0 million cash, a $4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of our common stock at an exercise price of $19.46 per share. In addition, we may be required to pay up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and a royalty percentage of future product net sales related to injectable meloxicam.

The up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with 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, 2017 and June 30, 2016, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue. All revenue is generated from our CDMO segment.

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* revenue**s—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, development and/or supply 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, development and/or supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Research and development revenue—Research and development revenue consists of funding that compensates us for formulation, and preparation of pre-clinical and clinical testing drug product materials prepared by our CDMO segment 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 hourly rate, plus direct external costs, if any. In an agreement which specifies milestones, we recognize revenue upon achievement of manufacturing and regulatory events.

Research and Development Expenses

Research and development expenses currently consist primarily of costs incurred in connection with the development of injectable meloxicam and other pipeline activities. 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 and manufacturing services;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in process research and development;
- costs associated with non-clinical and regulatory activities;
- salaries and related costs for personnel in research and development and regulatory functions.
- costs associated with pre-commercialization activities; and
- costs related to scale up and validation for injectable meloxicam.

The majority of our external research and development costs relate to clinical trials, manufacturing of drug supply for pre-commercial products analysis and testing of product candidates and patent costs. 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 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;
- Risk involved with development of manufacturing processes and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- 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 other risks disclosed in the section titled "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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 to primarily relate to injectable meloxicam for the foreseeable future as we advance this product candidate through the pre-commercialization scale-up, clinical and other pre-approval activities. We also expect to have expenses as we initiate clinical trials and related work for our other product candidates. 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. We expect our research and development costs to continue to increase as we continue clinical and pre-commercialization manufacturing activities for IV meloxicam, and engage in pipeline development activities.

In addition, research and development expenses consist of costs incurred by our CDMO segment in connection with research and development services performed for our commercial partners, as well as other product development activities. 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, pre-commercial 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.

We expect our general and administrative expenses to continue to increase as we build our Acute Care commercialization team, and engage in pre-commercialization IV meloxicam marketing, sales, market access and medical affairs activities. In addition, we will continue to incur costs relating to our operations as a public company, including increased headcount and increased salary, consulting, legal, patent and compliance, accounting, insurance and investor relations costs.

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 injectable meloxicam represents 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 injectable meloxicam in the Gainesville Transaction, we are required to pay up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and royalties on future net product sales of between 10% and 12% (subject to a 30% reduction when no longer covered by patent). 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.

Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding which contain a contingent net cash settlement feature, or an anti-dilution provision. The fair value of these warrants are remeasured through settlement or expiration with changes in fair value recognized as a period charge within the statement of operations.

Interest Expense

Interest expense for the three and six months ended June 30, 2017 and June 30, 2016 was a result of interest expense incurred on our OrbiMed senior secured term loan and the amortization of the related financing costs.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

	Three Months Ended June 30,	
	2017	2016
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 16,750	$ 16,933
Research and development revenue	184	346
Total revenues	16,934	17,279
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	10,448	9,547
Research and development	7,073	8,320
General and administrative	6,322	2,763
Amortization of intangible assets	646	646
Change in warrant valuation	(1,084)	1,240
Change in contingent consideration valuation	2,959	1,534
Total operating expenses	26,364	24,050
Operating loss	(9,430)	(6,771)
Other income (expense):		
Interest expense, net	(1,090)	(1,309)
Loss before income taxes	(10,520)	(8,080)
Income tax benefit	1,665	195
Net loss	$ (8,855)	$ (7,885)

Revenue and costs of sales. Our revenues were $16.9 million and $17.3 million and cost of sales were $10.4 million and $9.5 million for the three months ended June 30, 2017 and 2016, respectively. The decrease of $0.3 million in revenue, or 2%, for this quarter year-over-year, was primarily the result of a decrease in royalty revenue due to the change in the mix of generic and brand sales by our partners offset by an increase in profit sharing revenue due to increased sales volume and pricing by our partner. Cost of sales increased $0.9 million, or 9%, due to changes in the product mix of manufacturing revenue.

Research and Development. Our research and development expenses were $7.1 million and $8.3 million for the three months ended June 30, 2017 and 2016, respectively. Lower IV meloxicam clinical trial expenses of $4.3 million were offset by increases of $1.6 million of pre-commercialization manufacturing costs and other development costs for IV meloxicam, $0.8 million in IPR&D costs for the NMB Related Compounds and $0.5 million of salaries and benefits expense due to increased Acute Care clinical headcount.

General and Administrative. Our general and administrative expenses were $6.3 million and $2.8 million for the three months ended June 30, 2017 and 2016, respectively. The increase of $3.5 million was primarily due to increased headcount in our Acute Care division, and pre-commercialization and medical affairs expenses.

Amortization of Intangible Assets. Amortization expense was $0.6 million for each of the quarters ended June 30, 2017 and 2016, which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six-year estimated useful life.

Interest Expense, net. Interest expense, net was $1.1 million and $1.3 million during the three months ended June 30, 2017 and 2016, respectively. T he decrease in interest expense, net, was due to a lower principal balance on our OrbiMed senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. Income tax benefit was $1.7 million and $0.2 million for the three months ended June 30, 2017 and 2016, respectively, due to income tax benefit related to our a loss in our U.S. operations. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO's gross margin percentage was 38% and 45% in the three months ended June 30, 2017 and 2016, respectively. Our revenues decreased by $0.3 million, or 2%, and was primarily the result of a decrease in royalty revenue due to a change in the mix of generic and brand sales by our partners offset by an increase in profit sharing revenue due to increased sales volume and pricing by our partner. One of our commercial partners, Pernix, is out of stock for the 20mg dosage strength of Zohydro ER®. The 20mg dosage strength is one of six strengths we manufacture for Pernix. For fiscal year 2016, revenues across all Zohydro ER® strengths represented less than 10% of our total revenues. Cost of sales increased $0.9 million, or 9% as a result of our product mix of manufacturing revenue.

CDMO's operating expenses (excluding cost of sales) increased by $0.3 million, from $2.1 million in the three months ended June 30, 2016, to $2.4 million in the three months ended June 30, 2017. Research and development expenses increased by $0.2 million due to increased overhead costs in 2017. General and administration expenses increased by $0.1 million due to an increase in marketing expenses. All of the above contributed to CDMO's operating income of $4.1 million for the three months ended June 30, 2017, which included non-cash charges of $1.9 million for depreciation and amortization and $0.2 million for stock-based compensation.

Acute Care Segment-

Acute Care's operating expenses increased $1.1 million from $12.4 million in the three months ended June 30, 2016 to $13.5 million in the three months ended June 30, 2017. Research and development expenses decreased $1.5 million as a result of a decrease in our IV meloxicam clinical trial expenses, which was partially offset by increased costs in IV meloxicam pre-commercialization manufacturing costs, IPR&D costs for the acquisition of the NMB Related Compounds and increased headcount. General and administrative costs increased by $3.5 million as a result of increased headcount and increased pre-commercialization marketing expenses. Non-cash charges of the warrant valuation decreased $2.3 million and contingent consideration increased by $1.4 million. All of the above contributed to Acute Care's operating loss of $13.5 million for the three months ended June 30, 2017, which included non-cash charges of $1.2 million for stock-based compensation, depreciation and amortization.

Comparison of the Six Months Ended June 30, 2017 and 2016

	Six Months Ended June 30,	
	2017	2016
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 34,878	$ 34,072
Research and development revenue	798	949
Total revenues	35,676	35,021
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	20,946	19,818
Research and development	14,836	16,129
General and administrative	10,354	5,421
Amortization of intangible assets	1,292	1,291
Change in warrant valuation	(793)	(354)
Change in contingent consideration valuation	5,773	4,512
Total operating expenses	52,408	46,817
Operating loss	(16,732)	(11,796)
Other income (expense):		
Interest expense, net	(2,168)	(2,812)
Loss before income taxes	(18,900)	(14,608)
Income tax benefit	1,958	184
Net loss	$ (16,942)	$ (14,424)

Revenue and costs of sales. Our revenues were $35.7 million and $35.0 million and cost of sales were $20.9 million and $19.8 million for the six months ended June 30, 2017 and 2016, respectively. The increase of $0.7 million in revenue, or 2%, was primarily the result of increased profit share revenue due to increased sales volumes and pricing by our partner and was partially offset by a decrease in manufacturing revenue due to a change in the timing of product shipments compared to prior year and decreased royalty revenue due to a change in the mix of generic and brand sales by our partners. Cost of sales increased $1.1 million, or 6%, due to changes in the product mix of manufacturing revenue.

Research and Development. Our research and development expenses were $14.8 million and $16.1 million for the six months ended June 30, 2017 and 2016, respectively. Lower IV meloxicam clinical trial expenses of $5.5 million were offset by increases of $2.5 million of pre-commercialization manufacturing costs and other development costs for IV meloxicam, $0.8 million in IPR&D costs for the acquisition of the NMB Related Compounds and $0.9 million of salaries and benefits expense due to increased Acute Care clinical headcount.

General and Administrative. Our general and administrative expenses were $10.4 million and $5.4 million for the six months ended June 30, 2017 and 2016, respectively. The increase of $5.0 million was primarily due to increased headcount in our Acute Care division and pre-commercialization and medical affairs expenses.

Amortization of Intangible Assets. Amortization expense was $1.3 million for the six months ended June 30, 2017 and 2016 which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six-year estimated useful life.

Interest Expense, net. Interest expense, net was $2.2 million and $2.8 million during the six months ended June 30, 2017 and 2016, respectively. The decrease in interest expense, net, was due to a lower principal balance on our OrbiMed senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. Income tax benefit was $2.0 million and $0.2 million for the six months ended June 30, 2017 and 2016, respectively, due to income tax benefit related to our loss in our U.S. operations. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO's gross margin percentage was 41% and 43% in the six months ended June 30, 2017 and 2016, respectively. Our revenues increased by $0.7 million, or 2%, and was primarily the result of increased profit share revenue due to increased sales volumes and pricing by our partner and was partially offset by a decrease in manufacturing revenue due to a change in the timing of product shipments compared to prior year and decreased royalty revenue due to a change in the mix of generic and brand sales by our partners. One of our commercial partners, Pernix, is out of stock for the 20mg dosage strength of Zohydro ER®. The 20mg dosage strength is one of six strengths we manufacture for Pernix. For fiscal year 2016, revenues across all Zohydro ER® strengths represented less than 10% of our total revenues. Cost of sales increased $1.1 million, or 6%, as a result of our product mix of manufacturing revenue.

CDMO's operating expenses (excluding cost of sales) increased by $0.6 million, from $3.9 million in the six months ended June 30, 2016 to $4.5 million in the six months ended June 30, 2017. Research and development expenses increased by $0.5 million due to expanded investment in our future capabilities in 2017. General and administration expenses remained constant in the six months ended June 30, 2017 and 2016. All of the above contributed to CDMO's operating income of $10.3 million for the six months ended June 30, 2017, which included non-cash charges of $3.7 million for depreciation and amortization and $0.5 million for stock-based compensation.

Acute Care Segment-

Acute Care's operating expenses increased $3.9 million from $23.1 million in the six months ended June 30, 2016 to $27.0 million in the six months ended June 30, 2017. Research and development expenses decreased $1.9 million as a result of a decrease in our IV meloxicam clinical trial expenses, which was partially offset by increased costs in IV meloxicam pre-commercialization manufacturing costs and increased headcount. General and administrative costs increased by $5.0 million as a result of increased headcount and increased pre-commercialization marketing expenses. Non-cash charges of the warrant valuation decreased $0.4 million and contingent consideration increased by $1.3 million. All of the above contributed to Acute Care's operating loss of $27.0 million for the six months ended June 30, 2017, which included non-cash charges of $1.9 million for stock-based compensation, depreciation and amortization.

Liquidity and Capital Resources

As of June 30, 2017, we had $50.2 million in cash and cash equivalents and short-term investments.

Since inception through June 30, 2017, we have financed our product development, operations and capital expenditures primarily from sales of equity and debt securities, including sales of our common stock of $116.4 million, which includes $57.6 million raised in 2016. Revenues from our CDMO segment are used primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund the development and pre-commercialization activities of our Acute Care segment. During the six months ended June 30, 2017, our capital expenditures were $3.2 million.

We will need to raise substantial additional funds in order to fund the payments which may become due, including milestone payments owed to Alkermes or other licensing partners, to continue our clinical trials of our approved or development state product candidates, to commercialize any approved 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, and the costs of commercialization activities, as well as the continued profitability of our CDMO segment. If additional funds are required, we may raise such funds through debt refinancing, bank or other loans, through strategic research and development, licensing and/or marketing arrangements or through public or private sales of equity or debt securities 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 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 equal to (A) for full prepayments, $75 million less all previously prepaid principal amount and all previously paid interest or (B) for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and; and (ii) after the 36-month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require us to prepay a portion of the Loan balance based upon an Excess Cash Flow calculation. No payments under this option shall be subject to the buy-out premium. The credit agreement carries interest at three-month LIBOR plus 14.0% with 1.0% floor. This obligation is secured by substantially all of our assets. As of June 30, 2017, we have paid $22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

Sources and Uses of Cash

Cash used in operations was $11.0 million and $5.4 million for the six months ended June 30, 2017 and 2016, 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 and amortization of intangibles, as well as changes in operating assets and liabilities.

Cash used in investing activities was $44.8 million and $1.1 million for the six months ended June 30, 2017 and 2016, respectively, and reflected cash used for the purchase of short-term investments offset by maturities/redemption of investments in 2017 and property and equipment in 2017 and 2016. Our short-term investments are classified as available for sales securities maturities of less than one year.

There was $0.02 million cash provided by financing activities in six months ended June 30, 2017 from proceeds from exercise of options. Cash provided by financing activities was $1.5 million for the six months ended June 30, 2016, primarily as a result of $4.2 million in proceeds from the sale of shares of common stock through our common stock purchase agreement with Aspire Capital offset by excess cash flow payments of $2.6 million made related to the OrbiMed credit agreement.

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

- the timing and outcome of the FDA's review of an NDA for IV meloxicam;
- the timing and outcome of our Phase IIIB clinical studies for IV meloxicam;
- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of injectable meloxicam;
- the timing to fund the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of our commercialization activities, if our product candidates are approved by the FDA;
- the cost of purchasing manufacturing and other capital equipment for our product candidates;
- 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 in-license, acquire or invest in products, businesses and technologies;
- the timing and extent of our manufacturing and capital expenditures related to our CDMO division;
- our ability to maintain our relationships and contracts with our commercial partners;
- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and U.S. DEA requirements;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws.

We might use existing cash and cash equivalents on hand, additional debt or equity financing or a combination of the three 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 June 30, 2017.

Licenses

We have in-licensed product candidates that generally trigger or require 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 IND or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

We are party to exclusive licenses with Orion for the development and commercialization of Dex and Fado, under which we may be required to make certain milestone and royalty payments to Orion. We also license the NMB Related Compounds from Cornell pursuant to a license agreement pursuant to which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMB Related Compounds. See Note 5 and Note 13(a) to the Consolidated Financials Statements included in the Form 10-Q. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

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 and would seek appropriate compensation.

Contingent Consideration

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Through June 30, 2017, no milestones have been achieved. At the end of July 2017, we filed the NDA and have not made the election as to which milestone payment we will make as of the 10-Q filing date.

Product Manufacturing

We are party to a supply agreement with Alkermes for the clinical and, if approved by the FDA, commercial supply of injectable meloxicam. Pursuant to our agreement with Alkermes, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions. We are also party to an API supply agreement with Orion, whereby Orion provides us with API for the development and commercialization of our Dex product candidates. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed-upon amounts. Any amounts ordered by us that are greater than the planned supply will be charged at 50% of the supply price for commercial product.

Leases

On January 1, 2017, we entered into a six-year lease of our Malvern, Pennsylvania facility that expires on December 31, 2022. In February 2017, we also entered into a three-year lease for office space in Dublin, Ireland that expires in April 2020. We are also party to operating leases for office equipment and storage.

Debt

Pursuant to our credit agreement with OrbiMed, OrbiMed provided us with a term loan in the original principal amount of $50.0 million on April 10, 2015. The unpaid principal amount under the credit agreement is due and payable in April 2020. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow calculation. As of June 30, 2017, we have paid $22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

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

Our critical accounting policies and estimates are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K December 31, 2016 filed with the SEC on March 9, 2017. There have not been any significant changes to such critical accounting policies since.

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, 2017, we had approximately $47.6 million invested in money market instruments and government and agency bonds. We believe our policy of investing in highly-rated securities, whose liquidities are, at June 30, 2017, all less than one year, 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 $0.1 million of interest expense.

We have license agreements with Orion for Dex and Fado which require the payment of milestones upon the achievement of certain regulatory and commercialization events and royalties on product sales, which are required to be made in Euros. As of June 30, 2017, no milestones or royalties were due under these agreements, and we do not anticipate incurring milestone or royalty costs under these agreements until we advance our development of Dex or Fado. We do not believe foreign currency exchange rate risk is a material risk at this time; however, these agreements could, in the future, give rise to foreign currency transaction gains or losses. As a result, our results of operations and financial position could be exposed to changing currency exchange rates. In the future, we may periodically use forward contracts to hedge certain transactions or to neutralize exposures.

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, 2017. 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 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.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

As part of the Gainesville Transaction, we acquired the rights to Zohydro ER®, which we license to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® has been subject to six paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016 by Actavis and in December 2015 by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that the three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date in November 2019 or September 2034, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and our predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and, in 2015, we filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In addition, in April 2015, the U.S. Patent and Trademark Office declared an interference between one of our patent applications relating to a dosage form of Zohydro ER® and two Purdue Pharma, LP, or Purdue, applications. On April 29, 2016, the USPTO found our claims and the Purdue claims involved in the interference to be invalid. Purdue appealed this decision to the U.S. Court of Appeals for the Federal Circuit on June 28, 2016, and on June 13, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the USPTO.

Under our license agreement with Pernix, we have the right to control the enforcement of our patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse us for all reasonable costs of such actions. On September 29, 2016, we entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the District Court in the Actavis case ruled in our favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

Item 1A. Risk Factors.

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, 2016.

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

None.

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 INDEX

Exhibit No.	Description	Method of Filing
10.1†	Third Amendment to the Development, Manufacturing and Supply Agreement, dated June 15, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.2†	Licensing Agreement, dated June 30, 2017, by and between Cornell University and Recro Pharma, Inc.	Filed herewith.
10.3†	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Filed herewith.
10.4†	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Filed herewith.
10.5	Employment Agreement, dated June 5, 2017, between Recro Pharma, Inc. and Ryan D. Lake	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 9, 2017 (File No. 001-36329).
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.
31.3	Rule 13a-14(a)/15d-14(a) certification of Principal Accounting	

	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 (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

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 11, 2017

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

Date: August 11, 2017

By: /s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial Officer)

Date: August 11, 2017

By: /s/ Ryan D. Lake
Ryan D. Lake
Chief Accounting Officer
(Principal Accounting Officer)

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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 (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

Exhibit 10.1

Execution Version

[***] 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.

THIRD AMENDMENT TO DEVELOPMENT, MANUFACTURING AND SUPPLY AGREEMENT

This Third Amendment to Development, Manufacturing and Supply Agreement (this "**Third Amendment**") is made and entered into as of June 15, 2017 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 Ireland Limited, a private limited company organized and existing under the laws of the Republic of Ireland ("**Recro**"). Recro and Alkermes are sometimes hereinafter referred to each as a " **Party**" and collectively as the "**Parties**."

Recitals:

WHEREAS, Alkermes and Recro Pharma, Inc. entered into that certain Development, Manufacturing and Supply Agreement on July 10, 2015, as amended by that certain First Amendment to the Development, Manufacturing and Supply Agreement between Alkermes and Recro Pharma, Inc. dated as of October 19, 2016 and by that certain Second Amendment to the Development, Manufacturing and Supply Agreement between Alkermes and Recro Pharma, Inc. dated as of February 1, 2017 (the "**Agreement**");

WHEREAS, with effect from March 7, 2017, the Agreement was assigned by Recro Pharma, Inc. to Recro;

WHEREAS, the Parties desire to amend the terms of the Agreement as set forth herein to provide for certain requests by Recro, the procedure governing the calculation and payment of the amounts payable by Recro to Alkermes for all Services performed with respect to the Requirements under Section 7.1(c) of the Agreement and other miscellaneous matters.

Agreement:

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

Article 1
Definitions

1.1 All capitalized terms used but not otherwise defined herein (including in the Recitals hereto) shall have the meaning ascribed thereto in the Agreement.

Article 2
Amendments to Agreement

2.1 Article 6 of the Agreement is hereby amended by adding the following new Section 6.12:

"**6.12 Requests by Recro.** Notwithstanding any other provision of this Agreement, including without limitation, Sections 4.3, 4.4, 4.5, 6.4, 6.5 and 9.2, where Recro requests Alkermes to adopt a particular practice or approach, with which Alkermes reasonably disagrees, (a "**Request**"), Alkermes shall notify Recro in writing within [***] Business Days of Alkermes identifying an issue with the Request that could have a significant impact upon Alkermes' performance of its obligations under this Agreement; provided that Alkermes' disagreement shall not be considered reasonable where Recro has requested the relevant practice or approach in a timely manner and there is no commercial or regulatory alternative to such practice or approach. Such disagreement shall be referred to the Project Team for resolution pursuant to the dispute resolution procedures of Section 2.1(e). To the extent unresolved, or if agreed by the Parties, the Parties shall document such Request, in a Work Plan or other written agreement (a "**Request Agreement**"). Notwithstanding another provision in this Agreement, in circumstances where Alkermes Manufactures BC Parenteral Meloxicam or Finished Meloxicam in accordance with a Request and/or any Request Agreement and the Quality Agreement and such BC Parenteral Meloxicam or Finished Meloxicam fails to meet any applicable Specifications or there is a failure to pass any other testing or inspection procedures set out in the relevant Request Agreement, the following provisions shall apply:

(a) Alkermes will not bear, and is hereby released from, any responsibility or liability for any such BC Parenteral Meloxicam or Finished Meloxicam, for such failures or for the consequences thereof (including without limitation any obligation to supply replacement BC Parenteral Meloxicam or Finished Meloxicam) and will be deemed to have made such BC Parenteral Meloxicam or Finished Meloxicam available to Recro in compliance with the terms of this Agreement, irrespective of whether such BC Parenteral Meloxicam or Finished Meloxicam was, in fact, made available to Recro; and

(b) Recro will, on demand, indemnify Alkermes against any Liability incurred or suffered by Alkermes in connection with such BC Parenteral Meloxicam or Finished Meloxicam, including without limitation any payments due by Recro under this Agreement for such BC Parenteral Meloxicam or Finished

Meloxicam that, further to Section 6.12(a) above, are deemed to have been made available to Recro in compliance with this Agreement.

Provided that this Section 6.12 shall not relieve Alkermes from liability, or entitle Alkermes to indemnification, to the extent that any such liability resulted from the Alkermes actions and/or omissions referenced in Section 11.3 (a) of this Agreement and provided that Alkermes shall use commercially reasonable efforts to mitigate its Liability, including, when practicable, by consultation with Recro in order to seek Recro's assistance in mitigating such Liability. Without prejudice to the foregoing, the Parties shall continue to work together in good faith to identify alternative approaches to those documented in the relevant Request Agreement and if the Parties agree in writing (other than electronic communication) upon such approaches they shall use commercially reasonable efforts to implement such approaches as soon as commercially practicable in accordance with the terms of this Agreement, and such Request Agreement shall, with effect from the date on which such alternative approaches are fully implemented and fully replace existing approaches, and without prejudice to any rights or obligations which may have arisen on or before such date, cease to be a Request Agreement governed by the terms of this Section 6.12. In the event of (i) any conflict, inconsistency, ambiguity or uncertainty between any term of a Request Agreement and any term of this Agreement (including this Section 6.12), the term of the Request Agreement shall prevail, or (ii) any conflict, inconsistency, ambiguity or uncertainty between any term of this Section 6.12 and any other term of this Agreement, the term of this Section 6.12 shall prevail."

2.2 Section 7.1(c) of the Agreement is hereby amended by adding the following immediately after the first sentence thereof:

"All payments under this Section 7.1(c) are subject to the provisions of Section 7.4."

2.3 Article 7 of the Agreement is hereby amended by the deletion of the current Section 7.1(f) and its replacement by the following:

"**(f)** In respect of Services performed with respect to the Requirements, all invoices under this Agreement shall be issued by Alkermes upon or promptly after Alkermes' making available BC Parenteral Meloxicam, Ex Works the Alkermes Facility. All other invoices under this Agreement shall be issued by Alkermes in accordance with the relevant Work Plan. Subject to Section 7.1(g), Recro will pay such invoices within [***] days of receipt of the

applicable invoice. Invoices shall be emailed to [***]. 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."

2.4 Article 7 of the Agreement is hereby amended by adding the following new Section 7.4:

"**7.4 Procedure for Payments under Section 7.1(c)**. Further to Section 7.1(c), the Parties have agreed the following procedure for the calculation and payment of the amounts payable by Recro to Alkermes for all Services performed with respect to the Requirements:

(a) Prior to the manufacture of Launch Stock in accordance with Section 4.1(b) and at the beginning of each Calendar Year during the term of the Agreement subsequent to the Calendar Year in which the Launch Stock is manufactured, Alkermes shall estimate its Fully Burdened Costs for all Services to be performed with respect to the Requirements for the forthcoming Calendar Year (or remainder thereof), using the latest forecasted Requirements received from Recro in accordance with Section 4.2. Such estimated Fully Burdened Costs, plus [***] shall constitute the "**Estimated Supply Price**". The Estimated Supply Price will be the initial price charged for shipments during the relevant Calendar Year.

(b) Alkermes shall issue invoices to Recro in accordance with Section 7.1(f) in respect of the Services performed with respect to the Requirements.

(c) Within [***] business days following the end of every Calendar Quarter, either Party may request a recalculation of the then applicable Estimated Supply Price, whenever there is a deviation of more than [***]% of the total number of Batches forecast to be delivered for the Calendar Year.

(d) Within [***] days of the end of the Calendar Year, Alkermes shall calculate the actual Fully Burdened Cost for all Services performed with respect to the Requirements, plus [***] (the "**Actual Supply Price**").

(e) Alkermes will perform reconciliation for all units shipped during the previous Calendar Year, comparing the Estimated Supply Price invoiced with the Actual Supply Price. Alkermes will inform Recro in writing of:

(i) Any amounts (underpayments) owed by Recro in the event that the Actual Supply Price was higher than the Estimated Supply Price. Such underpayments will be invoiced by Alkermes and be payable by Recro within [***] days of receipt of invoice.

(ii) Any credits (overpayments) owed to Recro in the event that the Actual Supply Price was lower than the Estimated Supply Price. Such overpayments will be accounted for as a credit to Recro's account and will be credited against future Firm POs until fully offset against such Firm POs."

Article 3
General

3.1 No Other Amendments. Except as expressly set forth in this Third Amendment, this Third Amendment shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of either Party under the Agreement, or alter, modify, amend or in any way affect any of the other terms, obligations or covenants contained in the Agreement, all of which shall continue in full force and effect.

3.2 Miscellaneous Provisions. This Third Amendment shall be subject to the miscellaneous provisions contained in Article 13 of the Agreement, which are incorporated by reference herein, in each case, *mutatis mutandi*.

[*Remainder of this Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the Parties have caused this Third Amendment to be executed by their respective duly authorized representatives as of the date set forth above.

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Shane Cooke
(Signature)

Name: Shane Cooke

Title: Director

RECRO IRELAND LIMITED

By: /s/ Gerri Henwood
(Signature)

Name: Gerri Henwood

Title: Director

Exhibit 10.2
Execution Version

[***] 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.

LICENSE AGREEMENT

BETWEEN

RECRO PHARMA, INC.

AND

CORNELL UNIVERSITY

FOR

CTL Docket No. D-3999
CTL Docket No. D-4398
CTL Docket No. D-4708
CTL Docket No. D-5421

CTL CONTRACT NO. C2017-12-10946

TABLE OF CONTENTS

LICENSE AGREEMENT

This agreement ("Agreement") is made by and between Recro Pharma, Inc., a Pennsylvania corporation having an address at 490 Lapp Road, Malvern PA 19355 ("Licensee"), and Cornell University ("University") as represented by its Center for Technology Licensing ("CTL") at Cornell University at 395 Pine Tree Road, Ithaca, NY 14850 (University, CTL and CRF (as defined below) collectively "Cornell" and each of Licensee and Cornell a "Party" and collectively, the "Parties").

This Agreement is effective on June 30, 2017 ("Effective Date").

RECITALS

WHEREAS, the inventions disclosed in the following dockets:

Cornell Docket	**Title**
3999	Intermediate Duration Neuromuscular Blockers
4398	Symmetrical and Asymmetrical Isoquinolinium Maleates: Nondepolarizing Neuromuscular Blocking Drugs of Intermediate Duration Which are Immediately Reversible by Cysteine and Glutathione
4708	L-Cysteine Hydrochloride Injection Development (5026 Combined herein)
5421	Mixed Isoquinolinium/Piperidinium, Pyrrolidinium or Morpholinium Maleate, Fumarate or Chlorofumarate Diester Neuromuscular Blocking Agents of Ultra-Short and Intermediate Duration, Chemically Degraded and Antagonized by D or L-Cysteine

("Inventions"), were made in the course of research at Cornell by Dr. John Savarese and his associates (hereinafter and collectively, the "Inventors") and are covered by Patent Rights as defined below;

WHEREAS, the Inventors are as of the Effective Date or were, at the time of their making of the Invention(s), either employees of Cornell or otherwise under contract with Cornell and in either case were and are obligated to assign all of their right, title and interest in the Inventions to Cornell or Cornell Research Foundation, Inc. ("CRF") and have done so;

WHEREAS, CTL is the officially authorized unit at Cornell to manage Inventions and to grant rights subsisting therein for Cornell and CRF;

WHEREAS, Cornell desires that the Inventions be developed and utilized to the fullest possible extent so that their benefits can be enjoyed by the general public;

WHEREAS, Licensee desires to obtain certain rights from Cornell for commercial development, use, and sale of the Inventions, and Cornell is willing to grant such rights; and

WHEREAS, Licensee understands that Cornell may publish or otherwise disseminate information concerning the Inventions and Technology (as defined below), in accordance with Paragraph 2.3(b).

NOW, THEREFORE, the Parties agree:

ARTICLE 1. DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

1.1 "Affiliate" means any corporation or other business entity in which Licensee owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors, or in which Licensee is owned or controlled directly or indirectly by at least fifty percent (50%) of the outstanding stock or other voting rights entitled to elect directors; but in any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then an "Affiliate" includes any company in which Licensee owns or controls or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock or voting rights permitted by local law. Licensee will ensure that any Affiliate agrees to be bound by the terms set forth in this Agreement.

1.2 "Cover" means, when used with reference to a Patent Right in relation to any Licensed Product, that the development, manufacture, import, marketing, distribution or sale of the Licensed Product would infringe a Valid Claim of a Patent Right in the absence of a license under such Patent Right. The determination of whether a product is Covered by a particular Patent Right shall be made on a country by country basis.

1.3 "Field" means any and all uses of Licensed Products for the diagnosis, prevention or treatment of any disease or condition in humans and animals.

1.4 "Force Majeure Event" shall mean an event that materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected, not due to such Party's malfeasance, and which could not with the exercise of due diligence have been avoided, including an injunction, order or action by a governmental or regulatory authority, fire, accident, labor difficulty, strike, riot, civil commotion, act of God, delay or errors by shipping companies, change in applicable law, or unforeseen change in market conditions.

1.5 "Generic Equivalent" means any product with the same active ingredient and route of administration as a Licensed Product.

1.6 "IND" means an investigational new drug application filed with the FDA prior to beginning clinical trials in humans in the United States or any comparable application filed with the regulatory authority in any other country or group of countries.

1.7 "IND 106,913" shall mean the Investigational New Drug Application No. 106,913 for the Intermediate-acting Licensed Product and Reversal Agent Licensed Product.

1.8 "Independent Company" means, with respect to Licensee, that either or both of the following are true: (a) no unaffiliated entity has acquired greater than fifty percent (50%) of the voting capital stock of Licensee, other than through normal market capitalization (e.g., selling equity in the public markets) (a "Change of Control"), or (b) if a Change of Control has occurred, the market capitalization of the combined entity is at or below $6 Billion.

1.9 "Know-How" shall mean information, technology, methods, knowledge, know-how, data (including clinical and regulatory data), records and documentation.

1.10 "Licensed Method" means any method that uses Technology or is claimed in Patent Rights or the use of which would constitute, but for the license granted to Licensee under this Agreement, an infringement, an inducement to infringe or contributory infringement, of any pending or issued claim within Patent Rights.

1.11 "Licensed Product" means any service, composition or product that uses Technology, or is claimed in Patent Rights, or that is produced or enabled by Licensed Method, or the manufacture, use, sale, offer for sale, or importation of which would constitute, but for the license granted to Licensee under this Agreement, an infringement, an inducement to infringe or contributory infringement of any pending or issued claim within the Patent Rights. A "Short-acting Licensed Product" means a Licensed Product based on Cornell Docket 5421 or that has a short duration of action; an "Intermediate-acting Licensed Product" means a Licensed Product based on Cornell Dockets 3999 or 4398 or that has an intermediate duration of action; and a "Reversal Agent Licensed Product" means a Licensed Product that reverses the action of a Licensed Product that is a neuromuscular blocking agent.

1.12 "Licensee Know-How" means any Know-How created by Licensee which exists at the Effective Date or during the Term, including but not limited to any improvements, differentiations, or derivatives of the Technology that are created or developed by Licensee at any time.

1.13 "Net Sales" means the total of the gross invoice prices representing sales of Licensed Products by Licensee or its Sublicensees or Affiliates to third parties, less the sum of the following actual and customary deductions where applicable and separately listed: (i) cash, trade, or quantity discounts; (ii) sales, use, tariff, import/export duties or other excise taxes imposed on particular sales, including any governmental taxes, fees, or other charges on the production, importation, use or sale of any Licensed Product (except for value-added and income taxes imposed on the sales of Licensed Product in foreign countries); (iii) rebates, chargebacks, discounts and other adjustments allowed, given or accrued (including, but not limited to, cash, governmental and managed care rebates, hospital or other buying group chargebacks, and governmental taxes in the nature of a rebate based on usage levels or sales of a Licensed Product); (iv) transportation charges; or credits to customers through coupons; (v) samples provided for use in the trade or for clinical trial supply; (vi) actual bad debt (meaning unpaid invoices for Licensed Products which remain unpaid for more than one (1) year) not exceeding ten percent (10%) of all Net Sales for a given calendar year which Licensee can prove and document was not paid in spite of reasonable and diligent efforts to collect payment; and (vii) amounts repaid or credited by reasons of defects, rejections, recalls, rejections or returns. For purposes of calculating Net Sales, transfers to a Sublicensee or an Affiliate of Licensed Product under this Agreement for (x)

end use (but not resale), by the Sublicensee or Affiliate shall be treated as sales by Licensee at the list price of Licensee in an arm-length transaction, or (y) resale by a Sublicensee or an Affiliate shall be treated as sales at the list price of the Sublicensee or Affiliate. Any disposal of Licensed Product at no charge for, or use of such Licensed Product without charge in, clinical or preclinical trials and studies (including for registration or reimbursement) shall not be included in Net Sales. For the avoidance of doubt, in the event that a Licensed Product that is a neuromuscular blocking agent is sold in combination with one or more other Licensed Products (for example, a Short-acting Licensed Product sold together with a Reversal Agent Licensed Product) (a "Combination Product"), the Net Sales will be calculated once and only once based on the Licensed Products that are neuromuscular blocking agents within such Combination Product, and not based upon any average sale price of each Licensed Product within the Combination Product. In the event that any Licensed Product or Combination Product is sold together with one or more other products that are not a Licensed Product, the Net Sales will be calculated based on the average sale price of the Licensed Product that is a neuromuscular blocking agent or Combination Product included therein, without reference to the price of the other product sold with the Licensed Product or the Combination Product.

1.14 "Patent Costs" mean all out-of-pocket expenses for the preparation, filing, prosecution, and maintenance of all United States and foreign patents included in Patent Rights. Patent Costs shall also include reasonable out-of-pocket expenses for patentability opinions, inventorship review and determination, preparation and prosecution of patent application, re-examination, re-issue, interference, opposition activities related to patents or applications in Patent Rights [***].

1.15 "Patent Rights" means CRF's or Cornell's rights in any of the following: (i) the patent applications disclosing and claiming the Inventions, filed by the Inventors and assigned to CRF or Cornell and listed in Appendix A; (ii) applications which claim priority thereto, and continuing applications thereof including divisions, substitutions, and continuations-in-part (but only to extent the claims thereof are enabled by disclosure of the parent application); (iii) any patents issuing on said applications including reissues, reexaminations and extensions; and (iv) any corresponding foreign applications or patents. Up to and terminating on the third anniversary of the Effective Date, to the extent that any new inventions, patents or technology are developed by Cornell, based on further research and development of the Inventions by Cornell, the Parties shall negotiate in good faith to provide an exclusive license to Licensee for any such intellectual property on substantially similar terms to those contained in this Agreement.

1.16 "Royalty Term" means the period of time beginning on the first commercial sale of a Licensed Product in a given country and, expiring on a country-by-country basis with respect to each Licensed Product, upon the later of:

(i) [***];

(ii) [***]; or

(iii) [***].

1.17 "Sublicense" means an agreement into which Licensee enters with a third party that is not an Affiliate for the purpose of (i) granting certain rights; (ii) granting an option to certain rights; or (iii) forbearing the exercise of any rights, granted to Licensee under this Agreement after Effective Date, but excluding in each case any agreements between Licensee or its Affiliates and third parties under which said third parties provide outsourced contract research, regulatory, or manufacturing services directly to Licensee or its Affiliates pertaining to a Licensed Product. "Sublicensee" means a third party with whom Licensee enters into a Sublicense.

1.18 "Technology" means: (a) technology, related documentation, technical information and data, and Know-How created or owned by Cornell that is contained in the documents listed in Appendix B 1: Charles River Documents, the documents listed in Appendix B2: Files at IMPACT, and the materials listed in Appendix B3: Materials at Almac under Quote #15366, and relating to IND 106,913; and/or (b) the Inventions that Cornell or an Inventor provide or disclose to Licensee, in each case (of (a) and (b)) prior to the Effective Date or during the Term.

1.19 "Term" means the period of time beginning on the Effective Date and continuing until the earliest of (a) termination as set forth in Paragraphs 7.1 — 7.4 and (b) the last to expire Royalty Term.

1.20 "Territory" means worldwide, except as may be modified by Paragraph 3.3(c).

1.21 "Valid Claim" means either (i) a claim of an unexpired and issued patent included within Patent Rights that has not been permanently revoked or held unenforceable or invalid by a final unappealable decision or unappealed decision of a court of competent jurisdiction or (ii) a claim of a pending patent application included within Patent Rights which claim has been filed and is being prosecuted in good faith, has been pending for no longer than five (5) years, and has not been abandoned or disallowed without the possibility of appeal or refiling of the application.

ARTICLE 2. GRANTS

2.1 **License Grants**.

(a) Subject to Article 5.1 ("patent costs reimbursement obligations") and to the limitations set forth in this Agreement, Cornell hereby grants to Licensee and its Affiliates (i) an exclusive (except as to Cornell to the extent set forth in Paragraph 2.3), sublicensable (solely pursuant to Paragraph 2.2), royalty-bearing license under Patent Rights, and (ii) a non-exclusive, sublicensable (pursuant to Paragraph 2.2), royalty-bearing license under the Technology, in each case to make and have made, to use and have used, to sell and have sold, to offer for sale, and to import and have imported Licensed Products, to practice Licensed Methods and to use and further develop the Technology in the Field within the Territory and during the Term. (the "Licenses").

(b) In connection with the exercise of the Licenses by Licensee's Affiliates, Licensee agrees to provide to Cornell a written assurance from each of its Affiliates exercising rights under the Licenses to comply with all applicable terms of this Agreement.

2.2 **Sublicense**.

(a) Licensee may grant Sublicenses of its licensed rights hereunder to third parties in accordance with this Paragraph, through one or more tiers.

(b) With respect to any permitted Sublicense, Licensee shall:

(i) not receive, or agree to receive, anything of value in lieu of cash as consideration from a third party under a Sublicense granted pursuant to Paragraph 2.2(a) without the prior written consent of Cornell;

(ii) enter into a written agreement pursuant to which Sublicensee shall agree to comply with all applicable terms contained in this Agreement;

(iii) reasonably promptly provide Cornell with a copy of each Sublicense issued and any amendment made to any Sublicense; and

(iv) be responsible for collecting all payments due, directly or indirectly, to Cornell from Sublicensees, and summarizing and delivering all reports due, directly or indirectly, to Cornell from Sublicensees as required by this Agreement.

(c) Unless Cornell provides written consent to a Sublicense prior to its issuance by Licensee to the Sublicensee, solely upon termination of this entire Agreement for any reason, Cornell, at its sole discretion, shall determine whether Licensee shall cancel or assign to Cornell said Sublicense.

2.3 **Reservation of Rights**. Cornell reserves the right to:

(a) use the Inventions, Technology and Patent Rights solely for non-commercial educational and research purposes;

(b) publish or otherwise disseminate any information about the Inventions and Technology at any time provided that, to the extent that CTL has knowledge of such publication, CTL will provide Licensee 90 days' notice of such publication; and

(c) allow other nonprofit institutions to use Inventions, Technology and Patent Rights solely for non-commercial educational and research purposes.

ARTICLE 3. CONSIDERATION

3.1 **Fees and Royalties**. The Parties hereto understand that the fees and royalties payable by Licensee to Cornell under this Agreement are in consideration for the license granted herein to Licensee under Technology and Patent Rights. Licensee shall pay Cornell:

(a) an initial license issue fee of [***] ([***]) ("Initial License Fee") and a materials fee of [***] ([***]) ("Materials Fee"), each within thirty (30) days after the Effective Date;

(b) annual license maintenance fees, payable on each anniversary of the Effective Date according to the following schedule; provided however, that Licensee's obligation to pay this fee shall end upon the first commercial sale of any Licensed Product in any country in the Territory, whereupon the annual license maintenance fee shall be pro-rated for the number of months expired in that license year prior to such first commercial sale and be paid on the anniversary of the Effective Date.

Fee payable to Cornell	Date
[***]	1st anniversary
[***]	2nd anniversary
[***]	3rd anniversary
[***]	4th anniversary
[***]	5th anniversary
[***]	6th anniversary
[***]	7th anniversary
[***]	8th anniversary
[***]	9th and each anniversary thereafter

(c) during the Royalty Term, milestone payments ("Milestone Payments") in the amounts payable according to the following schedule of events upon the specified date or achievement of the specified event:

Amount	Milestone
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, the maximum, aggregate Milestone Payments due for each Licensed Product shall be $8,000,000.

(d) during the Royalty Term, on a per-Licensed-Product and country-by-country basis, an earned royalty on Net Sales of Licensed Products by Licensee and/or its Affiliate(s) and Sublicensees ("Earned Royalty") as follows:

When Licensed Product is:	the earned royalty rate is:
A Short-acting Licensed Product, (including any Combination Product in which a Short-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where a Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
A Short-acting Licensed Product (including any Combination Product in which a Short-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where no Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
An Intermediate-acting Licensed Product (including any Combination Product in which an Intermediate-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where a Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
An Intermediate-acting Licensed Product (including any Combination Product in which an Intermediate-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where no Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
A Reversal Agent Licensed Product, in countries where a Valid Claim Covers the applicable Licensed Product and solely where such Reversal Agent Licensed Product is sold as a stand-alone product and not as part of a Combination Product	[***]% of Net Sales of the applicable Licensed Product
A Reversal Agent Licensed Product, in countries where no Valid Claim Covers the applicable Licensed Product and solely where such Reversal Agent Licensed Product is sold as a stand-alone product and not as part of a Combination Product	[***]% of Net Sales of the applicable Licensed Product

In the event Licensee is required to pay royalties to one or more third parties for Patent Rights necessary to sell Licensed Products, and the total royalties payable by Licensee exceed [***], then Licensee may deduct [***]from the Earned Royalties payable to Cornell for every $1.00 Licensee actually pays to said third parties of the amount Licensee pays above the [***]; provided, however, in no event shall the amount payable to Cornell be less than [***]% of the amount otherwise due.

for every $1.00 Licensee actually pays to said third parties of the amount Licensee pays above the [***]; provided, however, in no event shall the amount payable to Cornell be less than [***]% of the amount otherwise due.

(e) during the Royalty Term, Sublicense fees relating to amounts received from Sublicensees in an amount equal to [***]; *provided, however,* that for purposes of this Paragraph 3.1(e), such fees received by Licensee from its Sublicensees shall be deemed reduced by the amount of any costs and expenses that Licensee is obligated, under the terms and conditions of the applicable Sublicense, to incur or pay with respect to the development of the applicable Licensed Product, and *provided, further,* that [***].

(f) during the Royalty Term, beginning the first full calendar year after the commercial sale of the first License Product by Licensee, its Sublicensee, or an Affiliate and if the total payments by Licensee under Paragraphs 3.1(d) to Cornell in any such year cumulatively are less than the amount ("Minimum Annual Royalty") illustrated below:

Year of Commercial Sale	Minimum Annual Royalty
1st	[***]
2nd	[***]
3rd	[***]
4th and each year thereafter	[***]

Licensee shall pay to Cornell on or before February 28 following the last quarter of such year the difference between the Minimum Annual Royalty for the applicable calendar year and the total Earned Royalty amount paid by Licensee for such year under Paragraph 3.1(d); *provided, however*, that for the year of commercial sales of the first Licensed Product, and for any year in which a Licensed Product is removed from the market temporarily or permanently due to regulatory action, the Minimum Annual Royalty payable shall be pro-rated for the number of months remaining in that calendar year.

All fees and royalty payments specified in Paragraphs 3.1(a) through 3.1(f) above shall be paid by Licensee pursuant to Paragraph 4.3 and shall be delivered by Licensee to Cornell as noted in Paragraph 10.1.

3.2 **Patent Costs**. Licensee shall reimburse Cornell for all Past Patent Costs (incurred prior to the Effective Date and in the amounts set forth below) and all Future Patent Costs (incurred on or after the Effective Date). Past Patent Costs shall be paid on June 30th and December 31st of the applicable years set forth in the table below. Future Patent Costs shall be paid within thirty (30) days following the date an itemized invoice is received by Licensee from Cornell, which invoices shall be sent monthly. Past Patent Costs are [***] as of June 30, 2017 and shall be paid according to the following schedule:

Date	Payment
December 31, 2017	[***]
June 30, 2018	[***]
December 31, 2018	[***]
June 30, 2019	[***]

3.3 **Due Diligence**.

(a) Licensee shall use commercially reasonable efforts to, either directly or through its Affiliate(s) or Sublicensee(s):

(i) diligently proceed with the development, manufacture and sale of such Licensed Products;

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***];

(vii) [***];

(viii) [***];

(ix) [***];

(x) [***];

(xi) [***];

(xii) [***];

(xiii) [***];

(xiv) reasonably fill the market demand for Licensed Products following commencement of marketing at any time during the term of this Agreement; and

(xv) obtain and maintain all necessary governmental approvals and permits for the manufacture, use and sale of Licensed Products in the Territory during the Term.

(b) If Licensee fails to perform any of its material obligations, then Cornell shall issue a Notice of Default to Licensee and the Parties shall discuss in good faith the key reasons for any such delay, and where any such delay or failure to meet the goals set forth above is due to any key scientific or technical challenges or complexities, regulatory challenges or changes, or unexpected development costs, challenges or complexities or safety issues, manufacturing challenges or hurdles, commercial factors, IP issues or any other key aspects of development and commercialization, the Parties shall discuss the matter in good faith and within sixty (60) days of such Notice of Default, Licensee shall propose a modified development plan in order to remedy or overcome any such challenges. If Cornell agrees, or the arbitrator determines pursuant to Appendix C, that there is a reasonable basis for said plan, then such modified development plan shall constitute Licensee's new development plan, and the failure described in the Notice of Default will be deemed timely cured. In the event that after Licensee initiates such modified development plan, Cornell does not believe that Licensee (directly or through its Sublicensee) is applying its commercially reasonable efforts towards the material objectives therein, then Cornell may request that the arbitrator determine pursuant to Appendix C whether Licensee (directly or through its Sublicensee) is applying such efforts, and if the arbitrator agrees with Cornell that Licensee (directly or through its Sublicensee) is not applying such efforts, then Cornell shall have the right and option to either terminate this Agreement or change Licensee's exclusive license to a nonexclusive license. This right, if exercised by Cornell, supersedes the rights granted in Article 2.

(c) If at any time during the Term, Licensee has not begun a genuine product or business development program for a specific Licensed Product in any country within the Territory and Cornell receives one or more legitimate inquiries to license Patent Rights for the commercialization of said specific Licensed Product in said country, Cornell shall refer such offers to Licensee. If (i) Licensee is no longer an Independent Company, and (ii) Licensee fails to satisfy the market demand (within 25%) in said country of the specific Licensed Product, and Licensee is unable to cure such failure within ninety (90) days from the date of notice, or fails to grant Sublicenses to the inquirers to satisfy such market demand (after Licensee has failed to cure such failure as set forth above), Cornell may then exclude said country, and only said country, from the Territory and license such rights to one or more third parties.

ARTICLE 4. REPORTS, RECORDS AND PAYMENTS

4.1 **Reports**.

(a) **Development Reports**. Beginning six (6) months after Effective Date and ending on the date of first commercial sale of a Licensed Product in the United States, Licensee shall report to Cornell progress covering Licensee's (and Affiliate's and Sublicensee's, as applicable) material activities and efforts in the development of any Licensed Products in the Field under this Agreement. Such reports shall be provided for the preceding six (6) months. The report shall include, but not be limited to, activities and efforts to develop and test all Licensed Products in the Field in the Territory and obtain governmental approvals necessary for marketing the same. Such semi-annual reports shall be due within sixty (60) days of the end of the applicable semi-annual reporting period and shall substantially conform to the form provided herein as Appendix D.

(b) **Commercialization Reports.** After the first commercial sale of a Licensed Product anywhere in the Territory, Licensee shall submit to Cornell semi-annual commercialization reports on or before each February 28 and August 31 of each year during the Term. Each report shall cover Licensee's (and each Affiliate's and Sublicensee's, as applicable) most recently completed calendar half and shall show:

(i) the gross sales and Net Sales (as defined in Paragraph 1.11) during the most recently completed calendar quarter and the royalties, in US dollars, payable with respect thereto;

(ii) the number of each type of Licensed Product sold (in units or stock keeping units, as applicable);

(iii) sublicense fees and royalties received during the most recently completed calendar half in US dollars, payable with respect thereto;

(iv) the method used to calculate the royalties;

(v) the exchange rates used; and

(vi) relevant business and corporate development efforts relating to the rights granted in this Agreement.

Licensee shall provide the above information using a form that substantially complies with the form shown in Appendix E and include information on the date of the first commercial sale of each Licensed Product in each country.

If no sales of Licensed Products have been made and no Sublicense revenue has been received by Licensee during the applicable reporting period, Licensee shall so report such information to Cornell, which such communication shall be deemed to satisfy in full Licensee's reporting obligations hereunder.

4.2 **Records & Audits**.

(a) Licensee shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct records of Net Sales and such records as are necessary to determine the amounts due to Cornell under this Agreement. Such records shall be retained by Licensee for at least five (5) years following a given reporting period.

(b) All records shall be available during normal business hours upon a mutually agreeable date and time and with at least fifteen (15) business days' advance written notice to Licensee for inspection, at the expense of Cornell, by an independent Certified Public Accountant selected by Cornell and in compliance with the other terms of this Agreement for the sole purpose of verifying reports and payments or other compliance issues. Such inspector shall not disclose to Cornell any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. In the event that any such inspection shows an undisputed under-reporting and underpayment in excess of five percent (5%) for any twelve-month (12-month) period, then Licensee shall pay the cost of the audit as well as any additional sum that would have been payable to Cornell had the Licensee reported correctly, plus an interest charge at a rate of ten percent (10%) per year. Such interest shall be calculated from the date the correct payment was due to Cornell up to the date when such payment is actually made by Licensee. For any undisputed underpayment not in excess of five percent (5%) for any twelve-month (12-month) period, Licensee shall pay the difference within thirty (30) days without inspection cost but with interest charge per the provisions of Paragraph 4.3(c).

4.3 **Payments**.

(a) All fees, reimbursements and royalties due Cornell shall be paid in United States dollars and all checks shall be made payable to "Cornell University", referencing Cornell's taxpayer identification number, [***], and sent to Cornell according to Paragraph 10.1 (Correspondence). When Licensed Products are sold in currencies other than United States dollars, Licensee shall first determine the Earned Royalty in the currency of the country in which Licensed Products were sold and then convert the amount into equivalent United States funds, using the exchange rate quoted in the Wall Street Journal on the last business day of the applicable reporting period.

(b) Royalty Payments.

(i) Royalties shall accrue when payments for the applicable Licensed Products are invoiced, or if not invoiced, when delivered to a third party or Affiliate.

(ii) Licensee shall pay Earned Royalties semi-annually on or before February 28 and August 31 of each calendar year for the previous calendar half. Each such payment shall be for earned royalties accrued within Licensee's most recently completed calendar half.

(iii) Royalties earned on sales occurring pursuant to this Agreement or under a Sublicense granted pursuant to this Agreement in any country outside the United States shall not be reduced by Licensee for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income, except that all payments made by Licensee in fulfillment of Cornell's tax liability in any particular country may be credited against earned royalties or fees due Cornell for that country. Licensee shall pay all bank charges resulting from the transfer of such royalty payments.

(iv) If at any time legal restrictions prevent the prompt remittance of part or all royalties by Licensee with respect to any country where a Licensed Product is sold or a Sublicense is granted pursuant to this Agreement, Licensee shall convert the amount owed to Cornell into US currency and shall pay Cornell directly from its US sources of funds for as long as the legal restrictions apply.

(v) In the event that any patent or patent claim within Patent Rights expires or is held invalid in a final decision by a patent office from which no appeal or additional patent prosecution has been or can be taken, or by a court of competent jurisdiction and last resort and from which no appeal has or can be taken, all obligation to pay royalties based solely on that patent or claim or any claim patentably indistinct therefrom shall cease as of the date of such final decision in the applicable country within the Territory. Licensee shall not, however, be relieved from paying any royalties that accrued before the date of such final decision in the applicable country within the Territory, or that are based on another patent or claim within the Patent Rights not involved in such final decision, or that are based on the use of the Technology in the applicable country within the Territory.

(c) Late Payments. In the event royalty, reimbursement and/or fee payments are not received by Cornell when due, Licensee shall pay to Cornell interest charges at a rate of [***]. Such interest shall be calculated from the date payment was due until actually received by Cornell.

ARTICLE 5. PATENT MATTERS AND TECHNOLOGY OWNERSHIP

5.1 **Patent Prosecution and Maintenance** .

(a) Provided that Licensee has reimbursed Cornell for Patent Costs pursuant to Paragraph 3.2, Cornell shall diligently prosecute and maintain the United States and, if available, foreign patents, and applications in Patent Rights using counsel that is mutually agreed upon by the Parties. Cornell shall provide Licensee with copies of all relevant documentation relating to such prosecution and an opportunity to review and comment upon the text of the applications relating to the Patent Rights as soon as practicable (but in no event less than thirty (30) days for new patent application filings and fifteen (15) days for all other filings) before filing. The counsel shall take instructions only from Cornell, and all patents and patent applications in Patent Rights shall be assigned solely to CRF or Cornell. Further, Cornell shall (i) consider

amending any patent application in Patent Rights to include claims reasonably requested by Licensee to protect the products contemplated to be sold as Licensed Products by Licensee under this Agreement; (ii) provide Licensee with a copy of each submission made to and document received from a patent authority, court or other tribunal relating to the Patent Rights reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Patent Rights as filed together with notice of its filing date and application number; (iii) keep Licensee apprised of the status of all material communications, actual and prospective filings or submissions regarding the Patent Rights, and give Licensee copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) reasonably consider in good faith Licensee's comments on the communications, filings and submissions for the Patent Rights. For the avoidance of doubt, Licensee shall be free to prosecute and maintain the United States and, if available elsewhere in the Territory, any and all patents and applications therefor using counsel of its choosing with respect to any inventions owned by Licensee.

(b) Licensee may elect to terminate its reimbursement obligations with respect to any patent application or patent in Patent Rights upon ninety (90) days written notice to Cornell. Cornell shall use reasonable efforts to curtail further Patent Costs for such application or patent when such notice of termination is received from Licensee. Cornell, in its sole discretion and at its sole expense, may continue prosecution and maintenance of said application or patent, and Licensee shall have no further license with respect thereto and shall not be responsible for any costs or fees associated therewith incurred by Cornell after said 90 day period has ended. Non-payment of any portion of Patent Costs with respect to any application or patent, which remains uncured for sixty (60) days following Cornell's Notice of Default with respect to such non-payment, may be deemed by Cornell as an election by Licensee to terminate its reimbursement obligations with respect to such application or patent. Cornell is not obligated to file, prosecute, or maintain Patent Rights outside of the territory at any time or to file, prosecute, or maintain Patent Rights to which Licensee has terminated its License hereunder.

(c) From and after the Effective Date, if Cornell proposes to abandon or fail to maintain any patent or patent application within the Patent Rights, it shall give Licensee reasonable notice thereof (with sufficient time for Licensee to assume control thereof and continue the prosecution or maintenance of such patent, trademark or application) and thereafter Licensee may, upon written notice to Cornell and at Licensee's sole cost, control the prosecution and maintenance with respect to such patent or application (such patent or patent application so assumed, a "Licensee Assumed Item"). Licensee shall control, itself or through outside counsel reasonably acceptable to Cornell and directed by Licensee, prosecution and maintenance with respect to Licensee Assumed Items in the Territory, at Licensee's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections therefor. Licensee shall provide Cornell with a copy of each material submission made to and document received from a patent authority regarding any Licensee Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Licensee Assumed Items as filed together with notice of its filing date and application number.

(d) No later than 120 days after the Effective Date, Cornell and Licensee shall discuss a prosecution strategy in respect of the Patents Rights. During the Term, if Licensee reasonably believes that Cornell's prosecution or maintenance of any Patent Rights is inconsistent with the prosecution strategy as agreed upon by the Parties, or otherwise believes that the Patent Costs attendant to the prosecution or maintenance of any such Patent Right are unreasonable, then the CEO of Recro Pharma, Inc. and the Director of Technology/Licensing for Cornell shall meet and attempt to come to a resolution. To the extent that the parties are unable to come to a mutually agreeable resolution, the dispute shall be settled in accordance with Paragraph 10.8 (Dispute Resolution) of this Agreement.

(e) Licensee shall have the right to apply for an extension of the term of any patent in Patent Rights if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or European, Japanese and other foreign counterparts of this law. Licensee shall prepare all documents for such application, and Cornell shall execute such documents and to take any other additional action as Licensee reasonably requests in connection therewith.

5.2 **Patent Infringement**.

(a) If either Party learns of any substantial infringement of Patent Rights, such Party shall reasonably promptly inform the other Party and provide the other Party with any available evidence of the infringement. Neither party shall notify a third party of the infringement of Patent Rights without the consent of the other party. Both Parties shall use reasonable efforts and cooperation to terminate infringement without litigation.

(b) From and after the Effective Date, Licensee shall have the first right, but not the obligation, to enforce Patent Rights against any actual, alleged or threatened infringement or misappropriation by third parties in the Territory, at Licensee's sole expense. In the event Licensee elects to bring and prosecute such an action, Cornell shall reasonably assist Licensee and cooperate in any such action at Licensee's request (and Licensee shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Cornell in connection therewith), and Licensee shall seek and reasonably consider Cornell's comments before determining the strategy. Without limiting the foregoing, Licensee shall keep Cornell advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Cornell copies of and an opportunity to review and comment on any such material communications, filings and submissions. Licensee shall not settle, or consent to any judgment in, any action under this Paragraph 5.2(b) without Cornell's prior written consent, not to be unreasonably withheld or delayed.

(c) From and after the Effective Date, Cornell may request that Licensee take legal action against a third party for the infringement of Patent Rights in the Field and within the Territory. Such request shall be made in writing and shall include any available evidence of such infringement and damages. If the infringing activity has not abated ninety (90) days following Cornell's request, Licensee shall elect to or not to commence suit on its own account. Licensee shall give notice of its election in writing to Cornell by the end of the one-hundredth (100th) day after receiving notice of such request from Cornell. Cornell may thereafter bring suit for patent infringement and any related claims at its own expense and Licensee will cooperate with Cornell. If Cornell elects to bring and prosecute such an action, then Cornell shall seek and reasonably

consider Licensee's comments on strategy. Without limiting the foregoing, Cornell shall keep Licensee advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Licensee copies of and an opportunity to review. Cornell shall not settle, or consent to any judgment in, any action under this Paragraph 5.2(c), without Licensee's prior written consent, not to be unreasonably withheld or delayed.

(d) Any recovery or settlement received in connection with any suit brought pursuant to Paragraphs 5.2(b) or 5.2(c) will [***].[***].[***]. Cornell and Licensee agree to be bound by all determinations of patent infringement, validity, and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Paragraph 5.2.

(e) Notwithstanding 5.2(d), any agreement made by Licensee for purposes of settling litigation or other dispute shall comply with the requirements of Paragraph 2.2 (Sublicense) of this Agreement.

(f) Each party shall cooperate with the other in litigation proceedings at the expense of the party bringing suit. Litigation shall be controlled by the party bringing the suit. CRF and/or Cornell may be represented by counsel of its choice at its own expense in any suit brought by Licensee. For the sake of clarity, each party may be represented by counsel of its choice in any suit brought against them by the alleged infringer.

5.3 **Patent Marking**. Licensee shall mark all Licensed Products made, used or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws.

5.4 **Ownership of Technology**

(a) Cornell retains ownership of the Technology, and Cornell shall be the sole owner of all right, title and interest to such Technology and all intellectual property rights therein. During the Term, Licensee shall make no use of Technology outside the scope of this Agreement and the licenses granted hereunder. Any such use shall be a material breach of this Agreement.

(b) Licensee retains ownership of the Licensee Know-How and Licensee shall be the sole owner of all right, title and interest to such Licensee Know-How and all intellectual property rights therein. Cornell shall make no use of the Licensee Know-How and any such use shall be a material breach of this Agreement.

(c) Promptly after receipt by Cornell of the Initial License Fee and the Materials Fee from Licensee pursuant to Paragraph 3.1(a), Cornell shall transfer IND 106,913 to Licensee by filing a letter with the FDA stating that all rights to IND 106,913 have been transferred to Licensee as the new owner, as of the effective date set forth therein, pursuant to 21 CFR 312.72 Change in Ownership of Application and in a form reasonably acceptable to Licensee. Cornell shall execute two (2) copies of such letter, and shall deliver one (1) copy to each of FDA and Licensee. Upon termination of this Agreement, the Parties will discuss and agree upon their desired treatment and disposition of IND 106,913.

ARTICLE 6. GOVERNMENTAL MATTERS

6.1 **Governmental Approval or Registration**. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee shall assume all legal obligations to do so and Cornell shall cooperate with Licensee in fulfilling any such obligations. Licensee shall notify Cornell if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. Licensee shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

6.2 **Export Control Laws**. Licensee shall observe all applicable United States and foreign laws with respect to the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations and the Export Administration Regulations.

ARTICLE 7. TERMINATION AND EXPIRATION OF THE AGREEMENT

7.1 **Termination by Cornell**.

(a) If Licensee fails to perform or violates any term and is in material breach of this Agreement, then Cornell may give written notice of default ("Notice of Default") to Licensee. If Licensee fails to cure the default within sixty (60) days of the Notice of Default, Cornell may terminate this Agreement and the license granted herein by a second written notice ("Notice of Termination") to Licensee. If a Notice of Termination is sent to Licensee, this Agreement shall automatically terminate on the effective date of that notice. Termination shall not relieve Licensee of its obligation to pay any fees owed at the time of termination and shall not impair any accrued right of Cornell.

(b) This Agreement will terminate immediately, without the obligation to provide written notices as set forth in Paragraph 7.1(a), if Licensee files a claim including in any way the assertion that any portion of CRF's or Cornell's Patent Rights is invalid or unenforceable where the filing is by the Licensee, a third party on behalf of the Licensee, or a third party at the written urging of the Licensee.

7.2 **Termination by Licensee**.

(a) Licensee shall have the right at any time and for any reason to terminate this Agreement upon ninety (90) days written notice to Cornell. Said notice shall state Licensee's reason (if any) for terminating this Agreement.

(b) Any termination under Paragraph 7.2(a) shall not relieve Licensee of any obligation or liability accrued under this Agreement or rescind any payment made to Cornell prior to the time termination becomes effective. Termination shall not affect in any manner any rights of Cornell or CRF arising under this Agreement prior to termination.

7.3 **Survival on Termination**. The following Paragraphs and Articles shall survive the termination of this Agreement:

(a) Article 4 (REPORTS, RECORDS AND PAYMENTS);

(b) Paragraph 7.3 (Survival on Termination);

(c) Paragraph 7.4 (Disposition of Licensed Products on Hand);

(d) Paragraph 7.5 (Post-Expiration License);

(e) Paragraph 8.2 (Indemnification);

(f) Article 9 (USE OF NAMES AND TRADEMARKS);

(g) Paragraph 10.2 hereof (Confidentiality); and

(h) Paragraph 10.5 (Failure to Perform).

7.4 **Disposition of Licensed Products on Hand**. Upon termination of this Agreement under Paragraph 7.1 or 7.2, Licensee may dispose of all previously made or partially made Licensed Product within a period of one hundred and twenty (120) days of the effective date of such termination provided that the sale of such Licensed Product by Licensee, its Sublicensees, or Affiliates shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and payment of royalties required under this Agreement.

7.5 **Post-Expiration License**. Effective upon the expiration of the Royalty Term for a given Licensed Product in a given country, Cornell hereby grants to Licensee and its Affiliates, and Licensee and its Affiliates will retain, a royalty-free, nonexclusive license, with the right to grant sublicenses, under the Technology, in each case to make and have made, to use and have used, to sell and have sold, to offer for sale, and to import and have imported Licensed Products, to practice Licensed Methods and to use and further develop the Technology in the Field in said country; the obligations to Cornell in Paragraph 8.2 and Article 9 remain in effect for as long as Licensee is using Technology and must be transferred with any transfer of Technology to a third party. The grant and obligations in this Paragraph 7.5 survive expiration of this Agreement. This Paragraph 7.5 does not apply if this Agreement is terminated under Paragraphs 7.1 or 7.2.

ARTICLE 8. LIMITED WARRANTY AND INDEMNIFICATION

8.1 **Limited Warranty**.

(a) Cornell warrants that (i) it has the lawful right to grant the licenses under this Agreement; (ii) neither it, CTL nor CRF have granted or will grant any right, license, or interest in, to, or under the Patent Rights or Technology that is inconsistent with the rights, licenses, and interests granted under the terms and conditions set forth in this Agreement including but not limited to (x) granting any rights or licenses under Patent Rights that would enable the development, manufacturing, import or commercialization of any Licensed Product in the Field or (y) granting any exclusive rights or licenses under Technology that would enable the

development, manufacturing, import or commercialization of any Licensed Product in the Field; (iii) prior to the Effective Date, to the best of its knowledge, without undue investigation, neither it nor CTL or CRF have received any written notice of any opposition or challenge against any Patent Rights in the Territory; and (iv) prior to the Effective Date, to the best of its knowledge, without undue investigation, neither it nor CTL or CRF have received any written notice from any third party or alleging that the use of the Patent Rights, Technology, IND 106,913, or the Licensed Method is infringing or is likely to infringe the rights of any third party.

(b) Except as otherwise set forth herein, the Licenses are provided "AS IS" and without WARRANTY OF MERCHANTABILITY or WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE or any other warranty, express or implied. Except as otherwise set forth herein, Cornell makes no representation or warranty that the Licensed Product, Licensed Method, or the use of Patent Rights, IND 106,913, or Technology will not infringe any other patent or other proprietary rights.

(c) IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM EXERCISE OF THE LICENSE GRANTED HEREIN OR THE USE OF THE INVENTIONS, LICENSED PRODUCT, LICENSED METHOD, IND 106,913 OR TECHNOLOGY. NOTHING IN THIS PARAGRAPH 8.1(C) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF LICENSEE UNDER SECTION 8.2 WITH RESPECT TO ANY DAMAGES OR SETTLEMENT PAYMENTS PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD-PARTY CLAIM.

(d) Except as otherwise set forth in Paragraph 8.1(a) or otherwise set forth in this Agreement, nothing in this Agreement shall be construed as:

(i) a warranty or representation by Cornell or CRF as to the validity or scope of any Patent Rights;

(ii) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;

(iii) an obligation to bring or prosecute actions or suits against third parties for patent infringement except as provided in Paragraph 5.2 hereof;

(iv) conferring by implication, estoppel or otherwise any license or rights under any patents of CRF or Cornell other than Patent Rights as defined in this Agreement, regardless of whether those patents are dominant or subordinate to Patent Rights; or

(v) an obligation to furnish any Know-How apart from Know-How related to the Patent Rights or otherwise included in the Technology; or

(vi) an obligation to update Technology.

(e) Licensee represents and warrants that:

(i) as of the Effective Date, Recro Ireland Limited is an Affiliate of Licensee; and

(ii) Licensee will provide prompt written notice to Cornell if any Affiliate of Licensee that has exercised rights under this Agreement ceases to be an Affiliate of Licensee, which written notice will describe the disposition of any Patent Rights, Technology, and Licensed Product that was in the possession or control of said former Affiliate.

8.2 **Indemnification**.

(a) Licensee shall indemnify, hold harmless and defend CRF, Cornell, and each of their respective trustees, directors, officers, employees, and agents; the sponsors of the research that led to the Inventions; and the Inventors of the patents and patent applications in Patent Rights and their employers (the "Cornell Indemnitee(s)") against any and all claims, suits, losses, damage, costs, fees, and expenses ("Losses") arising out arising out of any claim, action, lawsuit, or other proceeding (collectively, "Claims") brought against any Cornell Indemnitee by a third party to the extent such Losses result from the development or commercialization of the Licensed Products by Licensee or its Affiliates or Sublicensees, except to the extent involving or relating to (i) a material breach by Cornell of this Agreement, including any failure of Cornell's representations or warranties in Paragraph 8.1(a) to be true, or (ii) any gross negligence, willful misconduct or fraud of any Cornell Indemnitee.

(b) Whenever any Claim or Loss shall arise for which a Cornell Indemnitee (the "Indemnified Party") may seek indemnification under this Paragraph 8.2, the Indemnified Party shall promptly notify the other Party (the "Indemnifying Party") of the Claim or Loss and, when known, the facts constituting the basis for the Claim; *provided, however*, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Paragraph 8.2 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. Except as set forth in this Paragraph, the Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense. The Indemnifying Party shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to the Indemnified Party and shall cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party. The Indemnified Party shall not settle or compromise such Claim for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the Indemnified Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Paragraph 10.2.

The Indemnified Party shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. Notwithstanding the foregoing, the Indemnified Party will have the right to employ separate counsel at the Indemnifying Party's expense and to control its own defense of the applicable Claim if: (i) there are or may be legal defenses available to the Indemnified Party that are different from or additional to those available to the Indemnifying Party; or (ii) in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between the Indemnified Party and Indemnifying Party that would make such separate representation advisable; *provided* that in no event will the Indemnifying Party be required to pay fees and expenses under this sentence for more than one (1) firm of attorneys in any jurisdiction in any one (1) legal action or group of related legal actions. In such event, the Indemnified Party shall not settle or compromise such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

(c) Licensee, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain and maintain insurance or an equivalent program of self-insurance as follows:

(i) Prior to the first "in human" test of a Licensed Product: comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [***]; (B) products/completed operations aggregate, [***]; (C) personal and advertising injury, [***]; and (D) general aggregate (commercial form only), [***]; and

(ii) Commencing upon the first "in human" test of a Licensed Product: comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [***]; (B) products/completed operations aggregate, [***]; (C) personal and advertising injury, [***]; and (D) general aggregate (commercial form only), [***]; and

(iii) the coverage and limits referred to above shall not in any way limit the liability of Licensee.

(d) Licensee shall, upon request, furnish Cornell with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) provide for thirty (30) day advance written notice to Cornell of any modification; (ii) indicate that Cornell has been endorsed as an additionally insured party under the coverage referred to above; and (iii) include a provision that the coverage shall be primary and shall not participate with nor shall be excess over any valid and collectable insurance or program of self-insurance carried or maintained by Cornell.

ARTICLE 9. USE OF NAMES AND TRADEMARKS

9.1 Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either Party hereto (including contraction, abbreviation or simulation of any of the foregoing). Unless required by law, the use by Licensee of the name, "Cornell University" or "Cornell Research Foundation" is prohibited, without the express written consent of Cornell.

9.2 Cornell may acknowledge the existence of this Agreement and the extent of the grant in Article 2 to third parties, provided that the financial terms of this Agreement shall be deemed Confidential Information such that the obligations of Paragraph 10.2 shall apply to any disclosure(s) thereof.

9.3 Licensee may acknowledge or make press releases regarding the existence of this Agreement and the extent of the grant in Article 2 but Licensee shall not disclose the financial terms of this Agreement except where disclosure of Confidential Information is permitted in accordance with Paragraph 10.2(b)(iii) herein or otherwise required by law, regulation, exchange rules or legal process. To the extent Licensee makes any forward-looking statement regarding this Agreement in its press releases, Licensee shall seek the prior consent of Cornell, which shall not be unreasonably withheld or delayed.

ARTICLE 10. MISCELLANEOUS PROVISIONS

10.1 **Correspondence**. Any notice, invoice or payment required to be given to either Party under this Agreement shall be deemed to have been properly given and effective:

(a) on the date of delivery if delivered in person;

(b) one (1) day after the successful transmission in pdf file format if sent by electronic mail using the Internet; or

(c) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other Party.

If sent to Licensee:

[Reports and Notices Contact]:

Recro Pharma, Inc.
Attention: Gerri Henwood
490 Lapp Road
Malvern, PA 19355
Phone: 484-395-2470
Email: [***]

Accounts Payable Contact:

Recro Pharma, Inc.
Attention: Ryan Lake, Senior Vice President of Finance
490 Lapp Road
Malvern, PA 19355
Phone: 484-395-2470
Email: [***]

Intellectual Property Contacts:

Recro Pharma, Inc.
Attention: Vanessa Ragaglia
490 Lapp Road
Malvern, PA 19355
Phone: 484-395-2470
Email: [***]

and

Stradley Ronon Stevens & Young, LLP
Attention: Paul K. Legaard, Ph.D.
Great Valley Corp. Center, 30 Valley Stream Parkway
Malvern, PA 19355
Phone: 610-651-2277
Email: plegaard@stradley.com

If sent to Cornell:

For all correspondence *except payments* -

Center for Technology Licensing at Cornell University
Attention: Executive Director
395 Pine Tree Road, Suite 310
Ithaca, NY 14850
TEL: 607-254-5236
EMAIL: [***]

For all payments -

If sent by mail:
Center for Technology Licensing at Cornell University
PO Box 6899
Ithaca, NY 14851-6899

If remitted by electronic payments via ACH or Fed Wire :

Receiving bank name:	[***]
Bank account no.:	[***]
Bank routing (ABA) no.:	[***]
SWIFT code:	[***]
Bank account name:	[***]
Bank ACH format code:	[***]
Bank address:	[***]
Additional information:	[***]

An email copy of the wire transfer transaction receipt shall be sent to Director for Finance and Operations at [***]. Licensee is responsible for all bank charges of wire transfer of funds for payments. The bank charges shall not be deducted from total amount due to Cornell.

10.2 **Confidentiality**.

(a) "Confidential Information" shall mean any and all information and data, including all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, trade secret and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party or its Affiliates to the other Party or its Affiliates in connection with this Agreement. Information, including Technology, relating to the Inventions and disclosed by Cornell to Licensee during the Term of this Agreement shall be deemed the Confidential Information of Cornell. The Licensee Know-How shall be deemed the Confidential Information of Licensee. All Confidential Information shall remain the property of the disclosing Party.

(b) Each Party shall:

(i) solely use the Confidential Information of the disclosing Party for the purpose of performing its obligations and exercising its rights under this Agreement;

(ii) safeguard the Confidential Information of the disclosing Party against disclosure to others with the same degree of care as it exercises with its own data of a similar nature; and

(iii) not disclose Confidential Information to others (except to its employees, agents or consultants who are bound in writing to the receiving Party by a like obligation of confidentiality) without the express written permission of the disclosing Party.

Notwithstanding the foregoing, the receiving Party shall not be prevented from using or disclosing any of the Confidential Information that:

(A) the receiving Party can demonstrate by written records was previously known to it other than through a prior disclosure by or on behalf of the disclosing Party;

(B) is now, or becomes in the future, public knowledge other than through acts or omissions of the receiving Party or its Affiliates;

(C) (C)is lawfully obtained by the receiving Party from sources independent of the disclosing Party and not in violation of any confidentiality obligation to the disclosing Party not to disclose such Confidential Information; or

(D) is required to be disclosed by law, regulation or a court of competent jurisdiction; *provided, however*, that the receiving Party shall use commercially reasonable efforts to notify the disclosing Party of the receiving Party's intent to make such disclosure of such Confidential Information sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action the disclosing Party may deem to be appropriate to protect the confidentiality of the information.

(c) The confidentiality obligations of each Party hereunder shall continue for a period ending five (5) years from the termination or expiration date of this Agreement.

(d) Cornell may disclose to the Inventors the terms and conditions of this Agreement upon their request provided that Cornell shall first require in writing that the Inventors not disclose such terms and conditions which, for the avoidance of doubt, are Confidential Information hereunder.

10.3 **Assignability**. This Agreement may not be assigned by either Party, without the written consent of the other Party, such consent not to be unreasonably withheld; provided, however, that Licensee may assign without consent, but with notice of assignment, to Recro Ireland Limited, provided that such entity is financially capable (directly or through commitment of funds from Licensee) of performing the obligations of Licensee under this Agreement.

10.4 **No Waiver**. No waiver by either Party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

10.5 **Failure to Perform**. In the event of a failure of performance due under this Agreement and if it becomes necessary for either party to undertake legal action against the other on account thereof, then the prevailing party shall be entitled to reasonable attorney's fees in addition to reasonable and documented costs and necessary disbursements.

10.6 **Governing Laws**. THIS AGREEMENT SHALL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.

10.7 **Force Majeure**. A Party to this Agreement shall be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any Force Majeure Event. When such Force Majeure Event has abated, the non-performing Party's obligations herein shall resume.

10.8 **Dispute Resolution**. Any dispute arising between Cornell and Licensee under this Agreement shall be resolved under the Baseball Arbitration procedure described in Appendix C.

10.9 **Headings**. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.10 **Entire Agreement**. This Agreement embodies the entire understanding of the Parties and supersedes all previous communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof.

10.11 **Amendments**. No amendment or modification of this Agreement shall be valid or binding on the Parties unless made in writing and signed on behalf of each Party.

10.12 **Severability**. In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal, or unenforceable provisions had never been contained in it.

10.13 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which when taken together shall constitute one and the same agreement.

IN WITNESS WHEREOF, both Cornell and Licensee have executed this Agreement, in duplicate originals, by their respective and duly authorized officers on the day and year written.

RECRO IRELAND LIMITED:		**CORNELL UNIVERSITY:**	
By:	/s/ Gerri Henwood	By:	/s/ Brian. J. Kelly
	(Signature of an authorized officer)		(Signature of an authorized officer)
Name:	Gerri Henwood	Name:	Brian. J. Kelly, Ph.D.
Title:	CEO & Pres	Title:	Director, Technology Licensing
Date:	6/30/17	Date:	June 30, 2017

Appendix A: Patent Rights

Cornell Ref	Country	App. No.	Status	Patent No	Title
3999-01-US	United States	[***]	Converted		[***]
3999-02-US	United States	[***]	Issued	[***]	[***]
3999-03-PC	PCT	[***]	Converted		[***]
3999-04-AU	Australia	[***]	Issued	[***]	[***]
3999-05-CA	Canada	[***]	Issued	[***]	[***]
3999-06-CN	China	[***]	Issued	[***]	[***]
3999-07-EP	Europe	[***]	Issued	[***]	[***]
3999-08-IN	India	[***]	Filed		[***]
3999-09-JP	Japan	[***]	Issued	[***]	[***]
3999-10-DE	Germany	[***]	Issued	[***]	[***]
3999-11-FR	France	[***]	Issued	[***]	[***]
3999-12-GB	United Kingdom	[***]	Issued	[***]	[***]

4398-01-US	United States	[***]	Converted		[***]
4398-02-PC	PCT	[***]	Not Converted		[***]
4398-03-US	United States	[***]	Issued	[***]	[***]
4708-01-US	United States	[***]	Converted		[***]
4708-02-PC	PCT	[***]	Converted		[***]
4708-03-CN	China	[***]	Prosecution		[***]
4708-04-US	United States	[***]	Issued	[***]	[***]
5421-01-US	United States	[***]	Converted		[***]
5421-02-US	United States	[***]	Converted		[***]
5421-03-US	United States	[***]	Converted		[***]
5421-04-PC	PCT	[***]	Converted		[***]
5421-05-US	United States	[***]	Issued	[***]	[***]

5421-06-EP	Europe	[***]	Allowed		[***]
5421-07-JP	Japan	[***]	Filed		[***]

Appendix B1: Charles River Documents

Study No. (Sponsor Ref. No.) Sponsor Representative	Title Archived Material (Room temperature, unless otherwise specified)	Draft/Final Report Date End of Continued Storage	Cubic Footage Number of Samples
102222 John J. Savarese	[***] Raw Data (Paper & Multimedia)	December 10, 2010 August 31,2016	1ft^3 -
102223 John J. Savarese	[***] Raw Data (Paper & Multimedia)	December 10, 2010 August 31, 2016	1ft^3 -
142191 Jeff McGilvra	[***] Raw Data (Paper & Multimedia)	May 02, 2014 August 31, 2016	1 ft^3 -
142192 (PK-002) Jeff McGilvra	[***] Raw Data (Paper & Multimedia)	May 02, 2014 August 31, 2016	2 ft^3 -
142193 (CW002-001) Erica Allen	[***] Raw Data (Paper & Multimedia)	May 02, 2014 August 31, 2016	1ft^3 -
143029 John J. Savarese	[***] Raw Data (Paper)	April 09, 2012 August 31, 2016	1ft^3 -
143030 (PK-AD-001) John J. Savarese	[***] Raw Data (Paper 8 Multimedia)	January 17, 2012 August 31, 2016	1ft^3 -

143032 Robert Rizzolo	[***] Raw Data (Paper & Multimedia)	February 14, 2013 August 31. 2016	1ft^3 -
183136 John J. Savarese	[***] Raw Data (Paper & Multimedia)	November 17, 2010 August 31, 2016	1 ft^3 -
401066 Gilbert W. Carnathan	[***] Raw Data (Paper & Multimedia)	October 30, 2009 August 31, 2016	1 ft^3 -
401067 Gilbert W. Carnathan	[***] Raw Data (Paper & Multimedia)	November 03, 2009 August 31, 2016	1ft^3 -
503757 John J. Savarese	[***] Raw Data (Paper & Multimedia), Blacks, Hematology Slides, Pathology Slides. Wet Tissues	October 15, 2010 August 31, 2016	5 ft^3 -
600401 Gilbert W. (Chip) Carnathan	[***] Raw Data (Paper & Multimedia)	April 21, 2010 August 31, 2016	1ft^3
962374 John J. Savarese	[***] Raw Data (Paper & Multimedia)	May 19, 2009 August 31. 2016	1ft^3 -
962375 John J. Savarese	[***] Raw Data (Paper & Multimedia), Genetic Slides	May 22, 2009 August 31,2016	1ft^3 -
1400104 Robert Rizzolo	[***] Raw Data (Paper & Multimedia)	February 14, 2013 August 31, 2016	1ft^3 -
1400273 Alexander Smith	[***] Raw Data (Paper & Multimedia)	July 02, 2013 August 31, 2016	1ft^3 -

1400274 Alexander Smith	[***] Raw Data (Paper & Multimedia)	July 02,2013 August 31, 2016	$1ft^3$ -
2100001 John J. Savarese	[***] Raw Data (Paper & Multimedia)	November 15, 2012 August 31,2016	$1ft^3$ -
2100002 John J. Savarese	[***] Raw Data (Paper & Multimedia)	November 15, 2012 August 31, 2016	$1ft^3$ -
2100072 John J. Savarese	[***] Raw Data (Paper & Multimedia)	February 15, 2013 August 31, 2016	$1ft^3$ -
2100073 John J. Savarese	[***] Raw Data (Paper & Multimedia)	February 15, 2013 August 31, 2016	$1ft^3$ -

Appendix B2: Files at IMPACT

- Cornell IND (electronically) and submission #s 0000 through 0027
- All FDA correspondence (from pre-IND through present) with the possible exception of a gap in 2009 (April – November) when I switched companies and did not have access to the project.
- Meeting minutes from internal project meetings from April 2007 through Oct 2014 (again – with a gap in 2009).
- CDs with nonclinical studies:
  - 20034480
  - 20030605
  - 20038747
  - 21000058
  - 2100002
  - 20033131
  - 20027620
  - EQU00003
  - 503757
  - 183136
  - 102223
  - 2019549
  - 20033130
  - EQU00013
  - 20027635
- Trial Master File from Study CW002-001 which includes:
  - Protocol and amendments
  - Protocol violations/deviations forms
  - Investigator's Brochure
  - Study Reference Manual
  - Site Initiation Binder
  - Blank SAE/pregnancy forms
  - Blank CRFs
  - CRF completion guidelines

- Final CRFs
- Investigational product records
- Lab accreditations and reference ranges
- IRB member list and correspondence
- Informed consent form
- Pharmacist CV/licenses
- Investigator meeting slides
- Site monitoring/training documentation and reports
- Screening/Enrollment logs
- Drug accountability/shipping records
- Protocol agreement signatures
- 1572s/CVs/licenses/financial agreements for investigators
- Site personnel log
- Copies of advertising
- Safety Monitoring Board meeting records
- Data management plans
- Documents from Charles River regarding PK assessments/issues

• Clinical study report for CW002-001 and all related tables, listings, figures, appendices.

Appendix B3: Materials at Almac und er Quote #15366

SUB-INVENTORY	STORAGE-OS	LOCATOR CODE	STORAGE SITE	ITEM NUMBER	ITEM DESCRIPTION	LOT NUMBER	QUANTITY ON HAND	UOM	LOT AGING
Frzr -20	15366.00	430-014a	NC	12952	[***]	R090531	146.00	EA	1579.00
Frzr -20	15366.00	430-044b	NC	12952	[***]	R090531	146.00	EA	1579.00
Frzr -20	15366.00	430-038b	NC	12953	[***]	R090529	40.00	EA	1579.00
Frzr -20	15366.00	430-048a	NC	12953	[***]	R090529	148.00	EA	1579.00
Frzr -20	15366.00	430-018a	NC	12954	[***]	R090530	234.00	EA	1579.00
Frzr -20	15366.00	430-048b	NC	12954	[***]	R090530	146.00	EA	1579.00
Frzr -20	15366.00	430-036a	NC	10384	[***]	R090526	100.00	EA	
Frzr -20	15366.00	430-003a	NC	10383	[***]	R090528	100.00	EA	
Frzr -20	15366.00	430-049a	NC	10383	[***]	R090527	34.00	EA	1253.00
Returns	100672.00	DUR0206D	NC	R10000369	[***]	NC74512	1.00	EA	1020.00
Returns	100672.00	DUR0206D	NC	R10000369	[***]	NC105380	1.00	EA	919.00
Returns	100672.00	DUR0206D	NC	R10000369	[***]	NC105387	1.00	EA	919.00

Appendix C: Baseball Arbitration

(i) If a dispute arises under this Agreement which Cornell and the Licensee are not able to resolve through the mediation of their senior officers for a period of sixty (60) days, then either Cornell or the Licensee may at any time thereafter submit such matter to be finally settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules including the Optional Rules for Emergency Measures of Protection in effect at the time of submission, as modified by this Appendix C. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of experience in the pharmaceutical and life sciences industries, each of whom will be neutral. Cornell and the Licensee each will appoint one arbitrator and the third arbitrator will be selected by the two appointed arbitrators, or, failing agreement by the two appointed arbitrators within thirty (30) days following the date of receipt by the respondent of the request for mediation, the third arbitrator will be selected by the American Arbitration Association, such three (3) arbitrators being the "Panel". Such arbitration will take place in New York, New York. Fees, costs and expenses of arbitration are to be divided by Cornell and the Licensee in the following manner: Cornell will pay for the arbitrator it chooses, the Licensee will pay for the arbitrator it chooses, and Cornell and the Licensee will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by applicable Laws, neither Cornell nor the Licensee nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Cornell and the Licensee.

(ii) Cornell and the Licensee each will prepare and submit a written summary of its position and any relevant evidence in support thereof to the Panel within thirty (30) days of the selection of the Panel. Upon receipt of such summaries from Cornell and the Licensee, the Panel will provide copies of the same to the other. The Panel will be authorized to solicit briefing or other submissions on particular questions. Within fifteen (15) days of the delivery of such summaries by the Panel, Cornell and the Licensee each will submit a written rebuttal of the other's summary and may also amend and re-submit its original summary. Oral presentations will not be permitted unless otherwise requested by the Panel. The Panel will make a final decision with respect to the arbitration matter within thirty (30) days following receipt of the last of such rebuttal statements submitted by Cornell and the Licensee and will make a determination by selecting the resolution proposed by one of Cornell or the Licensee that as a whole is the most fair and reasonable to Cornell and the Licensee in light of the totality of the circumstances and that complies with the terms of this Agreement and will provide Cornell and the Licensee with a written statement setting forth the basis of the determination in connection therewith. For purposes of clarity, the Panel will only have the right to select a resolution proposed by one of Cornell or the Licensee in its entirety and without modification provided such resolution complies with the terms of this Agreement.

(iii) Cornell and the Licensee further agree that the decision of the Panel will be the sole, exclusive and binding remedy between them regarding the original dispute.

Appendix D: Development Report

Company Name	CTL Agreement No	Your Reference No

Reporting Period (*mm / dd / yyyy*)	Expected Date of first sale of Licensed Product(s)
From _____ / _____ / _____ Through _____ / _____ / _____	(*mm / dd / yyyy*) _____ / _____ / _____

Please Check One

Your Company Has: ☐ **less than 500 employees worldwide** ☐ **500 or more employees worldwide**

For the reporting period prescribed in the agreement, please provide detailed answers to the questions listed below. Please attach a separate report to this sheet if necessary.

1. Listing of milestones / performance requirements accomplished during the reporting period	Done Completed Date	In Progress Anticipated Date	Not Done Anticipated Date

2. List of Products being developed under this agreement					
Product Name		**Brief Description**		**Status**	
Product Name		**Brief Description**		**Status**	
Product Name		**Brief Description**		**Status**	
Product Name		**Brief Description**		**Status**	

3. Total expenditure spent in the reporting period (under this agreement)

4.Sublicense Activity *(if applicable)*			
List of Sublicenses granted during reporting period			**List of sublicenses terminated during reporting period**
Total Number of active sublicenses during reporting period			

Report Prepared & Approved By		
Name (*Please Print*)	**Title**	**Email**
Signature		**Date (** *mm / dd / yyyy* **)** _____ / _____ / _____

Please submit completed report either via mail or email at address below:

Center for Technology Licensing
At Cornell University
395 Pine Tree Rd., Suite 310
Ithaca, NY 14850
[***]

Appendix E: Commercialization Report

Company Name	CTL Agreement No	Your Reference No
Reporting Period (*mm / dd / yyyy*) From _____ / _____ / _____ Through _____ / _____ / _____	Date of first sale of Licensed Product(s) (*mm / dd / yyyy*) _____ / _____ / _____	

Please list all Licensed Product(s), with the relevant trade names, whether or not you had sales for the Licensed Product(s) during this reporting period.

Product Name	Licensed Invention or Patent Rights (No.) used if known or Docket No.	Country	Number of Units Sold	Gross Sales	Net Sales (A)	Royalty Rate[1] (B)	Total Royalties (A * B)

Royalty Subtotal	
Minimum Royalty already paid*	
Total Royalty Owed[2]	
Total Sublicense Fees* *(if applicable)*	
Total Payment	

1 Please refer to the license agreement for:
- □ applicable royalty rate, please provide as decimal;
- □ how Net Sales should be calculated;
- □ applicable share of sublicense fees;
- □ application of minimum royalty rate
- □ If sales were in a currency other than United States Dollars, please specify exchange rate used

2 Subtract minimum royalty already paid from royalty subtotal for Total Royalty Owed

Sublicense Activity *(if applicable)*	
List of sublicenses granted during the reporting period	List of sublicenses terminated or expired during the reporting period
Total Number of active sublicenses during reporting period	

List of Products being developed under this agreement					
Product Name		Brief Description		Status	
Product Name		Brief Description		Status	
Product Name		Brief Description		Status	
Product Name		Brief Description		Status	
Product Name		Brief Description		Status	

List of Licensed Product(s) Not Manufactured in the US	
Product Name	
Product Name	
Product Name	
Product Name	

Report Prepared & Approved By		
Name (*Please Print*)	Title	Email
Signature		Date (*mm / dd / yyyy*) _____ / _____ / _____

[***] 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.

Master Manufacturing Services Agreement

14 JULY 2017

Table of Contents

MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of 14 July 2017 (the "**Effective Date**")

B E T W E E N:

PATHEON UK LIMITED,

a corporation existing under the laws of England;

("**Patheon**"),

- and -

RECRO IRELAND LIMITED,

a private limited company incorporated in Ireland

("**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This "master" form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon's global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the parties to

the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**" , **"Active Pharmaceutical Ingredients" or "API"** means the materials listed in a Product Agreement on Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.2(a);

"**Actual Yearly Volume**" or "**AYV**" has the meaning specified in Section 4.2.1;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

"Annual Product Review Report" means the annual product review report prepared by Patheon or an Affiliate of Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report**" means the annual report to the FDA which is required to be prepared and filed by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B of a Product Agreement;

"**Applicable Laws**" means all Laws that apply to the Manufacturing Services, Manufacturing Sites, Products and other activities specified in this Agreement, respectively, including any Product Agreement entered into hereunder. Applicable Laws include, without limitation, the Federal Food, Drug and Cosmetic Act and applicable analogous Laws in any other jurisdiction;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

“**Breach Notice**” has the meaning specified in Section0;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United Kingdom, the jurisdiction where the Manufacturing Site is located or Philadelphia, Pennsylvania, United States of America;

“**Capital Equipment Agreement**” means a separate agreement that the parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"**cGMP**" means, as applicable, current good manufacturing practice as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) EC Directive 2003/94/EC; and

(c) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time, and analogous applicable requirements of a Regulatory Authority in any other jurisdiction in the Territory;

“Client Intellectual Property” means Intellectual Property (a) controlled, generated or derived by Client before entering into or during the term of this Agreement, or (b) generated or derived by Patheon while performing any Manufacturing Services, or otherwise generated or derived by Patheon in its business, which Intellectual Property is [***];

“**Client Property**” has the meaning specified in Section 8.3(a)(v);

“**Client-Supplied Components**” means those Components to be supplied by Client or that have been supplied by Client as set forth in a Product Agreement;

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

“**Confidential Information**” has the meaning specified in Section 11.1;

“**Conversion Fee**” means the Price for performing the Manufacturing Services [***];

“**CTD**” has the meaning specified in Section 7.8(c);

“C-TPAT” has the meaning specified in Section 2.1(f);

“**Deficiencies**” have the meaning specified in Section 7.8(d);

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

“Delivery Date” means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

“Disclosing Party” has the meaning specified in Section 11.1;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Orders**" has the meaning specified in Section 5.1(c);

“**Force Majeure Event**” has the meaning specified in Section 13.7;

[***];

"**GST**" has the meaning specified in Section 13.16(a)(iii);

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

“**Importer of Record**” has the meaning specified in Section 3.2(a);

“**Initial Product Term**” has the meaning specified in Section 8.1;

“**Initial Term**” has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know-how;

"**Invention**" means any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

“Long Term Forecast” has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the services set forth in this Agreement and a Product Agreement required to manufacture Product or Products using the Active Materials and Components, including, without limitation and as applicable, manufacturing, quality control, quality assurance, stability testing, packaging, and related services;

"**Manufacturing Site**" means the facility owned and operated by Patheon or an Affiliate of Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

“Materials” means all Components required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;

"**Minimum Order Quantity**" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B;

“**Obsolete Stock**” has the meaning specified in Section 5.2(b);

“**Patheon Competitor**” means [***];

“Patheon Intellectual Property” means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is [***];

“Price” means the fees to be charged by Patheon for performing the Manufacturing Services, [***];

"**Product(s)**" means the product(s) listed in a Product Agreement on Schedule A;

“**Product Agreement**” means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site for a particular Territory or Territories;

“**Product Claims**” have the meaning specified in Section 6.3(c);

"**Quality Agreement**" means the agreement between the parties entering into a Product Agreement, or between the applicable Affiliate of Patheon and Client if the Manufacturing Services are subcontracted to such Affiliate by Patheon, that sets out the quality control and quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Approval**" has the meaning specified in Section 7.8(a);

"**Regulatory Authority**" means, as applicable, the FDA, EMA, and Health Canada and any analogous regulatory agencies competent to grant Regulatory Approvals for pharmaceutical products, including the Products in the Territory;

"**Remediation Period**" has the meaning specified in Section 0;

"**Representatives**" means a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives;

"Resident Jurisdiction" has the meaning specified in Section 13.16(a)(i);

"**Shortfall**" has the meaning specified in Section 2.2(b);

"**Specifications**" means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"**Supply Failure**" means (a) a Force Majeure Event affecting Patheon's ability to supply Product in accordance with this Agreement and the applicable Product Agreement for a period of [***], or (b) a material breach by Patheon of its supply obligations under this Agreement, which breach is not cured within the Remediation Period;

"Surplus" has the meaning specified in Section 2.2(c);

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.2(a);

"**Tax**" or "**Taxes**" have the meaning specified in Section 13.16(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means the geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.16(d);

"**Year**" means in the first year of this Agreement or in the first year of a Product Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

"**Yearly Forecast Volume**" or "**YFV**" has the meaning specified in Section 4.2.1; and

"**Zero Forecast Period**" has the meaning specified in Section 5.1(f).

1.4 Currency.

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in EUROS.

1.5 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, an Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.6 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.7 Appendix 1, Schedules and Exhibits.

Appendix 1 (including the Schedules thereto) and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

Appendix 1 - Form of Product Agreement (Including Schedules A to D)

Exhibit A - Technical Dispute Resolution

Exhibit B - Quarterly Active Materials Inventory Report

Exhibit C - Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the Price specified in a Product Agreement in Schedules B and C to manufacture Products for Client. Schedule B to a Product Agreement sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in the Price are subject to additional fees to be paid by Client, provided, that all such additional fees are subject to Client's prior written consent. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld, and subject to any necessary approvals by Regulatory Authorities. Unless otherwise agreed in a Product Agreement and subject to Section 2.3 below, during the term of any Product Agreement, Client will purchase from Patheon [***] of its requirements for the Product in the Territory set forth in the applicable Product Agreement. In performing the Manufacturing Services, Patheon and Client agree that, unless otherwise set forth in a Product Agreement:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Product.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures; provided that Patheon shall provide Client notice of any material changes to Patheon's standard operating procedures that are applicable to the batch review and release of a Product in accordance with the terms of the Quality Agreement. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMP. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) [***] and as required by the Specifications.

(d) Stability Testing. If applicable, Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly, reasonably and in good faith, determine

the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance withthe Specifications and cGMP. Patheon will retain all stability test data and will provide such data to Client at Client's request.

(e) Packaging and Artwork. Patheon will package the Products in accordance with the Specifications. If applicable, Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed to the Products on each Product's label and on the shipping carton of each Product as outlined in the Specifications and as required by cGMP. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4; provided, that Patheon has promptly implemented any changes to labels, product inserts and other packaging for Products requested by Client. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Applicable Laws; or (ii) Patheon consents in writing to the use of its name. At least 120 days prior to the Delivery Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon, final camera ready artwork for all packaging Components to be used in the manufacture of the Product that meet the Specifications. For the avoidance of doubt, the parties acknowledge and agree that Client will be responsible for complying with any and all regulatory requirements for the labeling of the Product.

(f) Active Materials and Client-Supplied Components. At least 45 days before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010), at no cost to Patheon, with any VAT paid by Client, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received 45 days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. If Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, shipment may be delayed until a later date as agreed to by the parties; provided, that Patheon has used commercially reasonable efforts to reschedule the shipment date as close as possible to the original shipment date. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. For Active Materials or Client-Supplied Components which may be subject to import or export, Client agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism ("**C-TPAT**").

(g) Validation Activities (if applicable). Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees for this service are not included in the Price, and if Client requests such service, the parties will negotiate in good faith any applicable fees at reasonable rates, which fees will be set out separately in Schedule C to a Product Agreement.

(i) Additional Services. If Client requests services other than those expressly set forth herein or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), Patheon will provide a good faith and reasonable written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be set forth in a separate agreement signed by the parties. The terms and conditions of this Agreement will apply to these services.

2.2 Active Material Yield.

(a) Reporting. Patheon will give Client a quarterly inventory report, within twenty-four (24) hours of the end of the quarter, of the Active Materials held by Patheon using the inventory report form set out in Exhibit B, which will contain the following information for the quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period. Unless demonstrated otherwise by the results of agreed testing, and to the extent it was reasonable to identify defects using that testing, it is assumed that all Active Materials received at the Manufacturing Site during the applicable period complied with the Specifications.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products, including Active Materials lost in the warehouse prior to and during dispensing, and for clarity will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 0 or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMP, and Applicable Laws.

Within 60 days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit C including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

After Patheon has produced [***] commercial production batches of Product and has produced commercial production batches for [***] at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the parties will reasonably and in good faith agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually if [***] have been manufactured during the prior year, to reflect the actual manufacturing experience as agreed to reasonably and in good faith by the parties.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than [***] below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

[***]

(c) Surplus Calculation. If the Actual Annual Yield is more than the respective Target Yield in a Year, then the surplus for that Year (the "**Surplus**") will be determined based on the following calculation:

[***]

(d) Credits

(i) Shortfall Credit. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than 60 days after the end of such Year.

(ii) Surplus Credit. If there is a Surplus for a Product in a Year, then Patheon will be entitled to apply the amount of the Surplus as a credit against any Shortfall for that Product which may occur in the next Year. If there is no Shortfall in the next Year the Surplus credit will expire.

Each credit under this Section 2.2 will be summarized on the reconciliation report prepared in the form set forth in Exhibit C. Upon expiration or termination of a Product Agreement, any remaining Shortfall credit amount owing under this Section 2.2 will be paid to Client, it being understood that the amount of the Shortfall credit for the Year during which the Product Agreement expires or terminates shall be calculated pro-rata based on the portion of the Year occurring prior to such expiration or termination.

(e) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 for any Product in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to a Product Agreement.

(f) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 0 if the Actual Annual Yield is less than the Target Yield; provided, that this Section 2.2(f) shall not preclude a claim by Client for material breach of this Agreement with respect to any acts or omissions of Patheon (which are themselves material breaches) resulting in the Actual Annual Yield being less than the Target Yield.

2.3 Secondary Manufacturer.

Patheon recognizes that Client may wish to qualify and use an additional manufacturer to manufacture Product in order to, among other things, reduce or spread Client's business risk. Client shall be permitted to order from such additional manufacturer [***].

2.4 Records [***]. Patheon shall keep accurate and complete books and records of accounting pertaining to the API Yield performed (including the calculation of the Active Material Yield pursuant to Section 2.2), in sufficient detail to permit Client to confirm the accuracy of the invoices and reports submitted hereunder. [***].

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 **Payment**.

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under other parts of this Agreement.

3.2 **Active Materials and Qualification of Additional Sources of Supply**

(a) Client will at its sole cost and expense deliver the Active Materials to Patheon in accordance with Section 0. If applicable, Patheon and Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "**Importer of Record**" for Active Materials imported to the Manufacturing Site. The Active Materials and Client-Supplied Components will be held by Patheon on behalf of Client as set forth in this Agreement and (subject to Section 2.2) the risk of loss for the Active Materials and the Client-Supplied Components shall transfer to Patheon during any time when the Active Materials and the Client-Supplied Components are held by Patheon under this Agreement. Title to the Active Materials and Client-Supplied Components will at all times remain the property of Client. Any Active Materials and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services. Client will be responsible for paying for all rejected Product that arises from defects in the Active Materials which could not be reasonably discoverable by Patheon using the test methods set forth in the Specifications.

(b) If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon may agree to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will negotiate in good faith to agree in writing on the scope of work to be performed by Patheon at Client's cost. For an Active Material, unless otherwise agreed by the parties, this work at a minimum will include: (i) laboratory testing to confirm the Active Material meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on three months accelerated stability; and (iii) manufacture of three full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale). Section 6.1(d) will apply to all Products manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

(c) Patheon will promptly advise Client if it encounters supply problems, including delays and/or delivery of non-conforming Active Material or Components from a Client designated additional source. Patheon and Client will cooperate to reduce or eliminate any supply problems from these additional sources of supply. Client will be obligated to certify all Client designated sources of supply on an annual basis at its expense and will

provide Patheon with copies of these annual certifications. If Patheon agrees to certify a Client designated additional source of supply on behalf of Client, it will do so at Client's expense, subject to prior written agreement of the parties.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The Price for the first Year will be listed in Schedules B and C in a Product Agreement and will be subject to the adjustments set forth in Sections 4.2 and 4.3. If there are changes to the underlying manufacturing, packaging or testing assumptions set forth in Schedule B of the Product Agreement that result in an increase or decrease in the cost of performing the Manufacturing Services, the parties shall negotiate in good faith an amendment to the Product Agreement adjusting the Price to account for such increase or decrease.

4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year of the Product Agreement, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. Patheon may adjust the Conversion Fee component of the Price and the annual stability testing costs for inflation, based upon the preliminary number for any increase in the inflation index stated in the Product Agreement in June of the preceding Year compared to the final number for the same month of the Year prior to that (based on the average of the monthly changes over the 12-month period), unless the parties otherwise agree in writing. [***]. On or before November 1 of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year.

(b) Component Costs. If Patheon incurs an increase in Component (other than Client-Supplied Component) costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs at Patheon's cost; provided, that such increased Component costs are still in effect during the next Year. On or before November 1 of each Year, Patheon will give Client any information reasonably requested by Client about the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. If Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year, [***]

[***].

(d) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon Client's volume forecasts under Section 5.1. Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the 18 month forecast provided in September of the previous Year. Within 30 days after the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to Client for the amount of the overpayment within 60 days after the end of the Year or will issue payment to Client for the overpayment within 60 days after the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to Client under Section 5.5 for the amount of the underpayment within 60 days after the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within 30 days, the matter will be handled under Section 12.1.

(e) For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1 of each Year (or, if November 1 is not a Business Day, on the next Business Day following November 1) a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year.

4.2.1 Capacity Reservation Fee due to Volume Changes from Yearly Forecast Volumes for Sterile Products.

On the execution of a Product Agreement, Client will give to Patheon a forecast of the volume of Product required from Patheon for the [***] Years of the Product Agreement (the "**Yearly Forecast Volume**" or "**YFV**") that will become part of the Product Agreement. If at the end of the first Year the aggregate actual volume of Product ordered by Client and invoiced by Patheon under Section 5.5 ("**Actual Yearly Volume**" or "**AYV**") during the Year is less than [***], then Client will pay Patheon the Conversion Fee for the Product during the Year in an amount to be determined as follows:

[***]

On or before June 10 of each Year, the parties will agree on the YFV [***] Years of the Product Agreement on a rolling forward basis. The forecast of the volume of

Product for [***] Year may not vary by more than [***] from the original YFV for the [***] Year. Once agreed, the YFV for the next Year will become binding on the parties and any amount due to Patheon will be determined as set forth above.

4.3 Price Adjustments – Current Year Pricing.

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components (other than Client-Supplied Components) being materially greater than normal forecasted increases, then the parties will negotiate in good faith an amendment to the Product Agreement to adjust the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by [***] of the cost for that Component upon which the most recent Price or fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [***] of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a proposed revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following the parties' execution of an amendment to the Product Agreement. [***].

4.4 Adjustments Due to Technical Changes or Regulatory Authority Requirements.

Amendments to the Specifications or the Quality Agreement requested by Client will be implemented only following a technical and cost review that Patheon will perform at Client's cost and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld, conditioned or delayed, and subject to any necessary approvals by Regulatory Authorities. If Client accepts a proposed Price change, the Price change will become effective only for those orders of Product that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory held under the previous Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under

Section 5.2 will be cancelled where possible and as soon as possible, but if the orders may not be cancelled without penalty, they will be assigned to and paid for by Client. Additional payments or price increases may also be required to compensate Patheon for fees and other expenses incurred by Patheon to comply with Regulatory Authority requirements which apply to portions of the Manufacturing Services that are specific to Products, with such additional payments or price increases to be implemented only upon written consent of Client, which shall not be unreasonably withheld.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the changeover fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to the applicable Product Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Long Term Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [***] year forecast of Client's volume requirements for the Product for each Year during the term of the Product Agreement (the "**Long Term Forecast**"). The Long Term Forecast will thereafter be updated every six months (as of June 1 and December 1) during the Initial Product Term. If Patheon becomes aware at any time that it will be unable to timely accommodate any portion of the Long Term Forecast, it will notify Client as soon as practicable, in any event within thirty (30) days of becoming aware of its inability to timely accommodate such portion of the Long Term Forecast.

(b) Rolling 18 Month Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding 18 month forecast of the volume of Product that Client expects to order in the first 18 months of commercial manufacture of the Product. This forecast will then be updated by Client on or before the tenth day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [***]. The most recent 18 month forecast will prevail.

(c) Firm Orders. Unless otherwise agreed in the Product Agreement, the first [***] months of this updated forecast will be considered binding firm orders. Concurrent with the 18 month forecast, Client will issue a new firm written order for the binding portion of such forecast in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not be less than [***] days from the first day of the month following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely

manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within ten Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from Client, the Delivery Date for the Product ordered, which Delivery Date shall be within [***] Business Days of the delivery date requested by Client in the Firm Order, unless otherwise mutually agreed by the parties. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(e). If Patheon fails to acknowledge receipt of a Firm Order within the ten Business Day period, the Firm Order will be deemed to have been accepted by Patheon.

(e) Cancellation of a Firm Order. If Client cancels a Firm Order, Client will pay Patheon [***]. [***].

(f) Zero Volume Forecast. If Client forecasts zero volume for a period of nine successive months during the term of a Product Agreement (the "**Zero Forecast Period**"), then Patheon will have the option, at its sole discretion, to provide a 30 day notice to Client of Patheon's intention to terminate the Product Agreement on a stated day after the expiration of such 30 day period. Client thereafter will have 30 days to withdraw the zero forecast and re-submit an updated 18 month forecast other than a zero volume forecast. In the alternative, upon request by Client, Client and Patheon shall negotiate in good faith other commercially reasonable terms and conditions on which the Product Agreement will remain in effect. If Client has not submitted an updated 18 month forecast or submitted a request for negotiations to Patheon within such 30 day period, then Patheon will have the right to terminate the Product Agreement at the end of the 30 day notice period.

(g) Controlled Substance Quota Requirements (if applicable). Client will give Patheon the information set forth below for obtaining any required DEA or equivalent agency quotas needed to perform the Manufacturing Services. Patheon will be responsible for routine management of DEA quota information in accordance with DEA regulations. Patheon and Client will cooperate to communicate the information and to assist each other in DEA information requirements related to the Product as follows: (i) as of April 1 of each Year for the applicable Product, Client will provide to Patheon the next Year's annual quota requirements for the Product; (ii) as of August 1 of each Year, Client will provide to Patheon any changes to the next Year's quota requirements; (iii) Client will pro-actively communicate any changes to the quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize DEA filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional quota, Patheon will submit to the DEA, on a timely basis, all filings necessary to obtain DEA or equivalent agency quotas for Active Materials and will use commercially reasonable efforts to secure sufficient quota from the DEA so as to achieve Delivery Dates for Product as set forth in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for DEA's

refusal or failure to grant sufficient quota for reasons beyond the reasonable control of Patheon.

5.2 **Reliance by Patheon**.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. Patheon shall purchase and maintain at its cost and expense (subject to Section 5.2(b) below) a quantity of Components sufficient to satisfy the Manufacturing Services requirements for Products for [***]. Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon under Firm Orders or under Section 5.2(a) that are not included in finished Products manufactured for Client and that have expired or are rendered obsolete due to changes in artwork or applicable regulations during the period (collectively, "**Obsolete Stock**"). [***]. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(c) If Client fails to take possession or arrange for delivery of conforming finished Product not accepted by Client within [***] of batch release, Client will pay Patheon [***] for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [***]. Patheon may ship finished Product held by it longer than one month to Client at Client's expense on 14 days' written notice to Client.

5.3 **Minimum Orders**.

Client may order Manufacturing Services for batches of Products only in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 **Delivery and Shipping**.

The Product will be delivered to Client after it has been manufactured by Patheon and released to Client by Patheon. Delivery of Products will be made EXW (Incoterms 2010) Patheon's shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 Invoices and Payment.

Invoices will be sent by email to Accounts Payable – [***], or to such other email address given by Client to Patheon in writing from time to time. Invoices will be issued when the manufactured Product is released by Patheon. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the proposed invoice covering the shipment to be issued once the shipment is released by Patheon. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all undisputed invoiced amounts within [***] of the date of invoice. Patheon shall transmit the invoice on the date of issue to the email address specified above. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue [***].

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject any portion of any shipment of Product that was not manufactured in accordance with or deviate from (except for properly documented and approved deviations) the Specifications, cGMP, or Applicable Laws, without invalidating any remainder of the shipment. Unless otherwise agreed in the applicable Quality Agreement, Client will inspect the Product manufactured by Patheon promptly upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Product that was not manufactured in accordance with or deviates from (except for properly documented and approved deviations) the Specifications, cGMP, or Applicable Laws, within [***] days after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [***] days after discovery by Client, but not after the expiration date of the Product). If Client fails to give Patheon the Deficiency Notice within the applicable [***] day period, then the delivery will be deemed to have been accepted by Client on the [***] day after delivery or discovery, as applicable. Except as otherwise set forth in this Agreement, Patheon will have no liability for any deficiency for which it has not received notice within the applicable [***] day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have [***] days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within [***] days after Patheon's notice to Client as to whether any Product identified in the Deficiency Notice was not manufactured in accordance with or deviates from (except for properly documented and approved deviations) the Specifications, cGMP, or Applicable Laws, then the parties will select an independent laboratory of reputable standing reasonably acceptable to each party to evaluate the Product. This evaluation will be binding on the parties in respect of this Section 6 in the absence of manifest bias or error. If the evaluation certifies that any Product was not manufactured in accordance with or deviates from (except for properly documented and approved deviations) the Specifications, cGMPs or Applicable Laws, then such Product shall be deemed to be rejected by Client and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify, then Client will be deemed to have accepted delivery of the Product on the [***] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the [***] day

after discovery thereof by Client, but not after the expiration date of the Product), and Client will be responsible for the cost of the evaluation.

(c) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or other deviations from the applicable Firm Order, or a Price dispute, will be dealt with by reasonable and good faith agreement of the parties. Any claim for a shortage or other deviation from the applicable Firm Order or a Price dispute will be deemed waived if it has not been presented within [***] days of the date of invoice.

(d) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon. If after a full investigation as set forth in Section 6.1(b), it is determined that Patheon manufactured Product in accordance with the agreed upon process specifications, the batch production record, and Patheon's standard operating procedures for manufacturing, and a batch or portion of batch of Product does not meet a finished Product specification, Client will pay Patheon the applicable fee per unit for the non-conforming Product. The API in the non-conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any applicable Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any Regulatory Authorities to detain or destroy any of the Product. Recall will also include any action by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) Cooperation for Recalls. If (i) any Regulatory Authority issues a directive, order or written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required for any Product, Patheon will co-operate as reasonably required by Client and pursuant to all Applicable Laws.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Product. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Products

(a) Defective Product. If Client rejects Product under Section 6.1 and the deficiency is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMP or Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Product. If Client previously paid for the defective Product, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Product; (ii) offset the

amount paid against other amounts due to Patheon hereunder; or (iii) replace the Product with conforming Product (if Patheon is able to manufacture the replacement Product at the same Manufacturing Site as that of the rejected Product), without Client being liable for payment therefor under Section 3.1, and contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Product. For greater certainty, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled or Returned Product. To the extent that a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMP, or Applicable Laws, Patheon will be responsible for Client's documented expenses of the Recall or return and Patheon will promptly, at Client's election, either: (i) refund the invoice price for the Recalled or returned Product; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Product with conforming Product (if Patheon is able to manufacture the replacement Product at the same Manufacturing Site as that of the rejected Product), without Client being liable for payment therefor under Section 3.1, and contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Product. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense. If Client and Patheon fail to agree whether Patheon failed to perform the Manufacturing Services in accordance with the Specifications, cGMP, or Applicable Laws, with respect to any Recall, such disagreement shall be considered a technical dispute subject to Section 12.2 and Exhibit A. For clarity, any appointed expert will determine questions relating only to compliance with technical aspects of Patheon's obligations within the expert's field of expertise.

(c) Except as set forth in Sections 6.3(a) and (b) above, Sections 6.4 and 6.5 below or Section 10.3 below, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it (collectively, "**Product Claims**"). For greater certainty but not limitation, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Product or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications prior to use of the applicable Component in the performance of the Manufacturing Services, (iii) results from a defect in the Active Materials, Client-Supplied Components or Components supplied by a Client designated additional source that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of Client or third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

(d) Notwithstanding anything to the contrary in this Agreement, Patheon will only be required to replace or refund any batch or portion of a batch of recalled Product and will only be liable for Active Material contained therein to the extent the Product is unsold, returned, destroyed or otherwise disposed of by Client in accordance with the terms of this Agreement. The quantity of API contained in this Product will be included in the Quantity Dispensed but not in the Quantity Converted for purposes of calculating the Shortfall in Section 2.2(b).

6.4 Disposition of Defective or Recalled Products

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of

disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMP, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy in contract, tort, equity or otherwise for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMP, Applicable Laws or the applicable Firm Order.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

The relationship manager for Recro shall be Client's Sr. Director of Manufacturing & Supply Chain and the relationship manager for Patheon shall be Patheon's Technical Business Manager. Either party may change its relationship manager upon written notice to the other party. The relationship managers shall be responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental agency regarding the Products, including but not limited to governmental agencies responsible for granting Regulatory Approval for the Products, if, in the reasonable opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or Applicable Laws; provided, however, that Patheon will not communicate with governmental agencies responsible for granting Regulatory Approval of the Products without first notifying Client (where permitted by Applicable Laws).

Each party shall promptly notify the other party of such communications regarding the Products, and upon request, shall provide copies to the other party of any such written communications with government agencies (to the extent related to a Product).

7.3 Records and Accounting by Patheon

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with cGMPs, the Specifications, the Quality Agreement and other requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Unless otherwise agreed to in the Quality Agreement, copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by Applicable Laws, following which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired if Client fails to arrange for destruction or return within 30 days of receipt of notice from Patheon. Client is responsible for retaining samples of the Products necessary to comply with Applicable Laws.

7.4 Inspection.

Client may inspect Patheon reports, records, standard operating procedures and other documentation relating to the Manufacturing Services and this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 Access.

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Active Materials and Components are held, and in which the Products are manufactured, packaged, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. With the exception of "for-cause" audits, Client will be limited each Year to [***]. Client may request additional audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of [***] for each additional audit day and [***] per audit day for each additional auditor, except that these additional fees shall not apply in the event of a for-cause audit by Client. The right of access set forth in Sections 7.4 and 7.5 will not include a right to access or inspect Patheon's financial records. Patheon will support the first Pre- Approval Inspection ("**PAI**") of the FDA or equivalent regulatory inspection for other jurisdictions (where applicable) and provide a copy of the resulting report to Client [***]. [***].

7.6 Notification of Regulatory Inspections.

The parties' rights and obligations with respect to any inspections by and Authority shall be defined by the provisions of the Quality Agreement and this Article 7. Patheon will notify Client within one Business Day of any inspections by any Authority specifically involving the Products. Patheon will also notify Client of receipt of any FDA Form 483s, Establishment Inspection Reports, warning letters or any other inspectional findings that relate to the Products. Patheon shall promptly provide copies of such inspection-related documents (to the extent related to a Product, and redacted to remove third party confidential information) to Client and grant Client a reasonable opportunity to review and comment on Patheon's proposed responses to the same.

7.7 Reports.

Upon request, Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and

storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. Any additional data or report requested by Client beyond the scope of cGMP and customary FDA and EMA requirements, including Continuous Process Verification data, will be subject to an additional fee to be agreed upon between Patheon and Client.

7.8 Regulatory Filings.

(a) Regulatory Approval. Client will have the sole responsibility at Client's expense for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture, distribution and sale of the Products ("**Regulatory Approval**"). Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture, distribution and sale of all Products as quickly as reasonably possible.

(b) Verification of Data. Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and validity of those documents as they relate to Patheon generated data. Patheon generally requires 21 days to perform this review but the parties may agree to a shorter time for the review as needed.

(c) Verification of CTD. Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the Quality Module (Drug Product Section) of the Common Technical Document (all such documentation herein referred to as "**CTD**") related to any Regulatory Approval, such as a New Drug Application, Abbreviated New Drug Application or Biologics Licence Application in the U.S., or Marketing Authorisation Application in the E.U., Client will give Patheon a copy of relevant portions of the CTD as well as all supporting documents which have been relied upon to prepare relevant portions of the CTD. This disclosure will permit Patheon to verify that the relevant portions of the CTD accurately describe the validation or scale-up work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon generally requires 21 days to perform this review but the parties may agree to a shorter time for the review as needed. Client will give Patheon copies at the time of submission of CTD information that is relevant to the Manufacturing Services for the Product.

(d) Deficiencies. If Patheon reasonably determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(e) Client Responsibility. The parties agree that, in reviewing the documents referred to in clauses (b) and (c) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any

responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under subsections (b) and (c) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized as a result, Patheon may delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents; provided, that Patheon shall perform such review within 21 days of receipt of the requested documents.

(g) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Products pursuant to Applicable Laws. To the extent Patheon receives information regarding an adverse event related to a Product, Patheon shall collect and promptly forward this adverse event information to Client. At Client's cost, Patheon will cooperate as reasonably required to allow Client to follow up on any such adverse events in order to fulfill Client's obligations under Applicable Laws.

(h) No Patheon Responsibility. Patheon will not assume any responsibility for the accuracy or cost of any application for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of this Agreement. Patheon will not be obliged to undertake these activities or to pay for the fees or costs if, in Patheon's sole discretion, doing so is commercially inadvisable for Patheon.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2020 (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term from the Effective Date of the Product Agreement until December 31 of the Year agreed to by the parties in the Product Agreement (each, an "**Initial Product Term**"). Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of any of its

representations, warranties, or other obligations under this Agreement or the Product Agreement within [***] days following receipt of a written notice (the "**Remediation Period**") of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate under this Section 8.2(a) may only be exercised for a period of [***] days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice. The termination of a Product Agreement under this Section 8.2(a) will not affect any other Product Agreements where there has been no material breach of the other Product Agreements.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.3 below and under any Capital Equipment Agreement regarding the Product.

(d) Client may terminate a Product Agreement upon three months' prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.

(e) Patheon may terminate this Agreement or a Product Agreement upon six months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a Patheon Competitor.

(f) Client may terminate this Agreement or a Product Agreement in the event that Patheon fails to timely deliver batches of Product from three consecutive manufacturing campaigns.

8.3 **Obligations on Termination**.

(a) If a Product Agreement is completed, expires, is terminated by Patheon in accordance with Section 8.2(a), (b) or (e), or is terminated by Client in accordance with Section 8.2(c), 8.2(d) or 8.2(f), in whole or in part for any reason, then:

(i) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was placed;

(ii) Client will purchase, at Patheon's cost (including all third party costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2;

(iii)

Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;

(iv) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(v) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within [***] days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove Client Property within [***] days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon [***] for storing Client Property and will assume any third party storage charges invoiced to Patheon regarding Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.5 of this Agreement. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction.

(b) If a Product Agreement is terminated by Client in accordance with Section 8.2(a) because Patheon has delivered Product that does not conform to the Specifications, cGMPs or Applicable Laws, then (i) Section 8.3(a)(i) shall apply but only to the extent that the Product conforms to the Specifications, cGMPs or Applicable Laws, (ii) Section 8.3(a)(iv) shall apply, and (iii) Section 8.4(a)(v) shall apply but only with respect to all Client Property other than Inventory and Materials (but including Client-Supplied Components).

(c) Any completion, termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the completion, termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, completion, termination or expiration of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 6, 10, 11 and 13 and Sections 2.2, 5.4, 5.5, 7.3 and 7.7 and this Section 8.4 and any other provisions of this Agreement which by their terms are expressed to survive any completion, termination or expiration, all of which survive any completion, termination or expiration.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client represents and warrants to Patheon that, as of the date of the execution of a Product Agreement and solely with respect to the Product and the Client Intellectual Property (as applicable) relating to or covering the Product that is the subject of that Product Agreement:

(a) Non-Infringement.

(i) Client has the right to disclose the Specifications to Patheon;

(ii) (A) Client owns or controls any Client Intellectual Property used by Patheon in performing the Manufacturing Services according to the Specifications, and (B) the Client Intellectual Property may be lawfully used as directed by Client, and (C) the use of the Client Intellectual Property to perform the Manufacturing Services in accordance with this Agreement and the relevant Product Agreement does not misappropriate any Third Party Rights;

(iii) to Client's knowledge, there are no actions or other legal proceedings involving Client that concerns the infringement of Third Party Rights related to the Active Materials, processes covered by Client Intellectual Property, or the sale, use, or other disposition of the Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for the Product conforms to all applicable cGMP and Applicable Laws;

(ii) the Product, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMP and Applicable Laws (A) may be lawfully sold and distributed in the Territory, (B) will be fit for the purpose intended, and (C) will be safe for human consumption;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMP, the Quality Agreement, the applicable Firm Order and Applicable Laws;

(b) when manufactured and released by Patheon, the released Products will have been shown to conform to the Specifications and cGMP, as agreed in the applicable release Specifications;

(c) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(d) it will not in the performance of its obligations under this Agreement use the services of any person who is, or who to Patheon's knowledge is under consideration to be, debarred under 21 U.S.C. §335A, or excluded, suspended or declared ineligible under other Applicable Laws;

(e) it does not currently employ, and it will not hire, as an officer or an employee, or retain as an agent or contractor, any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States *Federal Food, Drug, and Cosmetic Act;* and

(f) it has the expertise and the facilities to perform the Manufacturing Services.

9.4 Permits.

(a) Patheon currently has, and will maintain at all relevant times, all governmental permits, licenses, approvals and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.5 No Warranty.

PATHEON MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. EXCEPT AS EXPRESSLY AGREED IN THIS AGREEMENT, PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential and Other Damages.

UNDER NO CIRCUMSTANCES WHATSOEVER WILL EITHER PARTY BE LIABLE TO THE OTHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR (I) ANY (DIRECT OR INDIRECT) LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS, OR GOODWILL OR (II) ANY RELIANCE DAMAGES, INCLUDING BUT NOT LIMITED TO COSTS OR EXPENDITURES INCURRED TO EVALUATE THE VIABILITY OF ENTERING INTO THIS AGREEMENT OR TO PREPARE FOR PERFORMANCE UNDER THIS AGREEMENT OR (III) FOR ANY OTHER LIABILITY, DAMAGE, COSTS, PENALTY, OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF THESE DAMAGES.

10.2 Limitation of Liability.

(a) Defective or Recalled Product. Patheon's maximum aggregate liability to Client for any obligation to (i) refund, offset or replace any defective Product under Section 6.3(a) or (ii) replace any recalled Products under Section 6.3(b), will not exceed [***]. [***].

(b) Active Materials. Except as expressly set forth in Section 2.2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(c) Maximum Liability. Subject to Section 10.2(d) below, Patheon's maximum aggregate liability to Client in any Year under this Agreement or any Product Agreement for any reason whatsoever (except Section 10.3, 10.2(a) and 10.2(d)), including, without limitation, any liability arising under Section 2.2 hereof or resulting from any and all breaches of its representations, warranties and other obligations under this Agreement or any Product Agreement, will not exceed [***].

(d) Death, Personal Injury and Fraudulent Misrepresentation Nothing contained in this Agreement (including the limitations set forth in Section 10.1 and 10.2) shall act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party, fraudulent misrepresentation [***].

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its officers, employees and agents, against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from or relating to (i) any claim of infringement or alleged infringement of any Third Party Rights by Patheon Intellectual Property used in the Manufacturing Services, or (ii) any claim of personal injury or property damage to the extent that the injury or damage is the result of: (A) a failure by Patheon to perform the Manufacturing Services in accordance with this Agreement, the Specifications, cGMP, and Applicable Laws, (B) breach of this Agreement by Patheon, or (C) Patheon's negligence or willful misconduct in the performance of its obligations under this Agreement, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are caused by the Client's breach, negligence or wilful misconduct or subject to indemnification by Client under Section 10.4.

(b) If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense; provided, that Patheon shall not settle any such claim without Client's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon, its officers, employees and agents, against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from or relating to (i) any claim of infringement or alleged infringement of any Third Party Rights by the Products or in the Client Intellectual Property (or Patheon's or its Affiliates' use of them); or (ii) any claim of personal injury or property damage to the extent that the injury or damage is the result of: (A) the breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein; or (B) Client's negligence or willful misconduct in the performance of its obligations under this Agreement,

except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are caused by the Patheon's breach, negligence or wilful misconduct, or subject to indemnification by Patheon under Section 10.3.

(b) If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense; provided, that Client shall not settle any such claim without Patheon's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations,

manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. For the purposes of this ARTICLE 11, a party or its Representative receiving Confidential Information under this Agreement is a "**Recipient**," and a party or its Representative disclosing Confidential Information under this Agreement is the **"Disclosing Party**."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using all reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were

publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party, including this Agreement (redacted as permitted by law and requested by the Disclosing Party), to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out herein. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form or is of a nature generally understood to be confidential or proprietary.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party and upon termination of this Agreement, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Article 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive and/or other equitable relief to prevent breaches of this Article 11 and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Article 11 but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 **Commercial Disputes**.

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party's relationship manager and one additional senior management member from each party (each of whom shall have full power and authority to resolve the dispute),will meet promptly as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the ten Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.17.

12.2 **Technical Dispute Resolution**.

If a dispute arises (other than disputes under Section 12.1 or Section 6.1(b)) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as possible and in any event no later than ten Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within 30 Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Exhibit A. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable Regulatory Approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 **Inventions**.

(a) For the term of the relevant Product Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property and Client-Owned Inventions which Patheon must use in order to perform the Manufacturing Services under such Product Agreement.

(b) All Client Intellectual Property will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license to use the Patheon Intellectual Property and Patheon-Owned Inventions used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Client shall own any Inventions generated or derived by Patheon while performing any Manufacturing Services, or otherwise generated or derived by Patheon in its business, and any Intellectual Property Rights therein, which [***] ("**Client-Owned Inventions**"). Patheon shall own all other Inventions generated or derived by Patheon while performing any Manufacturing Services, or otherwise generated or derived by Patheon in its business, and any Intellectual Property rights therein ("**Patheon-Owned Inventions**"). Each party will be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications owned by such party in accordance with this Section 13.1.

(f) Patheon will give Client written notice, as promptly as practicable, of all significant Inventions which are in Patheon's reasonable opinion owned by Client in accordance with this Section 13.1. Patheon shall assign, and hereby assigns, to Client all ownership rights in any Client-Owned Inventions. Patheon hereby agrees to reasonably cooperate with Client, at Client's expense, to execute all lawful papers and instruments, including obtaining and executing necessary powers of attorney and assignments by the named inventors, to make all rightful oaths and declarations, and to provide consultation and assistance as may be reasonably necessary in the assignment of Inventions in a manner consistent with this Section 13.1.

13.2 Intellectual Property.

Except as set forth in Section 13.1 above, neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of [***] years thereafter. This insurance will have policy limits of not less than (i) [***] for each occurrence for personal injury or property damage liability; and (ii) [***] in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good

faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances. Either Party may request that the other increase the insurance coverage set forth in this paragraph in the event that such coverage is no longer deemed to be sufficient, in which case the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate coverage.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.6 Assignment and Subcontracting.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. Any assignee consented to by Client will covenant in writing with Client to be bound by the terms of this Agreement or the Product Agreement, and Patheon will remain liable hereunder. Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement without the consent of Client if such subcontractors are set forth in the applicable Product Agreement or Quality Agreement. Further it is specifically agreed that Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to any of its Affiliates. Patheon will remain solely liable to Client for its obligations under this Agreement and each Product Agreement and Quality Agreement.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any Product Agreement or any assigned part thereof, on 12 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business to which this Agreement or a Product Agreement relates, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control,

including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance, and shall use commercially reasonable efforts to recommence performance as soon as possible. Either party may terminate this Agreement under Section 8.2(a) for a Force Majeure Event that has not resolved within 180 days. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.8 **Additional Product**.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, and D as applicable.

13.9 **Notices**.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or electronic mail addresses set forth below:

If to Client:

Recro Ireland Limited
Block 2, Harbour Square
Crofton Rd.
Dun Laoghaire, Co Dublin
Email address: To be confirmed in writing promptly

If to Patheon:

Patheon UK Limited
Kingfisher Drive
Covingham
Swindon
SN3 6BZ
United Kingdom
Attention: Legal Director
Email address: [***]

or to any other addresses or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability.

If any provision of this Agreement or any Product Agreement or Quality Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, together with the applicable Product Agreement and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.14 Execution in Counterparts.

This Agreement and any Product Agreement or Quality Agreement may be executed in two or more counterparts, by original, facsimile or “pdf” signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client’s name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client’s name

and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 **Taxes**.

(a) Client will bear all taxes, duties, levies and similar charges (and any related interest and penalties) ("**Tax**" or "**Taxes**"), however designated, imposed as a result of the provision by the Patheon of Services under this Agreement, except:

(i) any Tax based on net income or gross income that is imposed on Patheon by its jurisdiction of formation or incorporation ("**Resident Jurisdiction**");

(ii) any Tax based on net income or gross income that is imposed on Patheon by jurisdictions other than its Resident Jurisdiction if this tax is based on a permanent establishment or other taxable presence of Patheon; and

(iii) any Tax that is recoverable by Patheon in the ordinary course of business for purchases made by Patheon in the course of providing its Services, such as Value Added Tax (as more fully defined in subparagraph (d) below), Goods & Services Tax ("**GST**") and similar taxes.

(b) If Client is required to bear a tax, duty, levy or similar charge under this Agreement by any state, federal, provincial or foreign government, including, but not limited to, Value Added Tax, Client will pay the tax, duty, levy or similar charge and any additional amounts to the appropriate taxing authority as are necessary to ensure that the net amounts received by Patheon hereunder after all such payments or withholdings equal the amounts to which Patheon is otherwise entitled under this Agreement as if the tax, duty, levy or similar charge did not exist.

(c) Patheon will not collect an otherwise applicable tax if Client's purchase is exempt from Patheon's collection of the tax and a valid tax exemption certificate is furnished by Client to Patheon.

(d) If Section 13.16 (a)(iii) does not apply, any payment due under this Agreement for the provision of Services to Client by Patheon is exclusive of value added taxes, turnover taxes, sales taxes or similar taxes, including any related interest and penalties (hereinafter all referred to as "**VAT**"). If any VAT is payable on a Service supplied by Patheon to Client under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) Client. If VAT on the supplies of Patheon is payable by Client under a reverse charge procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), Client will ensure that Patheon will not effectively be held liable for this VAT by the relevant taxing authorities or other parties. Where applicable, Patheon will ensure that its invoices to Client are issued in such a way that these invoices meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so. Where the Manufacturing Services are cancelled or the value of the Manufacturing Services under this Agreement is adjusted Patheon shall issue to Client an adjustment note or other such document in accordance with the local tax law.

(e) Unless consented to by Patheon, any Tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon pursuant hereto may not be offset against sums due by Client to Patheon whether due pursuant to this Agreement or otherwise. Further, for any Tax

remitted by Client but as to which Patheon is liable hereunder, if so requested by Client, Patheon shall promptly reimburse Client for such amounts paid on Patheon's behalf.

13.17 **Governing Law**.

This Agreement and any Product Agreement, unless otherwise agreed by the parties in the Product Agreement and then only for purposes of that Product Agreement, will be construed and enforced in accordance with the laws of England and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON UK LIMITED

By: /s/ Andrew Robinson

Name: Andrew Robinson

Title: Director

Date: 17 July 2017

RECRO IRELAND LIMITED

By: /s/ Brian Harrison

Name: Brian Harrison

Title: Director

Date: 14-July 2017

APPENDIX 1

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated 14 July 2017 between Patheon UK Limited and **Recro Ireland Limited** (the "**Master Agreement**"), and is entered into **[insert effective date]** (the "**Effective Date**"), between Patheon UK Limited, a corporation existing under the laws of England **[or applicable founding jurisdiction for Patheon Affiliate]**, having a principal place of business at Kingfisher Drive, Covingham, Swindon, SN3 5BZ, England ("**Patheon**") and **[insert Client name, legal entity, founding jurisdiction and address]** ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:** (insert for sterile products if applicable under Section 4.2.1 of the Master Agreement)
6. **Territory**: (insert the description of the Territory here)
7. **Manufacturing Site**: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
8.

Inflation Index: pursuant to Section 4.2(a) of the Master Agreement, the inflation index is [ ] [***]

9. **Currency:** (if applicable under Section 1.4 of the Master Agreement)

10. **Initial Set Exchange Rate**: (if applicable if Currency included above)

11. **Initial Product Term:** (per Section 8.1 of the Master Agreement) from the Effective Date until December 31, 20__

12. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

13. **Other Modifications to the Master Agreement** (if applicable under Section 1.2 of the Master Agreement)

_____

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON UK LIMITED

By: _____

Name: _____

Title: _____

Date: _____

RECRO IRELAND LIMITED

By: _____

Name: _____

Title: _____

Date: _____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

[insert product list]

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the copies of originally executed copies of the Specifications as approved by the applicable Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon copies of the revised executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[Insert Price Table]

Manufacturing Assumptions:

Packaging Assumptions:

Testing Assumptions:

[Drafting Note: ensure that the costs included/not included are consistent with the quote]

The following cost items are included in the Price for the Products

[***]

[***]

The following cost items are not included in the Price for the Products

[***]

[***]

SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing including the Price for the Product withdrawn for the stability testing.

[NTD: Schedule C should clearly indicate when and/or under what conditions Patheon's responsibility to perform stability testing will end]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
l	l

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Client's actual cost for Active Materials not to exceed EUR_____per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement for any Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
	[***]

[End of Product Agreement]

EXHIBIT A

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert**. Within ten Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the ten Business Day period, or if there is a disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit A.

4. **Procedure**. Where an expert is appointed:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or another date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the parties except if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

EXHIBIT B

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: [name of Client]

FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated • (the "**Agreement**")

Reporting quarter: _____

Active Materials on hand
at beginning of quarter: _____ kg (A)

Active Materials on hand
at end of quarter: _____ kg (B)

Quantity Received during quarter: _____ kg (C)

Quantity Dispensed[1] during quarter: _____ kg
(A + C – B)

Quantity Converted during quarter: _____ kg
(total Active Materials in Products produced
and not rejected, recalled or returned or in work-in-process)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON UK LIMITED
[or applicable Patheon Affiliate]

DATE: _____

Per: _____
Name:
Title:

[1] Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the quarter.

EXHIBIT C

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: [name of Client]

FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated • (the "**Agreement**")

Reporting Year ending:	_____	
Active Materials on hand at beginning of Year:	_____ kg	(A)
Active Materials on hand at end of Year:	_____ kg	(B)
Quantity Received during Year:	_____ kg	(C)
Quantity Dispensed[2] during Year: (A + C - B)	_____ kg	(D)
Quantity Converted during Year: (total Active Materials in Products produced and not rejected, recalled or returned or in work-in-process)	_____ kg	(E)
Active Materials Credit Value:	EUR _____ / kg	(F)
Target Yield:	_____ %	(G)
Actual Annual Yield: ((E/D) * 100)	_____ %	(H)
Shortfall Credit: [***]	EUR _____ (if a negative number, insert zero)	(I)

[2] Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the Year.

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of EUR_____.

Surplus Credit: EUR_____ (J)
[***]

Based on the foregoing reimbursement calculation Patheon may carry forward one Year a Surplus Credit in the amount of EUR_____.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON UK LIMITED
[or applicable Patheon Affiliate]

Per: _____
Name:
Title:

[***] 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.

NCD Meloxicam IV (30mg/ml)

PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated **July 14th, 2017** between Patheon UK Limited and **Recro Ireland Limited** (the "**Master Agreement**"), and is entered into **July 14th, 2017** (the "**Effective Date**"), between Patheon UK Limited, a corporation existing under the laws of England, having a principal place of business at Kingfisher Drive, Covingham, Swindon, SN3 5BZ, England ("**Patheon**") and Recro Ireland Limited a private limited company incorporated in Ireland with registered number 562027, having its registered office at 25/28 North Wall, Dublin 1, ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:** (insert for sterile products if applicable under Section 4.2.1 of the Master Agreement)

Product	**[***]**				
	[***]	[***]	[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]

6. **Territory**: USA and EU
7. **Manufacturing Site**: Patheon Italia Monza Site Viale GB Stucchi 110, I-20900 Monza Italy.

8. **Inflation Index:** pursuant to Section 4.2(a) of the Master Agreement, the inflation index is the[***]

9. **Currency:** Euros

10. **Initial Set Exchange Rate**: Not Applicable

11. **Initial Product Term:** (per Section 8.1 of the Master Agreement) from the Effective Date until December 31, 2020

12. **Notices**: (Section 13.9 of the Master Agreement)

13. **Other Modifications to the Master Agreement**

[***]

[***]. [***]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON UK LIMITED

By:	/s/ Andrew Robinson
Name:	Andrew Robinson
Title:	Director
Date:	17 July 2017

RECRO IRELAND LIMITED

By:	/s/ Brian Harrison
Name:	Brian Harrison
Title:	Director
Date:	14-July 2017

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

NCD Meloxicam IV (30mg/ml)

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the copies of originally executed copies of the Specifications as approved by the applicable Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon copies of the revised executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY (MOQ), ANNUAL VOLUME, AND PRICE

Process Validation Batches

Product	[***]	[***]	[***]
			[***]
Meloxicam sterile liquid vials	[***]	[***]	**[***]**

*** Excludes the cost of the secondary packaging conversion price which will be charged at the commercial supply price as presented in the table on Page 5.**

Bulk Supply

Product	[***]	[***]	[***]	[***]	[***]		
					[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	**[***]**	[***]

Note: [***]

Packaging Supply Pricing Only

Product	[***]	[***]	[***]	[***]		
				[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]	[***]

* [***].

** [***].[***].[***].[***]

Annual Volumes

Product	[***]				
	[***]	[***]	[***]	[***]	[***]
NCD Meloxicam IV (30mg/ml)	[***]	[***]	[***]	[***]	[***]

Manufacturing Assumptions:

API – API (NCD Meloxicam Bulk Intermediate) will be stored under refrigerated conditions (2-8°C). In the case of capacity constraints Patheon may utilize a GMP approved sub-contract storage facility. In such a case, advance notification will be given to the client if the use of such storage will be necessary. Consideration will also be made of temperature controls, and shipping validation.

Batch size –Recro has confirmed that the maximum theoretical bulk batch size will be [***].

Manufacturing campaign – PV batches may not be produced in campaign. The Parties will meet and agree the appropriate protocols in this regard before the applicable manufacturing slots are reserved.

Product sterilization, filling process, and sealing – An aseptic filtration, filling and sealing process will be performed. Sterile filtration (0.22µm) of the solution will be performed prior to filling vials. Empty vials will be washed and depyrogenated using an in line washing and tunnel machine prior to filling vials.

Hold times – The process is carried out at room temperature. Only standard light protection is employed and no special precautions are required during formulation, filling, and inspection. During storage, brite stock will be wrapped in opaque black plastic.

Cleaning – Full cleaning occurs after each batch.

Visual inspection – 100% vials visual inspection is carried out by semiautomatic means.

Finished product storage – Finished product will be stored under controlled room temperature conditions – USP (15-30°C).

Packaging Assumptions:

Primary packaging components:

Component	Specification
Vial	[***]
Stopper	[***]
Seal	[***]

Secondary packaging – To be definitively established- see above "Packaging Supply"

- **Secondary packaging** – A single vial will be labelled and packaged in a pre-printed single carton with a patient information leaflet. Single cartons, or bundles of 10 cartons (bundled utilising cellophane wrap), will then be packed into tertiary containers and then into a bulk shipper.

- **Secondary packaging campaign** - **[***]**. Packaging orders must be placed in multiples of [***]. A whole bulk batch will be packed off into a single Stock Keeping Unit (SKU). PV batches will not be packaged in campaign.

To be definitively established- see above "Packaging Supply"

Tertiary packaging – According to Patheon's standard shipment preparations.

Testing Assumptions:

Patheon will only perform API ID testing.

QC test methods must be fully validated and robust at the time of manufacture.

Testing Requirements	
In-Process Controls	**Finished Product Testing**
[***]	[***]
[***]	

Supply Chain Assumptions:

Patheon will procure components (excluding the preprinted cartons and inserts which will be furnished by Client free of charge) and excipients for the manufacture of Meloxicam sterile liquid vials from Patheon qualified suppliers. Should Client require Patheon to source any materials from specified suppliers, then these suppliers will remain under the quality audit control of Client unless an agreement is reached for Patheon to take on this responsibility.

Components and excipients will be supplied by Patheon in accordance with the specifications agreed. Patheon will issue formal Patheon specifications for each material.

Each lot of incoming components and excipients will be sampled and tested according to the agreed specifications.

The API will be provided free issue/released to Patheon by Client or its qualified supplier.

The API and all excipients used for the manufacture will be GMP grade and from TSE/BSE certified sources.

Finished product will be made available at Patheon's proposed manufacturing site (supplied EXW according to Incoterms® 2010).

The following cost items are included in the Price for the Products :

[***]

The following cost items are not included in the Price for the Products :

[***]

SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

If applicable Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing including the Price for the Product withdrawn for the stability testing. At the time of signing it is not envisaged that any stability testing will be performed by Patheon. Patheon will ensure that the required number of samples are taken for Recro's designated stability program. The samples will be made available at Patheon's manufacturing site (EXW according to Incoterms® 2010).

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
NCD Meloxicam Bulk Intermediate	Alkermes

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
NCD Meloxicam IV (30mg/ml)	Meloxicam	[***]

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement for any Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
NCD Meloxicam IV (30mg/ml)	[***]

SCHEDULE E

QUALITY AGREEMENT

Either a copy, or a reference to the relevant Quality Agreement between the Client and Patheon Italy will be appended to this schedule once completed. For the avoidance of doubt, no product may be released for commercial sale until the Quality Agreement is signed by both parties.

[End of Product Agreement]

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)) and internal control over financial reports (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

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

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

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

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

5. The registrant's other certifying 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 11, 2017

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

Exhibit 31.2

CERTIFICATION

I, Michael Celano, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying 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 11, 2017

/s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.3

CERTIFICATION

I, Ryan D. Lake, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying 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 11, 2017

/s/ Ryan D. Lake
Ryan D. Lake
Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Recro Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017, 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 11, 2017

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

/s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial Officer)

/s/ Ryan D. Lake
Ryan D. Lake
Chief Accounting Officer
(Principal Accounting Officer)