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: September 30, 2017

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**000-28508**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Block 10-1, Blanchardstown Corporate Park
Ballycoolin
Dublin 15, Ireland
(Address of Principal Executive Office and Zip Code)

+353-1-485-1200
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 Website, 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, 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	☐	(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 Section 13(a) of the Exchange Act ☐

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

At November 2, 2017, 39,762,209 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

TABLE OF CONTENTS

Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934 ("Exchange Act"). The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. In particular, information appearing under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements.

Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from our expectations.

More information on factors that could cause actual results or events to differ materially from those anticipated is set forth in Part II, Item 1A (“Risk Factors”) of this quarterly report on Form 10-Q and is included from time to time in our other reports filed with the Securities and Exchange Commission (SEC), including our annual report on Form 10-K for the year ended December 31, 2016, in particular under the captions “Forward-Looking Statements” and “Risk Factors.”

All forward-looking statements speak only as of the date of this report and are expressly qualified in their entirety by the risk factors and other cautionary statements included or referenced in or incorporated by reference into this report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this report.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product sales and services	$ 39,147	$ 31,340	$ 138,009	$ 104,858
License and research revenue	528	747	484	2,303
Total	39,675	32,087	138,493	107,161
Operating expenses:				
Cost of products and services sold	3,790	2,844	12,253	10,657
Research and development expenses	8,095	8,143	22,093	21,135
Selling, general and administrative expenses	11,563	12,740	35,804	33,491
Intangible asset amortization	564	3,702	1,692	10,918
(Gain)/loss - changes in fair value of related party contingent consideration	(9,906)	20,848	(30,107)	52,989
Restructuring (income) costs	(549)	—	3,173	—
Total operating expenses	13,557	48,277	44,908	129,190
Operating income (loss)	26,118	(16,190)	93,585	(22,029)
Investment income, net	1,110	490	2,689	1,080
Interest expense, net	(263)	(264)	(789)	(702)
Other income (expense) - changes in fair value of related party payable	768	(1,828)	2,988	(6,135)
Foreign exchange gain (loss)	(133)	1,249	(127)	(12)
Income (loss) before income taxes	27,600	(16,543)	98,346	(27,798)
Income tax provision	5,921	3,451	21,830	18,212
Net income (loss)	$ 21,679	$ (19,994)	$ 76,516	$ (46,010)
Net income (loss) per share - basic	$ 0.54	$ (0.48)	$ 1.87	$ (1.12)
Net income (loss) per share - diluted	0.52	(0.48)	1.81	(1.12)
Weighted average number of shares outstanding - basic	40,061	41,241	40,839	41,241
Weighted average number of shares outstanding - diluted	41,339	41,241	42,194	41,241

See accompanying notes to condensed consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Net income (loss)	$ 21,679	$ (19,994)	$ 76,516	$ (46,010)
Other comprehensive income (loss), net of tax:				
Foreign currency translation gain (loss)	(229)	1,567	18	3,927
Net other comprehensive income (loss), net of $92, $152, $0 and ($49) tax, respectively	(512)	(2,405)	126	(958)
Total other comprehensive income (loss), net of tax	(741)	(838)	144	2,969
Total comprehensive income (loss)	$ 20,938	$ (20,832)	$ 76,660	$ (43,041)

See accompanying notes to condensed consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,449	$ 39,215
Marketable securities	78,161	114,980
Accounts receivable	24,080	17,839
Inventories, net	5,870	3,258
Prepaid expenses and other current assets	3,373	5,894
Total current assets	148,933	181,186
Property and equipment, net	3,180	3,320
Goodwill	18,491	18,491
Intangible assets, net	94,256	22,837
Research and development tax credit receivable	3,547	1,775
Income tax deferred charge	—	10,342
Other	9,020	7,531
Total assets	$ 277,427	$ 245,482
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 301	$ 268
Current portion of long-term related party payable	30,986	34,177
Accounts payable	8,564	7,105
Deferred revenue	1,927	2,223
Accrued expenses	47,997	17,222
Income taxes	7,026	1,200
Other	507	226
Total current liabilities	97,308	62,421
Long-term debt, less current portion	614	547
Long-term related party payable, less current portion	76,131	135,170
Other	6,911	5,275
Total liabilities	180,964	203,413
Shareholders' equity:		
Preferred shares, $0.01 nominal value; 50,000 shares authorized; none issued or outstanding at September 30, 2017 and December 31, 2016, respectively	—	—
Ordinary shares, nominal value of $0.01; 500,000 shares authorized; 41,435 and 41,371 issued and outstanding at September 30, 2017 and December 31, 2016, respectively	414	414
Treasury shares, at cost, 1,673 and 0 shares held at September 30, 2017 and December 31, 2016, respectively	(17,506)	—
Additional paid-in capital	391,416	385,020
Accumulated deficit	(254,440)	(319,800)
Accumulated other comprehensive loss	(23,421)	(23,565)
Total shareholders' equity	96,463	42,069
Total liabilities and shareholders' equity	$ 277,427	$ 245,482

See accompanying notes to condensed consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Nine Months Ended September 30,	
	2017	**2016**
Cash flows from operating activities:		
Net income (loss)	$ 76,516	$ (46,010)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	2,664	11,555
Loss on disposal of property and equipment	—	110
Loss (gain) on sale of marketable securities	(550)	666
Foreign exchange loss	127	12
Grants recognized in research and development expenses	—	(70)
Remeasurement of related party acquisition-related contingent consideration	(30,107)	52,989
Remeasurement of related party financing-related contingent consideration	(2,988)	6,135
Change in deferred tax and income tax deferred charge	322	(5,680)
Stock-based compensation expense	6,019	10,541
Increase (decrease) in cash from:		
Accounts receivable	(6,240)	(7,594)
Inventories	(2,612)	2,080
Prepaid expenses and other current assets	1,924	671
Research and development tax credit receivable	(1,576)	(1,794)
Accounts payable & other current liabilities	804	1,291
Deferred revenue	(283)	(2,198)
Accrued expenses	9,324	2,700
Accrued income taxes	5,826	—
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(24,729)	(14,486)
Royalty payments for related party payable in excess of original fair value	(3,446)	(1,790)
Other long-term assets and liabilities	(517)	2,032
Net cash provided by operating activities	30,478	11,160
Cash flows from investing activities:		
Purchases of property and equipment	(533)	(1,000)
Acquisitions of businesses	—	628
Purchase of intangible assets	(52,139)	—
Proceeds from sales of marketable securities	153,398	46,483
Purchases of marketable securities	(115,893)	(96,199)
Net cash used in investing activities	(15,167)	(50,088)
Cash flows from financing activities:		
Earn-out payments for related party contingent consideration	(961)	(6,834)
Royalty payments for related party payable	—	(1,117)
Reimbursement of loans	—	(61)
Cash proceeds from issuance of ordinary shares and warrants	376	—
Share repurchases	(16,707)	—
Net cash used in financing activities	(17,292)	(8,012)
Effect of foreign currency exchange rate changes on cash and cash equivalents	215	656
Net decrease in cash and cash equivalents	(1,766)	(46,284)
Cash and cash equivalents at January 1,	39,215	65,064
Cash and cash equivalents at September 30,	$ 37,449	$ 18,780

See accompanying notes to condensed consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except per share data)

NOTE 1 : Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc ("Avadel," the "Company," "we," "our," or "us") is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid, liquid oral and alternative dosage forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa™ (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock™ (controlled release of opioid analgesics with potential abuse deterrent properties).

- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received three drug approvals through this "unapproved-to-approved" strategy, including: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission and seeks to identify additional product candidates for development with this strategy.

- the acquisition of commercial and or late-stage products or businesses. On September 1, 2017, the Company entered into an Exclusive License and Assignment Agreement ("ELAA") with Serenity Pharmaceuticals, LLC. The ELAA grants the Company the sole right to commercialize and further develop Noctiva™ in the United States. Noctiva is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected intranasal delivery system. It is the first and only product approved by the U.S. Food and Drug Administration ("FDA") for the treatment of nocturia due to nocturnal polyuria. Additionally, the Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics ("FSC") on February 5, 2016. We will consider further acquisitions and the Company continues to look for assets that could fit strategically into our current or potential future commercial sales force.

The Company was incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Our headquarters is in Dublin, Ireland and we have operations in St. Louis, Missouri, United States, and Lyon, France.

The Company is the successor to Flamel Technologies S.A., a French société anonyme ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. As a result of the Merger Agreement:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.

- our authorized share capital is $5,500 divided into 500,000 ordinary shares with a nominal value of $0.01 each and 50,000 preferred shares with a nominal value of $0.01 each

    - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Company, $0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying $5,937 on our balance sheet from ordinary shares to additional paid-in capital

    - our Board of Directors is authorized to issue preferred shares on a non-pre-emptive basis, for a maximum period of five years, at which point it may be renewed by shareholders. The Board of Directors has discretion to dictate terms attached to the preferred shares, including voting, dividend, conversion rights, and priority relative to other classes of shares with respect to dividends and upon a liquidation.

- all outstanding American Depositary Shares (ADSs) representing ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for ADSs representing ordinary shares of the Company.

Thus, the Merger changed the jurisdiction of our incorporation from France to Ireland, and an ordinary share of the Company held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger.

References in these condensed consolidated financial statements and the notes thereto to “Avadel,” the “Company,” “we,” "our," “us,” and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires.

Prior to completion of the Merger, the Flamel ADSs were listed on the Nasdaq Global Market (“Nasdaq”) under the trading symbol “FLML”; and immediately after the Merger the Company’s ADSs were listed for and began trading on Nasdaq on January 3, 2017 under the trading symbol “AVDL.”

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the Securities and Exchange Commission on May 1, 2017, and within the 2016 Annual Report on Form 10-K.

Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the Company's proxy statement filed with the SEC as of July 5, 2016. Upon completion of the Merger, the Company did not have any distributable reserves. On February 15, 2017, the Company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable reserves for the purposes of Irish law. On March 6, 2017, the High Court issued its order approving the reduction of the Company's share premium by $317,254 which can be treated as distributable reserves.

Basis of Presentation. The Condensed Consolidated Balance Sheet as of December 31, 2016, which is primarily derived from the prior year 2016 audited consolidated financial statements, and the interim condensed consolidated financial statements presented herein, have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP), the requirements of Form 10-Q and Article 10 of Regulation S-X and, consequently, do not include all information or footnotes required by U.S. GAAP for complete financial statements or all the disclosures normally made in an annual report on Form 10-K. Accordingly, the condensed consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s 2016 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2017.

The condensed consolidated financial statements include the accounts of the Company and subsidiaries, and reflect all adjustments (consisting only of normal recurring adjustments) that are, in the opinion of management, necessary for a fair presentation of the Company’s financial position, results of operations and cash flows for the dates and periods presented. All material intercompany accounts and transactions have been eliminated. Results for interim periods are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

Foreign Currency Translation. The reporting currency of the Company and our wholly-owned subsidiaries is the U.S. dollar. Subsidiaries that do not use the U.S. dollar as their functional currency translate:

- profit and loss accounts at the weighted average exchange rates during the reporting period,
- assets and liabilities at period end exchange rates, and
- shareholders' equity accounts at historical rates.

Resulting translation gains and losses are included as a separate component of shareholders' equity in Accumulated Other Comprehensive Loss. Assets and liabilities, excluding available-for-sale marketable securities, denominated in a currency other than the subsidiary's functional currency are translated to the subsidiary's functional currency at period end exchange rates with resulting gains and losses recognized in the condensed consolidated statements of income (loss).

Revenue. Revenue includes sales of pharmaceutical products, amortization of licensing fees, and, if any, milestone payments for R&D achievements.

Product Sales and Services

Revenue is generally realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller’s price to the buyer is fixed or determinable, and collectability is reasonably assured. The Company records revenue from product sales when title and risk of ownership have been transferred to the customer, which

is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of deductions in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

For generic products and branded products sold in mature markets where the ultimate net selling price to customer is estimable, the Company recognizes revenues upon delivery to the wholesaler. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. As part of the third quarter 2016 launch of Akovaz, the Company determined that sufficient data was available to determine the ultimate net selling price to the customer and therefore recognized revenue upon delivery to our wholesaler customers.

Prior to the second quarter 2016, the Company did not have sufficient historical data to estimate certain revenue deductions. As such, it could not accurately estimate the ultimate net selling price of our Éclat portfolio of products and as a result delayed revenue recognition until the wholesaler sold the product through to end customers.

During the second quarter of 2016, the Company determined that it had sufficient evidence, history, data and internal controls to estimate the ultimate selling price of our products upon delivery to our customers, the wholesalers. Accordingly, we discontinued the sell through revenue approach and now recognize revenue once the product is shipped from our warehouse.

License and Research Revenue

The Company's license and research revenues consist of fees and milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over our projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured.

NOTE 2 : Newly Issued Accounting Pronouncements

In March 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2017-07, "*Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Costs.*" The standard requires the service component of pension and other postretirement benefit expense to be presented in the same statement of income lines as other employee compensation costs, however, the other components will be presented outside of operating income. In addition, only the service cost component will be eligible for capitalization in assets. The standard is effective starting in 2018, with early adoption permitted. Retrospective application is required for the guidance on the statement of income presentation. Prospective application is required for the guidance on the cost capitalization in assets. The Company does not believe this standard will materially impact our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, "*Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment."* This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Company in the first quarter of fiscal 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company will assess the timing of adoption and impact of this guidance to future impairment considerations.

In January, 2017, the FASB issued ASU 2017-01, "*Business Combinations (Topic 805): Clarifying the Definition of a Business*." This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is permitted for transactions not previously reported in the Company's consolidated financial statements. In September, 2017 the Company entered into an ELAA to acquire from Serenity Pharmaceuticals, LLC intellectual property rights to further develop and commercialize Noctiva in the United States. The Company elected to early adopt ASU 2017-01 and determined the intangible assets acquired as part of the ELAA should be accounted for as an acquisition of a single group of assets and not as a business combination.

In October 2016, the FASB issued ASU 2016-16, "*Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory*," which requires companies to recognize the income tax consequences of an intra-entity transfer of an asset other than

inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company elected to early-adopt ASU 2016-16 on a modified-retrospective basis as of January 1, 2017. Adoption of ASU 2016-16 eliminated the $11,156 income tax deferred charge recorded within the consolidated balance sheet as of December 31, 2016 and such elimination is reflected as an adjustment to accumulated deficit as of January 1, 2017.

In August 2016, the FASB issued ASU 2016-15, *"Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*." ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the Company for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. ASU 2016-15 should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company does not believe this standard will materially impact our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 "*Revenue from Contracts with Customers*" which supersedes the most current revenue recognition requirements. This ASU requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. Through May 2016, the FASB issued ASU 2016-08 "*Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*," ASU 2016-10 "*Identifying Performance Obligations and Licensing*," and ASU 2016-12, "*Narrow-Scope Improvements and Practical Expedients*," which provide supplemental adoption guidance and clarification to ASU 2014-09, respectively. These ASUs will be effective for annual and interim periods beginning after December 15, 2017 with early adoption for annual and interim periods beginning after December 15, 2016 permitted and should be applied retrospectively to each prior reporting period presented or as a modified retrospective adjustment as of the date of adoption.

The Company is currently evaluating this pronouncement to determine the impact of adoption on our consolidated financial statements, including which transition approach will be applied. The Company has decided not to early adopt the new pronouncement. The Company has assembled an implementation team consisting of a project manager as well as a cross functional project team responsible for assessing the impact the new revenue pronouncement will have on its consolidated financial statements and related disclosures. The implementation team is in the assessment phase, which consists of in depth analysis around the Company's contracts and will result in a comparison of historical accounting policies and practices to the requirements of the new revenue pronouncement. The implementation team will then identify any potential changes to business processes, systems and controls necessary to support recognition and disclosure under the new revenue pronouncement.

In February 2016, the FASB issued ASU 2016-02, "*Leases*" which supersedes ASC 840 "*Leases*" and creates a new topic, ASC 842 "*Leases*." This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the effect of this update on our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *"Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*." The amendments in this update address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is not permitted. The new guidance will require the change in fair value of equity investments with readily determinable fair values to be recognized through the statement of income. We are currently evaluating the full impact of the standard; however, upon adoption, the change in the fair value of our available-for-sale equity investments will be recognized in our consolidated statement of income (loss) rather than as a component of our consolidated statement of comprehensive income (loss).

NOTE 3 : Fair Value Measurement

The Company is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value extensively when accounting for and reporting certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business combination. Fair value is estimated by applying the hierarchy described below, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

ASC 820, *Fair Value Measurements and Disclosures* defines fair value as a market-based measurement that should be determined based on the assumptions that marketplace participants would use in pricing an asset or liability. When estimating fair value, depending on the nature and complexity of the asset or liability, we may generally use one or each of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.
- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

As a basis for considering the assumptions used in these techniques, the standard establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Quoted prices for identical assets or liabilities in active markets.
- Level 2 - Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means.
- Level 3 - Unobservable inputs that reflect estimates and assumptions.

The following table summarizes the financial instruments measured at fair value on a recurring basis classified in the fair value hierarchy (Level 1, 2 or 3) based on the inputs used for valuation in the accompanying consolidated balance sheets:

	As of September 30, 2017			As of December 31, 2016		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see Note 4)						
Equity securities	$ 454	$ —	$ —	$ 4,033	$ —	$ —
Money market funds	44,312	—	—	—	—	—
Corporate bonds	—	18,986	—	—	57,348	—
Government securities - U.S.	—	11,133	—	—	42,814	—
Government securities - Non-U.S.	—	69	—	—	233	—
Other fixed-income securities	—	3,207	—	—	10,471	—
Other securities	—	—	—	—	81	—
Total assets	$ 44,766	$ 33,395	$ —	$ 4,033	$ 110,947	$ —
Related party payables (see Note 7)	—	—	107,117	—	—	169,347
Total liabilities	$ —	$ —	$ 107,117	$ —	$ —	$ 169,347

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the periods ended September 30, 2017 and December 31, 2016, there were no transfers into and out of Level 1, 2, or 3. During the three and nine month periods ended September 30, 2017 and 2016, we did not recognize any other-than-temporary impairment loss.

Some of the Company's financial instruments, such as cash and cash equivalents, accounts receivable and accounts payable, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature. Additionally, the Company's long-term debt is reflected in the balance sheet at carrying value, which approximates fair value, as these represent non-interest bearing grants from the French government and are repayable only if the research project is technically or commercially successful.

NOTE 4 : Marketable Securities

The Company has investments in available-for-sale marketable securities which are recorded at fair market value. Unrealized gains and losses are recorded as other comprehensive income (loss) in shareholders’ equity, net of income tax effects.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of September 30, 2017 and December 31, 2016, respectively:

	As of September 30, 2017			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Equity securities	$ 438	$ 26	$ (10)	$ 454
Money market funds	44,311	1	—	44,312
Corporate bonds	19,014	84	(112)	18,986
Government securities - U.S.	11,220	21	(108)	11,133
Government securities - Non-U.S.	70	—	(1)	69
Other fixed-income securities	3,212	—	(5)	3,207
Total	$ 78,265	$ 132	$ (236)	$ 78,161

	As of December 31, 2016			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Equity securities	$ 3,689	$ 409	$ (65)	$ 4,033
Corporate bonds	57,871	89	(612)	57,348
Government securities - U.S.	43,049	515	(750)	42,814
Government securities - Non-U.S.	247	—	(14)	233
Other fixed-income securities	10,281	221	(31)	10,471
Other securities	81	—	—	81
Total	$ 115,218	$ 1,234	$ (1,472)	$ 114,980

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We recognized gross realized gains of $2,978 and $635 for the three months ended September 30, 2017, and 2016, respectively. These realized gains were offset by realized losses of $2,432 and $756 for the three months ended September 30, 2017, and 2016, respectively. We recognized gross realized gains of $4,228 and $709 for the nine months ended September 30, 2017, and 2016, respectively. These realized gains were offset by realized losses of $3,755 and $1,430 for the nine months ended September 30, 2017, and 2016, respectively. We reflect these gains and losses as a component of investment income in the accompanying condensed consolidated statements of income (loss).

The following table summarizes the estimated fair value of our investments in marketable debt securities, accounted for as available-for-sale securities and classified by the contractual maturity date of the securities as of September 30, 2017:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	1,361	16,219	1,136	270	18,986
Government securities - U.S.	172	8,547	348	2,066	11,133
Government securities - Non-U.S.	—	—	69	—	69
Other fixed-income securities	—	2,473	734	—	3,207
Total	$ 1,533	$ 27,239	$ 2,287	$ 2,336	$ 33,395

The Company has classified our investment in available-for-sale marketable securities as current assets in the condensed consolidated balance sheets as the securities need to be available for use, if required, to fund current operations. There are no restrictions on the sale of any securities in our investment portfolio.

NOTE 5 : Inventories

The principal categories of inventories, net of reserves of $2,039 and $3,223 at September 30, 2017 and December 31, 2016, respectively, are comprised of the following:

Inventory:	September 30, 2017	December 31, 2016
Finished goods	$ 4,605	$ 2,429
Raw materials	1,265	829
Total	$ 5,870	$ 3,258

NOTE 6 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at September 30, 2017 and December 31, 2016 are as follows:

	As of September 30, 2017			As of December 31, 2016		
Goodwill and Intangible Assets:	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets:						
Acquired developed technology - Noctiva	$ 73,111	$ —	$ 73,111	$ —	$ —	$ —
Acquired developed technology - Vazculep	12,061	(9,411)	2,650	12,061	(8,801)	3,260
Acquired product marketing rights	16,600	(1,854)	14,746	16,600	(1,019)	15,581
Acquired developed technology	4,300	(551)	3,749	4,300	(304)	3,996
Total amortizable intangible assets	$ 106,072	$ (11,816)	$ 94,256	$ 32,961	$ (10,124)	$ 22,837
Unamortizable intangible assets:						
Goodwill	$ 18,491	$ —	$ 18,491	$ 18,491	$ —	$ 18,491
Total unamortizable intangible assets	$ 18,491	$ —	$ 18,491	$ 18,491	$ —	$ 18,491

The Company recorded amortization expense related to amortizable intangible assets of $564 and $3,702 for the three months ended September 30, 2017 and 2016, respectively. The Company recorded amortization expense related to amortizable intangible assets of $1,692 and $10,918 for the nine months ended September 30, 2017 and 2016, respectively.

During the period, the Company acquired $73,111 in developed technology as part of the ELAA with Serenity Pharmaceuticals, LLC. The aggregate cost was composed of an upfront payment of $50,000, an accrued payment of $20,000 due within one year, and $3,111 of transaction costs. The Company will amortize the developed technology over a 13 year period beginning October 1, 2017.

Amortizable intangible assets are amortized over their estimated useful lives, which range from three to fifteen years. Estimated amortization of intangible assets for the next five years is as follows:

Estimated Amortization Expense:	Amount
2017	$ 3,664
2018	7,882
2019	7,882
2020	7,882
2021	7,067

NOTE 7 : Long-Term Related Party Payable

Long-term related party payable and related activity are reported at fair value and consist of the following for the three months ended September 30, 2017:

		Activity during the Three Months Ended September 30, 2017			
			Changes in Fair Value of Related Party Payable		
Long-Term Related Party Payable:	**Balance, June 30, 2017**	**Payments to Related Parties**	**Operating Expense / (Income)**	**Other Expense / (Income)**	**Balance, September 30, 2017**
Acquisition-related contingent consideration:					
Warrants - Éclat Pharmaceuticals (a)	$ 10,400	$ —	$ (2,173)	$ —	$ 8,227
Earn-out payments - Éclat Pharmaceuticals (b)	84,094	(8,214)	(7,685)	—	68,195
Royalty agreement - FSC (c)	8,010	(296)	(48)	—	7,666
Financing-related:					
Royalty agreement - Deerfield (d)	6,743	(784)	—	(520)	5,439
Royalty agreement - Broadfin (e)	3,212	(374)	—	(248)	2,590
Long-term liability - FSC (f)	15,000	—	—	—	15,000
Total related party payable	127,459	$ (9,668)	$ (9,906)	$ (768)	107,117
Less: Current portion	(40,615)				(30,986)
Total long-term related party payable	$ 86,844				$ 76,131

Long-term related party payable and related activity are reported at fair value and consist of the following for the nine months ended September 30, 2017:

		Activity during the Nine Months Ended September 30, 2017			
			Changes in Fair Value of Related Party Payable		
Long-Term Related Party Payable:	**Balance, December 31, 2016**	**Payments to Related Parties**	**Operating Expense / (Income)**	**Other Expense / (Income)**	**Balance, September 30, 2017**
Acquisition-related contingent consideration:					
Warrants - Éclat Pharmaceuticals (a)	$ 11,217	$ —	$ (2,990)	$ —	$ 8,227
Earn-out payments - Éclat Pharmaceuticals (b)	121,377	(24,729)	(28,453)	—	68,195
Royalty agreement - FSC (c)	7,291	(961)	1,336	—	7,666
Financing-related:					
Royalty agreement - Deerfield (d)	9,794	(2,332)	—	(2,023)	5,439
Royalty agreement - Broadfin (e)	4,668	(1,113)	—	(965)	2,590
Long-term liability - FSC (f)	15,000	—	—	—	15,000
Total related party payable	169,347	$ (29,135)	$ (30,107)	$ (2,988)	107,117
Less: Current portion	(34,177)				(30,986)
Total long-term related party payable	$ 135,170				$ 76,131

(a) As part of the consideration for the Company's acquisition of Éclat on March 13, 2012, the Company issued two warrants to a related party with a six-year term which allow for the purchase of a combined total of 3,300 ordinary shares of Avadel. One warrant is exercisable for 2,200 shares at an exercise price of $7.44 per share, and the other warrant is exercisable for 1,100 shares at an exercise price of $11.00 per share.

The fair value of the warrants is estimated on a quarterly basis using a Black-Scholes option pricing model with the following assumptions as of September 30:

Assumptions for the Warrant Valuation:	September 30, 2017	September 30, 2016
Stock price	$ 10.50	$ 12.40
Weighted average exercise price per share	8.63	8.63
Expected term (years)	0.50	1.50
Expected volatility	40.30%	58.40%
Risk-free interest rate	1.20%	0.68%
Expected dividend yield	—	—

These Black-Scholes fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. The fair value of the warrant consideration is most sensitive to movement in the Company's share price and expected volatility at the balance sheet date.

Expected term: The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Expected volatility: The expected volatility is calculated based on an average of the historical volatility of the Company's stock price.

Risk-free interest rate: The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant and a maturity that approximates the expected term.

Expected dividend yield: The Company has not distributed any dividends since our inception and has no plan to distribute dividends in the foreseeable future.

At the closing date of the 2012 Éclat acquisition and at September 30, 2017, it was uncertain as to whether the Company would ultimately fulfill our obligation under these warrants using Company shares or cash. Accordingly, pursuant to the guidance of ASC 480, the Company determined that these warrants should be classified as a liability. This classification as a liability was further supported by the Company's determination, pursuant to the guidance of ASC 815-40-15-7(i), that these warrants could also not be considered as being indexed to the Company's own stock, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Company at the closing date of the Éclat acquisition was the Euro.

(b) In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. ("Breaking Stick", formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by the Company's CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity.

(c) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part included a commitment to pay quarterly a 15% royalty on the net sales of certain FSC products, up to $12,500 for a period not exceeding ten years.

(d) As part of a February 2013 debt financing transaction conducted with Deerfield, the Company received cash of $2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with such debt financing transaction, the Company granted Deerfield a security interest in the product registration rights of the Eclat products.

(e) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Company received cash of $2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until December 31, 2024.

(f) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part consists of payments totaling $1,050 annually for five years with a final payment in January 2021 of $15,000. Substantially all of FSC's, and its subsidiaries, assets are pledged as collateral under this agreement.

At September 30, 2017, the fair value of each related party payable listed in (b) through (e) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat and FSC products using an appropriate risk-adjusted discount rate ranging from 15% to 22%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related related party payables, resulting primarily from management's revision of key assumptions, will be recorded in the consolidated statements of income (loss) in the line items entitled *"Changes in fair value of related party contingent consideration"* for items noted in (b) and (c) above and in *"Other income (expense) - changes in fair value of related party payable"* for items (d) and (e) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements in Part II, Item 8 of the Company's 2016 Annual Report on Form 10-K for more information on key assumptions used to determine the fair value of these liabilities.

The Company has chosen to make a fair value election pursuant to ASC 825, "*Financial Instruments*" for our royalty agreements detailed in items (d) and (e) above. These financing-related liabilities are recorded at fair market value on the consolidated balance sheets and the periodic change in fair market value is recorded as a component of "Other expense – changes in fair value of related party payable" on the consolidated statements of income (loss).

The following table summarizes changes to the related party payables, a recurring Level 3 measurement, for the nine-month periods ended September 30, 2017 and 2016, respectively:

Related Party Payable Rollforward:	**Balance**
Balance at December 31, 2015	$ 122,693
Additions [2]	22,695
Payment of related party payables	(24,227)
Fair value adjustments [1]	59,124
Balance at September 30, 2016	180,285
Balance at December 31, 2016	169,347
Payment of related party payable	(29,135)
Fair value adjustments [1]	(33,095)
Balance at September 30, 2017	$ 107,117

[1] Fair value adjustments are reported as Changes in fair value of related party contingent consideration and Other income (expense) - changes in fair value of related party payable in the Condensed Consolidated Statements of Income (Loss).

[2] Relates to the acquisition of FSC. See items (c) and (f) above.

NOTE 8 : Income Taxes

The components of income (loss) before income taxes are as follows:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
Income (Loss) Before Income Taxes:	**2017**	**2016**	**2017**	**2016**
Ireland	$ (6,111)	$ (3,485)	$ 1,924	$ (17,413)
United States	29,627	(6,814)	96,288	4,948
France	3,313	(6,244)	(1,950)	(15,333)
Other	771	—	2,084	—
Total income before income taxes	$ 27,600	$ (16,543)	$ 98,346	$ (27,798)

The items accounting for the difference between the income tax provision computed at the statutory rate and the Company's effective tax rate are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Income Tax Rate Reconciliation:	**2017**	**2016**	**2017**	**2016**
Statutory tax rate	12.5 %	33.3 %	12.5 %	33.3 %
International tax rates differential	24.9 %	(3.6)%	20.5 %	(13.3)%
Valuation allowance on net operating loss	(1.6)%	(2.0)%	0.5 %	(15.3)%
Nondeductible change in fair value of contingent consideration	(12.8)%	(38.9)%	(10.9)%	(62.0)%
Other	(1.6)%	(9.6)%	(0.3)%	(8.2)%
Effective income tax rate	21.4 %	(20.8)%	22.3 %	(65.5)%
Income tax provision - at statutory tax rate	$ 3,449	$ (5,509)	$ 12,294	$ (9,257)
International tax rates differential	6,861	591	20,120	3,706
Valuation allowance on net operating loss	(438)	339	476	4,252
Nondeductible change in fair value of contingent consideration	(3,521)	6,436	(10,751)	17,236
Other	(430)	1,594	(309)	2,275
Income tax provision - at effective income tax rate	$ 5,921	$ 3,451	$ 21,830	$ 18,212

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Accordingly, beginning in the fourth quarter of 2016, the Company reports the Irish tax jurisdiction as our domestic jurisdiction. For periods prior to the fourth quarter of 2016, the French tax jurisdiction was the domestic jurisdiction.

The income tax provision for the three months ended September 30, 2017 and 2016 was $5,921 and $3,451, respectively. The increase in the income tax provision for the three months ended September 30, 2017 is primarily the result of increases in income in the United States, which was partially offset by a reduction in the amount of nondeductible contingent consideration.

The income tax provision for the nine months ended September 30, 2017 and 2016 was $21,830 and $18,212, respectively. The increase in the income tax provision for the nine months ended September 30, 2017 is primarily the result of increases in income in the United States and Ireland, which was partially offset by a reduction in the amount of nondeductible contingent consideration.

NOTE 9 : Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	**September 30, 2017**	**December 31, 2016**
Valued-added tax recoverable	$ 1,049	$ 736
Prepaid expenses	1,002	3,442
Advance to suppliers and other current assets	726	1,265
Income tax receivable	596	451
Total	$ 3,373	$ 5,894

Other Non-Current Assets:	**September 30, 2017**	**December 31, 2016**
Deferred tax assets	$ 7,110	$ 7,432
Other	1,910	99
Total	$ 9,020	$ 7,531

Accrued Expenses:	September 30, 2017	December 31, 2016
Accrued compensation	$ 3,456	$ 3,291
Accrued social charges	827	794
Accrued employee severance (see Note 10)	1,926	—
Customer allowances	13,453	7,981
Accrued amounts due to contract research organization	1,472	1,764
Accrued ELAA payment	20,000	—
Accrued CMO charges	2,380	936
Other	4,483	2,456
Total	$ 47,997	$ 17,222

Other Non-Current Liabilities:	September 30, 2017	December 31, 2016
Provision for retirement indemnity	$ 2,137	$ 2,431
Customer allowances	1,883	905
Unrecognized tax benefits	2,456	1,565
Other	435	374
Total	$ 6,911	$ 5,275

NOTE 10 : Restructuring Costs

During the first quarter of 2017, the Company announced a plan to reduce our workforce at our Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with our ongoing and future planned projects. In July 2017, the Company completed negotiations with the works council and received approval from the French Labor Commission (DIRECCTE) to implement the plan. The reduction is substantially complete at the end of the third quarter. However, the Company expects to incur other cost of up to approximately $500, which are likely to be recognized through the first half of 2018. Restructuring income of $549 and charges of $3,173 were recognized during the three and nine months ended September 30, 2017. No similar amounts were recorded during the three and nine months ended September 30, 2016. The restructuring income resulted from a retirement indemnity curtailment gain of $549 in the three months ended September 30, 2017 associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force.

The following table sets forth activities for the Company’s cost reduction plan obligations for the nine months ended September 30, 2017. There were no restructuring related charges in the nine months ended September 30, 2016:

Severance Obligation:	2017
Balance of accrued costs at January 1,	$ —
Charges for employee severance, benefits and other	3,722
Payments	(2,164)
Foreign currency impact	368
Balance of accrued costs at September 30,	$ 1,926

Total accrued employee severance in the Company’s condensed consolidated balance sheet at September 30, 2017 is included under current liabilities in “Accrued expenses.”

NOTE 11 : Net Income (Loss) Per Share

Basic net income (loss) per share is calculated using the weighted average number of shares outstanding during each period. The diluted net income (loss) per share calculation includes the impact of dilutive equity compensation awards and contingent consideration warrants.

A reconciliation of basic and diluted net income (loss) per share, together with the related shares outstanding in thousands is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Income (Loss) Per Share:	**2017**	**2016**	**2017**	**2016**
Net income (loss)	$ 21,679	$ (19,994)	$ 76,516	$ (46,010)
Weighted average shares:				
Basic shares	40,061	41,241	40,839	41,241
Effect of dilutive securities—options and warrants outstanding	1,278	—	1,355	—
Diluted shares	41,339	41,241	42,194	41,241
Net income (loss) per share - basic	$ 0.54	$ (0.48)	$ 1.87	$ (1.12)
Net income (loss) per share - diluted	$ 0.52	$ (0.48)	$ 1.81	$ (1.12)

Potential common shares of 5,008 and 6,860 were excluded from the calculation of weighted average shares for the three months ended September 30, 2017 and 2016, respectively, because their effect was considered to be anti-dilutive. Potential common shares of 5,086 and 6,860 were excluded from the calculation of weighted average shares for the nine months ended September 30, 2017 and 2016, respectively, because their effect was considered to be anti-dilutive.

NOTE 12 : Comprehensive Income (Loss)

The following table shows the components of accumulated other comprehensive loss for the three and nine months ended September 30, 2017 and 2016, respectively, net of tax effects:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Accumulated Other Comprehensive Loss:	**2017**	**2016**	**2017**	**2016**
Foreign currency translation adjustment:				
Beginning balance	$ (23,089)	$ (19,952)	$ (23,336)	$ (22,312)
Foreign currency translation gain (loss)	(229)	1,567	18	3,927
Balance at September 30,	$ (23,318)	$ (18,385)	$ (23,318)	$ (18,385)
Unrealized gain (loss) on marketable securities, net				
Beginning balance	$ 409	$ 1,102	$ (229)	$ (345)
Net other comprehensive income (loss), net of $92, $152, $0 and ($49) tax, respectively	(512)	(2,405)	126	(958)
Balance at September 30,	$ (103)	$ (1,303)	$ (103)	$ (1,303)
Accumulated other comprehensive loss at September 30,	$ (23,421)	$ (19,688)	$ (23,421)	$ (19,688)

The effect on the Company’s condensed consolidated financial statements of amounts reclassified out of accumulated other comprehensive loss was immaterial for all periods presented.

NOTE 13 : Shareholders' Equity

The following table presents a reconciliation of the Company's beginning and ending balances in shareholders' equity for the nine months ended September 30, 2017:

Shareholders' Equity:	**2017**
Shareholders' equity - January 1,	$ 42,069
Net income	76,516
Adjustment to accumulated deficit (see Note 2)	(11,156)
Other comprehensive income	144
Stock option exercised	377
Stock-based compensation expense	6,019
Share repurchases	(17,506)
Shareholders' equity - September 30,	$ 96,463

Share Repurchases

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depositary Shares. Under this authorization, which has an indefinite duration, share repurchases may be made in the open market, in block transactions on or off the exchange, in privately negotiated transactions, or through other means as determined by the Board of Directors and in accordance with the regulations of the Securities and Exchange Commission. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2017, the Company had repurchased 1,673 ordinary shares for $17,506, of which $799 remained unsettled within accounts payable at September 30, 2017.

NOTE 14 : Company Operations by Product

The Company has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on our proprietary polymer based technology. The Company's Chief Operating Decision Maker is the CEO. The CEO and the Board review profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products are included in one segment because the majority of the Company's products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

The following table presents a summary of total revenues by these products:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
Revenues by Product:	**2017**	**2016**	**2017**	**2016**
Bloxiverz	$ 9,920	$ 15,591	$ 37,541	$ 65,958
Vazculep	9,573	9,340	29,906	29,167
Akovaz	18,561	5,568	65,110	5,568
Other	1,093	841	5,452	4,165
Total product sales and services	39,147	31,340	138,009	104,858
License and research revenue	528	747	484	2,303
Total revenues	$ 39,675	$ 32,087	$ 138,493	$ 107,161

NOTE 15 : Commitments and Contingencies

Litigation

The Company is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2017 and December 31, 2016, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

Material Commitments

The Company has a commitment to purchase finished product from a contract manufacturer for a six-year period commencing in 2018. Commitments for this arrangement, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

Purchase Commitment:	**Balance**
2018	$ 3,241
2019	3,704
2020	3,704
2021	3,704
2022	3,704
Thereafter	3,704
Total	$ 21,761

Other than commitments disclosed in Note 14 - Contingent Liabilities and Commitments to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2016 Annual Report on Form 10-K and those noted above, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt and post-retirement benefit plan obligations which are disclosed in Note 9 - Long-Term Debt and Note 12 – Post-Retirement Benefit Plans, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2016 Annual Report on Form 10-K and long-term contingent consideration payable as disclosed in Note 7 – Long-Term Related Party Payable, to the Company's condensed consolidated financial statements included in Part I, Item 1 of this report.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis

(In thousands, except per share data)

(Unaudited)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 2 together with our condensed consolidated financial statements and the related notes appearing elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Disclosure Regarding Forward-Looking Statements" set forth immediately following the Table of Contents of the Company's 2016 Annual Report on Form 10-K filed with the SEC on March 28, 2017 (the "2016 Annual Report") for further information on the forward-looking statements herein. In addition, you should read the "Risk Factors" section in Part I, Item 1A of the 2016 Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this quarterly report.

Overview

Nature of Operations

Avadel Pharmaceuticals plc ("Avadel," the "Company," "we," "our," or "us") is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa™ (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock™ (controlled release of opioid analgesics with potential abuse deterrent properties).

- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission and seeks to identify additional product candidates for development with this strategy.

- the acquisition of commercial and or late-stage products or businesses. On September 1, 2017, the Company entered into an Exclusive License and Assignment Agreement ("ELAA") with Serenity Pharmaceuticals, LLC . The ELAA grants the Company the sole right to commercialize and further develop Noctiva™ in the United States. Noctiva is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected intranasal delivery system. It is the first and only product approved by the U.S. Food and Drug Administration ("FDA") for the treatment of nocturia due to nocturnal polyuria. Additionally, the Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics ("FSC") on February 5, 2016. We will consider further acquisitions and the Company continues to look for assets that could fit strategically into our current or potential future commercial sales force.

The Company was incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Our headquarters is in Dublin, Ireland and we have operations in St. Louis, Missouri, United States, and Lyon, France.

The Company is the successor to Flamel Technologies S.A., a French société anonyme ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. As a result of the Merger Agreement:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.
- our authorized share capital is $5,500 divided into 500,000 ordinary shares with a nominal value of $0.01 each and 50,000 preferred shares with a nominal value of $0.01 each
    - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Company, $0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying $5,937 on our balance sheet from ordinary shares to additional paid-in capital
    - our Board of Directors is authorized to issue preferred shares on a non-pre-emptive basis, for a maximum period of five years, at which point it may be renewed by shareholders. The Board of Directors has discretion to dictate terms attached to the preferred shares, including voting, dividend, conversion rights, and priority relative to other classes of shares with respect to dividends and upon a liquidation.
- all outstanding American Depositary Shares (ADSs) representing ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for ADSs representing ordinary shares of the Company.

Thus, the Merger changed the jurisdiction of our incorporation from France to Ireland, and an ordinary share of the Company held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger.

References in these condensed consolidated financial statements and the notes thereto to “Avadel,” the “Company,” “we,” "our," “us,” and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires.

Prior to completion of the Merger, the Flamel ADSs were listed on the Nasdaq Global Market (“Nasdaq”) under the trading symbol “FLML”; and immediately after the Merger the Company’s ADSs were listed for and began trading on Nasdaq on January 3, 2017 under the trading symbol “AVDL.”

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the Securities and Exchange Commission on May 1, 2017, and within the Company's 2016 Annual Report on Form 10-K.

Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the Company's proxy statement filed with the SEC as of July 5, 2016. Upon completion of the Merger, the Company did not have any distributable reserves. On February 15, 2017, the Company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable reserves for the purposes of Irish law. On March 6, 2017, the High Court issued its order approving the reduction of the Company's share premium which can be treated as distributable reserves.

Strategy

The Company's business strategy is designed to drive overall sales and earnings growth while maintaining a return on invested capital at an appropriate premium above the Company's cost of capital. Our key areas of focus address the most significant opportunities and challenges we face, including:

- ***Unapproved to Approved Marketed Drug Development***: The Company derives a majority of its sales and cash flow from FDA approvals through this “unapproved-to-approved” strategy for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). During the three months ended September 30, 2017 the Company generated $38,054 of sales from these products compared to $30,499 in the same period of 2016, respectively. During the nine months ended September 30, 2017 the Company generated $132,557 of sales from these products compared to $100,693 in the same period of 2016, respectively.
    - Bloxiverz, which had sales of $9,920 and $37,541 for the three and nine months ended September 30, 2017, respectively, was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S.
    - Vazculep, which had sales of $9,573 and $29,906 for the three and nine months ended September 30, 2017, respectively, was approved by the FDA on September 27, 2014 and launched in October 2014 in the U.S.

- Akovaz, which had sales of $18,561 and $65,110 for the three and nine months ended September 30, 2017, respectively, was approved by the FDA April 29, 2016. The Company began marketing this product in August 2016.

Each of the above products is currently sold in the United States by Avadel's subsidiary Avadel Legacy Pharmaceuticals, LLC (formerly Éclat). Through our acquisition of Éclat, we obtained marketing and licensing knowledge of the commercial and regulatory processes in the U.S. and E.U, which. we believe has enhanced our ability to identify drug product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and license and market products in the U.S and E.U. The cash flow generated from these products, among other things, is used to fund our second strategy, the development and commercialization of drug delivery products.

- ***Development and Commercialization of the Company's Drug Delivery Pipeline Products***: In addition to the unapproved to approved drug development strategy, the Company is continuing to advance the development of our innovative drug delivery platforms. We have enhanced our ability to identify new product candidates and to pursue commercial opportunities associated with our drug delivery platforms. The Company's drug delivery platforms allow the creation of competitive and differentiated drug product profiles (e.g., with improved pharmacokinetics, efficacy and/or safety). We own and develop drug delivery platforms that address key formulation challenges, leading to the development of differentiated drug products for administration in various forms (e.g., capsules, tablets, sachets or liquid suspensions for oral use; or injectables for subcutaneous administration) and can be applied to a broad range of drugs (novel, already-marketed, or off-patent). Application of these technologies to pharmaceuticals allows us to protect our potential products through patent protection and product differentiation. As a result of developing our own drug delivery platforms our business is now less dependent on the development activities performed by partners, and relies more on the development of our own, self-funded, products. Our proprietary drug delivery platforms include:

    - **Micropump®** is a microparticulate system that allows the development and marketing of modified and/or controlled release solid oral dosage formulations of drugs (Micropump®-carvedilol and Micropump®-aspirin formulations have been approved in the U.S. and in the E.U., respectively).

    - **LiquiTime®** allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or patients having issues swallowing tablets or capsules. Unlike most liquid pharmaceuticals, LiquiTime® technology is not limited to ionic drugs as with resin-complex based technologies and can be applied to the development of combination products.

    - **Trigger Lock™** allows development of abuse-deterrent modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse.

    - **Medusa™** allows the development of extended/modified release of injectable dosage formulations of drugs (*e.g.*, peptides, polypeptides, proteins, and small molecules).

Several products formulated using our proprietary drug delivery platforms are currently under various stages of development for possible marketing either by the Company and/or by partners via licensing/distribution agreements. In particular, the Company has started a Phase III trial, titled *"A Double-blind, Randomized, Placebo Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension ("FT218") for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy,"* We have branded this trial REST-ON. On October 6, 2016, the Company announced that our Irish subsidiary, Avadel Ireland Holdings, has reached agreement with the U.S. Food and Drug Administration (FDA) for the design and planned analysis of the noted Phase III clinical trial of FT218, a once nightly formulation of sodium oxybate utilizing the Company's proprietary drug delivery platform, Micropump®. The agreement was reached through the Special Protocol Assessment ("SPA") process. A SPA is an acknowledgment by FDA that the design and planned analysis of the Company's pivotal clinical trial of FT218 adequately addresses the objectives necessary to support a regulatory submission. In December 2016, the Company initiated patient enrollment and dosing for our REST-ON Phase III clinical trial to assess the safety and efficacy of our once nightly formulation of Micropump® sodium oxybate (FT218) for the treatment of excessive daytime sleepiness ("EDS") and cataplexy in patients suffering from narcolepsy. The sole-source market for sodium oxybate, dosed twice nightly, is estimated at $1.1 billion in 2016. We believe that our product could offer significant advantages over the existing product to narcolepsy patients.

- **The key elements of our pipeline strategy include:**

    - Continuing to build commercially successful products utilizing Micropump®;

    - Identifying opportunities and optimizing time-to-market for our LiquiTime® drug delivery platform;

- Maximizing the technical potential of our existing drug delivery platforms for developing new and proprietary products; and
- Developing and validating improved and complementary drug delivery platforms related to our current drug delivery capabilities.

- **Inorganic growth through Acquisitions and/or Partnerships:** The Company maintains a strong balance sheet with substantial liquidity and no bank debt. As part of our overall enterprise strategy, the Company expects to explore and pursue appropriate inorganic growth opportunities that complement our drug delivery platforms or to acquire proprietary products that enhance profitability and cash flow. This was evidenced in September 2017 with the execution of the ELAA with Serenity Pharmaceuticals, LLC to commercialize and further develop Noctiva in the United States. Additionally, the Company will leverage the capabilities of our existing and future proprietary products and/or drug delivery platforms with pharmaceutical and biotechnology partnerships or licensing transactions. As an example in 2015, the Company completed a licensing transaction for exclusive U.S. rights to our LiquiTime® technology-based Over-the-Counter ("OTC") products which was licensed to Elan Pharma International Limited.

- **Divestitures and out licensing:** We have a stated objective to narrow our focus to our two most developed platforms, Micropump® and LiquiTime®. As a result, we are pursuing the divestiture or out licensing of Trigger Lock™ for abuse deterrence, and Medusa™ for extended-release subcutaneous injection. We believe both platforms are robust and well protected from an IP standpoint; however, their development and FDA approval will likely require substantial investments in clinical work and infrastructure, which we are not currently prepared to support.

Key Business Trends and Highlights

In operating our business and monitoring our performance, we consider a number of performance measures, as well as trends affecting our industry as a whole, which include the following:

- **Healthcare and Regulatory Reform**: Various health care reform laws in the U.S. may impact our ability to successfully commercialize our products and technologies. The success of our commercialization efforts may depend on the extent to which the government health administration authorities, the health insurance funds in the E.U. Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of healthcare products and services.

- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche branded or generic specialty pharmaceutical products or drug delivery platforms. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our drug delivery platforms obsolete or noncompetitive.

- **Pricing Environment for Pharmaceuticals**: The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing and reimbursement for our products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.

- **Generics Playing a Larger Role in Healthcare**: Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. Specifically, we have seen, or likely will see, additional generic competition to our current and future products and we continue to expect generic competition in the future.

- **Access to and Cost of Capital**: The process of raising capital and associated cost of such capital for a company of our financial profile can be difficult and potentially expensive. If the need were to arise to raise additional capital, access to that capital may be difficult and/or expensive and, as a result, could create liquidity challenges for the Company.

Highlights of our condensed consolidated results for the three and nine months ended September 30, 2017 are as follows:

- Revenue was $39,675 and $138,493 for the three and nine months ended September 30, 2017, compared to $32,087 and $107,161 in the same period last year, respectively. This increase was primarily the result of the launch of Akovaz in August 2016 partially offset by declines in Bloxiverz unit volumes and net selling price as a result of additional competition.

- Operating income was $26,118 and $93,585 for the three and nine months ended September 30, 2017, compared to operating loss of $16,190 and $22,029 for the same period last year, respectively. The primary reasons for the increase

in operating income for the three months ended September 30, 2017 were changes in the fair value of related party contingent consideration and the gross margin on $7,807 of higher product sales and services. The company recognized a $9,906 gain resulting from changes in the fair value of related party contingent consideration for the three months ended September 30, 2017 compared to a loss of $20,848 in the same period last year. The primary reasons for the increase in operating income for the nine months ended September 30, 2017 was also due to changes in the fair value of related party contingent consideration, as well as an increased gross margin on an increase in product sales and services of $33,151 and a decrease in intangible asset amortization expense of $9,226. The company recognized a $30,107 gain resulting from changes in the fair value of related party contingent consideration for the nine months ended September 30, 2017 compared to a loss of $52,989 in the same period last year.

- Net income was $21,679 and $76,516 for the three and nine months ended September 30, 2017, compared to a net loss of $19,994 and $46,010 in the same period last year, respectively.
- Diluted net income per share was $0.52 and $1.81 for the three and nine months ended September 30, 2017, compared to a diluted net loss per share of $0.48 and $1.12 in the same period last year, respectively.
- Cash and marketable securities declined $38,585 to $115,610 at September 30, 2017, from $154,195 at December 31, 2016. This decline was primarily due to $52,139 used to fund the ELAA and $16,707 for repurchases of our ordinary shares, partially offset by $30,478 in operating cash flow for the nine months ended September 30, 2017.

Critical Accounting Estimates

The Company’s condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. To prepare these financial statements, management must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as the disclosures of contingent assets and liabilities. Actual results could be significantly different from these estimates.

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our 2016 Form 10-K. The SEC suggests companies provide additional disclosure on those accounting policies considered most critical. The SEC considers an accounting policy to be critical if it is important to our financial condition and results of operations and requires significant judgments and estimates on the part of management in its application. Our estimates are often based on complex judgments, probabilities and assumptions that management believes to be reasonable, but that are inherently uncertain and unpredictable. It is also possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For a complete discussion of our critical accounting policies, see the “Critical Accounting Policies” section of the MD&A in our 2016 Form 10-K. There were no significant changes to our critical accounting policies during the three months ended September 30, 2017.

Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended September 30, 2017 and 2016:

Comparative Statements of Income (Loss)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Product sales and services	$ 39,147	$ 31,340	$ 7,807	24.9 %
License and research revenue	528	747	(219)	(29.3)%
Total revenues	39,675	32,087	7,588	23.6 %
Operating expenses:				
Cost of products and services sold	3,790	2,844	946	33.3 %
Research and development expenses	8,095	8,143	(48)	(0.6)%
Selling, general and administrative expenses	11,563	12,740	(1,177)	(9.2)%
Intangible asset amortization	564	3,702	(3,138)	(84.8)%
(Gain) loss on changes in fair value of related party contingent consideration	(9,906)	20,848	(30,754)	(147.5)%
Restructuring costs (income)	(549)	—	(549)	*n/a*
Total operating expenses	13,557	48,277	(34,720)	(71.9)%
Operating income (loss)	26,118	(16,190)	42,308	261.3 %
Investment income	1,110	490	620	126.5 %
Interest expense	(263)	(264)	1	0.4 %
Other income (expense) - changes in fair value of related party payable	768	(1,828)	2,596	142.0 %
Foreign exchange gain (loss)	(133)	1,249	(1,382)	(110.6)%
Income (loss) before income taxes	27,600	(16,543)	44,143	266.8 %
Income tax provision	5,921	3,451	2,470	71.6 %
Net income (loss)	$ 21,679	$ (19,994)	$ 41,673	208.4 %
Income (loss) per share - diluted	$ 0.52	$ (0.48)	$ 1.00	208.3 %

The following is a summary of our financial results (in thousands, except per share amounts) for the nine months ended September 30, 2017 and 2016:

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2017 vs. 2016	
Comparative Statements of Income (Loss)	**2017**	**2016**	**$**	**%**
Product sales and services	$ 138,009	$ 104,858	$ 33,151	31.6 %
License and research revenue	484	2,303	(1,819)	(79.0)%
Total revenues	138,493	107,161	31,332	29.2 %
Operating expenses:				
Cost of products and services sold	12,253	10,657	1,596	15.0 %
Research and development expenses	22,093	21,135	958	4.5 %
Selling, general and administrative expenses	35,804	33,491	2,313	6.9 %
Intangible asset amortization	1,692	10,918	(9,226)	(84.5)%
Changes in fair value of related party contingent consideration	(30,107)	52,989	(83,096)	(156.8)%
Restructuring costs	3,173	—	3,173	*n/a*
Total operating expenses	44,908	129,190	(84,282)	(65.2)%
Operating income (loss)	93,585	(22,029)	115,614	524.8 %
Investment income	2,689	1,080	1,609	149.0 %
Interest expense	(789)	(702)	(87)	12.4 %
Other income (expense) - changes in fair value of related party payable	2,988	(6,135)	9,123	148.7 %
Foreign exchange loss	(127)	(12)	(115)	(958.3)%
Income (loss) before income taxes	98,346	(27,798)	126,144	453.8 %
Income tax provision	21,830	18,212	3,618	19.9 %
Net income (loss)	$ 76,516	$ (46,010)	$ 122,526	266.3 %
Income (loss) per share - diluted	$ 1.81	$ (1.12)	$ 2.93	261.6 %

The revenues for each of the Company's significant products for the three months ended September 30, 2017 and 2016 are as follows:

			Three Months Ended *Increase / (Decrease)*	
	Three Months Ended September 30,		2017 vs. 2016	
Revenues:	**2017**	**2016**	**$**	**%**
Bloxiverz	$ 9,920	$ 15,591	$ (5,671)	(36.4)%
Vazculep	9,573	9,340	233	2.5 %
Akovaz	18,561	5,568	12,993	233.4 %
Other	1,093	841	252	30.0 %
Total product sales and services	39,147	31,340	7,807	24.9 %
License and research revenue	528	747	(219)	(29.3)%
Total revenues	$ 39,675	$ 32,087	$ 7,588	23.6 %

Product sales and services revenues were $39,147 for the three months ended September 30, 2017 compared to $31,340 for the same prior year period. Bloxiverz's revenue declined $5,671 when compared to the same period last year, primarily due to a loss of market share and decrease in net selling price driven largely by two factors: a) lost business as a result of a new competitor in the neostigmine market who entered the market in the first quarter of 2016 and b) a new molecule approved by the FDA in late 2015 and launched in 2016 with a similar indicated use as Bloxiverz. Vazculep's revenue was up slightly as the phenylephrine market for which this product is used was largely unchanged. Revenue from Akovaz increased $12,993 due to its launch in August 2016. Other revenues, which includes our pediatric products, were up slightly in the third quarter of 2017 when compared to the prior year's quarter. Revenues from our pediatric products were $1,911 for the three months ended September 30, 2017, compared to $390 in the same period last year.

License and research revenue was $528 for the three months ended September 30, 2017 compared to $747 in the same period last year.

The revenues for each of the Company's significant products for the nine months ended September 30, 2017 were as follows:

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2017 vs. 2016	
Revenues:	**2017**	**2016**	**$**	**%**
Bloxiverz	$ 37,541	$ 65,958	$ (28,417)	(43.1)%
Vazculep	29,906	29,167	739	2.5 %
Akovaz	65,110	5,568	59,542	1,069.4 %
Other	5,452	4,165	1,287	30.9 %
Total product sales and services	138,009	104,858	33,151	31.6 %
License and research revenue	484	2,303	(1,819)	(79.0)%
Total revenues	$ 138,493	$ 107,161	$ 31,332	29.2 %

Product sales and services revenues were $138,009 for the nine months ended September 30, 2017 compared to $104,858 for the same prior year period. Revenues for the nine months ended September 30, 2016 include $5,981 in additional non-recurring revenue as a result of our change in accounting estimate previously described in our Form 10-K for the year ended December 31, 2016. Excluding the impact of this revenue change, total product sales and services for the nine months ended September 30, 2016 would have been $98,877. Bloxiverz's revenue declined $28,417 when compared to the same period last year, primarily due to a $23,820 loss of market share and decrease in net selling price driven largely by two factors: a) lost business as a result of a new competitor in the neostigmine market who entered the market in the first quarter of 2016 and b) a new molecule approved by the FDA in late 2015 and launched in 2016 with a similar indicated use as Bloxiverz. The decline in Bloxiverz revenue was also due to the non-recurring effect of the change in the revenue estimate, noted above, of $4,597. Vazculep's revenue was up slightly as a $2,123 increase in price and volume was partially offset by the effect of the non-recurring revenue estimate change of $1,384. Revenue from Akovaz, which was launched in August 2016, contributed $65,110 to product sales for the nine months ended September 30, 2017. Other revenues, which includes our pediatric products, were up $1,287 in the nine months ended September 30, 2017 compared to the same prior year period. Revenues from our pediatric products, which were acquired in February 2016 were $5,355 for the nine months ended September 30, 2017, compared to $2,963 in the same period last year.

License and research revenue was $484 for the nine months ended September 30, 2017 compared to $2,303 in the same period last year. In the second quarter of 2017, the Company made a determination that the performance period associated with a specific license will be longer than previously estimated and, accordingly, increased the amortization period to better match the contractual requirements of the license. Use of this longer amortization period had the effect of reducing license revenue recognized in the nine months ended September 30, 2017 by $1,819 when compared to the same period last year.

Cost of Products and Services Sold:	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Cost of products and services sold	$ 3,790	$ 2,844	$ 946	33.3%
Percentage of sales	9.6%	8.9%		

Cost of products and services sold increased $946 or 33.3% during the three months ended September 30, 2017 compared to the same prior year period. As a percentage of sales, cost of products sold was up slightly to 9.6% compared to 8.9% as a result of product mix changes.

Cost of Products and Services Sold:	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 $	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 %
Cost of products and services sold	$ 12,253	$ 10,657	$ 1,596	15.0%
Percentage of sales	8.8%	9.9%		

Cost of products and services sold increased $1,596 or 15.0% compared to the same prior year period. As a percentage of sales, cost of products sold was slighly lower than the prior year period due primarily to $1,525 of inventory reserve adjustments recorded during the first quarter of 2016 that did not recur in 2017.

Research and Development Expenses:	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Research and development expenses	$ 8,095	$ 8,143	$ (48)	(0.6)%
Percentage of sales	20.4%	25.4%		

Research and development expenses were largely unchanged when compared to the same period last year. The Company continues to spend a substantial portion of its research and development spending on its Phase III FT218 clinical study.

Research and Development Expenses:	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 $	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 %
Research and development expenses	$ 22,093	$ 21,135	$ 958	4.5%
Percentage of sales	16.0%	19.7%		

Research and development expenses increased $958 as compared to the same period in 2016. This increase is due to higher spending associated with our Phase III FT218 clinical study. A substantial portion of the Company's research and development spending is associated with its Phase III FT218 clinical study.

Selling, General and Administrative Expenses:	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Selling, general and administrative expenses	$ 11,563	$ 12,740	$ (1,177)	(9.2)%
Percentage of sales	29.1%	39.7%		

Selling, general and administrative expenses decreased $1,177 during the three months ended September 30, 2017 as compared to the same prior year period. This decrease was largely due to a decrease in stock based compensation expense of $2,136 period over period, partially offset by higher payroll and benefit costs of $584 as we continue to add people to support the future growth of the business.

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2017 vs. 2016	
Selling, General and Administrative Expenses:	**2017**	**2016**	**$**	**%**
Selling, general and administrative expenses	$ 35,804	$ 33,491	$ 2,313	6.9%
Percentage of sales	25.9%	31.3%		

Selling, general and administrative expenses increased $2,313 as compared to the same prior year period. This increase was primarily due to higher payroll and benefit costs of $2,813 as we continue to add people to support the future growth of the business. Additionally, we incurred higher advertising and promotion costs of $1,247 primarily associated with certain business development activities and pre-launch marketing research studies for sodium oxybate. This increase was partially offset by a decrease in stock based compensation expense of $2,971 period over period.

			Three Months Ended *Increase / (Decrease)*	
	Three Months Ended September 30,		2017 vs. 2016	
Intangible Asset Amortization:	**2017**	**2016**	**$**	**%**
Intangible asset amortization	$ 564	$ 3,702	$ (3,138)	(84.8)%
Percentage of sales	1.4%	11.5%		

Intangible asset amortization expense decreased $3,138 during the three months ended September 30, 2017 as compared to the same prior year period as the Bloxiverz in process R&D asset was fully amortized as of December 31, 2016.

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2017 vs. 2016	
Intangible Asset Amortization:	**2017**	**2016**	**$**	**%**
Intangible asset amortization	$ 1,692	$ 10,918	$ (9,226)	(84.5)%
Percentage of sales	1.2%	10.2%		

Intangible asset amortization expense decreased $9,226 compared to the same prior year period as the Bloxiverz in process R&D asset was fully amortized as of December 31, 2016.

			Three Months Ended *Increase / (Decrease)*	
	Three Months Ended September 30,		2017 vs. 2016	
Changes in Fair Value of Related Party Contingent Consideration:	**2017**	**2016**	**$**	**%**
(Gain)/loss - changes in fair value of related party contingent consideration	$ (9,906)	$ 20,848	$ (30,754)	(147.5)%
Percentage of sales	(25.0)%	65.0%		

We compute the fair value of the related party contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions or other factors, the fair value of these liabilities change as well.

As a result, changes in the estimates of the underlying assumptions used to determine the fair values of a) our acquisition-related contingent consideration earn-out payments - Éclat, b) acquisition related warrants and c) acquisition related FSC royalty liabilities we recorded a gain of $9,906 to reduce the fair value of these liabilities in the third quarter of 2017 compared to an expense of

$20,848 to increase the fair value of these liabilities in the third quarter of 2016. As noted in our critical accounting estimates, described in our December 31, 2016 Form 10-K, there are numerous estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the three months ended September 30, 2017, as a result of changes to these estimates when compared to these same estimates at June 30, 2017, we recognized a gain of $7,685 to lower the fair value of acquisition related liabilities for the Éclat products primarily as a result of changes in the pricing environment for Akovaz and a weaker long-term sales and gross profit outlook for Bloxiverz due to increased competition. Additionally, we decreased the fair value of the acquisition related warrants which resulted in a gain of $2,173, primarily due to changes in the AVDL stock price at September 30, 2017 compared to June 30, 2017, changes in the volatility of AVDL stock and a shorter remaining term of the warrants.

For the three months ended September 30, 2016, as a result of changes to these estimates when compared to the same estimates at June 30, 2016 we recognized expense of $19,720 to increase the fair value of acquisition related liabilities for the Éclat products primarily as a result at that time of a stronger long-term sales and gross profit outlook for Bloxiverz. Additionally, we increased the fair value of the acquisition related warrants which resulted in an expense of $2,058 primarily due to changes in the AVDL stock price at September 30, 2016 compared to June 31, 2016, changes in the volatility of AVDL stock, partiality offset by a shorter remaining term of the warrants.

Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our consolidated statements of income (loss), balance sheet and cash flows.

			Nine Months Ended	
			Increase / (Decrease)	
	Nine Months Ended September 30,		2017 vs. 2016	
Changes in Fair Value of Related Party Contingent Consideration:	**2017**	**2016**	**$**	**%**
(Gain)/ loss - changes in fair value of related party contingent consideration	$ (30,107)	$ 52,989	$ (83,096)	(156.8)%
Percentage of sales	(21.7)%	49.4%		

We compute the fair value of the related party contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions the fair value of these liabilities change as well.

As a result changes in the estimates of the underlying assumptions used to determine the fair values of a) our acquisition-related contingent consideration earn-out payments - Éclat, b) acquisition related warrants and c) acquisition related FSC royalty liabilities we recorded a gain of $30,107 to reduce the fair value of these liabilities for the nine months ended September 30, 2017 compared to an expense of $52,989 to increase the fair value of these liabilities for the nine months ended September 30, 2016. As noted in our critical accounting estimates, there are numerous estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the nine months ended September 30, 2017, as a result of changes to these estimates when compared to the same estimates at December 31, 2016, we recognized a gain of $28,453 to lower the fair value of acquisition related liabilities for the Éclat products primarily as a result of changes in the pricing environment for Akovaz and a weaker long-term sales and gross profit outlook for Bloxiverz due to more competition. Additionally, we decreased the fair value of the acquisition related warrants which resulted in a gain of of $2,990, primarily due to changes in the AVDL stock price at September 30, 2017 compared to December 31, 2016, changes in the volatility of AVDL stock, partially offset by a shorter remaining term of the warrants.

For the nine months ended September 30, 2016, as a result of changes to these estimates when compared to the same estimates at December 31, 2015 we recognized expense of $58,081 to increase the fair value of acquisition related liabilities for the Éclat products primarily as a result at that time of a stronger long-term sales and gross profit outlook for Bloxiverz. Additionally, we reduced the fair value of the acquisition related warrants which resulted in a gain of $3,097 primarily due to changes in the AVDL stock price at September 30, 2016 compared to December 31, 2015, changes in the volatility of AVDL stock partially offset by a shorter remaining term of the warrants.

Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our consolidated statements of income (loss), balance sheet and cash flows.

			Three Months Ended	
			Increase / (Decrease)	
	Three Months Ended September 30,		2017 vs. 2016	
Restructuring Costs	**2017**	**2016**	**$**	**%**
Restructuring (income) costs	$ (549)	$ —	$ (549)	*n/a*
Percentage of sales	(1.4)%	—%		

We recorded a reduction of $549 in restructuring charges during the three months ended September 30, 2017. During the first quarter of 2017, we announced a plan to reduce our workforce at our Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with our ongoing and future planned projects. In July 2017, the Company completed negotiations with the works council and received approval from the French Labor Commission to implement the plan. The reduction was substantially complete at the end of the third quarter. However, the Company expects to incur additional restructuring costs of up to approximately $500, which are likely to be recognized through the first half of 2018. The Company recorded a curtailment gain of $549 in the three months ended September 30, 2017 associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force.

			Nine Months Ended	
			Increase / (Decrease)	
	Nine Months Ended September 30,		2017 vs. 2016	
Restructuring Costs	**2017**	**2016**	**$**	**%**
Restructuring costs	$ 3,173	$ —	$ 3,173	*n/a*
Percentage of sales	2.3%	—%		

Restructuring charges of $3,173 were recognized during the nine months ended September 30, 2017 associated with the workforce reduction noted above.

			Three Months Ended	
			Increase / (Decrease)	
	Three Months Ended September 30,		2017 vs. 2016	
Other Income (Expense) - Changes in Fair Value of Related Party Payable	**2017**	**2016**	**$**	**%**
Changes in fair value of related party payable	$ 768	$ (1,828)	$ 2,596	142.0%
Percentage of sales	1.9%	(5.7)%		

We recorded a gain of $768 to reduce the fair value of related party payables during the three months ended September 30, 2017 due to the same reasons associated with the Éclat product sales described in the section *Changes in fair value of related party contingent consideration* for this period. As noted in our critical accounting estimates described in the December 31, 2016 Form 10-K, there are a number of estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition and other factors.

We recorded expense of $1,828 to increase the fair value of these liabilities during the three months ended September 30, 2016 due to the same reasons associated with the Éclat product sales described in the section *Changes in fair value of related party contingent consideration* for this period. As noted in our critical accounting estimates, there are a number of estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition and other factors.

Other Income (Expense) - Changes in Fair Value of Related Party Payable	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 $	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 %
Changes in fair value of related party payable	$ 2,988	$ (6,135)	$ 9,123	148.7%
Percentage of sales	2.2%	(5.7)%		

We recorded a gain of $2,988 to reduce the fair value of these liabilities during the nine months ended September 30, 2017 due to the same reasons associated with the Éclat product sales described in the section *Changes in fair value of related party contingent consideration* for this period. As noted in our critical accounting estimates described in the December 31, 2016 Form 10-K, there are a number of estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition and other factors.

We recorded expense of $6,135 to increase the fair value of these liabilities during the nine months ended September 30, 2016 due to the same reasons associated with the Éclat product sales described in the section *Changes in fair value of related party contingent consideration* for this period. As noted in our critical accounting estimates, there are a number of estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition and other factors.

Investment Income:	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Investment income	$ 1,110	$ 490	$ 620	126.5%
Percentage of sales	2.8%	1.5%		

Investment income increased $620 during the three months ended September 30, 2017 as compared to the same prior year period as gains were realized on a higher volume of sales of marketable securities period over period.

Investment Income:	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 $	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 %
Investment income	$ 2,689	$ 1,080	$ 1,609	149.0%
Percentage of sales	1.9%	1.0%		

Investment income increased $1,609 during the nine months ended September 30, 2017 as compared to the same prior year period as gains were realized on a higher volume of sales of marketable securities period over period.

Income Tax Provision:	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Three Months Ended Increase / (Decrease) 2017 vs. 2016 $	Three Months Ended Increase / (Decrease) 2017 vs. 2016 %
Income tax provision	$ 5,921	$ 3,451	$ 2,470	71.6%
Percentage of income (loss) before income taxes	21.5%	(20.9)%		

The items accounting for the difference between the income tax provision computed at the statutory rate and the Company's effective tax rate for the three months ended September 30, 2017 and 2016, are as follows:

	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016
Statutory tax rate	12.5 %	33.3 %
International tax rates differential	24.9 %	(3.6)%
Valuation allowance on net operating losses	(1.6)%	(2.0)%
Nondeductible contingent consideration	(12.8)%	(38.9)%
Other	(1.6)%	(9.6)%
Effective income tax rate	21.4 %	(20.8)%
Income tax provision - at statutory tax rate	$ 3,449	$ (5,509)
International tax rates differential	6,861	591
Valuation allowance on net operating losses	(438)	339
Nondeductible contingent consideration	(3,521)	6,436
Other	(430)	1,594
Income tax provision - at effective income tax rate	$ 5,921	$ 3,451

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Accordingly, beginning in the fourth quarter of 2016, the Company reports the Irish tax jurisdiction as our domestic jurisdiction. For periods prior to the fourth quarter of 2016, the French tax jurisdiction was the domestic jurisdiction.

The income tax provision for the three months ended September 30, 2017 and 2016 was $5,921 and $3,451, respectively. The increase in the income tax provision for the three months ended September 30, 2017 is primarily the result of increases in income in the United States, which was partially offset by a reduction in the amount of nondeductible contingent consideration.

Income Tax Provision:	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 $	Nine Months Ended Increase / (Decrease) 2017 vs. 2016 %
Income tax provision	$ 21,830	$ 18,212	$ 3,618	19.9%
Percentage of income (loss) before income taxes	22.2%	(65.5)%		

The items accounting for the difference between the income tax provision computed at the statutory rate and the Company's effective tax rate for the nine months ended September 30, 2017 and 2016, are as follows:

	Nine Months Ended September 30,	
	2017	2016
Statutory tax rate	12.5 %	33.3 %
International tax rates differential	20.5 %	(13.3)%
Valuation allowance on net operating losses	0.5 %	(15.3)%
Nondeductible contingent consideration	(10.9)%	(62.0)%
Other	(0.3)%	(8.2)%
Effective income tax rate	22.3 %	(65.5)%
Income tax provision - at statutory tax rate	$ 12,294	$ (9,257)
International tax rates differential	20,120	3,706
Valuation allowance on net operating losses	476	4,252
Nondeductible contingent consideration	(10,751)	17,236
Other	(309)	2,275
Income tax provision - at effective income tax rate	$ 21,830	$ 18,212

The income tax provision for the nine months ended September 30, 2017 and 2016 was $21,830 and $18,212, respectively. The increase in the income tax provision for the nine months ended September 30, 2017 is primarily the result of increases in income in the United States and Ireland, which was partially offset by a reduction in the amount of nondeductible contingent consideration.

Liquidity and Capital Resources

The Company's cash flows from operating, investing and financing activities, as reflected in the condensed consolidated statements of cash flows, are summarized in the following table:

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2017 vs. 2016	
Net cash provided by (used in):	**2017**	**2016**	**$**	**%**
Operating activities	$ 30,478	$ 11,160	$ 19,318	173.1 %
Investing activities	(15,167)	(50,088)	34,921	69.7 %
Financing activities	(17,292)	(8,012)	(9,280)	(115.8)%

Operating Activities

Net cash provided by operating activities of $30,478 for the nine months ended September 30, 2017 increased $19,318 compared to the same prior year period. This increase in operating cash flow is primarily due to higher cash earnings (net income or loss adjusted for non-cash credits and charges) of $21,755 when compared to the same period last year, largely driven from higher gross margin (revenues less cost of goods sold) on the increase in revenues. The increase in operating cash flow was partially offset by lower cash provided by changes in operating assets and liabilities of $2,437 when compared to the same period last year. Cash used for earn-out payments on related party contingent consideration in excess of acquisition-date fair value increased $11,899 when compared to the same period last year. This increase is driven from high payments due to high royalty bearing revenues and a shift in the classification of these payments from financing activities to operating activities. For a period of time in 2016, the cumulative life-to-date payments had not yet reached the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition, and as such, the Company classified all such payments within financing activities. Payments less than the original fair value totaling $6,834 were classified within financing activities for the nine months ended September 30, 2016, compared to the same period in 2017 during which all such cash payments were classified as operating activities as the Company had exceeded the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition.

Investing Activities

Cash used in investing activities of $15,167 for the nine months ended September 30, 2017 decreased $34,921 compared to the same prior year period. This decrease was primarily due to less net cash used in the purchase and redemption of marketable securities offset partially by $52,139 used to fund the ELAA. During the nine months ended September 30, 2017, we generated cash through the sales of net marketable securities (sales of marketable securities less purchases) of $37,505 compared to net purchases of marketable securities of $49,716 for the nine months ended September 30, 2016.

Financing Activities

Cash used in financing activities of $17,292 for the nine months ended September 30, 2017 increased $9,280 compared to the same prior year period. The increase was primarily attributed to our use of $16,707 in cash for share repurchases during the nine months ended September 30, 2017 that did not occur in 2016. This increase was partially offset by a decrease in cash used for earn-out payments for related party contingent consideration of $6,990. See *Operating Activities* for an explanation of the lower earn-out payments for related party contingent consideration.

Liquidity and Risk Management

We believe that our existing cash and marketable securities balances and cash we expect to generate from operations will be sufficient in the next twelve months to fund our operations and to meet our existing obligations during this time period. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product revenues and expenses, the timing and amount of commercial launch expenses related to Noctiva, as well as the other factors set forth in Part II, Item 1A ("Risk Factors") of this quarterly report on form 10-Q and under the caption "Risk Factors" within Part I, Item 1A of the Company's 2016 Annual Report on Form 10-K filed with the SEC. To continue to grow our business, we will need to commit substantial resources, especially associated with the commercial launch of Noctiva, which could result in future losses and significantly reduce our liquidity. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

In addition to the substantial resources we intend to commit to the commercial launch of Noctiva and the completion of our FT218 clinical trial, we will continue to evaluate a variety of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue or have completed could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity or equity-linked debt financing would be dilutive to our shareholders.

Share Repurchase Program

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depositary Shares. Under this authorization, which has an indefinite duration, share repurchases may be made in the open market, in block transactions on or off the exchange, in privately negotiated transactions, or through other means as determined by the Board of Directors and in accordance with the regulations of the Securities and Exchange Commission. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2017, the Company had repurchased 1,673 ordinary shares for $17,506, of which $799 remained unsettled within accounts payable at September 30, 2017.

Other Matters

Litigation

The Company is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2017 and December 31, 2016, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative

or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

Material Commitments

The Company has a commitment to purchase finished product from a contract manufacturer for a six-year period commencing in 2018. Commitments for this arrangement, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

Purchase Commitment:	**Balance**
2018	$ 3,241
2019	3,704
2020	3,704
2021	3,704
2022	3,704
Thereafter	3,704
Total	$ 21,761

Other than commitments disclosed in Note 14 - Contingent Liabilities and Commitments to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2016 Annual Report on Form 10-K and those noted above, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt and post-retirement benefit plan obligations which are disclosed in Note 9 - Long-Term Debt and Note 12 – Post-Retirement Benefit Plans, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2016 Annual Report on Form 10-K and long-term contingent consideration payable as disclosed in Note 7 – Long-Term Related Party Payable, to the Company's condensed consolidated financial statements included in Part I, Item 1 of this report.

Contractual Obligations

Disclosures regarding contractual obligations are included in Part II, Item 7 of the Company's 2016 Annual Report on Form 10-K and updated in Note 7 – Long-Term Contingent Consideration Payable to the Company's condensed consolidated financial statements included in Part I, Item 1 of this Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

The Company is subject to interest rate risk as a result of our portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities.

Foreign Exchange Risk

We have significant operations in Europe as well as in the U.S. Prior to December 31, 2016 each of the Company's non-U.S. subsidiaries and the parent entity, Flamel Technologies S.A., used the Euro as its functional currency. At December 31, 2016, in conjunction with the cross-border merger, the surviving entity in the merger and our new public holding company, Avadel Pharmaceuticals plc or the "Company," determined the U.S. dollar is our functional currency. The functional currency of certain foreign subsidiaries is the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S.

dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in Euro.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign exchange gain (loss) in the consolidated statements of income (loss). As of September 30, 2017, our primary exposure to transaction risk related to USD net monetary assets and liabilities held by subsidiaries with a Euro functional currency. Realized and unrealized foreign exchange losses resulting from transactional exposure were $362 and $109 for the three and nine months ended September 30, 2017.

ITEM 4. CONTROLS AND PROCEDURES.

Management of the Company, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2017, the end of the period covered by this quarterly report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were not effective because of the material weaknesses in our internal control over financial reporting as described in Item 9A in our Annual Report on Form 10-K as of December 31, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the nine months ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for the Company's continued implementation of action plans to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. While we have made progress in all areas of our remediation plan relating to the material weaknesses described in our Form 10-K as of December 31, 2016, we specifically focused on strengthening the design and documentation of controls around our significant non-routine and complex transactions and reserves for rebates and expired products to ensure these controls are operating with an appropriate level of precision. Our Audit Committee contributes to establishing the appropriate tone at the top by emphasizing to senior leadership the importance of a sound internal control environment and also by approving our remediation plan and the subsequent monitoring of our progress.

PART II – OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS.

The information contained in Note 15 – Commitments and Contingencies to the Company's condensed consolidated financial statements included in Part I, Item 1 of this Report is incorporated by reference herein.

ITEM 1A. RISK FACTORS.

Risks related to our exclusive license agreement for Noctiva.

Consumer purchases of Noctiva are subject risks related to reimbursement from government agencies and other third parties.

We anticipate that a substantial majority of our Noctiva sales will be reimbursed by third-party payors such as the Medicare Part D program in the U.S. and private health insurance companies. The commercial success of Noctiva will therefore depend substantially on the availability and levels of reimbursements by these payors. Government authorities and private health insurance companies decide which drugs they will cover and establish payment levels, and we cannot guaranty the availability or levels of any such reimbursements for Noctiva. If reimbursement for Noctiva is unavailable or limited by governmental or private insurance programs, our Noctiva business and our results of operations will suffer a material adverse effect.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for Noctiva.

In recent years, government health programs such as Medicare and other third-party payors in the United States have increased their efforts to:

- limit the price of covered drugs, including by challenging the prices charged by manufacturers, or by seeking other cost saving measures such as mandatory discounts or rebates, stricter requirements for initial reimbursement approvals and other similar measures;
- limit the use of covered drugs, including by shifting additional cost burden to patients, typically by requiring a co-payment or co-insurance percentage that increases significantly when the medicine is not covered or is not preferred; and
- limit the use of covered drugs by mandating treatment protocols that require additional healthcare administrative actions (in the form of a prior authorization for reimbursement) and or step edit therapy (requiring a patient to fail another therapy before getting access to the desired therapy).

Governmental agencies in the United States have enacted or adopted, are considering, and may in the future enact and adopt, various legislative and regulatory proposals to change the healthcare system, often with a particular focus on the pharmaceutical industry; and any changes resulting from such proposals may affect our ability to sell Noctiva profitably.

Any significant changes in the healthcare system in the United States would likely have a substantial impact on the manner in which we conduct our Noctiva business and could have a material adverse effect on our commercialization efforts for Noctiva.

We may have overestimated the market opportunity for Noctiva or we may not effectively exploit such market opportunity.

Our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate, which we have licensed from Serenity Pharmaceuticals, LLC (“Serenity”) and which we intend to market under the brand name “Noctiva”. If one or more of the assumptions underlying our internal analyses are incorrect, the benefits we anticipate from our exclusive license agreement with Serenity (the “Exclusive License Agreement”) for Noctiva may not be realized or may be smaller than expected. We may also fail to effectively exploit the market opportunity for Noctiva, and such failure could have a material adverse effect on our business, financial condition and operating results.

Significant safety or drug interaction problems could arise with respect to Noctiva.

Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels were derived from controlled clinical trials of limited duration in limited patient populations with Noctiva and from existing scientific knowledge and previous clinical assessments of the active pharmaceutical ingredient (Desmopressin Acetate). As Noctiva is used over longer periods of time and by more patients, some of whom may have underlying health problems or may be taking other medicines, new issues relating to safety, tolerability, resistance or drug-interaction could arise, which may require us to provide additional warnings or contraindications on product labels, or otherwise narrow Noctiva’s approved indications. Further, additional

information from ongoing research or clinical trials of Noctiva may raise doubts or concerns about its efficacy. If serious safety, tolerability, resistance, drug-interaction, efficacy, or any other such concerns or issues arise with respect to Noctiva, sales of Noctiva could be impaired, limited or abandoned.

We may not successfully increase awareness of nocturia and or the potential benefits of Noctiva.

Our ability to establish effective marketing and advertising campaigns for Noctiva will be key to our success in commercializing the drug. If we are unable to increase awareness of nocturia (i.e., adult night-time non-incontinent urination, which Noctiva is intended to reduce), the establishment of nocturnal polyuria as the critical etiology that must be treated despite any other co-morbidities and the potential benefits of Noctiva, our efforts to build a substantial customer base for the drug may not be successful. In addition, our overall marketing activities or pricing strategies may not be successful in promoting or selling Noctiva. If our marketing and advertising programs are not adequate to support future growth of Noctiva sales, our expected results may experience a material adverse effect.

We depend on a third-party supplier to manufacture Noctiva and any failure of such supplier to deliver sufficient quantities of Noctiva would have a material adverse effect on our business.

We will depend on a single contract manufacturing organization, Renaissance Lakewood, LLC, for the manufacturing and supply of Noctiva. If the supplies of Noctiva are interrupted for any reason, our manufacturing and marketing of Noctiva could be delayed. These delays could be extensive and expensive, especially in situations where a substitute is not readily available, or where additional regulatory approval is required. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We may be unable to adequately protect or enforce the intellectual property rights relating to Noctiva.

We may fail to adequately protect and enforce the intellectual property rights relating to Noctiva, and such failure could have a material adverse effect on our success. The patent positions of biopharmaceutical products or formulas can be highly uncertain and can involve complex legal and factual questions. The patent rights licensed to us under the Exclusive License Agreement may not be upheld in a court of law if challenged or may not provide a competitive advantage for Noctiva, and may be infringed upon or circumvented by our competitors. Because of the large number of patent filings in the biopharmaceuticals field, our competitors may have filed applications, may have been issued patents, or may obtain additional patents and proprietary rights relating to substances or processes competitive with or similar to Noctiva. We cannot be certain that U.S. or Canadian patents do not exist or will not be issued that would harm our ability to successfully commercialize Noctiva in such markets.

Our costs to commercialize Noctiva could exceed our estimates or such costs may not provide the intended results.

Our past and future internal budgets, plans and projections may underestimate the costs we will incur to develop and commercialize Noctiva, including transaction and integration costs and the costs of other financial, business and strategic initiatives related to the Exclusive License Agreement. Even if we adequately control such costs, our expenditures in developing and commercializing Noctiva may not yield the desired results. Further, we may incur higher than expected operating costs, and we may encounter general economic and business conditions that adversely affect us relating to the Exclusive License Agreement.

The development and commercialization of Noctiva will likely require significant management attention, which could disrupt our business and adversely affect our financial results.

We anticipate that our management will devote substantial time and attention to develop and commercialize Noctiva. By diverting management's attention away from our other products, our ongoing operations could suffer, which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Other than the foregoing, there were no material changes to the risk factors previously disclosed in the Company's 2016 Annual Report on Form 10-K under Item 1A. Risk Factors.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

(In thousands, except per share data)

The following table summarizes the repurchase activity of our ordinary shares during the three and nine months ended September 30, 2017. The repurchase activity presented below includes both market repurchases of shares and deemed repurchases in connection with the vesting of restricted share units under employee benefit plans to satisfy minimum statutory tax withholding obligations.

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depositary Shares. Under this authorization, which has an indefinite duration, share repurchases may be made in

the open market, in block transactions on or off the exchange, in privately negotiated transactions, or through other means as determined by the Board of Directors and in accordance with the regulations of the Securities and Exchange Commission. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of September 30, 2017, the Company had repurchased approximately 1,673 ordinary shares for $17,506 detailed below:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under Plans or Programs
April 2017	—	$ —	—	$ 25,000
May 2017	316	9.94	316	21,864
June 2017	1,035	10.82	1,035	10,662
July 2017	—	—	—	10,662
August 2017	—	—	—	10,662
September 2017	322	9.84	322	7,494
Total	1,673			

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
10.1*+	Employment Agreement by and between Avadel Management Corporation and Michael S. Anderson dated August 15, 2017.
10.2*+	Employment Agreement by and between Avadel Management Corporation and Gregory J. Divis dated September 5, 2017.
10.3*+	Employment Agreement by and between Avadel Management Corporation and Sandra Hatten dated August 15, 2017.
10.4*+	Employment Agreement by and between Avadel Management Corporation and Michael F. Kanan dated September 5, 2017.
10.5*+	Employment Agreement by and between Avadel Management Corporation and Phillandas T. Thompson dated August 15, 2017.
10.6*‡	Exclusive Right of Negotiation Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of August 11, 2017.
10.7*‡	Exclusive License and Assignments Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017.
10.8A*‡	Manufacturing Agreement by and between Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC) and Serenity Pharmaceuticals, LLC dated as of July 14, 2014.
10.8B*	Renaissance Agreements Assignment and Assumption Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017.
10.9*	Master Manufacturing Services Agreement by and between Patheon UK Limited and Éclat Pharmaceuticals L.L.C. dated as of November 8, 2012.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed herewith.

** Furnished herewith.

\+ Indicates management contract or compensatory plan or arrangement.

‡ Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

AVADEL PHARMACEUTICALS PLC
(Registrant)

Date: November 9, 2017

By: /s/ Michael F. Kanan
Michael F. Kanan
Senior Vice President and Chief Financial Officer
(Duly Authorized Officer and *Principal Financial Officer)*

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the fifteenth (15th) day of August 2017 (the "Effective Date") by and among Michael S. Anderson, a citizen of the United States currently residing at 1847 Oxborough Ct., Chesterfield, Missouri 63017 ("the Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri, USA 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel plc").

W I T N E S S E T H

WHEREAS, as of May 24, 2016, Avadel Legacy Pharmaceuticals, LLC, a Delaware limited liability company (and an affiliate of the Company) which was formerly known as Éclat Pharmaceuticals LLC ("Legacy"), Flamel Technologies S.A., a French *société anonyme* ("Flamel"), and the Executive entered into that certain Employment Agreement (the "2016 Employment Agreement") pursuant to which, among other things, Legacy and Flamel agreed to employ the Executive (such employment having commenced on March 13, 2012 pursuant to terms and conditions set forth in an agreement dated June 22, 2012 (the "2012 Employment Agreement"); and effective upon the merger (the "Merger") of Flamel with and into Avadel plc at 11:59:59 p.m. (Central Europe Time) on December 31, 2016, Avadel plc assumed the obligations of Flamel under the 2016 Employment Agreement.

WHEREAS, the Company and the Executive desire to replace the 2016 Employment Agreement in order to (i) provide that the Executive will be employed by the Company to provide services with respect to the management of Avadel plc and its subsidiaries including the Company and (ii) more accurately set forth the terms and conditions of the Executive's employment by the Company.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. The Executive shall serve as the Chief Executive Officer of Avadel plc and as the Chief Executive Officer of the Company, and shall carry out such work as may be reasonably required by the Company in the course of its business consistent with such positions and the terms and conditions of this Agreement. With respect to his position as the Chief Executive Officer of Avadel plc, the Executive shall have all the duties, powers and responsibilities customary for such position at a company with equity securities registered under the United States Securities Exchange Act of 1934. The Executive shall be allowed to work from Charleston, South Carolina, but shall also travel to and work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, Missouri) and the offices of the Company's affiliates in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time will make the best use of the Executive's energy, knowledge, and training, to advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Board of Directors of Avadel plc, the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined) during his employment with the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of his duties to or with respect to Avadel plc, the Company and their affiliated entities as provided in this Agreement. As used in this Agreement, the "Avadel Group of Companies" shall mean Avadel plc and each of its direct or indirect subsidiaries including the Company. The Executive will comply with all written policies of the Avadel Group of Companies, to the extent applicable to the Executive.

(b) Reporting. In his capacities as the Chief Executive Officer of Avadel plc and the Chief Executive Officer of the Company, the Executive shall report directly to the Board of Directors of Avadel plc and the Board of Directors of the Company, respectively.

1.2 Status. It is the intent of the parties that, at all times during the Executive's employment with the Company, he will remain a citizen of the United States.

1.3 Duration. The term of this Agreement shall commence as of the Effective Date set forth above and shall continue for one (1) year beginning on such date, with the Agreement automatically renewing for successive one- (1-) year periods, unless the Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. Notwithstanding the foregoing, this Agreement shall automatically terminate

on the date the Executive reaches the age of seventy-five (75), unless otherwise agreed by the Board of Directors of Avadel plc. At the termination of this Agreement, the Executive's employment with the Company shall terminate simultaneously. As of the Effective Date, this Agreement supersedes and replaces the 2016 Employment Agreement, which shall be null and void thereafter.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of Five Hundred Eighty-One Thousand Nine Hundred Forty-Six Dollars ($581,946) per year payable in accordance with the Company's normal payroll practices in effect from time to time (but not less frequently than monthly), subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to sixty percent (60%) of the Executive's base salary, subject to proration for any partial year (provided that for this purpose the Executive shall be given credit for his prior employment during 2017 under the 2016 Employment Agreement). Payment of the annual bonus will be based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date of payment, any bonus payments due hereunder shall be paid to the Executive, no later than the last day of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2.3 Prior Stock Option and Additional Equity Grants.

(a) Prior Grant. The Company and the Executive acknowledge and agree that, (i) in connection with the execution and delivery of the 2012 Employment Agreement, Flamel granted to the Executive an option (the "Original Stock Option") to purchase Two Hundred Seventy-Five Thousand (275,000) American Depositary Shares (ADSs), with each such ADS representing one (1) of Flamel's ordinary shares, at an exercise price equal to the fair market value of the Flamel ADSs as of the date of grant of the Original Stock Option; (ii) the board of directors of Flamel approved the grant of the Original Stock Option; and (iii) pursuant to the Merger, Avadel adopted and assumed such Original Stock Option and, as a result, upon and after the Merger, the Original Stock Option became and is exercisable for an equal number of the ADSs of Avadel plc. The terms and conditions of the Original Stock Option (including the vesting provisions thereof) shall continue in effect as adopted and assumed by Avadel plc without modification by this Agreement.

(b) Additional Discretionary Equity Grants. From time to time after the 2016 Employment Agreement and after the date of this Agreement, Flamel and/or Avadel plc may have granted, or (in the case of Avadel plc) may grant, to the Executive additional ADSs or ordinary shares (including free share awards or restricted share awards), or options for the purchase thereof or other such awards relating thereto, in accordance with applicable equity incentive plans (any such additional shares, options or other awards, the "Additional Equity Grants"). Except as specifically set forth above, however, nothing herein shall require Avadel plc or any of its subsidiaries or affiliates (including without limitation the Company) to make any equity grants or other awards to the Executive in any specific year. The terms and conditions of each Additional Equity Grant are, or as applicable shall be, set forth in a separate written agreement between the Executive and Avadel plc (either directly or by Avadel plc's assumption of the obligations of Flamel).

2.4 Auto Allowance. The Company shall make an automobile available to Executive based upon Executive's reasonable choosing. The Company shall pay all costs and expenses incidental to the ownership, operation, and maintenance of the automobile, including, but not limited to, automobile insurance, taxes and repair costs.

2.5 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and his family in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established in accordance with the terms and conditions of such plans or programs. The Executive acknowledges that the current insurance plans are offered through the Company and are subject to reasonable changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other executives at similar levels of authority with respect to Avadel plc and the Company (currently twenty (20) days per year). The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at the Executive's discretion in accordance with the normal Company paid vacation and time-off policies.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any

claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to the Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.6 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company with or without "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (iii) a relocation of the Company's offices of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; (iv) a material breach by the Company of this Agreement; or (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of Avadel plc or the Company.

(c) In the event that the Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that the Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-) day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof at least thirty (30) days prior to the date that such termination will be effective.

(e) The Executive's employment shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

3.2 Severance. If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause or the Executive reaching the age of seventy-five (75), including non-renewal of this Agreement by the Company (but not including any

circumstances that would give rise to a payment to the Executive pursuant to Section 3.3(a) hereof), the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.5 times the Executive's then-current annual base salary, such amount to be paid in equal installments over the 18-month period immediately following the date of termination in accordance with the Company's normal payroll practices with such installments to be no less frequent than monthly and to commence on the first payroll date following the date of termination; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of eighteen (18) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA.

All payments set forth in the foregoing items (i) and (iii) hereof are defined as the "Severance Indemnity." The Executive's receipt of the foregoing Severance Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any Severance Indemnity payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable; and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause or the Executive reaching the age of seventy-five (75), including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in lieu of a payment to the Executive pursuant to Section 3.2 above:

(i) upon such termination the Company shall pay to the Executive a change of control indemnity equal to the sum of: (A) the Severance Indemnity as defined in Section 3.2 hereof payable in accordance with the terms set forth in such Section 3.2; and (B) a lump-sum payment, payable no later than thirty (30) days after the later of the Change in Control or the termination of the Executive's employment, equal to one hundred percent (100%) of the higher of: (x) the greater of (I) the Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (II) the Executive's target bonus as in effect for the fiscal year in which the Executive's termination of employment occurs; or (y) the Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) upon the later of the Change in Control or the termination of the Executive's employment, subject to the release requirement below, the Executive shall become immediately vested in full in all theretofore any outstanding unvested rights of the Executive under the Original Stock Option and each and every Additional Equity Grant, including without limitation stock option awards and agreements and unvested or unissued rights to "free shares," restricted share awards and similar rights, and, without duplication and for the avoidance of doubt, any unvested rights under any of the foregoing (*i.e.*, the right to purchase any ADSs or ordinary shares under the Original Stock Option and under or in connection with any Additional Equity Grant), to the extent such rights and awards would have vested based solely on the continued employment of the Executive and the vesting of such rights and awards does not cause any violation of Section 409A of the Code.

(b) For avoidance of doubt, the amount paid to the Executive pursuant to Section 3.3(a) hereof (a) will be in lieu of, and not in addition to, any amount that would otherwise be payable to the Executive under Section 3.2 hereof, and (b) will not be prorated based on the actual amount of time the Executive is employed by the Company during the fiscal year (or the relevant performance period if different than a fiscal year) during which this termination occurs. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments and benefits set forth in items (i) and (iii) of Section 3.3(a) hereof are defined as the "Change of Control Indemnity."

(c) The Executive's receipt of the foregoing Change of Control Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable, and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or (ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or (iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions. Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code. (b) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and his employment with the Company other than for Good Reason or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive (or, after the Executive's death, his estate) all accrued or awarded but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Non-Disparagement. The Executive agrees not to disparage or otherwise refer to any member of the Avadel Group of Companies or any of their executives, officers or directors in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of the Executive's Employment and any benefits paid hereunder. The Company, together with all other members of the Avadel Group of Companies, and their executive officers and directors, agree not to disparage or otherwise refer to the Executive in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc).

4.3 Non-Solicitation of Employees and Contractors. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.3 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.4 Non-Solicitation of Customers and Suppliers. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements (including without limitation the 2016 Employment Agreement), either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof. For purposes of terminating the 2016 Employment Agreement, the Company hereby confirms that it is the duly authorized agent of Legacy and Avadel plc, and by the signatures below of the Company and the Executive, the 2016 Employment Agreement is terminated and superseded by this Agreement. Notwithstanding the foregoing, in no event shall the termination of the 2016 Employment Agreement, in connection with the execution of this Agreement, be considered a termination as set forth in Section 3 of the 2016 Employment Agreement or entitle Executive to any termination-related payment, including without limitation any Severance Indemnity pursuant to Section 3.2 or Change of Control Indemnity under Section 3.3 of the 2016 Employment Agreement.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.3 hereof, Section 2.5(c) hereof, Section 3 hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3 of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any

determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law**.** Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover from the other party his or its reasonable costs and attorneys' fees associated with the arbitration no later than thirty (30 days after the arbitration becomes final and binding. The non-prevailing party shall also be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 No Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by him at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or

other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF**,** the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: /s/ Phillandas T. Thompson
Name: Phillandas T. Thompson
Title: Senior Vice President, General Counsel and Corporate Secretary

THE EXECUTIVE

/s/ Michael S. Anderson
Name: Michael S. Anderson

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the fifth (5th) day of September 2017 (the "Effective Date") by and among Gregory J. Divis, a citizen of the United States currently residing at 1146 Greystone Manor Parkway, Chesterfield, Missouri 63005 ("the Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri, USA 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel plc").

W I T N E S S E T H

WHEREAS, the Company, Avadel plc and the Executive are parties to that certain Employment Agreement dated as of January 4, 2017 (the "Original Agreement"), pursuant to which, among other things, the Company and Avadel plc agreed to employ the Executive.

WHEREAS, the Company and the Executive desire to replace the Original Agreement in order to (i) provide that the Executive will be employed by the Company to provide services with respect to the management of Avadel plc and its subsidiaries including the Company and (ii) more accurately set forth the terms and conditions of the Executive's employment by the Company.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. The Executive shall serve as the Executive Vice President and Chief Commercial Officer of Avadel plc and as the Executive Vice President and Chief Commercial Officer of the Company, and shall carry out such work as may be reasonably required by the Company in the course of its business consistent with such positions and the terms and conditions of this Agreement. With respect to his position as Executive Vice President and Chief Commercial Officer of Avadel plc, the Executive shall have all the duties, powers and responsibilities customary for such position at a company with equity securities registered under the United States Securities Exchange Act of 1934. The Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, Missouri), but shall also travel to and work from offices of the Company's affiliates in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time will make the best use of the Executive's energy, knowledge, and training, to advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Chief Executive Officer of Avadel plc, the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined) during his employment with the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of his duties to or with respect to Avadel plc, the Company and their affiliated entities as provided in this Agreement. As used in this Agreement, the "Avadel Group of Companies" shall mean Avadel plc and each of its direct or indirect subsidiaries including the Company. The Executive will comply with all written policies of the Avadel Group of Companies, to the extent applicable to the Executive.

(b) Reporting. In his capacities as the Executive Vice President and Chief Commercial Officer of Avadel plc and the Executive Vice President and Chief Commercial Officer of the Company, the Executive shall report directly to Avadel plc's Chief Executive Officer and the Company's Chief Executive Officer, respectively, each of which positions is currently held by Michael S. Anderson.

1.2 Status. It is the intent of the parties that, at all times during the Executive's employment with the Company, he will remain a citizen of the United States.

1.3 Duration. The term of this Agreement shall commence as of the Effective Date set forth above and shall continue for one (1) year beginning on such date, with the Agreement automatically renewing for successive one- (1-) year periods, unless the Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, the Executive's employment with the Company shall terminate simultaneously. As of the Effective Date, this Agreement supersedes and replaces the Original Agreement, which shall be null and void thereafter.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of Three Hundred Seventy-Five Thousand Dollars ($375,000) per year payable in accordance with the Company's normal payroll practices in effect from time to time (but not less frequently than monthly), subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to fifty percent (50%) of the Executive's base salary, subject to proration for any partial year (provided that for this purpose the Executive shall be given credit for his prior employment during 2017 under the Original Agreement). Payment of the annual bonus will be based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date of payment, any bonus payments due hereunder shall be paid to the Executive, no later than the last day of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2.3 Prior Stock Option and Additional Equity Grants.

(a) Prior Grant. The Company and the Executive acknowledge and agree that, (i) in connection with the execution and delivery of the Original Agreement, Avadel plc granted to the Executive an option (the "Original Stock Option") to purchase One Hundred Fifty Thousand (150,000) American Depositary Shares (ADSs), with each such ADS representing one (1) of Avadel plc's ordinary shares, at an exercise price equal to the fair market value of the Avadel plc ADSs as of the date of grant of the Original Stock Option; and (ii) the board of directors of Avadel approved the grant of the Original Stock Option. The terms and conditions of the Original Stock Option (including the vesting provisions thereof) shall continue in effect without modification by this Agreement.

(b) Additional Discretionary Equity Grants. From time to time after the Original Agreement and after the date of this Agreement, Avadel plc may have granted, or may grant, to the Executive additional ADSs or ordinary shares (including free share awards or restricted share awards), or options for the purchase thereof or other such awards relating thereto, in accordance with applicable equity incentive plans (any such additional shares, options or other awards, the "Additional Equity Grants"). Except as specifically set forth above, however, nothing herein shall require Avadel plc or any of its subsidiaries or affiliates (including without limitation the Company) to make any equity grants or other awards to the Executive in any specific year. The terms and conditions of each Additional Equity Grant are, or as applicable shall be, set forth in a separate written agreement between the Executive and Avadel plc.

2.4 Auto Allowance. The Company shall provide the Executive an automobile allowance of One Thousand Dollars ($1,000.00) per month, payable no less frequently monthly.

2.5 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and his family in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established in accordance with the terms and conditions of such plans or programs. The Executive acknowledges that the current insurance plans are offered through the Company and are subject to reasonable changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other executives at similar levels of authority with respect to Avadel plc and the Company (currently twenty (20) days per year). The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at the Executive's discretion in accordance with the normal Company paid vacation and time-off policies.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to the Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.6 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company with or without "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (iii) a relocation of the Company's offices of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; (iv) a material breach by the Company of this Agreement; or (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of Avadel plc or the Company.

(c) In the event that the Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that the Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-) day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof at least thirty (30) days prior to the date that such termination will be effective.

(e) The Executive's employment shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

3.2 Severance. If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company (but not including any circumstances that would give rise to a payment to the Executive pursuant to Section 3.3(a) hereof), the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, such amount to be paid in equal installments over the 12-month period immediately following the date of termination in accordance with the Company's normal payroll practices with such installments to be no less frequent than monthly and to commence on the first payroll date following the date of termination; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no

later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of twelve (12) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA.

All payments set forth in the foregoing items (i) and (iii) hereof are defined as the "Severance Indemnity." The Executive's receipt of the foregoing Severance Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any Severance Indemnity payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable; and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in lieu of a payment to the Executive pursuant to Section 3.2 above:

(i) upon such termination the Company shall pay to the Executive a change of control indemnity equal to the sum of: (A) the Severance Indemnity as defined in Section 3.2 hereof payable in accordance with the terms set forth in such Section 3.2; and (B) a lump-sum payment, payable no later than thirty (30) days after the later of the Change in Control or the termination of the Executive's employment, equal to one hundred percent (100%) of the higher of: (x) the greater of (I) the Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (II) the Executive's target bonus as in effect for the fiscal year in which the Executive's termination of employment occurs; or (y) the Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) upon the later of the Change in Control or the termination of the Executive's employment, subject to the release requirement below, the Executive shall become immediately vested in full in all theretofore any outstanding unvested rights of the Executive under the Original Stock Option and each and every Additional Equity Grant, including without limitation stock option awards and agreements and unvested or unissued rights to "free shares," restricted share awards and similar rights, and, without duplication and for the avoidance of doubt, any unvested rights under any of the foregoing (*i.e.*, the right to purchase any ADSs or ordinary shares under the Original Stock Option and under or in connection with any Additional Equity Grant), to the extent such rights and awards would have vested based solely on the continued employment of the Executive and the vesting of such rights and awards does not cause any violation of Section 409A of the Code.

(b) For avoidance of doubt, the amount paid to the Executive pursuant to Section 3.3(a) hereof (a) will be in lieu of, and not in addition to, any amount that would otherwise be payable to the Executive under Section 3.2 hereof, and (b) will not be prorated based on the actual amount of time the Executive is employed by the Company during the fiscal year (or the relevant performance period if different than a fiscal year) during which this termination occurs. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments and benefits set forth in items (i) and (iii) of Section 3.3(a) hereof are defined as the "Change of Control Indemnity."

(c) The Executive's receipt of the foregoing Change of Control Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable, and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or (ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or (iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions. Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code. (b) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and his employment with the Company other than for Good Reason or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive (or, after the Executive's death, his estate) all accrued or awarded but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Non-Disparagement. The Executive agrees not to disparage or otherwise refer to any member of the Avadel Group of Companies or any of their executives, officers or directors in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of the Executive's Employment and any benefits paid hereunder. The Company, together with all other members of the Avadel Group of Companies, and their executive officers and directors, agree not to disparage or otherwise refer to the Executive in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc).

4.3 Non-Solicitation of Employees and Contractors. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.3 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.4 Non-Solicitation of Customers and Suppliers. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements (including without limitation the Original Agreement), either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof. For purposes of terminating the Original Agreement, the Company hereby confirms that it is the duly authorized agent of Avadel plc, and by the signatures below of the Company and the Executive, the Original Agreement is terminated and superseded by this Agreement. Notwithstanding the foregoing, in no event shall the termination of the Original Agreement, in connection with the execution of this Agreement, be considered a termination as set forth in Section 3 of the Original Agreement or entitle Executive to any termination-related payment, including without limitation any Severance Indemnity pursuant to Section 3.2 or Change of Control Indemnity under Section 3.3 of the Original Agreement.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.3 hereof, Section 2.5(c) hereof, Section 3 hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3 of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law**.** Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive

personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover from the other party his or its reasonable costs and attorneys' fees associated with the arbitration no later than thirty (30 days after the arbitration becomes final and binding. The non-prevailing party shall also be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 No Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by him at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF**,** the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: /s/ Phillandas T. Thompson
Name: Phillandas T. Thompson
Title: Senior Vice President, General Counsel and Corporate Secretary

THE EXECUTIVE

/s/ Gregory J. Divis
Name: Gregory J. Divis

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the fifteenth (15th) day of August 2017 (the "Effective Date") by and among Sandra Hatten, a citizen of the United States currently residing at 546 Donne Avenue, University City, Missouri 63130 ("the Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri, USA 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel plc").

W I T N E S S E T H

WHEREAS, as of July 15, 2015, Avadel Legacy Pharmaceuticals, LLC, a Delaware limited liability company (and an affiliate of the Company) which was formerly known as Éclat Pharmaceuticals LLC ("Legacy"), Flamel Technologies S.A., a French *société anonyme* ("Flamel"), and the Executive entered into that certain Employment Agreement (the "Original Agreement") pursuant to which, among other things, Legacy and Flamel agreed to employ the Executive (such employment having commenced on June 29, 2015); and effective upon the merger (the "Merger") of Flamel with and into Avadel plc at 11:59:59 p.m. (Central Europe Time) on December 31, 2016, Avadel plc assumed the obligations of Flamel under the Original Agreement.

WHEREAS, the Company and the Executive desire to replace the Original Agreement in order to (i) provide that the Executive will be employed by the Company to provide services with respect to the management of Avadel plc and its subsidiaries including the Company and (ii) more accurately set forth the terms and conditions of the Executive's employment by the Company.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. The Executive shall serve as the Senior Vice President, Quality and Regulatory Affairs of Avadel plc and as the Senior Vice President, Quality and Regulatory Affairs of the Company, and shall carry out such work as may be reasonably required by the Company in the course of its business consistent with such positions and the terms and conditions of this Agreement. With respect to her position as Senior Vice President, Quality and Regulatory Affairs of Avadel plc, the Executive shall have all the duties, powers and responsibilities customary for such position at a company with equity securities registered under the United States Securities Exchange Act of 1934. The Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, Missouri), but shall also travel to and work from offices of the Company's affiliates in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time will make the best use of the Executive's energy, knowledge, and training, to advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Chief Executive Officer of Avadel plc, the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined) during her employment with the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of her duties to or with respect to Avadel plc, the Company and their affiliated entities as provided in this Agreement. As used in this Agreement, the "Avadel Group of Companies" shall mean Avadel plc and each of its direct or indirect subsidiaries including the Company. The Executive will comply with all written policies of the Avadel Group of Companies, to the extent applicable to the Executive.

(b) Reporting. In her capacities as the Senior Vice President, Quality and Regulatory Affairs of Avadel plc and the Senior Vice President, Quality and Regulatory Affairs of the Company, the Executive shall report directly to Avadel plc's Chief Executive Officer and the Company's Chief Executive Officer, respectively, each of which positions is currently held by Michael S. Anderson.

1.2 Status. It is the intent of the parties that, at all times during the Executive's employment with the Company, she will remain a citizen of the United States.

1.3 Duration. The term of this Agreement shall commence as of the Effective Date set forth above and shall continue for one (1) year beginning on such date, with the Agreement automatically renewing for successive one- (1-) year periods, unless the Executive or the Company provides written notice to the other of her or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, the Executive's employment with the

Company shall terminate simultaneously. As of the Effective Date, this Agreement supersedes and replaces the Original Agreement, which shall be null and void thereafter.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of Three Hundred Five Thousand Two Hundred Eighty-Six Dollars ($305,286) per year payable in accordance with the Company's normal payroll practices in effect from time to time (but not less frequently than monthly), subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to forty percent (40%) of the Executive's base salary, subject to proration for any partial year (provided that for this purpose the Executive shall be given credit for her prior employment during 2017 under the Original Agreement). Payment of the annual bonus will be based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date of payment, any bonus payments due hereunder shall be paid to the Executive, no later than the last day of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2.3 Prior Stock Option and Additional Equity Grants.

(a) Prior Grant. The Company and the Executive acknowledge and agree that, (i) in connection with the execution and delivery of the Original Agreement, Flamel granted to the Executive an option (the "Original Stock Option") to purchase One Hundred Thousand (100,000) American Depositary Shares (ADSs), with each such ADS representing one (1) of Flamel's ordinary shares, at an exercise price equal to the fair market value of the Flamel ADSs as of the date of grant of the Original Stock Option; (ii) the board of directors of Flamel approved the grant of the Original Stock Option; and (iii) pursuant to the Merger, Avadel adopted and assumed such Original Stock Option and, as a result, upon and after the Merger, the Original Stock Option became and is exercisable for an equal number of the ADSs of Avadel plc. The terms and conditions of the Original Stock Option (including the vesting provisions thereof) shall continue in effect as adopted and assumed by Avadel plc without modification by this Agreement.

(b) Additional Discretionary Equity Grants. From time to time after the Original Agreement and after the date of this Agreement, Flamel and/or Avadel plc, may have granted, or (in the case of Avadel plc) may grant, to the Executive additional ADSs or ordinary shares (including free share awards or restricted share awards), or options for the purchase thereof or other such awards relating thereto, in accordance with applicable equity incentive plans (any such additional shares, options or other awards, the "Additional Equity Grants"). Except as specifically set forth above, however, nothing herein shall require Avadel plc or any of its subsidiaries or affiliates (including without limitation the Company) to make any equity grants or other awards to the Executive in any specific year. The terms and conditions of each Additional Equity Grant are, or as applicable shall be, set forth in a separate written agreement between the Executive and Avadel plc (either directly or by Avadel plc's assumption of the obligations of Flamel).

2.4 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and her family in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established in accordance with the terms and conditions of such plans or programs. The Executive acknowledges that the current insurance plans are offered through the Company and are subject to reasonable changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other executives at similar levels of authority with respect to Avadel plc and the Company (currently twenty (20) days per year). The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at the Executive's discretion in accordance with the normal Company paid vacation and time-off policies.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by her under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against her if she undertakes to repay the funds advanced, with interest, should it later be determined that she is not entitled to indemnification under this Section 2.4(c).

(ii) The Company shall provide coverage to the Executive for her general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.5 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to her regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to her regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company with or without "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the failure of the Company to timely pay to the Executive any compensation owed to her under this Agreement; (ii) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (iii) a relocation of the Company's offices of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; (iv) a material breach by the Company of this Agreement; or (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of Avadel plc or the Company.

(c) In the event that the Executive desires to resign from the Company, she shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that the Executive desires to resign from the Company for Good Reason, she shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-) day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof at least thirty (30) days prior to the date that such termination will be effective.

(e) The Executive's employment shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

3.2 Severance. If the Executive terminates this Agreement and her employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company (but not including any circumstances that would give rise to a payment to the Executive pursuant to Section 3.3(a) hereof), the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, such amount to be paid in equal installments over the 12-month period immediately following the date of termination in accordance with the Company's normal payroll practices with such installments to be no less frequent than monthly and to commence on the first payroll date following the date of termination; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of twelve (12) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA.

All payments set forth in the foregoing items (i) and (iii) hereof are defined as the "Severance Indemnity." The Executive's receipt of the foregoing Severance Indemnity is conditioned upon her execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any Severance Indemnity payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable; and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and her employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in lieu of a payment to the Executive pursuant to Section 3.2 above:

(i) upon such termination the Company shall pay to the Executive a change of control indemnity equal to the sum of: (A) the Severance Indemnity as defined in Section 3.2 hereof payable in accordance with the terms set forth in such Section 3.2; and (B) a lump-sum payment, payable no later than thirty (30) days after the later of the Change in Control or the termination of the Executive's employment, equal to one hundred percent (100%) of the higher of: (x) the greater of (I) the Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (II) the Executive's target bonus as in effect for the fiscal year in which the Executive's termination of employment occurs; or (y) the Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) upon the later of the Change in Control or the termination of the Executive's employment, subject to the release requirement below, the Executive shall become immediately vested in full in all theretofore any outstanding unvested rights of the Executive under the Original Stock Option and each and every Additional Equity Grant, including without limitation stock option awards and agreements and unvested or unissued rights to "free shares," restricted share awards and similar rights, and, without duplication and for the avoidance of doubt, any unvested rights under any of the foregoing (*i.e.*, the right to purchase any ADSs or ordinary shares under the Original Stock Option and under or in connection with any Additional Equity Grant), to the extent such rights and awards would have vested based solely on the continued employment of the Executive and the vesting of such rights and awards does not cause any violation of Section 409A of the Code.

(b) For avoidance of doubt, the amount paid to the Executive pursuant to Section 3.3(a) hereof (a) will be in lieu of, and not in addition to, any amount that would otherwise be payable to the Executive under Section 3.2 hereof, and (b) will not be prorated based on the actual amount of time the Executive is employed by the Company during the fiscal year (or the relevant performance period if different than a fiscal year) during which this termination occurs. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option

right will not extend beyond its original maximum term of the original date of the grant. All payments and benefits set forth in items (i) and (iii) of Section 3.3(a) hereof are defined as the "Change of Control Indemnity."

(c) The Executive's receipt of the foregoing Change of Control Indemnity is conditioned upon her execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable, and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or (ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or (iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions. Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code. (b) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and her employment with the Company other than for Good Reason or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive (or, after the Executive's death, her estate) all accrued or awarded but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform her obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date her employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Non-Disparagement. The Executive agrees not to disparage or otherwise refer to any member of the Avadel Group of Companies or any of their executives, officers or directors in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of the Executive's Employment and any benefits paid hereunder. The Company, together with all other members of the Avadel Group of Companies, and their executive officers and directors, agree not to disparage or otherwise refer to the Executive in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc).

4.3 Non-Solicitation of Employees and Contractors. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.3 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.4 Non-Solicitation of Customers and Suppliers. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements (including without limitation the Original Agreement), either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof. For purposes of terminating the Original Agreement, the Company hereby confirms that it is the duly authorized agent of Legacy and Avadel plc, and by the signatures below of the Company and the Executive, the Original Agreement is terminated and superseded by this Agreement. Notwithstanding the foregoing, in no event shall the termination of the Original Agreement, in connection with the execution of this Agreement, be considered a termination as set forth in Section 3 of the Original Agreement or entitle Executive to any termination-related payment, including without limitation any Severance Indemnity pursuant to Section 3.2 or Change of Control Indemnity under Section 3.3 of the Original Agreement.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.3 hereof, Section 2.4(c) hereof, Section 3 hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed.

Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3 of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law**.** Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover from the other party her or its reasonable costs and attorneys' fees associated with the arbitration no later than thirty (30 days after the arbitration becomes final and binding. The non-prevailing party shall also be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 No Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by her at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: /s/ Phillandas T. Thompson
Name: Phillandas T. Thompson
Title: Senior Vice President, General Counsel and Corporate Secretary

THE EXECUTIVE

/s/ Sandra Hatten
Name: Sandra Hatten

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the fifth (5th) day of September 2017 (the "Effective Date") by and among Michael F. Kanan, a citizen of the United States currently residing at 1572 Highland Valley, Wildwood, Missouri 63005 ("the Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri, USA 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel plc").

W I T N E S S E T H

WHEREAS, as of May 23, 2016, Avadel Legacy Pharmaceuticals, LLC, a Delaware limited liability company (and an affiliate of the Company) which was formerly known as Éclat Pharmaceuticals LLC ("Legacy"), Flamel Technologies S.A., a French *société anonyme* ("Flamel"), and the Executive entered into that certain Employment Agreement (the "Original Agreement") pursuant to which, among other things, Legacy and Flamel agreed to employ the Executive (such employment having commenced on November 23, 2015); and effective upon the merger (the "Merger") of Flamel with and into Avadel plc at 11:59:59 p.m. (Central Europe Time) on December 31, 2016, Avadel plc assumed the obligations of Flamel under the Original Agreement.

WHEREAS, the Company and the Executive desire to replace the Original Agreement in order to (i) provide that the Executive will be employed by the Company to provide services with respect to the management of Avadel plc and its subsidiaries including the Company and (ii) more accurately set forth the terms and conditions of the Executive's employment by the Company.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. The Executive shall serve as the Senior Vice President and Chief Financial Officer of Avadel plc and as the Senior Vice President and Chief Financial Officer of the Company, and shall carry out such work as may be reasonably required by the Company in the course of its business consistent with such positions and the terms and conditions of this Agreement. With respect to his position as Senior Vice President and Chief Financial Officer of Avadel plc, the Executive shall have all the duties, powers and responsibilities customary for such position at a company with equity securities registered under the United States Securities Exchange Act of 1934. The Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, Missouri), but shall also travel to and work from offices of the Company's affiliates in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time will make the best use of the Executive's energy, knowledge, and training, to advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Chief Executive Officer of Avadel plc, the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined) during his employment with the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of his duties to or with respect to Avadel plc, the Company and their affiliated entities as provided in this Agreement. As used in this Agreement, the "Avadel Group of Companies" shall mean Avadel plc and each of its direct or indirect subsidiaries including the Company. The Executive will comply with all written policies of the Avadel Group of Companies, to the extent applicable to the Executive.

(b) Reporting. In his capacities as the Senior Vice President and Chief Financial Officer of Avadel plc and the Senior Vice President and Chief Financial Officer of the Company, the Executive shall report directly to Avadel plc's Chief Executive Officer and the Company's Chief Executive Officer, respectively, each of which positions is currently held by Michael S. Anderson.

1.2 Status. It is the intent of the parties that, at all times during the Executive's employment with the Company, he will remain a citizen of the United States.

1.3 Duration. The term of this Agreement shall commence as of the Effective Date set forth above and shall continue for one (1) year beginning on such date, with the Agreement automatically renewing for successive one- (1-) year periods, unless the Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, the Executive's employment with the Company shall terminate simultaneously. As of the Effective Date, this Agreement supersedes and replaces the Original Agreement, which shall be null and void thereafter.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of Three Hundred Fifty-Seven Thousand Five Hundred Dollars ($357,500) per year payable in accordance with the Company's normal payroll practices in effect from time to time (but not less frequently than monthly), subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to forty percent (40%) of the Executive's base salary, subject to proration for any partial year (provided that for this purpose the Executive shall be given credit for his prior employment during 2017 under the Original Agreement). Payment of the annual bonus will be based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date of payment, any bonus payments due hereunder shall be paid to the Executive, no later than the last day of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2.3 Prior Stock Option and Additional Equity Grants.

(a) Prior Grant. The Company and the Executive acknowledge and agree that, (i) in connection with the Executive's initial employment by Legacy and Flamel in 2015, Flamel granted to the Executive an option (the "Original Stock Option") to purchase One Hundred Thousand (100,000) American Depositary Shares (ADSs), with each such ADS representing one (1) of Flamel's ordinary shares, at an exercise price equal to the fair market value of the Flamel ADSs as of the date of grant of the Original Stock Option; (ii) the board of directors of Flamel approved the grant of the Original Stock Option; and (iii) pursuant to the Merger, Avadel adopted and assumed such Original Stock Option and, as a result, upon and after the Merger, the Original Stock Option became and is exercisable for an equal number of the ADSs of Avadel plc. The terms and conditions of the Original Stock Option (including the vesting provisions thereof) shall continue in effect as adopted and assumed by Avadel plc without modification by this Agreement.

(b) Additional Discretionary Equity Grants. From time to time after the Original Agreement and after the date of this Agreement, Flamel and/or Avadel plc, may have granted, or (in the case of Avadel plc) may grant, to the Executive additional ADSs or ordinary shares (including free share awards or restricted share awards), or options for the purchase thereof or other such awards relating thereto, in accordance with applicable equity incentive plans (any such additional shares, options or other awards, the "Additional Equity Grants"). Except as specifically set forth above, however, nothing herein shall require Avadel plc or any of its subsidiaries or affiliates (including without limitation the Company) to make any equity grants or other awards to the Executive in any specific year. The terms and conditions of each Additional Equity Grant are, or as applicable shall be, set forth in a separate written agreement between the Executive and Avadel plc (either directly or by Avadel plc's assumption of the obligations of Flamel).

2.4 Auto Allowance. The Company shall provide the Executive an automobile allowance of One Thousand Dollars ($1,000.00) per month, payable no less frequently monthly.

2.5 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and his family in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established in accordance with the terms and conditions of such plans or programs. The Executive acknowledges that the current insurance plans are offered through the Company and are subject to reasonable changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other executives at similar levels of authority with respect to Avadel plc and the Company (currently twenty (20) days per year). The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at the Executive's discretion in accordance with the normal Company paid vacation and time-off policies.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against him if he undertakes to

repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to the Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.6 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company with or without "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (iii) a relocation of the Company's offices of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; (iv) a material breach by the Company of this Agreement; or (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of Avadel plc or the Company.

(c) In the event that the Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that the Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-) day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof at least thirty (30) days prior to the date that such termination will be effective.

(e) The Executive's employment shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

3.2 Severance. If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company (but not including any circumstances that would give rise to a payment to the Executive pursuant to Section 3.3(a) hereof), the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, such amount to be paid in equal installments over the 12-month period immediately following the date of termination in accordance

with the Company's normal payroll practices with such installments to be no less frequent than monthly and to commence on the first payroll date following the date of termination; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of twelve (12) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA.

All payments set forth in the foregoing items (i) and (iii) hereof are defined as the "Severance Indemnity." The Executive's receipt of the foregoing Severance Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any Severance Indemnity payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable; and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in lieu of a payment to the Executive pursuant to Section 3.2 above:

(i) upon such termination the Company shall pay to the Executive a change of control indemnity equal to the sum of: (A) the Severance Indemnity as defined in Section 3.2 hereof payable in accordance with the terms set forth in such Section 3.2; and (B) a lump-sum payment, payable no later than thirty (30) days after the later of the Change in Control or the termination of the Executive's employment, equal to one hundred percent (100%) of the higher of: (x) the greater of (I) the Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (II) the Executive's target bonus as in effect for the fiscal year in which the Executive's termination of employment occurs; or (y) the Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) upon the later of the Change in Control or the termination of the Executive's employment, subject to the release requirement below, the Executive shall become immediately vested in full in all theretofore any outstanding unvested rights of the Executive under the Original Stock Option and each and every Additional Equity Grant, including without limitation stock option awards and agreements and unvested or unissued rights to "free shares," restricted share awards and similar rights, and, without duplication and for the avoidance of doubt, any unvested rights under any of the foregoing (*i.e.*, the right to purchase any ADSs or ordinary shares under the Original Stock Option and under or in connection with any Additional Equity Grant), to the extent such rights and awards would have vested based solely on the continued employment of the Executive and the vesting of such rights and awards does not cause any violation of Section 409A of the Code.

(b) For avoidance of doubt, the amount paid to the Executive pursuant to Section 3.3(a) hereof (a) will be in lieu of, and not in addition to, any amount that would otherwise be payable to the Executive under Section 3.2 hereof, and (b) will not be prorated based on the actual amount of time the Executive is employed by the Company during the fiscal year (or the relevant performance period if different than a fiscal year) during which this termination occurs. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock

options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments and benefits set forth in items (i) and (iii) of Section 3.3(a) hereof are defined as the "Change of Control Indemnity."

(c) The Executive's receipt of the foregoing Change of Control Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable, and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or (ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or (iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions. Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code. (b) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and his employment with the Company other than for Good Reason or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive (or, after the Executive's death, his estate) all accrued or awarded but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief

Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Non-Disparagement. The Executive agrees not to disparage or otherwise refer to any member of the Avadel Group of Companies or any of their executives, officers or directors in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of the Executive's Employment and any benefits paid hereunder. The Company, together with all other members of the Avadel Group of Companies, and their executive officers and directors, agree not to disparage or otherwise refer to the Executive in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc).

4.3 Non-Solicitation of Employees and Contractors. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.3 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.4 Non-Solicitation of Customers and Suppliers. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and

after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements (including without limitation the Original Agreement), either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof. For purposes of terminating the Original Agreement, the Company hereby confirms that it is the duly authorized agent of Legacy and Avadel plc, and by the signatures below of the Company and the Executive, the Original Agreement is terminated and superseded by this Agreement. Notwithstanding the foregoing, in no event shall the termination of the Original Agreement, in connection with the execution of this Agreement, be considered a termination as set forth in Section 3 of the Original Agreement or entitle Executive to any termination-related payment, including without limitation any Severance Indemnity pursuant to Section 3.2 or Change of Control Indemnity under Section 3.3 of the Original Agreement.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.3 hereof, Section 2.5(c) hereof, Section 3 hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may

require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3 of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law**.** Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover from the other party his or its reasonable costs and attorneys' fees associated with the arbitration no later than thirty (30 days after the arbitration becomes final and binding. The non-prevailing party shall also be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 No Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by him at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: /s/ Phillandas T. Thompson
Name: Phillandas T. Thompson
Title: Senior Vice President, General Counsel and Corporate Secretary

THE EXECUTIVE

/s/ Michael F. Kanan
Name: Michael F. Kanan

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the fifteenth (15th) day of August 2017 (the "Effective Date") by and among Phillandas T. Thompson, a citizen of the United States currently residing at 16329 Justus Post Road, Chesterfield, Missouri 63017 ("the Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri, USA 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel plc").

W I T N E S S E T H

WHEREAS, as of July 7, 2015, Avadel Legacy Pharmaceuticals, LLC, a Delaware limited liability company (and an affiliate of the Company) which was formerly known as Éclat Pharmaceuticals LLC ("Legacy"), Flamel Technologies S.A., a French *société anonyme* ("Flamel"), and the Executive entered into that certain Employment Agreement (the "Original Agreement") pursuant to which, among other things, Legacy and Flamel agreed to employ the Executive (such employment having commenced on November 25, 2013); and effective upon the merger (the "Merger") of Flamel with and into Avadel plc at 11:59:59 p.m. (Central Europe Time) on December 31, 2016, Avadel plc assumed the obligations of Flamel under the Original Agreement.

WHEREAS, the Company and the Executive desire to replace the Original Agreement in order to (i) provide that the Executive will be employed by the Company to provide services with respect to the management of Avadel plc and its subsidiaries including the Company and (ii) more accurately set forth the terms and conditions of the Executive's employment by the Company.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. The Executive shall serve as the Senior Vice President, General Counsel and Corporate Secretary of Avadel plc and as the Senior Vice President, General Counsel and Corporate Secretary of the Company, and shall carry out such work as may be reasonably required by the Company in the course of its business consistent with such positions and the terms and conditions of this Agreement. With respect to his position as Senior Vice President, General Counsel and Corporate Secretary of Avadel plc, the Executive shall have all the duties, powers and responsibilities customary for such position at a company with equity securities registered under the United States Securities Exchange Act of 1934. The Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, Missouri), but shall also travel to and work from offices of the Company's affiliates in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time will make the best use of the Executive's energy, knowledge, and training, to advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Chief Executive Officer of Avadel plc, the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined) during his employment with the Company. Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of his duties to or with respect to Avadel plc, the Company and their affiliated entities as provided in this Agreement. As used in this Agreement, the "Avadel Group of Companies" shall mean Avadel plc and each of its direct or indirect subsidiaries including the Company. The Executive will comply with all written policies of the Avadel Group of Companies, to the extent applicable to the Executive.

(b) Reporting. In his capacities as the Senior Vice President, General Counsel and Corporate Secretary of Avadel plc and the Senior Vice President, General Counsel and Corporate Secretary of the Company, the Executive shall report directly to Avadel plc's Chief Executive Officer and the Company's Chief Executive Officer, respectively, each of which positions is currently held by Michael S. Anderson.

1.2 Status. It is the intent of the parties that, at all times during the Executive's employment with the Company, he will remain a citizen of the United States.

1.3 Duration. The term of this Agreement shall commence as of the Effective Date set forth above and shall continue for one (1) year beginning on such date, with the Agreement automatically renewing for successive one- (1-) year periods, unless the Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, the Executive's employment with the

Company shall terminate simultaneously. As of the Effective Date, this Agreement supersedes and replaces the Original Agreement, which shall be null and void thereafter.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of Three Hundred Twenty-Six Thousand Seven Hundred Fifty-Seven Dollars ($326,757) per year payable in accordance with the Company's normal payroll practices in effect from time to time (but not less frequently than monthly), subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to forty percent (40%) of the Executive's base salary, subject to proration for any partial year (provided that for this purpose the Executive shall be given credit for his prior employment during 2017 under the Original Agreement). Payment of the annual bonus will be based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date of payment, any bonus payments due hereunder shall be paid to the Executive, no later than the last day of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2.3 Prior Stock Option and Additional Equity Grants.

(a) Prior Grant. The Company and the Executive acknowledge and agree that, (i) in connection with the Executive's initial employment by Legacy and Flamel in 2013, Flamel granted to the Executive an option (the "Original Stock Option") to purchase One Hundred Thousand (100,000) American Depositary Shares (ADSs), with each such ADS representing one (1) of Flamel's ordinary shares, at an exercise price equal to the fair market value of the Flamel ADSs as of the date of grant of the Original Stock Option; (ii) the board of directors of Flamel approved the grant of the Original Stock Option; and (iii) pursuant to the Merger, Avadel adopted and assumed such Original Stock Option and, as a result, upon and after the Merger, the Original Stock Option became and is exercisable for an equal number of the ADSs of Avadel plc. The terms and conditions of the Original Stock Option (including the vesting provisions thereof) shall continue in effect as adopted and assumed by Avadel plc without modification by this Agreement.

(b) Additional Discretionary Equity Grants. From time to time after the Original Agreement and after the date of this Agreement, Flamel and/or Avadel plc, may have granted, or (in the case of Avadel plc) may grant, to the Executive additional ADSs or ordinary shares (including free share awards or restricted share awards), or options for the purchase thereof or other such awards relating thereto, in accordance with applicable equity incentive plans (any such additional shares, options or other awards, the "Additional Equity Grants"). Except as specifically set forth above, however, nothing herein shall require Avadel plc or any of its subsidiaries or affiliates (including without limitation the Company) to make any equity grants or other awards to the Executive in any specific year. The terms and conditions of each Additional Equity Grant are, or as applicable shall be, set forth in a separate written agreement between the Executive and Avadel plc (either directly or by Avadel plc's assumption of the obligations of Flamel).

2.4 Auto Allowance. The Company shall provide the Executive an automobile allowance of Seven Hundred Fifty Dollars ($750.00) per month, payable no less frequently monthly.

2.5 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and his family in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established in accordance with the terms and conditions of such plans or programs. The Executive acknowledges that the current insurance plans are offered through the Company and are subject to reasonable changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other executives at similar levels of authority with respect to Avadel plc and the Company (currently twenty (20) days per year). The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at the Executive's discretion in accordance with the normal Company paid vacation and time-off policies.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing;

provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to the Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.6 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company with or without "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (iii) a relocation of the Company's offices of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; (iv) a material breach by the Company of this Agreement; or (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of Avadel plc or the Company.

(c) In the event that the Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that the Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-) day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof at least thirty (30) days prior to the date that such termination will be effective.

(e) The Executive's employment shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

3.2 Severance. If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company (but not including any circumstances that would give rise to a payment to the Executive pursuant to Section 3.3(a) hereof), the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, such amount to be paid in equal installments over the 12-month period immediately following the date of termination in accordance with the Company's normal payroll practices with such installments to be no less frequent than monthly and to commence on the first payroll date following the date of termination; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of twelve (12) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA.

All payments set forth in the foregoing items (i) and (iii) hereof are defined as the "Severance Indemnity." The Executive's receipt of the foregoing Severance Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any Severance Indemnity payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable; and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in lieu of a payment to the Executive pursuant to Section 3.2 above:

(i) upon such termination the Company shall pay to the Executive a change of control indemnity equal to the sum of: (A) the Severance Indemnity as defined in Section 3.2 hereof payable in accordance with the terms set forth in such Section 3.2; and (B) a lump-sum payment, payable no later than thirty (30) days after the later of the Change in Control or the termination of the Executive's employment, equal to one hundred percent (100%) of the higher of: (x) the greater of (I) the Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (II) the Executive's target bonus as in effect for the fiscal year in which the Executive's termination of employment occurs; or (y) the Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs; and

(ii) all accrued but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements; and

(iii) upon the later of the Change in Control or the termination of the Executive's employment, subject to the release requirement below, the Executive shall become immediately vested in full in all theretofore any outstanding unvested rights of the Executive under the Original Stock Option and each and every Additional Equity Grant, including without limitation stock option awards and agreements and unvested or unissued rights to "free shares," restricted share awards and similar rights, and, without duplication and for the avoidance of doubt, any unvested rights under any of the foregoing (*i.e.*, the right to purchase any ADSs or ordinary shares under the Original Stock Option and under or in connection with any Additional Equity Grant), to the extent such rights and awards would have vested based solely on the continued employment of the Executive and the vesting of such rights and awards does not cause any violation of Section 409A of the Code.

(b) For avoidance of doubt, the amount paid to the Executive pursuant to Section 3.3(a) hereof (a) will be in lieu of, and not in addition to, any amount that would otherwise be payable to the Executive under Section 3.2 hereof, and (b) will not be prorated based on the actual amount of time the Executive is employed by the Company during the fiscal year (or the relevant

performance period if different than a fiscal year) during which this termination occurs. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments and benefits set forth in items (i) and (iii) of Section 3.3(a) hereof are defined as the "Change of Control Indemnity."

(c) The Executive's receipt of the foregoing Change of Control Indemnity is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors and contractors, and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within sixty (60) days following the date of termination of the Executive's employment. Any payments that the Executive would otherwise be entitled to receive prior to the time the aforementioned release becomes effective and irrevocable shall be accumulated and paid in a lump sum after the release becomes effective and irrevocable, and if the permissible period during which the Executive may execute and deliver the release and during which the applicable revocation period could expire spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or (ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or (iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions. Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code. (b) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and his employment with the Company other than for Good Reason or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive (or, after the Executive's death, his estate) all accrued or awarded but unpaid bonuses for any completed fiscal year and vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid bonuses for any completed fiscal year and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of

Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Non-Disparagement. The Executive agrees not to disparage or otherwise refer to any member of the Avadel Group of Companies or any of their executives, officers or directors in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of the Executive's Employment and any benefits paid hereunder. The Company, together with all other members of the Avadel Group of Companies, and their executive officers and directors, agree not to disparage or otherwise refer to the Executive in an unfavorable manner before, during and after the term of the Executive's employment with the Company, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc).

4.3 Non-Solicitation of Employees and Contractors. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.3 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.4 Non-Solicitation of Customers and Suppliers. During the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company, the Executive shall not directly or indirectly solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any

member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements (including without limitation the Original Agreement), either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof. For purposes of terminating the Original Agreement, the Company hereby confirms that it is the duly authorized agent of Legacy and Avadel plc, and by the signatures below of the Company and the Executive, the Original Agreement is terminated and superseded by this Agreement. Notwithstanding the foregoing, in no event shall the termination of the Original Agreement, in connection with the execution of this Agreement, be considered a termination as set forth in Section 3 of the Original Agreement or entitle Executive to any termination-related payment, including without limitation any Severance Indemnity pursuant to Section 3.2 or Change of Control Indemnity under Section 3.3 of the Original Agreement.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.3 hereof, Section 2.5(c) hereof, Section 3 hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section

409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3 of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the

Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law**.** Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover from the other party his or its reasonable costs and attorneys' fees associated with the arbitration no later than thirty (30 days after the arbitration becomes final and binding. The non-prevailing party shall also be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 No Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by him at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF**,** the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

THE EXECUTIVE

/s/ Phillandas T. Thompson
Name: Phillandas T. Thompson

CONFIDENTIAL TREATMENT REQUESTED

THE PORTIONS OF THIS AGREEMENT, INCLUDING EXHIBIT A, MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

August 11, 2017

Serenity Pharmaceuticals, LLC
105 Hawk Court
Milford, PA 18327
Attention: Samuel Herschkowitz, M.D.

Re: Exclusive Right of Negotiation Agreement

Ladies and Gentlemen:

Avadel Specialty Pharmaceuticals, LLC, a Delaware limited liability company ("Avadel"), is pleased to have entered into discussions with Serenity Pharmaceuticals, LLC, a Delaware limited liability company ("Serenity"), regarding a proposed exclusive license and assignment agreement in substantial form and substance as set forth on Exhibit A, between Serenity and Avadel (the "ELAA Agreement"), relating to Serenity's right, title and/or interest in certain intellectual property (the "IP Rights") in a certain formulation of the drug desmopressin acetate (the "Drug"), the New Drug Application for the Drug approved by the U.S. Food and Drug Administration (the "NDA"), and certain supply agreements relating to the Drug (the "Supply Agreements"). Under the terms and conditions of the ELAA Agreement, Serenity would grant to Avadel an exclusive license or sublicense (as applicable) under the IP Rights to develop and commercialize the Drug in the United States, Canada, and their respective territories and possessions (the "Territory") and assign to Avadel the NDA and Serenity's rights under the Supply Agreements (such license and assignments being the "Proposed Transaction"). Serenity recognizes that Avadel's continued evaluation and pursuit of the Proposed Transaction will require Avadel to continue to expend significant additional time, effort, and resources to negotiate and consummate the Proposed Transaction. In consideration of, among other things, the willingness of Avadel to rapidly devote such additional time, effort, and resources to negotiate the Proposed Transaction, Serenity and Avadel (each a "Party"; collectively, the "Parties"), intending to be legally bound, hereby agree as follows (as so set forth, this "Agreement"):

1. (a) During the period (the "Exclusivity Period") commencing on the date of this Agreement and ending on the earliest to occur of (1) 11:59 p.m., U.S. East Coast time on September 7, 2017 (subject to extension as provided below, the "Expiration Date"), (2) the time at which either Party receives written notice from the other Party that the other Party is thereby terminating negotiations of the ELAA Agreement in accordance with the provisions hereof (any such notice being a "Termination Notice"), and (3) the date of execution of a definitive ELAA Agreement between Serenity and Avadel, Avadel shall have the exclusive right (subject to the proviso set forth below) to negotiate with Serenity regarding the Proposed Transaction, and Serenity shall not, and shall cause its respective officers,

directors, employees, attorneys, accountants, financial advisors, agents and other representatives (collectively, the "Representatives") not to, directly or indirectly:

(i) initiate, solicit, encourage, or knowingly facilitate or induce the submission of any inquiries, proposals or offers that constitute, or may reasonably be expected to lead to, any Alternative Transaction Proposal (as defined below);

(ii) engage or participate in any discussions or negotiations regarding, or provide or cause to be provided any non-public information or data relating to, Serenity in furtherance of, or have any discussions with any person relating to, an actual or proposed Alternative Transaction Proposal; or

(iii) enter into any letter of intent, agreement in principle, option agreement, or other similar statement of intention or agreement relating to any Alternative Transaction Proposal.

(b) Immediately after the execution and delivery of this Agreement, Serenity will, and will instruct its Representatives to, immediately cease and terminate any existing solicitation, encouragement, discussion, or negotiation with any third Parties conducted heretofore by Serenity or any of its Representatives with respect to any possible Alternative Transaction Proposal (as defined below).

(c) If during the period from the date of this Agreement until and including the Expiration Date specified in Section 1(a) hereof, Avadel has been and is continuing to be engaged with Serenity in good faith negotiations relating to the Proposed Transaction and circumstances beyond the control of the Parties have made it unlikely to complete such negotiations and execute and deliver the ELAA Agreement by such Expiration Date, then, if at the time of such Expiration Date it is reasonable to assume that continuation of such negotiations will result in completion of such negotiations and execution and delivery by the Parties of the ELAA Agreement by 11:59 p.m., U.S. East Coast time on September 14, 2017, then the Expiration Date shall be extended to that later date.

(d) As used in this Agreement "Alternative Transaction Proposal" means any proposal or offer (whether or not in writing) from any person or "group" of persons (within the meaning of Section 13(d) of the Securities Exchange Act of 1934, as amended), other than Avadel, regarding Serenity providing to such person or group of persons the rights under the IP Rights, the NDA, and/or the Supply Agreements to develop and/or commercialize the Drug in the Territory.

2. Unless and until a mutually acceptable definitive written ELAA Agreement between Serenity and Avadel with respect to the Proposed Transaction has been executed and delivered, neither Party will be under any legal obligation following the Expiration Date to continue discussions or negotiations about, to enter into definitive written agreements for, or to consummate the Proposed Transaction or any other transaction by virtue of this Agreement or any other written or oral expression with respect thereto. Neither Party shall have any obligation to authorize the Proposed Transaction or any other transaction

with the other Party. Subject to the provisions of Section 3 hereof, either Party may terminate this Agreement at any time prior to the Expiration Date by providing a Termination Notice to the other Party. Notwithstanding the foregoing, in the event that Serenity receives an unsolicited offer for an Alternative Proposed Transaction that is superior to Avadel's offer for the Proposed Transaction, Serenity shall notify Avadel of such Alternative Proposed Transaction and shall provide Avadel with the opportunity to match such offer within five (5) Business Days.

3. (a) In consideration of Serenity's agreement to the terms and conditions of this Agreement, including, without limitation, Serenity's agreement to negotiate exclusively with Avadel in respect of the Proposed Transaction during the Exclusivity Period, Avadel agrees to deposit by wire transfer within three (3) days after the execution and delivery of this Agreement the amount of Five Million U.S. Dollars (US$5,000,000) (the "Escrow Amount") with Signature Bank (the "Escrow Agent"), to be held and transferred by the Escrow Agent as set forth below.

(b) If the Parties execute and deliver the ELAA Agreement prior to the Expiration Date, the Escrow Agent will wire transfer to an account specified by Serenity the Escrow Amount in partial satisfaction of any upfront payment to be made by Avadel to Serenity required under the ELAA Agreement, which transfer will occur promptly following receipt by the Escrow Agent of written notice of such execution and delivery executed by both Parties.

(c) If Avadel terminates this Agreement without Cause (as defined below with respect to such termination by Avadel), Serenity terminates this Agreement with Cause (as defined below with respect to such termination by Serenity), or the Parties fail to execute and deliver the ELAA Agreement by the Expiration Date (notwithstanding Serenity's good faith efforts to do so and provided that the ELAA Agreement is in substantial form and substance as set forth on Exhibit A), then upon receipt by the Escrow Agent of either a certified copy of the applicable Termination Notice or a written notice from either Party of the failure of the Parties to have executed and delivered the ELAA Agreement by the Expiration Date provided that the ELAA Agreement is in substantial form and substance as set forth on Exhibit A (an "Expired Negotiations Period Notice"), the Escrow Agent will wire transfer to an account specified by Serenity the Escrow Amount and Avadel shall also pay to Serenity by wire transfer an additional amount of Five Million U.S. Dollars (US$5,000,000) (the "Additional Avadel Payment") within three (3) days of either providing or receiving such Termination Notice or Expired Negotiations Period Notice, as applicable. The sum of the Escrow Amount and the Additional Avadel Payment will be deemed to be consideration to Serenity for granting Avadel the exclusive negotiating rights hereunder.

(d) If Avadel terminates this Agreement with Cause or Serenity terminates this Agreement without Cause, then upon receipt by the Escrow Agent of a certified copy of the applicable Termination Notice, the Escrow Agent will return to Avadel the full amount of the Escrow Amount; and, in addition to such return to Avadel of the Escrow Amount, if Serenity terminates this Agreement without Cause, then Serenity shall pay to Avadel by wire transfer the additional amount of Ten Million U.S. Dollars (US$10,000,000) (the "Serenity Payment") within three (3) days of providing such Termination Notice to Avadel. The Serenity Payment will be deemed to be consideration for Avadel's expenditure of significant time, effort, and resources to evaluate, pursue, and negotiate the Proposed Transaction.

(e) For purposes of this Agreement, the term "Cause" means, with respect to termination of this Agreement by Avadel with Cause, (a) the receipt by Avadel of an opinion of counsel, which counsel shall be reasonably acceptable to Serenity, that Avadel will not have freedom to commercialize the Drug in the United States as such commercialization is contemplated by the ELAA Agreement because of

intellectual property rights held by third parties, (b) a change affecting the IP Rights, the NDA, or the Supply Agreements that would have a material and adverse effect on the commercialization by Avadel of the Drug in the United States contemplated by the Proposed Transaction, (c) a material misstatement or omission by Serenity in its disclosures to Avadel about the IP Rights, the NDA, or the Supply Agreements, (d) the bankruptcy or insolvency of Serenity, (e) the breach of the covenants set forth in Section 1(a)(i) – (iii) above by Serenity or (f) Serenity does not agree to execute the ELAA Agreement in substantial form and substance as set forth on Exhibit A by the Expiration Date (notwithstanding Avadel's good faith effort to do so).

(f) For purposes of this Agreement, the term "Cause" means, with respect to termination of this Agreement by Serenity with Cause, (a) a material adverse change in the business, operations, or financial condition of Avadel, (b) a material misstatement or omission by Avadel in its disclosures to Serenity about Avadel or Avadel's intentions with respect to the Proposed Transaction, that has a material and adverse effect on the Proposed Transaction or (c) the bankruptcy or insolvency of Avadel.

4. Each Party represents that it has the power, authority, and legal right, and is free to enter into this Agreement.

5. This Agreement shall be binding upon and inure solely to the benefit of the Parties, and nothing in this Agreement is intended, expressly or implicitly, to confer upon any other person any rights or remedies of any nature whatsoever under or by reason of this Agreement.

6. This Agreement is delivered in reliance upon, and shall be held confidential in accordance with, the provisions of that certain Confidentiality Agreement between Avadel and Serenity dated April 3, 2017 (the "Confidentiality Agreement"). Notwithstanding the foregoing and for clarity sake, this provision shall not apply for any disclosures or releases required by the U.S. Securities and Exchange Commission; however Avadel agrees to provide Serenity any such release in a reasonably timely manner for Serenity's review and approval.

7. This Agreement may be amended, modified or supplemented only pursuant to a written instrument signed by the Parties. It is understood and agreed that no failure or delay by either Party in exercising any of its rights hereunder shall operate as a waiver thereof, nor shall any single or partial waiver thereof preclude any other or further exercise thereof. This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes other prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof.

8. All notices and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when personally delivered or sent by confirmed facsimile or email (with hard copy to follow); (b) one (1) Business Day after sent by reputable overnight express courier (charges prepaid); or (c) five (5) Business Days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, such notices to each Party shall be sent to the addresses indicated below:

If to Serenity, addressed to:

Serenity Pharmaceuticals, LLC
105 Hawk Court
Milford, PA 18327
Attention: Samuel Herschkowitz, M.D.

If to Avadel, addressed to:

Avadel Specialty Pharmaceuticals, LLC
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005
Attn: President
With a copy to: General Counsel

9. This Agreement will be governed by and construed in accordance with the laws of the State of New York (without giving effect to principles of conflicts of laws). In the event of any dispute between the Parties under this Agreement (a "Dispute") that the Parties are not able to resolve amicably within thirty (30) days after one Party provides to the other Party written notice of such Dispute, either Party may at any time after such thirty (30) day period submit such Dispute to be finally settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") in effect at the time of submission. The arbitration shall be heard and determined by three (3) arbitrators. Each such Party shall each appoint one arbitrator and the third arbitrator shall be selected by the two Party-appointed arbitrators, or, failing agreement within thirty (30) days following the date of receipt by the respondent of the claim, by the AAA. Such arbitration shall take place in New York City in the State of New York. The arbitration award so given shall be a final and binding determination of the Dispute, and shall be fully enforceable in any court of any state or federal court located in New York City in the State of New York. Each Party (a) irrevocably and unconditionally consents and submits to the jurisdiction of the state and federal courts located in New York City in the State of New York for purposes of any action, suit or proceeding brought by either Party to enforce any such arbitration award; (b) agrees that service of any process, summons, notice or document by U.S. registered mail to the address set forth above shall be effective service of process for any action, suit or proceeding to enforce any such arbitration award brought against such Party; (c) irrevocably and unconditionally waives any objection to the laying of venue of any such action, suit or proceeding to enforce any such arbitration award in any state or federal court located in New York City in the State of New York; and (d) irrevocably and unconditionally waives the right to plead or claim, and irrevocably and unconditionally agrees not to plead or claim, that any action, suit or proceeding to enforce any such arbitration award that is brought in any state or federal court located in New York City in the State of New York has been brought in an inconvenient forum.

10. This Agreement may be executed and delivered (including, without limitation, by facsimile transmission or electronically transmitted PDF) in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

If Serenity is in agreement with the terms and conditions of this Agreement and desires to proceed on that basis with the negotiation of the ELAA Agreement as contemplated in this Agreement, please sign this Agreement in the space provided below and return an executed copy to Avadel, upon which this Agreement will be a binding agreement between us.

AVADEL SPECIALTY PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: President

ACCEPTED AND AGREED
as of the date first written above:

SERENITY PHARMACEUTICALS, LLC.

By: /s/ Samuel Herschkowitz, M.D.
Name: Samuel Herschkowitz, M.D.
Title: Chief Executive Officer

CONFIDENTIAL TREATMENT REQUESTED

THE PORTIONS OF THIS AGREEMENT, INCLUDING EXHIBIT A, MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A

FORM OF ELAA AGREEMENT

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

EXCLUSIVE LICENSE AND ASSIGNMENT AGREEMENT

Contents

Exhibits and other Agreements (in the order in which they appear in the Agreement):

(1) to be attached to this Agreement upon execution
(2) to be drafted following execution of this Agreement
(3) to be provided separately

Schedules (in the order in which they appear in the Agreement):

EXCLUSIVE LICENSE AND ASSIGNMENTS AGREEMENT

This Exclusive License and Assignments Agreement (this "Agreement") is made as of _____ __, 2017 (the "Effective Date") by and among SERENITY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensor"), with offices at 105 Hawk Court, Milford, PA 18327, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensee"), with offices at16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005. Licensor and Licensee are each sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Licensor has developed the Product (herein defined) for treating certain medical conditions characterized by abnormalities or disorders in voiding and other urinary functions, and the FDA (herein defined) has approved a New Drug Application (herein defined) for treating certain of these medical conditions (herein defined as the "First Approved NDA);

WHEREAS, Licensee is engaged in the business of the development, distribution, sale and marketing of pharmaceutical products;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to grant to Licensee, and Licensee desires to be so granted, an exclusive license and sublicense to the Licensed Rights (herein defined) and the Sublicensed Rights (herein defined), respectively, for the purpose of: (a) Commercializing (herein defined) Products in the Field (herein defined) throughout the Territory (herein defined) and (b) Developing (herein defined) and Commercializing the Product for the PNE Indication and Additional Indications (herein defined) in the Field and Territory;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and to delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related regulatory obligations in respect of, the First Approved NDA and the related IND (herein defined); and

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related obligations under, the Renaissance Supply Agreements (herein defined),

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties intending to be legally bound agree as follows:

1. DEFINITIONS.

When used in this Agreement each of the following terms whether used in the singular or plural shall have the following meanings.

1.1 "A/B Rated" means, (a) inside the United States, "therapeutically equivalent" as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations", and (b) outside the United States, such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law.

1.2 “Acceptance” and its correlative “Accepted” means with respect to an NDA submitted to the FDA, receipt by the sponsor thereof of written notice from the FDA that the FDA deems such NDA to be sufficiently complete for filing and filed by the FDA pursuant to 21 C.F.R. 314.101 and any regulation successor thereto.

1.3 “Additional Indications” means any other Indication for the Product in the Field in the Territory other than the PNE Indication.

1.4 “Adverse Drug Experience” has the meaning set forth in 21 CFR Sec. 314.80 and any regulation successor thereto.

1.5 “Affiliate” means any Person who, directly or indirectly through one or more intermediates, controls or is controlled by or is under common control with another Person, but only for so long as such relationship exists. For purposes of this definition, the term “control” (including, with correlative meanings, the terms “controlled by” and “under common control with”) as used with respect to a Person means the possession, directly or indirectly through one or more intermediates, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Such power will be deemed to exist in the case of ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, or status as a general partner in any partnership. The Parties acknowledge that, in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity.

1.6 “Agreement” has the meaning set forth in the Preamble.

1.7 “Alliance Manager” means, with respect to each of Licensor and Licensee, the individual designated by such Party in accordance with Section 3.2(h).

1.8 “Applicable Law” means, with respect to any action taken or omitted to be taken by a Party under this Agreement, the Laws in any country and any jurisdiction therein that are applicable to such action or omission.

1.9 “Bankruptcy Code” means the United States Bankruptcy Code, as amended and set forth in Title 11 of the United States Code.

1.10 “Branding Strategy” means the strategy, including messaging, for branding the Product for use in the Field in the Territory, to be set forth in the Commercialization Plans for each combination of Product and Indication.

1.11 “Business Day” means a day other than any Saturday, Sunday or other day on which banking institutions in New York, New York are required by Applicable Law to remain closed.

1.12 “Calendar Quarter” means each calendar quarter ending on the last day of each March, June, September and December during the Term of this Agreement; provided, however, that (a) the first Calendar Quarter of the Term of this Agreement will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.13 “Calendar Year” means each calendar year ending on December 31 of such year; provided, however, that (a) the first Calendar Year of the Term of this Agreement will extend from the

Effective Date to and including December 31, 2017; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.14 "CFR" means the United States Code of Federal Regulations.

1.15 "Change of Control" means with respect to Licensee:

(a) Licensee enters into a merger, consolidation, stock sale or sale or transfer of all or substantially all of its assets to which this Agreement relates, or other similar transaction or series of transactions with a Third Party, unless, following such transaction or transactions, (i) the individuals and entities who were the beneficial owners of the outstanding voting securities of Licensee immediately prior to such transaction beneficially own, directly or indirectly, at ***least*** fifty percent (50%) of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors or similar governing persons of the corporation or other entity resulting from such transaction ("Successor") in substantially the same proportions as their ownership immediately prior to such transaction of such outstanding voting securities, (ii) at least fifty percent (50%) of the members of the Board of Directors or similar governing body of the Successor were members of the Board of Directors of Licensee at the time of the execution of the initial agreement, or the action of the Board of Directors of Licensee, providing for such transaction, (iii) Licensee retains title ownership after the transaction or transactions to properties and assets (x) representing more than fifty percent (50%) of such Third Party's consolidated total assets or (y) from which more than fifty percent (50%) of such Third Party's consolidated operating income for its most recent fiscal year was derived, and (iv) Licensee is the surviving entity in such transaction or transactions; or

(b) any transaction or series of related transactions in which any Third Party or group of Third Parties acquires beneficial ownership of ***securities*** of Licensee representing more than fifty percent (50%) of the combined voting power of the then outstanding securities of Licensee.

Notwithstanding subsections (a) or (b), above, a stock sale to underwriters of a public or private offering of Licensee's capital stock shall not constitute a Change of Control.

1.16 "Clinical Study" means (a) a Phase 1 Clinical Study, a Phase 2 Clinical Study, a Phase 3 Clinical Study, (b) variations of such studies and/or trials (for example, a Phase 2/3 Clinical Study), as such terms are defined and understood by the FDA, and (c) such other tests and studies in human patients that are required by Applicable Law, or otherwise recommended by applicable Regulatory Authorities in the Territory, to obtain or maintain Regulatory Approvals, but excluding Post-Market Approval Studies not required to be conducted under an IND.

1.17 "CMC" means, as required by the context, the chemistry, manufacturing and controls processes applicable to the manufacture of a product or the section of an IND or NDA that contains information on such processes.

1.18 "Combination Product" means any product that comprises (a) the Compound and (b) at least one clinically active therapeutic, or prophylactic ingredient or component (whether packaged together or in the same formulation) that is not the Compound.

1.19 “Commercialize”, “Commercializing” or “Commercialization” means, with respect to any drug product, any and all activities directed to using, launching, marketing, market researching, detailing, promoting, advertising, educating, importing, exporting, distributing, selling, offering for sale, post-market approval pharmacovigilance and safety reporting, legal, customer service, securing from both government agency payors and non-government third-party payors reimbursement of such drug product after Regulatory Approval has been obtained (including, without limitation, obtaining pricing and reimbursement approvals), regulatory compliance, planning with respect to each of the foregoing, and reporting. For clarity, “Commercialization” shall not include any activities related to clinical research or Development of Products or to Manufacturing of Products.

1.20 “Commercialization Activities” means any of the activities described in the definition of “Commercialize”.

1.21 “Commercialization Plan” means, from time to time and with respect to any period during the Term, Licensee’s plan then in effect for Commercializing the Product during such period.

1.22 “Commercially Reasonable Efforts” means, from to time to time with respect to the performance at such time of any Development, Commercialization or other obligation of a Party under this Agreement that expressly requires efforts characterized as such, the performance by such Party of such obligation by expending reasonable, diligent, good faith efforts to accomplish such obligation as a similarly situated pharmaceutical company would use to accomplish a similar obligation under similar circumstances through the exercise of reasonable business judgment, where the assessment of being similarly situated would be undertaken by reference to company size and financial position, competitive factors in the relevant market relating to the proprietary position of the relevant product in terms of market and profit potential, the safety and effectiveness profile of the relevant product, strategic value, and applicable regulatory matters; provided, that, with respect to the Development and Commercialization of the Compound or the Product, such efforts shall be substantially equivalent to those efforts and resources that a pharmaceutical company would generally devote to its own internally discovered compounds or products of similar market and profit potential, safety and effectiveness profile, strategic value, and regulatory matters at a similar stage in their development or life cycle, with respect to which it does not owe license payments, milestone payments, royalties or similar financial obligations to licensors or other Persons, and based on conditions then prevailing, with the goal of maximizing the revenue potential of such compounds or products. Commercially Reasonable Efforts shall be determined on a country by country basis.

1.23 “Compound” means “(a) the compound designated as Desmopressin (1-desamino-8-D-arginine vasopressin) and (b) any and all functionally equivalent analogues thereof having antidiuretic activity disclosed in a patent or patent application within the Patent Rights licensed and sublicensed hereunder.

1.24 “Confidential Information” has the meaning set forth in Section 13.1.

1.25 “Control” or “Controlled” means, with respect to any Know-How or Patent Right, the possession by a Party, whether by ownership, license, sublicense or otherwise (other than pursuant to a license granted under this Agreement), of the ability to grant the right to access or use, or to grant a license or a sublicense under, or to grant the right to disclose or transfer, such Know-How or Patent Right, without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party. For clarity, the Patent Right or Know-

How licensed to Licensee under this Agreement shall be deemed to be Controlled by Licensee.

1.26 "Cover", "Covered", or "Covering" means, (a) with respect to an issued patent, that, in the absence of a license granted to a Person under a Valid Claim included in such patent, the practice by such Person of an invention claimed in such Patent Right would infringe such Valid Claim, or (b) with respect to a patent application, that, in the absence of a license granted to a Person under a Valid Claim included in such patent application, the practice by such Person of an invention claimed in such patent application would infringe such Valid Claim if such patent application were to issue as a patent.

1.27 "CPEX" means CPEX Pharmaceuticals, Inc. (formerly Bentley Pharmaceuticals, Inc.), a corporation organized under the laws of Delaware.

1.28 "CPEX License Agreement" means that certain Development and License Agreement, dated February 4, 2008 and as amended March 31, 2010, by and among Licensor and CPEX.

1.29 "Detail" means a meeting (either in person or through live video conferencing) in respect of the Product (i) with one or more physicians and other persons included in other medical professional categories (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail), who are permitted under the Applicable Law of the country in which they work to prescribe the Product and (ii) in which key attributes of the Product are orally presented, but shall not include merely a reminder or a Sample or promotional material drop). When used as a verb, "Detail" and "Detailing" shall have correlative meanings.

1.30 "Develop" or "Development" means the undertaking of all activities relating to obtaining Regulatory Approval for a product and all Manufacturing Activities reasonably required for development of CMC processes. For the sake of clarity, such activities include preclinical testing, toxicology, formulation, Clinical Studies, and regulatory affairs required for Regulatory Approval, and activities relating to the manufacture of Products that relate to regulatory matters are included in the definition of Manufacturing.

1.31 "Development Activities" means any of the activities described in the definition of "Develop".

1.32 "Development Budget" means, for any Development Activities to be undertaken with respect to the Product, the PNE Indication and any Additional Indications, the detailed budget for all Development Costs for the Development Activities set forth in any Development Plan in respect of such Development Activities.

1.33 "Development Costs" means, in respect of the Development Activities described in any Development Plan, the following costs: (i) Out-of-Pocket Costs attributable to such Development Activities and (ii) FTE Costs of Licensee's internal personnel that are attributable or reasonably allocable to such Development Activities. Such costs shall be determined in accordance with GAAP.

1.34 "Development Plan" means, in respect of the Product, the PNE Indication and each Additional Indication, from time to time during the Term of this Agreement, any plan then in effect for the conduct of Development Activities in respect thereof, and includes, without limitation, the Development Budget for such Development Activities.

1.35 "Disclosing Party" means, with respect to any disclosure by a Party of any of its Confidential Information to the other Party, the Party so disclosing such Confidential Information.

1.36 “Disposition” means any disposition by Licensee of any of its assets, including any direct or indirect sale, lease, exchange, transfer, contribution, license, spinoff, recapitalization, dividend, grant or other disposition, with or without value; provided, however, that any sale of inventory by a Licensee Change of Control Party in the ordinary course of business, an offering of debt or equity securities in a public financing, or any pledge of assets to secure acquisition debt financing on customary terms which would not involve the issuance of equity that would otherwise result in a Change of Control, shall not be deemed a Disposition hereunder.

1.37 “Dispute” has the meaning set forth in Section 15.8(b).

1.38 “Dollars” or “$” means U.S. dollars.

1.39 “Drug Master File” or “DMF” has the meaning set forth in 21 CFR Section 314.420 (and any regulation successor thereto).

1.40 [***].

1.41 “Effective Date” has the meaning set forth in the Preamble.

1.42 “Enforceable IP Right(s)” shall mean any Patent Rights, Trademarks, Copyrights, or other intellectual property rights within the Licensed Rights or the Sublicensed Rights that would be infringed by any Exploitation of any product in the Territory in the absence of a valid and enforceable license, sublicense, or other right to engage in such Exploitation.

1.43 “Exploit” and, with correlative meaning, “Exploitation”, means to Develop, Commercialize, Manufacture, and otherwise exploit.

1.44 “FDA” means the United States Food and Drug Administration and any agency successor thereto.

1.45 “FDCA” means the United States Food, Drug and Cosmetic Act of 1938, as amended, and any law successor thereto.

1.46 “Field” means the use of the Product for the Treatment in humans and animals of medical conditions characterized by abnormalities or disorders in voiding and other urinary functions of a subject to control urination.

1.47 “First Approved NDA” means U.S. NDA #201656, dated and received by the FDA on February 4, 2016 and as thereafter amended, and approved by the FDA, as evidenced by that certain letter, signed March 3, 2017, from the FDA to Serenity.

1.48 “First Approved Product” means the Product that is the subject of the First Approved NDA.

1.49 “First Commercial Sale” means, with respect to the Product in each country in the Territory, the first sale in such country by Licensee or any Third Party Distributor for consumption or use. Sales or transfers of reasonable quantities of the Product for Clinical Study purposes or for compassionate or similar use, shall not be considered a first sale for consumption or use.

1.50 “First Position” means, with respect to the Detail of an applicable product, that the product is presented in such Detail before any other product, such that the average time spent on all Details in any Calendar Quarter during the First Position Period is approximately fifty (50%), excluding any Detail to a person or group of persons where for good reason Detailing of the Product should either not be made or, if made, made substantially shorter than such average.

1.51 “First Position Period” has the meaning set forth in Section 14.3(b).

1.52 “Force Majeure” has the meaning set forth in Section 15.12.

1.53 "FTE" means the hours of work devoted to or in support of Commercialization, Manufacture, or Development, as applicable, of the Product, in accordance with the applicable Commercialization Plan, Manufacturing Plan, or Development Plan, that is carried out by one or more employees, contract personnel or consultants of a Party, measured in accordance with such Party's normal time allocation practices from time to time. In no event shall an individual account for more than one FTE year in any Calendar Year.

1.54 "GAAP" means United States Generally Accepted Accounting Principles as applied in the United States.

1.55 "Generic Product" means, with respect to the Product, any product Commercialized by a Third Party in any country in the Territory, that meets the following criteria: (i) such product contains a Low Dosage formulation of a compound that is an active pharmaceutical ingredient in a product that is A/B Rated with respect to the Licensed Product (including, without limitation, any salt, free acid or base, hydrate, isotopic, deuterated, solvate, polymorphic, crystalline, or non-crystalline form of such Compound), and (ii) is A/B Rated with respect to the Product.

1.56 "Generic TRxs-to-Total TRxs Percentage" means, with respect to any Calendar Quarter during the Term of this Agreement in each country in the Territory, the quotient, expressed as a percentage, of (a) total TRxs for Generic Products during such Calendar Quarter in such country DIVIDED BY (b) the sum of total TRxs for Generic Products during such Calendar Quarter in such country PLUS total TRxs for Products during such Calendar Quarter in such country.

1.57 "Governmental Authority" means any legislative, executive, judicial, regulatory, or administrative unit of any governmental entity (multinational, foreign, federal, state, or local) or any department, commission, board, agency, bureau, ministry, official, arbitrator (public), or other similar body exercising executive, legislative, regulatory, administrative, or judicial authority or functions of or pertaining to government to perform any such functions.

1.58 "IND" means, with respect to any investigational product, an Investigational New Drug Application filed with the FDA under 21 CFR Part 312 (and any regulation successor thereto) or similar foreign application or submission in any country in the Territory for permission to conduct human clinical investigations of such investigational product.

1.59 "Indemnification Claim" has the meaning set forth in Section 11.2.

1.60 "Indication" shall mean any human disease or condition, and any subcategories thereof, or sign or symptom of a human disease or condition, and any subcategories thereof.

1.61 "Inventions" means any and all inventions made, conceived, or discovered solely by employees, independent contractors, or agents of either Party or their respective or jointly by employees, independent contractors, or agents of each of the Parties or their respective Affiliates.

1.62 "Joint Steering Committee" or "JSC" means the committee formed by designees of Licensor and Licensee for the purpose of monitoring the Development, Commercialization, and Manufacture of the Product as contemplated by this Agreement and governed in accordance with Article 3.

1.63 "JSC Subcommittee" means any subcommittee established by the JSC in accordance with Article 3.

1.64 “Know-How” means any nonpublic information, ideas, data, inventions, works of authorship, trade secrets technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissues, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, and whether stored or transmitted in oral, documentary, electronic or any other form, including all Regulatory Documentation.

1.65 “Launch” means, with respect to the Product or any Generic Product for an Indication in a country in the Territory, the Product or such Generic Product first becoming available for commercial sale.

1.66 “Law” means any law, statute, rule, regulation, ordinance, regulatory guidance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision in each country in the Territory, including, without limitation, (a) the FDCA in the United States and counterparts thereof in each other country in the Territory, (b) good clinical practices and adverse event reporting requirements and all other rules, regulations and requirements of the FDA and Regulatory Authorities that are counterparts of the FDA, as applicable, (c) the Foreign Corrupt Practices Act of 1977, as amended, in the United States and any comparable laws in each other country in the Territory, and (d) all export control laws in any country in the Territory.

1.67 “LIBOR Rate” means, for any applicable interest period, the rate per annum equal to the average of the one month US Dollar Rate Intercontinental Exchange London Interbank Offered Rate, as published by Thomson Reuters (or, if Thomson Reuters does not publish quotations of such rate, another commercially available source providing quotations thereof as reasonably selected by agreement of the Parties), with the average determined by adding such rate for each day on which such rate is published during the applicable period, divided by the number of such days during such period. If such rate is not available at such time for any reason, then the rate for that interest period will be determined by such alternate method as reasonably selected by agreement of the Parties.

1.68 “Licensed CPEX Patent Rights” means the Patent Rights set forth in Exhibit 1.68.

1.69 “Licensed Reprise Know-How” means the Know-How licensed by Reprise to Serenity under the Reprise License Agreement.

1.70 “Licensed Reprise Patent Rights” means the Patent Rights set forth in Exhibit 1.70.

1.71 “Licensed Reprise Rights” means the Licensed Reprise Patent Rights and the Licensed Reprise Know-How.

1.72 “Licensed Rights” means the rights under the licenses granted by Licensor to Licensee in Sections 2.1(a),(b), and (c).

1.73 “Licensed Serenity Copyrights” means the copyrights set forth in Exhibit 1.73.

1.74 “Licensed Serenity Know-How” means the Know-How described in Exhibit 1.74.

1.75 “Licensed Serenity Patent Rights” means the Patent Rights in the issued patents and patent applications set forth in Exhibit 1.75.

1.76 “Licensed Serenity Trademarks” means the trademarks set forth in Exhibit 1.76.

1.77 “Licensee” has the meaning set forth in the Preamble.

1.78 “Licensee Change of Control Party” means Licensee or any Affiliate of Licensee to the extent Licensee or such Affiliate of Licensee, as applicable, is the subject of a Change of Control.

1.79 “Licensee Insurance Policies” has the meaning set forth in Section 11.3.

1.80 “Licensee Indemnitee(s)” means any of Licensee and its directors, officers, employees, agents, contractors and agent of Licensee and its Affiliates (including without limitation Avadel Pharmaceuticals plc).

1.81 “Licensee Inventions” means any and all Inventions with respect to the Product, Controlled by Licensee and not made, conceived, or discovered by any employees, independent contractors, or agents of Licensor or any of its Affiliates, contractors, or agents.

1.82 “Licensee’s Sales and Marketing Force” means, from time to time, Licensee’s sales and marketing personnel responsible for managing, coordinating and overseeing the Commercialization of the Product in the Field in the Territory.

1.83 “Licensor” has the meaning set forth in the Preamble.

1.84 “Licensor Indemnitee(s)” means any of Licensor and its directors, officers, employees, agents, contractors and agents of Licensor and its Affiliates (including, without limitation, Serenity).

1.85 “Long Term Care” or “LTC” means the provision of health care in skilled nursing and other long-term care and assisted living facilities.

1.86 “Losses” means, with respect to any Claim for which one Party as an Indemnitee hereunder seeks indemnification hereunder from the other Party as an Indemnitor hereunder, any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and reasonable attorneys’ fees) of any kind payable to Third Parties (including attorneys for such Indemnitees) incurred by the Indemnitees and arising out of such Claim.

1.87 “Low Dosage” means, with respect to any product containing the Compound, that such product produces a peak blood concentration (measured as a Cmax) equal to or less than [***] per milliliter of blood plasma or serum ([***]), where “Cmax” means the maximum concentration of the Compound measured in blood plasma or serum following administration of the product and prior to a subsequent administration of the product.”

1.88 “LTC Activities” means, for each combination of Product, Indication, and country in the Territory, (a) meetings (either in person or through live video conferencing), other than Details, with one or more physicians, administrators, and other medical or other professional categories identified in the Annual Commercialization Plan for the purpose of marketing and promoting such combination of Product and Indication to LTC organizations in such country and (b) activities connected with pricing, rebate and other contract-related negotiations, contracting, and processing and implementation of agreements with LTC organizations.

1.89 “Manufacture”, “Manufacturing”, or “Manufacturing Activities” means, as applicable, all activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, and storage of bulk and finished forms of bulk and finished forms of Products and/or any components thereof, including, without limitation, process and formulation development, process validation, stability testing, manufacturing scale-up, manufacture for preclinical and clinical studies and Commercialization, analytical development, product characterization, quality assurance and quality control development, testing and release, and any technical support activities that are necessary for Regulatory Approval and Commercialization of Products.

1.90 “Manufacturing and Supply Plan” means the plan attached as Exhibit __ to the Manufacturing and Supply Agreement and relating to the manufacture by or for Licensee of

quantities of the Product and subsequent supply thereof for Commercialization [and Development Activities] by Licensee, as such plan may be modified from time to time for the Territory.

1.91 "Marketing Authorization Application" or "MAA" means, with respect to any product and each country in the Territory, an application to the applicable Regulatory Authority for approval to commercially market and sell the product in such country. For the sake of clarity, this term (and its abbreviation) includes NDAs and sNDAs in the United States.

1.92 "New Drug Application" or "NDA" means, with respect to any product, the application referred to as such by FDA and that must be approved by FDA before such product can be commercially marketed and sold in the United States, and such term includes, without limitation, and, unless the context otherwise states to the contrary, any supplemental NDAs ("sNDAs"), each such application having the form and containing the substance specified by the FDA for such applications and supplemental applications.

1.93 "Net Sales" means, with respect to a given period of time, gross sales of the Product in such period to unrelated Third Parties in bona fide arm's length transactions, (excluding sales or dispositions for use in Clinical Studies or other scientific testing or reasonable quantities of samples, in each case for which Licensee and any such Third Party Distributors receive no revenue), less the following deductions which are actually incurred, allowed, paid, accrued or specifically allocated to such gross sales amounts of the Product and not separately invoiced:

(a) credits or allowances actually granted for damaged Product, returns or rejections of Product, price adjustments, and billing errors;

(b) governmental and other rebates (or equivalents thereof) granted to: managed health care organizations; pharmacy benefit managers (or equivalents thereof); federal, state/provincial, local and other governments, their agencies and purchasers and payors, including, without limitation, any state or federal Medicare, Medicaid or similar program); or trade customers;

(c) normal and customary trade, cash and quantity discounts, allowances and credits actually allowed and taken specifically with respect to sales of other dispositions of the Product;

(d) distribution services agreement fees allowed or paid to Third Party distributors;

(e) transportation costs, including without limitation insurance, for outbound freight related to delivery of the Product to the extent included in the gross amount invoiced;

(f) excise and sales taxes, tariffs, duties, value added taxes, and other taxes applied to the sale of the Product imposed upon and paid directly with respect to such sales or (reduced by any refunds of such taxes deducted in the calculation of Net Sales for prior periods and, for the avoidance of doubt, no deduction shall be permitted for income, withholding, corporate or similar taxes); and

(g) any other items that reduce gross sales amounts as required by GAAP.

Transfers and sales of the Product between or among a Party and its Affiliates or Third Party Distributors shall be excluded from the computation of Net Sales, but the subsequent final sales of the Product to Third Parties by such Affiliates or Third Parties shall be included in the computation of Net Sales.

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. The deductions set forth above in this definition of Net Sales shall be determined in accordance with GAAP, as consistently applied by Licensee and such Third Party Distributors across all of their products. The amounts set forth in clauses (a) through (g) above shall only be deducted from gross invoiced sales where gross invoiced sales before deductions are non-discounted gross sales amounts.

In the event Licensee or such Third Party Distributors sell the Product together with other products to Third Parties in a particular country in the Territory and the price attributable to the Product is less than the average price of "arm's length" sales of the Product alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of "arm's length" sales of the Product alone), Net Sales for any such sales shall be the average price of "arm's length" sales by Licensee or Third Party Distributors, as applicable, of the Product alone and in the country during the reporting period in which such sales occur. If the average price of "arm's length" sale of the Product cannot be determined in any given country, the Net Sales will be determined by the value of the Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities. Any dispute as to the determination of fair market value that cannot be resolved through discussion between the Parties shall be determined in accordance with Section 3.2(i). Notwithstanding the foregoing, in the event the Product is sold as a Combination Product, for purposes of determining the royalties payable by Licensee to Licensor hereunder, Net Sales shall be calculated by the Net Sales for such Combination Product in a manner to be negotiated and agreed upon by Licensor and Licensee, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the respective fair market values of the active pharmaceutical ingredients in such Combination Product; provided that in no event shall the royalty rate payable by Licensee to Licensor for such Combination Product be greater than the royalty rate of the Product containing the Compound as the sole active ingredient.

1.94 "Nocturia Indication" means an Indication characterized by urination in a human aged 18 years or older wherein, during a defined period of such human's normal period of sleep at night, two or more non-incontinent urinary void(s) of any volume during such period of sleep, each such void following an initial period of sleep and, thereafter, followed by sleep or an attempt to sleep.

1.95 "Out-of-Pocket Costs" means the direct expenses paid or payable by Licensee to any Third Parties in respect of any Development Activities or Commercialization Activities, as applicable, performed for such Party (or its Affiliates) by such Third Party.

1.96 "Party" means Licensor or Licensee; "Parties" means Licensor and Licensee.

1.97 "Patent Rights" means, with respect to each country in the Territory (except as otherwise stated to be with respect to any country in or outside the Territory), (a) patent applications (including provisional applications) pending in such country, (b) any patents issuing in such country from such patent applications (including certificates of invention), (c) all patents and patent applications issued or pending, as applicable, in such country based on, corresponding to or claiming the priority date(s) of any of the foregoing, (d) rights in such country derived from any of (a), (b) or (c), including any substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations in part, reexaminations, renewals, revalidations, revivals, patents of addition, and (e) all patents and patent applications issued or pending, as applicable, in such country claiming overlapping priority therefrom.

1.98 “Person” means any individual, corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, or any other entity or body.

1.99 “Pharmacovigilance Agreement” means the pharmacovigilance agreement to be entered into by Parties, Third Party Distributors, and any Third Parties which such Third Parties are licensed or sublicensed to Commercialize the Product in countries outside the Territory.

1.100 “Phase 1 Clinical Study”, with respect to any investigational drug product, means a human clinical study that provides for the introduction into humans of such investigational drug product and that is intended to initially evaluate the safety, tolerance or pharmacological effects of such investigational drug product in human subjects, or that is otherwise described in 21 CFR Sec 312.21 (a) or its foreign counterpart.

1.101 “Phase 2 Clinical Study” means a human clinical study that is intended to initially evaluate the dosing and effectiveness of the Product, and to further evaluate the safety of the Product, or that is otherwise described in 21 CFR Sec. 312.21(b) or its foreign counterpart.

1.102 “Phase 3 Clinical Study” means a human clinical study that is prospectively designed to demonstrate statistically whether the Product is safe and effective to control, mitigate, prevent, treat or cure a particular Indication in a manner sufficient to obtain Regulatory Approval to market the Product, or that is otherwise described in 21 CFR Sec. 312.21(c) or its foreign counterpart.

1.103 “PNE Indication” means the Primary Nocturnal Enuresis Indication and is characterized by the occurrence of one or more incontinent urinary voids occurring during sleep in a person under the age of eighteen (18) years.

1.104 “Post-Market Approval Study” means a human clinical study in respect of the Product for a specified Indication that is conducted under the Applicable Law of any country in the Territory after Regulatory Approval of the Product for such Indication has been obtained from the applicable Regulatory Authority in that country, and includes trials conducted (a) voluntarily for the purpose of enhancing marketing or scientific knowledge of such Indication or (b) at the request or requirement of the applicable Regulatory Authority.

1.105 “Product” means any product for a specific Indication within the Field that contains the Compound in any form, presentation, formulation and dosage form, and (a) is at any time during the Term of this Agreement Covered by a Licensed Serenity Patent Right, Licensed CPEX Patent Right, or Licensed Reprise Patent Right. For purposes of this Agreement, Net Sales of any such Product so Covered by any such Patent Right at any time during the Term of this Agreement will continue to be treated, from and after the time that the Product is no longer Covered by any Valid Claim of any such Patent Right, as a Product for purposes of calculating any payments to be made to Licensor under Article 8. For the sake of clarity, the term “Product” includes the First Approved Product.

1.106 “Product Regulatory Approvals and Documentation” means all Regulatory Approvals and Regulatory Documentation in respect of the Product and each country in the Territory (including, without limitation, the First Approved NDA and any INDs in respect of the Product open as of the Effective Date).

1.107 “Promotional Materials” means any printed or other materials bearing the name (trade name or generic name) used to promote the Product in any country in the Territory, including brochures, journal ads, selling aids, posters, reprints, video or audio tapes, press releases, Internet pages and websites, radio or television advertisements and textbooks.

1.108 “Publication” means any publication in a scientific journal, any abstract to be presented to any scientific audience, any presentation at any scientific conference, any other scientific presentation and any other oral, written or electronic disclosure directed to a scientific audience which pertains to the Product or the use of the Product.

1.109 “Receiving Party” means, with respect to the receipt by a Party of any Confidential Information from the other Party, the Party so receiving such Confidential Information.

1.110 “Regulatory Approval” means, with respect to a drug product and a specified country in the Territory, the act of the applicable Regulatory Authority in such country necessary for the marketing and commercial sale of such drug product in such country (including pricing and/or reimbursement approval in such country in which such pricing and/or reimbursement approval is required by Applicable Laws), including, without limitation, the approval of an NDA for the Product by the FDA and other regulatory agencies in the Territory.

1.111 “Regulatory Authority” means, in any country in the Territory, any applicable government regulatory authority involved in the granting of Regulatory Approval for the Product in such country or regulatory jurisdiction, including the FDA in the United States and counterparts thereof in other country in the Territory.

1.112 “Regulatory Documentation” means, with respect to the Product, all INDs, NDAs (including, without limitation, sNDAs), MAAs or other regulatory applications submitted to any Regulatory Authority, preclinical and clinical data and information, regulatory materials, drug dossiers, master files (including, without limitation, Drug Master Files), and any other reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Product, including, without limitation, those materials necessary to Develop, Manufacture, Commercialize and otherwise Exploit the Product, including, without limitation, any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database.

1.113 “Regulatory Exclusivity” means, with respect to a country, any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority with respect to the Product in such country, other than a Patent Right.

1.114 “Regulatory Rights Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee of the Product Regulatory Approvals and Documentation relating to the Commercialization and Development of Products in each country in the Territory, including, without limitation, U.S. IND 076667 and U.S. NDA 201656 (also referred to herein as the First Approved NDA), and the assumption by Licensee of all of the obligations under Applicable Law as the sponsor thereunder.

1.115 “Remedial Action” means any recall, market withdrawal, safety alert, corrective action or other regulatory action taken with respect to the Product by virtue of Applicable Laws.

1.116 “Renaissance” means Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC), a limited liability company organized under the laws of the State of Delaware.

1.117 “Renaissance Agreements” means (a) that certain Manufacturing Agreement, dated July 14, 2014, between Serenity and Renaissance, relating to the manufacture by Renaissance of Product and supply thereof to Serenity or any third party designated by Serenity and (b) that certain Quality Agreement, dated January 16, 2015, between Serenity and Renaissance, relating to compliance with current Good Manufacturing Practices guidances and directives applicable to the manufacture by Renaissance of Products.

1.118 “Renaissance Agreements Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee and the assumption by Licensee of the Renaissance Agreements.

1.119 “Reprise” means Reprise Biopharmaceutics, LLC, a limited liability company organized under the laws of the State of New York.

1.120 “Reprise License Agreement” means that certain license agreement, effective as of May 28, 2017, by and between Reprise and Serenity, relating to the grant by Reprise to Serenity of an exclusive license under the patent rights and know-how specified therein.

1.121 “Right of Reference or Use” has the meaning set forth in 21 CFR Sec. 314.3(b) with respect to the United States, and any provisions equivalent thereto in the Applicable Laws of any other country in the Territory.

1.122 “Royalty Term” means, with respect to the Product and each country in the Territory, the period of time commencing on the date of First Commercial Sale by Licensee or its Sublicensees of the Product in such country and ending upon the termination of this Agreement in accordance with Article 14.

1.123 “Serenity” has the meaning set forth in the Preamble.

1.124 “Serenity Trademark Standards” means the set of policies, specifications, directions, and standards for use of the Licensed Serenity Trademarks to be prepared in accordance with Section 4.4 and to be attached hereto as Exhibit 1.124.

1.125 “Sublicensed Rights” has the meaning set forth in Section 2.2(b).

1.126 “Term” means the period commencing on Effective Date and ending upon the termination of this Agreement in accordance with Article 14.

1.127 “Territory” means the United States, Canada, and each of their respective territories and possessions.

1.128 “Third Party” means any Person other than the Parties and their Affiliates.

1.129 “Third Party Distributor” means any Third Party engaged and authorized by Licensee Party to distribute, import, market, promote and sell the Product in any country in the Territory.

1.130 “Third Party Infringement Claim” has the meaning set forth in Section 9.4(a).

1.131 “Third Party License(s)” has the meaning set forth in Section 8.3(b)(ii)(A).

1.132 “Third Party Supply Agreements” means the agreements originally executed by and between Serenity and the Third Parties named therein, relating to the manufacture and supply of certain components of the First Approved Product (including, without limitation, the applicable drug substance, ingredients for formulating the applicable drug product, and intranasal delivery device) and the manufacture and supply of the First Approved Product in finished form, including, the Renaissance Agreements and the other agreements set forth in Exhibit 1.132.

1.133 “Toll Period” has the meaning set forth in Section 14.2(b).

1.134 “TRx” shall mean total prescriptions of a product for a specified period.

1.135 “Treatment” (or, when required by the context, “Treat” or “Treats”) means, with respect to an Indication, the diagnosis, prevention, palliation, amelioration, control, mitigation, treatment, cure, or prognosis of such Indication.

1.136 “Unexpected Adverse Drug Experience” has the meaning set forth in 21 CFR Section 314.80 and any regulation successor thereto.

1.137 “Valid Claim” means, with respect to a particular country in the Territory, a claim within an issued patent or patent application included in the Licensed Serenity Patent Rights, Licensed Reprise Patent Rights, or Licensed CPEX Patent Rights that has not expired, lapsed, or been abandoned, and that has not been held unenforceable, invalid, or been cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including without limitation through opposition, re-examination, reissue, or disclaimer.

2. LICENSES AND ASSIGNMENTS.

2.1 **Licenses of Patent Rights, Know-How, Trademark, and Copyrights.**

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor’s right, title, and/or interest in or to the Licensed Serenity Patent Rights and the Licensed Serenity Know-How, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (subject to Section 2.5, even as to Licensor) license to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory**.**

(b) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor’s right, title, and/or interest in or to the Licensed Serenity Trademarks, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use the Licensed Serenity Trademarks to Commercialize the Product in the Field throughout the Territory.

(c) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor’s right, title, and/or interest in or to the Licensed Serenity Copyrights, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use, copy, publish, and distribute the content that is the subject of the Licensed Serenity Copyrights for the purpose of Commercializing the Product in the Field throughout the Territory.

(d) The license in, to, and under the Licensed Patents granted in Sections 2.1(a), (b) and (c) includes, without limitation,

(i) the right to sue for past and future infringement, violation, or misappropriation of any of such Licensed and any invention claimed therein and all applications for industrial property protection hereafter filed for any such invention, including, without limitation, all applications for patents, utility models, and designs which may be filed for any such invention in any country or countries in the Territory,

(ii) the right to file such applications in such countries in the Territory,

(iii) the right to claim for such applications the priority rights derived from the corresponding patent application under the patent laws of the United States, the International Convention for the Protection of Industrial Property, or any other

international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and

(iv) all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for any such invention in any country or countries in the Territory and all extensions, renewals and reissues thereof.

2.2 **Grant of Sublicenses to Licensee.** Subject to the terms and conditions of this Agreement, the CPEX License Agreement, and the Reprise License Agreement, Licensor hereby grants Licensee under Licensor's rights in the Licensed CPEX Patent Rights and the Licensed Reprise Rights (collectively, the "Sublicensed Rights") a transferable (subject to Section 15.2), sublicenseable (subject to the terms of Section 2.4, and each of the CPEX License Agreement and the Reprise License Agreement, as applicable), royalty-, fee-, and milestone payment-bearing, exclusive (even as to Licensor) sublicense to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory.

2.3 **Assignments.**

(a) ***Assignment of Supply Agreement.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Renaissance Supply Agreement Assignment and Assumption Agreement.

(b) ***Assignment of Regulatory Rights.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Regulatory Rights Assignment and Assumption Agreement.

2.4 **Sublicensing by Licensee.**

(a) Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant to Third Parties sublicenses under the license to the Licensed Rights granted to Licensee in Sections 2.1(a), (b) and (c) and the sublicense to the Sublicensed Rights granted to Licensee in Section 2.2; provided that Licensee hereby covenants that it will not grant any such sublicense unless (i) in the case of any such sublicense of the Licensed Rights or the Sublicensed Rights, Licensor has consented thereto, which such consent shall not be unreasonably withheld, conditioned or delayed, (ii) in the case of any such sublicense of the Sublicensed Rights, such sublicense complies with the terms and conditions set forth in the CPEX License Agreement or Reprise License Agreement, as applicable; and provided, further, that except for sublicenses granted in respect of Development and Commercialization of the Product in Canada, Licensee will not grant any such sublicenses during the first two (2) years immediately following the Effective Date.

(b) Licensee will be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.4.

(c) Each such sublicense granted by Licensee in accordance with this Section 2.4 will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of (i) this Agreement as are applicable to Licensee as licensee hereunder and (ii) the CPEX License Agreement and the Reprise License Agreement as are applicable to Licensee as a sublicensee thereunder.

(d) Licensee will provide Licensor with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(e) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement (except to the existence of any obligations to disclose such sublicense agreement to the licensors under CPEX License Agreement or the Reprise License Agreement, as applicable).

(f) Each such sublicense granted by Licensee will terminate immediately upon the termination of this Agreement, unless:

(i) such sublicensee is not in material breach of its obligations thereunder,

(ii) if this Agreement was terminated for Licensee's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensee within thirty (30) days after such termination; and

(iii) such sublicensee agrees in writing to be bound directly to (A) Licensor as licensee under the Licensed Rights and sublicensee under the Sublicensed Rights in accordance with the terms and conditions of this Agreement and (B) CPEX and Reprise in accordance with terms and conditions of the CPEX License Agreement and the Reprise License Agreement, respectively.

2.5 **Licenses Granted by Licensee to Serenity.**

(a) ***License for Development and Commercialization Activities***. Subject to the terms and conditions of this Agreement Licensee hereby grants to Serenity and its Affiliates, under

Licensee's rights in any and all intellectual property (including, without limitation, Know-How and any Patent Rights, trademarks, and copyrights) with respect to the Product that Licensee or any of its Affiliates owns or otherwise controls by license or otherwise,

(i) an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to Develop, Commercialize, and Manufacture outside the Territory Products for any Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments;

(ii) in the event that Licensor engages, in accordance with Section 2.6, Section 6.2, Article 14, or otherwise under the terms and conditions of this Agreement, in any Development, Commercialization, or Manufacture of Products in the Territory for any Indications, an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to so Develop, Commercialize in the Territory, and Manufacture such Products for such Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments; and

(iii) in the event that Licensor engages in any Development of Products in the Territory for any Indications in connection with any Development Activities contemplated by Article 6, a non-exclusive sublicense to Develop such Products for such Indications, which such sublicense shall not bear any royalties, fees, or milestone payments.

(b) Sublicensing by Licensor.

(i) Subject to the terms and conditions of this Agreement, Licensor shall have the right to grant to Third Parties sublicenses under the license granted to Licensor under Section 2.5(a); provided that Licensor hereby covenants that it will not grant any such sublicense unless Licensee has provided its consent, which consent shall not be unreasonably withheld or delayed and such sublicense complies with the terms and conditions set forth in this Agreement.

(ii) Licensor shall be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.5(b).

(iii) Each sublicense agreement granted by Licensor in accordance with this Section 2.5(b) will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of this Agreement as are applicable to the intellectual property so licensed by Licensee to Licensor under Section 2.5(a).

(iv) Licensor will provide Licensee with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(v) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement.

(vi) Each such sublicense granted by Licensor in accordance with this Section 2.5(b) shall terminate immediately upon the termination of this Agreement, unless:

(A) such sublicensee is not in material breach of its obligations thereunder,

(B) if this Agreement was terminated for Licensor's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensor within thirty (30) days after such termination; and

(C) sublicensee agrees in writing to be bound directly to Licensee as licensee under the intellectual property sublicensed under such sublicense.

(c) Right of Reference or Use.

(i) Licensee hereby grants to Licensor a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation (for purposes of this Section 2.5(c), "Licensee Regulatory Approvals and Regulatory Documentation") relating to the Compound and any Products in respect of which Licensee is the sponsor for purposes of:

(A) Licensor's Development, Commercialization, or Manufacture of Products outside the Territory and

(B) Licensor's Development, Commercialization, or Manufacture of Products for any Indications inside the Territory in the event that Licensor engages in any such Development, Commercialization, or Manufacture of Products in the Territory for such Indications in accordance with Section 2.6, Section 6.3, and/or Article 14, or otherwise under the terms and conditions of this Agreement.

(ii) The Parties agree that prior to any exercise by Licensor of the Right of Reference or Use granted by Licensee to Licensor under Section 2.5(c)(i), the Parties will mutually agree upon the amount and timing of one or more payments by Licensor to Licensee as consideration to Licensee for the grant of such Right of Reference or Use, which such payments shall be fair and reasonable in respect of the expenditures that Licensee incurs to obtain such Regulatory Approvals and Regulatory Documents and only payable in the event that such Regulatory Approvals and/or Regulatory Documents are referenced or used by Licensor to support a Regulatory Approval of the Product that is granted by the applicable Regulatory Authority.

(iii) The Parties agree that for purposes of Section 2.5(c)(ii),

(A) [***]; and

(B) to the extent Licensor licenses or sublicenses the Commercialization of any Products pursuant to any arrangement that becomes effective following the first anniversary of the Effective Date and in respect of which the applicable Regulatory Approval has been supported at least in part by any Regulatory Approvals or Regulatory Documents of Licensee that are referenced or used as contemplated by this Section 2.5(c), payments of such consideration in respect of any Calendar Quarter will not exceed more than [***] percent ([***]%) of

the consideration received by Licensor from any sublicensee of Licensor in respect of such Commercialization.

2.6 **Right of First Negotiation**. Licensee covenants and agrees that if at any time during the Royalty Term with respect to any country in the Territory, Licensee decides to seek to negotiate an agreement with any Third Party relating to the Commercialization of Generic Products in such country by such Third Party, Licensee will not enter into any such negotiations with any such Third Party before providing Licensor prior written notice thereof, whereupon Licensor will, upon written notice to Licensee within thirty (30) days after the receipt of such notice from Licensee, have the right to enter into good faith, exclusive negotiations with Licensee with respect to Licensor obtaining the right to so Commercialize in such country Generic Products, and further provided that as a condition to Licensee agreeing to grant Licensor any rights to so Commercialize any Generic Products for any Indications in any country in the Territory, Licensor must demonstrate that Licensor possesses or otherwise has access to the resources required to so Commercialize any such Generic Products and Licensor agrees not to otherwise Commercialize any Generic Products in the Territory. Notwithstanding anything to the contrary set forth herein, Licensee has the right to Develop and Commercialize Generic Products in any country in the Territory and the TRxs in respect of such Commercialization of Generic Products by Licensee will be included in TRxs of Generic Products for purposes of the definition of Royalty Term, provided that if Licensee Launches any such Generic Product prior to the Launch of a Generic Product in any country in the Territory prior to the Launch in such country of a Generic Product by a Third Party, then Licensee must obtain the written consent of Licensor prior to such Launch.

With respect to Products, Licensor from time to time may notify and demonstrate to Licensee that Licensor possesses or has access to the Commercialization resources required for Commercialization of such Products in the Territory. Licensee agrees that upon demonstration that Licensor possesses or has access to such resources, Licensee will in good faith consider Licensor to provide such Commercialization activities prior to negotiating an agreement with a Third Party related to such Commercialization activities.

2.7 **No Implied Rights or Licenses**. No Party grants to the other Parties any rights or licenses in or to any intellectual property right or regulatory right whether by implication, estoppel, or otherwise, except to the extent expressly provided in this Agreement. Nothing in this Agreement shall in any manner limit the activities of Licensor or its Affiliates with respect to the Product outside the Territory.

3. JOINT STEERING COMMITTEE AND ALLIANCE MANAGERS.

3.1 **Generally**.

(a) ***Joint Steering Committee***. Licensor and Licensee shall form the Joint Steering Committee. The JSC will have only such powers as are specifically delegated to it in this Agreement, and such powers shall be subject to the terms and conditions set forth in this Agreement.

(b) ***JSC Subcommittees***. The JSC is hereby authorized to appoint one or more JSC Subcommittees to which the JSC may assign responsibility for specific matters (including, without limitation, matters arising with respect to Development, Commercialization, and Manufacturing. Each JSC Subcommittee will have only such powers as are specifically delegated to it by the JSC, and the delegation of any such powers to any JSC Subcommittee shall be subject to the terms and conditions set forth in this Agreement.

(c) ***Limitation of Power of JSC and JSC Subcommittees***. Without limiting the generality of Sections 3(a) and 3(b), neither the JSC nor any JSC Subcommittee shall have any power to amend this Agreement or bind or incur liability on behalf of either Party without such Party's express prior written authorization.

(d) ***Compliance with JSC and JSC Subcommittee Decisions***. Each Party will comply with the decisions of the JSC and any JSC Subcommittee to the extent such decisions arise from the JSC or such JSC Subcommittee, as applicable, carrying out its powers and responsibilities as set forth in this Agreement and not otherwise inconsistent with the terms and conditions of this Agreement. Notwithstanding the foregoing, and is expressly set forth herein, Licensee shall have the sole and absolute right and discretion to decide matters related to the Commercialization, Manufacturing, or Development of the Product.

3.2 **Membership and Governance of JSC and JSC Subcommittees.**

(a) ***Membership.***

(i) The JSC will be comprised of six (6) members who, except as otherwise provided in clause (iii) of this Section 3.2(a), are employees of the Parties (each a "JSC Member"), with three (3) JSC Members designated by Licensor and three (3) JSC Members designated by Licensee.

(ii) Each JSC Subcommittee will be comprised of the total number of members (each a "JSC Subcommittee Member") as is designated by the JSC in forming such JSC Subcommittee, with the number of JSC Subcommittee Members appointed to such JSC Subcommittee from each Party to be designated by the JSC in forming such JSC Subcommittee. In determining the number of JSC Subcommittee Members to serve on any JSC Subcommittee formed by the JSC, the JSC will provide that the number of such JSC Subcommittee Members to be designated by each Party will be reasonable with respect to the experience and expertise of the human resources of each such Party in respect of the matters for which such JSC Subcommittee is responsible.

(iii) Each of Licensor and Licensee, upon prior written notice to the other Party, may (i) replace each person such Party has designated as a JSC Member or a JSC Subcommittee Member for any reason at any time, upon prior written notice to the other Party, (ii) designate a substitute for each person such Party has designated as a JSC Member or JSC Subcommittee Member, and (iii) appoint non-employees of such Party as JSC Members and JSC Subcommittee Members only upon the prior consent and approval of the other Party.

(b) ***Decision-Making***. While the JSC and each JSC Subcommittee will seek to decide matters under their respective consideration by consensus of all of its members, Licensee reserves the right to decide each such matter in its sole and absolute discretion.

(c) ***Meetings***. The JSC and each JSC Subcommittee will meet as agreed upon by the JSC Members or the applicable JSC Subcommittee Members, respectively, in person or by teleconference or video-teleconference; provided that the first meeting of the JSC Committee or such JSC Subcommittee, as applicable, will be within ninety (90) days after the Effective Date.

(d) ***Observers***. Except for matters in respect of which the JSC or any JSC Subcommittee needs to meet in executive session, the meetings of the JSC and any JSC Subcommittee

may be attended by non-Member observers at the invitation of an executive officer of either Party (the "Inviting Party"), provided that (i) the Inviting Party provides reasonable prior notice of such invitation to the other Party, (ii) the other Party has consented to such invitation in advance of the applicable meeting, which such consent shall not be unreasonably withheld, delayed or conditioned and (iii) any such observer has agreed in writing to obligations to safeguard the confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations in Section 13.2.

(e) Chairperson.

(i) Of JSC. At the first meeting of the JSC following the Effective Date and at the first meeting of the JSC in each calendar year beginning after the Effective Date, the JSC Members will select a chairperson to serve until such person's successor has been designated in accordance herewith. The chairperson of the JSC shall rotate annually between JSC Members designated by Licensor and those designated by Licensee. The first chairperson of the JSC shall be selected from the JSC Members designated by the Licensee.

(ii) Of Each JSC Subcommittee. Each JSC Subcommittee shall have a chairperson appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(f) Secretary.

(i) Of JSC. The chairperson of the JSC shall designate a secretary of the JSC who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within thirty (30) days after each meeting of such committee setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JSC. Such minutes shall be effective only after being approved by both Parties. Definitive minutes of all committee meetings shall be finalized no later than sixty (60) days after the meeting to which the minutes pertain.

(ii) Of Each JSC Subcommittee. Each JSC Subcommittee shall have a secretary appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(g) Term of JSC and JSC Subcommittees.

(i) The JSC shall continue to exist for the Term of this Agreement or upon its termination upon mutual agreement of the Parties.

(ii) Each JSC Subcommittee shall continue to exist for the term to be set forth by the JSC in establishing such JSC Subcommittee, but in no event for a period extending beyond the Term of this Agreement

(h) Alliance Managers.

(i) Each of Licensor and Licensee shall appoint an Alliance Manager, who shall be an individual authorized to act as such Party's point of contact for communications between and among the Parties relating to the Commercialization, Manufacturing and Supply, and any Development Activities contemplated by this Agreement. Each Party may change its designated Alliance Manager from time to time upon written

notice to the other Party. The Alliance Manager of a Party may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

(ii) Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between and among the Parties and within the JSC and each JSC Subcommittee.

(iii) Each Alliance Manager will also: (i) be the point of first referral in all matters of conflict resolution; (ii) identify and bring disputes to the attention of the JSC or the relevant JSC Subcommittee, as applicable, in a timely manner; (iii) plan and coordinate cooperative efforts and internal and external communications; and (iv) take responsibility for ensuring that governance activities, such as the conduct of required JSC and JSC Subcommittee meetings and production of meeting minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed

(i) Dispute Resolution.

(i) In the event that any dispute arises with respect to matters falling within the scope of the role and the powers and responsibilities of the JSC or any JSC Subcommittee as set forth in or contemplated by this Article 3 or elsewhere in this Agreement, then either Licensor or Licensee or any of the Members of such Committee may notify the Alliance Managers of such disputed matter.

(ii) The Alliance Managers shall discuss in good faith any such disputed matter referred to them in accordance with Section 3.2(i)(i). If the Alliance Managers are unable to resolve any such matter, either Licensor or Licensee may refer the matter to the Chief Executive Officer or President of Licensor and the Chief Executive Officer, President, or an Executive Vice President of Licensee, which such two individuals shall meet at an agreed location or by telephone to resolve the matter within twenty (20) days after the meeting at which such matter arose.

(iii) If such two officers of the Parties are unable to resolve the disputed matter so referred to them in accordance with Section 3.2(i)(ii) within an additional thirty (30) day period, then the following procedures shall apply:

(A) in the case of matters with respect to which Licensee is authorized hereunder to decide in its sole and absolute discretion, including, without limitation, any Commercialization or Manufacturing and Supply matter, Licensee shall have final decision-making rights with respect thereto and shall promptly provide written notice to Licensor of its final position regarding such matter and Licensor will comply with the position taken by Licensee on such matter unless compliance with such position would result in the incurrence of a direct material financial expenditure or imposition of some other non-financial burdensome obligation upon Licensor that would be greater than would have been the case absent compliance with such position, which in such case shall be referred for dispute resolution under Section 15.8 and

(B) in the case of matters with respect to which Licensee is not authorized hereunder to decide such matters in its sole and absolute discretion, such matters shall be referred for dispute resolution under Section 15.8.

3.3 **Committee Oversight of Commercialization Activities.**

(a) ***Role***. The JSC and any JSC Subcommittee established for the purpose of oversight of Commercialization Activities, will monitor, assess, and make recommendations to Licensee in respect of the Commercialization of the Product contemplated in Article 4 of this Agreement.

(b) ***Powers and Responsibilities***. With respect to Product Commercialization Activities, the powers and responsibilities of the JSC and any JSC Subcommittee established for the purpose of oversight of such Commercialization Activities are limited to the matters set forth in this Section 3.3 and Article 4. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify, or waive compliance with this Agreement with respect to Commercialization Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Commercialization Plans for the Product and any Indications. Notwithstanding the foregoing, Licensee reserves the right to decide each such Commercialization matter in its sole and absolute discretion, including amending or modifying any Commercialization Plan.

(c) ***Annual Review of Commercialization Plan***. On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities will review, analyze, and comment on the Annual Commercialization Plan then in effect and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Commercialization Activities contemplated by the Annual Commercialization Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Commercialization Plan;

(ii) an assessment of whether the strategic objectives set forth in the Annual Commercialization Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(iii) the submission to Licensee of any recommended revisions to the Annual Commercialization Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

(d) ***Regulatory Exclusivity***. The JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor the process of applying for and securing Regulatory Exclusivity that may be available under the applicable Law of countries in the Territory, including, without limitation, any data or market exclusivity periods such as those periods listed in the FDA's Orange Book. Each of Licensor and Licensee shall use Commercially Reasonable Efforts to cooperate with each other and to take such reasonable actions to obtain such Regulatory Exclusivity in each country in the Territory.

3.4 **Oversight of Manufacturing and Supply Activities.**

(a) ***Role***. The JSC and any JSC Subcommittee responsible for oversight of Manufacturing and Supply Activities will monitor, assess, and make recommendations to Licensee in respect of the manufacture and supply of the Product as contemplated in Article 5 for purposes of Commercializing the Product for any Indications that are the subject of Regulatory Approvals and any Development Activities in respect of the Product for the PNE Indication, any Additional Indications and the Nocturia Indication throughout the Territory.

(b) ***Powers and Responsibilities***. With respect to Product Manufacturing Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Manufacturing Activities are limited to the matters set forth in this Section 3.4 and Article 5. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Manufacturing Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Manufacturing and Supply Plan for the Product. Notwithstanding the foregoing, Licensee reserves the right to decide each such manufacturing and supply matter in its sole and absolute discretion, including amending or modifying any Manufacturing and Supply Plan.

(c) ***Annual Review of Manufacturing and Supply Plan***. On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Manufacturing Activities will review, analyze, and comment on the Manufacturing and Supply Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Manufacturing Activities contemplated by the Manufacturing and Supply Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Manufacturing and Supply Plan; and

(ii) an assessment of whether the strategic objectives set forth in the Manufacturing and Supply Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties.

3.5 **Oversight of Development Activities.**

(a) ***Role***. The JSC and any JSC Subcommittee responsible for oversight of any Development Activities contemplated in Article 6 of this Agreement will monitor such Development Activities. In this role the JSC or such JSC Subcommittee, as applicable, will (i) assist Licensee in overseeing any Development of, Clinical Studies for, and preparation and submission of Regulatory Documentation for obtaining Regulatory Approval of the Product contemplated by any Development Plan, including, without limitation, review of any relevant Regulatory Documents and Regulatory Documentation and (ii) provide a forum for sharing advice, progress, and results and documents, including, without limitation, relevant Clinical Study designs, protocols, study reports, and any other material information with respect to any such Development Activities.

(b) ***Powers and Responsibilities***. With respect to any Product Development Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Development Activities are limited to the matters set forth in this Section 3.5 and Article 6. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Development Activities, including, without limitation, any Development Plan in effect from time to time. Notwithstanding the foregoing, Licensee reserves the right to decide each such Development matter in its sole and absolute discretion, including amending or modifying any Development Plan.

(c) ***Annual Review of Development Plan***. If Licensee determines to engage in any Product Development Activities in accordance with Article 6, on an annual basis, beginning in

the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC and any JSC Committee responsible for oversight of Development Activities that Licensee may so determine to undertake in accordance with Article 6 will review, analyze, and comment on the Development Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(A) an assessment of whether the Development Activities contemplated by the Development Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Development Plan;

(B) an assessment of whether the strategic objectives set forth in the Development Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(C) the submission to Licensee of any recommended revisions to the Development Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

4. COMMERCIALIZATION.

4.1 **Preparation and Scope of Commercialization Plan.**

(a) ***Preparation***. Licensee agrees to prepare and provide to Licensor within one hundred twenty (120) days immediately following the Effective Date the initial Commercialization Plan.

(b) ***Scope***. The Commercialization Plan for the Product in respect of the Nocturia Indication, PNE Indication and any Additional Indication will consist of a Pre-Launch Commercialization Plan, an Annual Commercialization Plan, and, in respect of the initial three-year period following the Effective Date, the three-year Commercialization Plan described below.

4.2 **Timing of Product Launches**. The initial Commercialization Plan will set forth the timing of the Launch of the Product in the United States for the Nocturia Indication. To the extent, Licensee or any sublicensee intends in accordance with Article 6 to engage in any Development Activities in order to (a) Commercialize the Product for the Nocturia Indication in Canada, the Commercialization Plan then in effect will be amended to include such Commercialization at such time and (b) Commercialize any Product for the PNE Indication and any Additional Indication in either country in the Territory, the Commercialization Plan then in effect will be amended to include such Commercialization at such time.

4.3 **Diligent Commercialization of the Product in the Territory.**

(a) Licensee covenants that at all times during the Term of this Agreement it will use Commercially Reasonable Efforts to Commercialize the Product in each country in the Territory, including, without limitation, the making and implementation of decisions and allocation of Licensee's resources for the purpose of achieving the objectives set forth in the Commercialization Plan, which such objectives will include, without limitation, the placement of the Product in First Position in all Detailing of the Product with the Sales Representatives for the Product for the First Position Period achieving the timing and geographic extent of Detailing of the Product set forth in the Commercialization Plan, and the continued optimization of such Detailing to maximize Net Sales of the Product.

Failure by Licensee to use Commercially Reasonable Efforts to Commercialize the Product will be deemed to be a material breach of this Agreement for purposes of Section 14.3.

(b) The term "First Position Period" means the four (4) year period commencing upon the Launch of the Product in the United States; provided, however, that if Licensee has not been the subject of a Change of Control prior to the end of such four-year period, the First Position Period shall be extended to the earlier of (x) the fifth (5th) anniversary of the commencement thereof and (y) any such Change of Control; and further, provided, however, that if any such Change of Control occurs prior to the fourth (4th) anniversary of the commencement of the First Position Period, then the party surviving such Change of Control will be obligated to continue Detailing of the Product in First Position until such fourth (4th) anniversary and Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until the fifth (5th) anniversary of the commencement of the First Position Period, and if such Change of Control occurs after the fourth (4th) anniversary of such commencement of the First Position Period but before the fifth (5th) such anniversary, then Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until such fifth (5th) anniversary.

4.4 **Commercialization Plan and Budgets, Generally.**

(a) In General. Subject to the terms of this Agreement, the preparation of the Commercial Plan and any and all updates, revisions, amendments, and the like thereof will be the responsibility of Licensee, and Licensee will bear the expense of the preparation of the initial Commercial Plan and any and all updates, revisions, amendments and the like thereof. The Commercialization Plan for the Product for each Indication for which Regulatory Approval is obtained in each country in the Territory will include the following:

(i) prior to the Launch of a Product, a detailed Pre-Launch Commercialization Plan covering the period from the date such pre-Launch Commercialization Plan as approved by the JSC or the JSC Subcommittee responsible for oversight of Commercialization and adopted by Licensee (generally, upon commencement of the first Phase 3 Clinical Studies in respect of such combination through the end of the second (2nd) full Calendar Year following Launch of the Product for such Indication in such country (the "Pre-Launch Commercialization Plan"), provided that the Pre-Launch Commercialization Plan for the Product for the Nocturia Indication for the United States is set forth in the Commercialization Plan in Exhibit 4.4 to be attached hereto following its preparation and adoption in accordance with the provisions of this Agreement);

(ii) an annual Commercialization plan and budget for such Product (the "Annual Commercialization Plan") for each full Calendar Year following the end of the period of time covered in the Pre-Launch Commercialization Plan for such Product, each of which such annual Commercialization Plans shall be reviewed and analyzed by the JSC (or the JSC Subcommittee responsible for oversight of Commercialization) in accordance with Section 3.3(c)(ii);

(iii) a three-year Commercialization plan and budget (the "Long-Term Commercialization Plan") that sets forth the Branding Strategy for the Product for

the initial three year period, the anticipated Commercialization programs and funding requirements for the Commercialization of the Product for such combination during such three-year period, and anticipated gross sales and Net Sales of the Product during each quarter in such three-year period, and which such Long-Term Commercialization Plan will be used to guide the formulation of the applicable Pre-Launch Commercialization Plan and the Annual Commercialization Plan for such Product.

(b) ***Content of Commercialization Plan, More Specifically***. The Commercialization Plan will specify in detail the content of the Commercialization Activities contemplated hereby.

(c) ***Preparation of Serenity Trademark Standards***. As part of the preparation of the initial Commercialization Plan, Licensee will prepare a proposed set of Serenity Trademark Standards for review and approval by the JSC (or the JSC Subcommittee responsible for Commercialization matters) in accordance with Section 3.3(b).

4.5 **Annual Commercialization and Pre-Launch Commercialization Plans.**

(a) Interim Updating Annual Commercialization Plan. Each Annual Commercialization Plan shall be updated by Licensee as frequently as needed during a Calendar Year to take into account developments in the Commercialization of the Product for the applicable Indication and country.

(b) Pricing and Reimbursement Approvals.

(i) Where pricing and reimbursement approvals are required for Commercialization of the Product in any country in the Territory, Licensee, will be responsible for obtaining such approvals in a timely manner, and shall consider in good faith any suggestions and comments from or on behalf of Licensor with respect thereto.

(ii) As part of its responsibility for oversight of Commercialization Activities, the JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall review and comment on matters relating to pricing and reimbursement approvals in respect of the Product. Such review shall include review of any materials, presentations, documents, agendas, and other relevant information to be presented or followed in meetings and communications with Regulatory Authorities and third party payors to the extent the timing of such meetings and communications reasonably allows for such review and the outcome of any such meetings.

(iii) Following any meetings or material communications with Regulatory Authorities and third party payors relating to pricing and reimbursement approvals, Licensee will provide to the members of the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities, copies of any materials, presentations, documents, agendas, and other relevant information to be presented or followed at such meetings, to the extent not previously provided to the members of the JSC or such JSC Subcommittee pursuant to clause (ii) of this Section 4.5(b), and a summary of the outcome of such meetings.

4.6 **Sales Training.**

As specified in the Commercialization Plan and in accordance with dates specified therein, Licensee, at its expense, will develop a sales training plan and sales training materials for the Product for the Nocturia Indication in the United States and, if Licensee determines to Develop, directly or indirectly through a sublicensee, the Product for the Nocturia Indication in Canada, a sales training plan and sales training materials therefor. The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities, as applicable, will review such training materials and make recommendations for any revisions and updates thereto as the JSC or such JSC Subcommittee, as applicable, may deem appropriate. Thereafter, Licensee, at its expense, will train its Sales Representatives in accordance with such sales training plan and sales training materials in sufficient time to ensure that the Sales Representatives are fully trained prior to the date specified in the Commercialization Plan for the Launch of the Product for the Nocturia Indication in the United States and, if applicable, Canada.

4.7 **Advertising and Promotional Materials and Promotional Policies.**

(a) Tools, Materials, and Samples.

(i) Licensee, at its expense, and in accordance with the Commercialization Plan, will develop all advertising and promotional tools and materials relating to the Commercialization of the Product in the Territory.

(ii) The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor Licensee's use of such tools and materials.

(b) Use of Promotional Materials by Sales Representatives. Licensee agrees that:

(i) it will instruct its Sales Representatives to use, and will use Commercially Reasonable Efforts to train and monitor its Sales Representatives to ensure that such Sales Representatives use, only promotional materials, the Product Samples, and literature approved for use under this Section 4.6 for the promotion of the Product in the Territory;

(ii) any promotional material, promotional literature, and the Product Samples supplied to it shall not be misbranded, changed, altered or adulterated by it or any of its agents in any way prior to their distribution or use by such Party or its Sales Representatives; and

(iii) it will instruct its Sales Representatives to do, and will use Commercially Reasonable Efforts to train its Sales Representatives to do, and will establish appropriate internal systems, policies and procedures for the monitoring of its Sales Representatives with the goal of ensuring that such personnel do, the following:

(A) limit claims of efficacy and safety for the Product to those that are (1) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of the Product in any respect from those claims of efficacy and safety that are contained in, the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (2) consistent with Applicable Law, and (C) consistent with the Product labeling approved by the FDA and other Regulatory Authorities;

(B) (1) refrain from making any changes in promotional materials and literature provided in accordance with this Section 4.6, and (2) use promotional materials, literature, and Samples within the Territory only in a manner that is consistent with (I) the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (II) applicable Law and (III) the Product labeling approved by the FDA or other applicable Regulatory Authorities; (3) promote the Product in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, such as the FDA Guidance for Industry-Supported Scientific and Educational Activities; the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals; the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers; the Accreditation Council for Continuing Medical Education Standards for Commercial Support of Continuing Medical Education; the American Medical Association Gifts to Physicians From Industry Guidelines; the Pharmaceutical Marketing Research Group Guidelines on market research activities; the Prescription Drug Marketing Act of 1987, as amended, and the rules, regulations and guidelines promulgated thereunder; federal, state and

local agencies and all “fraud and abuse”, and consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti- Kickback Law (42 USC Sec 1320a-7b(b)) and the “Safe Harbor Regulations” which are found at 42 CFR Sec 1001_952 et seq.; the U.S. Foreign Corrupt Practices Act (and foreign equivalents); the U.S. Physician Payments Sunshine Act of 2010; and, to the extent not inconsistent with the foregoing, such Party’s policies communicated in writing to its Sales Representatives in accordance with this Article 4; and (4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any government, or of any agency or instrumentality of any government, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of the Product.

(c) Detailing.

(i) Licensee will use Commercially Reasonable Efforts to Detail the Product in accordance with the Commercialization Plan.

(ii) All written, electronic and visual communications provided by Licensee to its Sales Representatives Detailing the Product regarding Product strategy, positioning, Regulatory Approval, or selling messages for use by such personnel in Detailing the Product will be subject to being monitored by the JSC or the JSC Subcommittee responsible for oversight of Commercialization.

(d) Medical Education Activities. Funding for Medical Education Activities for the Product in the Territory will be set forth in the applicable Annual Commercialization Plan.

(e) Direct-to-Consumer Advertising. In each country in the Territory, Licensee will observe any and all Applicable Law relating to direct-to-consumer advertising for the Product in such country.

(f) Obligations in Respect of Product Samples.

(i) Licensee will: (i) maintain an investigation, corrective and preventive action program for the handling of Product Samples in accordance with its internal policies and procedures; (ii) maintain monitoring and auditing programs capable of detecting losses, potential diversion and falsification of records related to Product Samples; (iii) implement processes for the inventory, distribution reconciliation and storage of Product Samples; (iv) review with the JSC its practices with respect to its contacts and communications with Regulatory Authorities with respect to matters relating to the Product Samples; and (v) administer the Product Samples program described in any applicable Annual Commercialization Plan in accordance with such standard operating procedures for product sampling that comply with “best practices” in the pharmaceutical industry.

(ii) Licensee will be responsible for compliance with Applicable Law with respect to its Product Samples program.

4.8 **Sales and Distribution**. Licensee will be responsible for warehousing and distributing in the Territory the Product and will perform related distribution activities. Licensee will also be solely responsible for handling all returns, recalls (in accordance with Section 4.11), order processing, invoicing and collection, distribution and inventory and receivables.

4.9 **Sales Representatives**.

The following provisions shall apply to each Party's Sales Representatives in the Territory:

(a) Licensee will use Commercially Reasonable Efforts to ensure that it has the appropriate number of Sales Representatives and managers to Commercialize the Product.

(b) Except as otherwise provided in this Article 4, Licensee's Sales Representatives will be full-time employees of Licensee or its Affiliates or an individual acting as an independent contractor as permitted below.

(c) Licensee may engage individuals as independent contractors to provide the Details to be provided by it in a country in the Territory and may use such independent contractors as Sales Representatives for the Product in a country in the Territory. Licensee will inform the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities of the extent to which Licensee engages such independent contractors for purposes of Detailing.

(d) Licensee will be responsible for the compliance by its independent contractors engaged pursuant to this section with applicable terms and conditions of this Agreement and shall be jointly and severally liable with any independent contractors who serve as Licensee's Sales Representatives for any breach of this Agreement or failure by independent contractors to perform such delegated duties (as well as for any breach by such independent contractors of its agreement with Licensee), and shall use Commercially Reasonable Efforts to cause such independent contractor to perform his, her or its services as a Sales Representative in compliance with the provisions of this Agreement. All compensation, reimbursement of costs and other payments to be made to any of such independent contractors shall be solely a matter between Licensee and such independent contractor.

(e) Licensee may from time to time use part-time employee Sales Representatives to sell the Product on behalf of Licensee in a country to the extent that such use is consistent with Licensee's practice in such country with respect to the majority of its other pharmaceutical products.

(f) Licensee will use Commercially Reasonable Efforts to provide full training (both general and Product-specific training) to its Sales Representatives, to deploy such number of Sales Representatives as may be necessary to fulfill its duties to Commercialize the Product and, consistent with its normal business practices, to minimize turnover of its Sales Representatives Detailing the Product and to cause its Sales Representatives to adhere to the sales call plan included in the Annual Commercialization Plan. Licensee will establish reasonable qualifications and experience levels (measured in years of experience selling or promoting ethical pharmaceutical products to health care professionals with actual prescribing authority) for Sales Representatives, and Licensee will use Commercially Reasonable Efforts to provide Sales Representatives that meet such qualifications and experience levels. Unless the JSC establishes a different time, within forty-five (45) days after the end of each Year, Licensee will provide Licensor and the JSC with a report with respect to the number of its Sales Representatives assigned to the promotion of the Product and the length of time each such Sales Representative has been assigned to the promotion of the Product to the extent not previously provided to the JSC.

(g) In the event that information comes to Licensor's attention that provides it a reasonable basis to believe that Licensee's Sales Representatives may have (i) violated any Applicable Law, or (ii) failed to provide satisfactory service or to comply with this Agreement, Licensor will have the right to request that Licensee immediately assess the performance of such individual, and to exercise any other rights or remedies available to Licensor under this Agreement, at law or in equity. Licensee will promptly use Commercially Reasonable Efforts to evaluate and resolve such issue in accordance with its policies or as it may otherwise deem appropriate, will (to the extent permitted by Applicable Law) keep Licensor informed of the progress of, and information learned during, its evaluation, and within fifteen (15) Business Days after Licensor first brought such information to Licensee's attention will provide Licensor, to the extent possible in compliance with Applicable Law, with a reasonably detailed written report summarizing any steps taken toward resolution of the matter.

(h) Licensee will comply with all Applicable Laws, rules and regulations applicable to the hiring, employment, and discharge of its Sales Representatives and its employees involved in marketing and promoting the Product. Licensee represents to Licensor that Licensee is an equal opportunity employer and does not discriminate against any person because of race, color, creed, age, sex, or national origin.

(i) Licensee will be responsible for any failure of its Sales Representatives or employees to comply with the terms of this Agreement.

(j) Licensee will be solely responsible and liable for all probationary and termination actions taken by it with respect to its Sales Representatives, as well as for the formulation, content, and for the dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its Sales Representatives.

(k) Licensee shall in its sole discretion have the right to determine the configuration of its sales force(s) including, the geographical assignments of its Sales Representatives.

4.10 **Incentive Plans for Sales Representatives**. Licensee, in its sole discretion, will establish and implement a target bonus or sales incentive program whereunder Licensee's Sales Representatives are compensated for their efforts with respect to the Product in a manner consistent with such Party's other programs for similar products (and taking into consideration the commercial life cycle of the Product). All such programs shall be in compliance with all Applicable Law.

4.11 **Product Claims**. Licensee will not, and will cause each of its Sublicensees, contractors, and other agents not to, make any medical or promotional claim for the Product beyond the scope of the relevant Regulatory Approvals then in effect for the Product; provided, that Licensee may, subject to Section 13.7, distribute any information concerning the Product or its use, including scientific articles, reference publications and healthcare economic information, in accordance with Applicable Law.

4.12 **Recalls and Withdrawals**.

(a) Following consultation between Licensee and Licensor (or its designee), Licensee shall have final decision-making authority with respect to any recall or withdrawal of the Product from any market.

(b) The costs of any such recall or withdrawal will be borne by Licensee.

(c) In the event of any recall or withdrawal, Licensee shall implement any necessary action, with assistance from Licensor as reasonably requested by Licensee.

5. MANUFACTURE AND SUPPLY OF PRODUCTS.

5.1 **Manufacture and Supply of the Product, Generally**. Licensee will be responsible for the manufacture and supply of the Product for Commercialization and any Development.

5.2 **Scope of Manufacturing and Supply Plan**. In accordance with Article 5, the Manufacturing and Supply Plan for the Product in respect of the Nocturia Indication, the PNE Indication and any Additional Indication will address manufacturing and supply requirements for both the Commercialization Activities and any Development Activities contemplated by this Agreement.

5.3 **Existing Inventory**. Upon request of the Licensee, Licensor agrees to sell to Licensee at Licensor's cost, any and all inventory of Product, both in bulk drug and finished product form, existing as of the Effective Date. Licensee will make payment for any such inventory of Product requested by Licensee in two equal installments each at the time Licensee makes it first and second royalty payments to Licensee, respectively, in accordance with Article 8.

5.4 **Manufacturing for Licensor**. Licensee agrees that following any written request from Licensor during or after the Term of this Agreement, Licensee will within sixty (60) days after the date of such request, will use Commercially Reasonable Efforts to enter into an agreement with Licensor (which shall be transferable and sublicensable by Licensor to the same extent as contemplated in Section 2.5 in respect of sublicenses granted under this Agreement by Licensee to Licensor) containing fair and reasonable terms and conditions to be negotiated by Licensor and Licensee pursuant to which Licensee will designate under each of the Third Party Supply Agreements (and any successor agreements thereto and additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof) Licensor (and any transferee, sublicensee, or subcontractor of Licensor) as a party for which the applicable Third Party under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements) will manufacture and supply Products thereunder on terms and conditions no less favorable to Licensor as those applicable to Licensee under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements), subject to the agreement of such Third Party. Licensor acknowledges and agrees that any use of such Product so manufactured and supplied will only be used by Licensor for purposes not in conflict with Licensee's rights under this Agreement. With respect to any such additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof, Licensee will use Commercially Reasonable Efforts to cause to be included in such additional agreements provisions that so allow Licensee to so designate Licensor (and any transferee, sublicensee, or subcontractor of Licensor) to so obtain Products and any components thereof in accordance with this Section 5.3.

5.5 **Manufacturing and Supply Plan**. The Manufacturing and Supply Plan for the First Approved Product will be set forth in Exhibit 5.5 to be attached to this Agreement. The JSC or any JSC Subcommittee responsible for reviewing, assessing, and revising this Plan in accordance with Section 3.4(c), including, without limitation, such revision as are necessary to address Development and Commercialization of Products for the Nocturia Indication in Canada, the PNE Indication and any Additional Indications in the United States and/or Canada.

6. DEVELOPMENT ACTIVITIES BY LICENSEE.

6.1 **Determination by Licensee to Engage in Development Activities.**

(a) Within one hundred eighty (180) days immediately following the Effective Date, Licensee will provide written notice to Licensor of Licensee's decision to undertake Development of the Product for the Nocturia Indication in Canada and the PNE Indication in the United States and/or Canada. For any such Indication and country in respect of which Licensee timely provides such notice of its decision to undertake Development of the Product, Licensor and Licensee hereby agree to engage in good faith negotiations in respect of the consideration to be received by Licensor from Licensee from the Commercialization of the Product for the Indication and the country for which Regulatory Approval is obtained as a result of such Development, including, without limitation, consideration in the form of licensing fees, development and

commercialization milestone payments, and royalties. Upon mutual agreement of the Parties, such time period which Licensee must provide its written notice of its decision pursuant to this Section 6.1 may be extended.

(b) As part of the process by which Licensee determines whether to engage in Development of the Product for the Nocturia Indication in Canada and the PNE Indication and any Additional Indications in the United States and/or Canada, the Parties will engage in good faith discussions as to Development Activities that Licensor can undertake to support and collaborate with Licensee with respect to Licensee's undertaking of such Development.

6.2 **Development Plan**. In respect of any Development of the Product specified in Section 6.1 that Licensee decides to undertake in accordance with Section 6.1, Licensee shall include with the notice specified in Section 6.1 a copy of the initial Development Plan in respect of such Development, which such Development Plan will describe the Development Activities necessary or advisable to obtain Regulatory Approvals of the Product for the Nocturia Indication in Canada and/or the PNE Indication and in the United States and/or Canada, as the case may be.

6.3 **Licensor's Rights to Develop and Commercialize**. For the PNE Indication in either country in the Territory and the Nocturia Indication in Canada in respect of which Licensee does not decide in accordance with Section 6.1 to undertake Development, Licensor has the right, as contemplated by Section 2.5(c), to engage in such Development and the Commercialization of the Product for such Indication and country for which Regulatory Approval is obtained as a result of such Development. To the extent that Licensor engages in any such Development Activities and Commercialization Activities under this Section 6.3, Licensor will keep Licensee informed thereof. To the extent that Licensee believes in good faith that such Commercialization Activities by Licensor would compete with the Commercialization of the Product by Licensee contemplated by this Agreement, the Parties will discuss such matter in good faith and seek to agree upon such measures as are reasonable to minimize any adverse impact of such Commercialization Activities by Licensor on such Commercialization of the Product in the Territory by Licensee.

7. REGULATORY MATTERS.

7.1 **Ownership of Product Regulatory Approvals and Documentation**. Licensee shall own all Product Regulatory Approvals and Documentation in respect of each country in the Territory.

7.2 **Conduct and Management of Regulatory Activities**. Licensee will use its Commercially Reasonable Efforts:

(a) to maintain the First Approved NDA in the United States;

(b) to obtain Regulatory Approval for the Product for the Nocturia Indication in each other country in the Territory in accordance with the Development Plan;

and

(c) to obtain Regulatory Approval for the Product for the PNE Indication in each country in the Territory in accordance with the Development Plan.

Any breach by Licensee of its obligations under Section 7.2(a) shall be deemed to be a material breach of this Agreement for purposes of Article 14.

7.3 **Transfer to Licensee of Product Regulatory Approvals and Documentation**. Following the transfer to Licensee of ownership of the Product Regulatory Approvals and Documentation in each such country in the Territory pursuant to Section 2.3(b),

(a) Licensee or its designee shall be the owner of any and all Product Regulatory Approvals and Documentation in each such country in the Territory, subject to the Right of Reference or Use hereby granted by Licensee to Licensor in Section 2.5(c) for purposes of Development and Commercialization of Products outside the Territory;

(b) Except for the Development and Commercialization of Products by Licensor in the Territory pursuant to Section 6.3, Licensee shall have the responsibility, at its expense, for all regulatory activities (including, without limitation, Development Activities undertaken to support obtaining or maintaining Regulatory Approvals) and interactions relating to the Product in each country in the Territory, including without limitation preparing, obtaining, and maintaining Regulatory Approvals in each country in the Territory and all substantive interactions with such Regulatory Authorities relating thereto; and

(c) Licensee shall determine, in its sole discretion, the content of all such submissions and of all correspondence with Regulatory Authorities relating to the Product in the Territory.

(d) To the extent Licensor has not undertaken any Product Development Activities in the Territory under Section 2.5(c), Section 2.6, Section 6.1 and/or Article 14, Licensor hereby grants to Licensee a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation in respect of the Compound and any Products in respect of which Licensor is the sponsor for purposes of Licensee's Development and Commercialization of Products in the Field and in the Territory. In consideration of such grant, Licensee will make one or more payments to Licensor determined in accordance with the same provisions set forth in clauses (ii) and (iii) in Section 2.5(c) in respect of Licensee's grant of the Right of Reference or Use set forth in clause (i) of Section 2.5(c).

7.4 **Regulatory Documentation for Generic Products.**

(a) Each Party shall deliver written notice to the other Party of any notice it receives as to the submission, filing, or approval of an application, including, without limitation, an Abbreviated New Drug Application in the United States or the equivalent thereof in any other country in the Territory, in respect of a Generic Product within three (3) days after receipt or such notice thereof.

(b) Licensee shall have the sole right to respond to each such application, provided that Licensee shall consult with Licensor regarding any such application and the response thereto.

7.5 **Audits**. Licensor will have the continuing right during the Term of this Agreement, upon reasonable prior written notice to Licensee, to inspect, audit, and investigate any facilities, equipment, record-keeping procedures, and records utilized by Licensee and its subcontractors in connection with the Manufacture and Commercialization of the Product and any Development (including, without limitation, the conduct of Clinical Studies) of the Product.

7.6 **Regulatory Authority Communications Received by a Party**.

(a) Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection, or communication by or from any Person, including, without limitation, any Regulatory Authority in any country in the Territory, that may affect the safety or efficacy claims of the Product, have a material adverse effect on the Commercialization of the Product, or that otherwise suggests the Product may be in violation of Applicable Laws in such country.

(b) Upon receipt of such information described in Section 7.7(a), the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for Licensee to take at Licensee's expense.

(c) Each Party shall keep the other Party informed, in a timely manner consistent with the reporting requirements of Regulatory Authorities, of notification of any action by any Regulatory Authority, or notification or other information that the Party receives (directly or indirectly) from any such Regulatory Authority, and provide to such other Party copies of all documents, if any, it received from such Regulatory Authority.

(d) Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to in this Section 7.7.

7.7 **Adverse Event Reporting and Safety Data Exchange.**

(a) Licensee shall be responsible, at Licensee's expense, in each country in the Territory for the monitoring of all clinical experiences, post-marketing experiences, and filing of all required reports with respect to the Product.

(b) Licensor shall transfer to Licensee the patient database, including without limitation the databases, in their entirety, containing pharmacokinetic, pharmacodynamic, efficacy, and safety information, developed in connection with the conduct of Clinical Studies for the Product under U.S. IND 076667, and all information relating thereto, in the format requested by Licensee. Licensor shall have the right to retain a copy of any and all such information transferred to Licensee.

(c) Each Party shall (i) notify the other Party immediately, but in no event later than three (3) Business Days, after becoming aware of any information concerning any complaint involving the possible failure of Product to meet any requirement of Applicable Laws, and any Unexpected Adverse Drug Experience or other serious or unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidents associated with the distribution or use of the Product and (ii) with respect to adverse events, comply with the provisions of this Section 7.7, and the applicable agreements described herein. Specific details regarding the exchange and management of information relating to adverse events related to the use of the Product shall be delineated and product labeling personnel of each Party shall work in good faith together during such time to negotiate an agreement that:

(i) identifies which safety information shall be exchanged, which shall include without limitation all adverse events for any Indication or condition;

(ii) identifies when such information shall be exchanged (which SAE information shall be provided within two (2) Business Days after notification of such SAE);

(iii) provides that Licensee shall (i) have regulatory reporting responsibilities, (ii) manage the global safety database, (iii) be obligated to obtain follow-up information on incomplete safety reports, (iv) review the literature for safety report information, and (v) prepare required periodic safety updates;

(iv) sets forth the roles and responsibilities of the Parties related to review and approval of safety information for inclusion in the Product labeling; provided that Licensee shall have the final decision-making authority with respect to any disputes regarding such activities with respect to Product in accordance with the terms and conditions hereof;

(v) identifies any other details required to appropriately manage safety information for the Product; and

(vi) as soon as reasonably practicable following the Effective Date, but in no event later than sixty (60) days thereafter Licensor and Licensee will agree upon the terms and conditions of the Pharmacovigilance Agreement and will thereupon execute and deliver to the other Party a copy of such Agreement.

7.8 **Remedial Actions.**

(a) Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Product in the Field may be subject to a Remedial Action.

(b) The Parties will assist each other in gathering and evaluating such information as is required to determine the necessity of conducting a Remedial Action with respect to the Product in the Field in the Territory; provided, however, that Licensee shall have sole responsibility for collecting information from its customers in the Territory, including, without limitation, customer complaints, in accordance with the terms and conditions hereof.

(c) Each Party will maintain adequate records to permit the Parties to trace the manufacture of the Product in the Field and the distribution and use of the Product in the Field. In the event Licensee determines that any Remedial Action with respect to the Product in the Field in the Territory should be commenced or Remedial Action is required by any Governmental Authority having jurisdiction over the matter, Licensee will control and coordinate all efforts necessary to conduct such Remedial Action, provided that Licensee shall consult with Licensor or its designee regarding any such Remedial Action.

(d) The cost and expense of a Remedial Action (including the Parties' reasonable costs and expenses in conducting such Remedial Action, but excluding claims described in Article 10) shall be allocated as follows:

(i) If such Remedial Action is due to Licensee's gross negligence or willful misconduct, material breach of this Agreement, or material violation of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensee;

(ii) if and to the extent that such Remedial Action is due to Licensor's gross negligence or willful misconduct, Licensor's material breach of this Agreement, or Licensor's material breach of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensor; and

(iii) if and to the extent that such Remedial Action is due to reasons other than as set forth in Sections 7.8(d)(i) and (ii), then: (A) Licensor shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensor, as Licensor's predecessor in interest; and (B) except for the Development and Commercialization of Product in the Territory by Licensor pursuant to Section 6.3, Licensee shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensee and its contractors; provided, however, that nothing in this Section 7.8(d)(iii) is

intended to limit or supersede any obligation that Renaissance may have in respect of any such lots of the Product subject to such Remedial Action.

8. PAYMENT OBLIGATIONS.

8.1 **Initial Fee**. In consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall pay to Licensor a one-time, nonrefundable, non-creditable initial fee of [***] Dollars ($[***]) on the Effective Date.

8.2 **Commercialization Milestone Payments**. Licensee shall notify Licensor promptly, but in no event later than thirty (30) days, after the first achievement of the relevant sales milestone for the Product as set forth in the table below in this Section 8.2. In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, Licensee shall make the following one-time, nonrefundable, non-creditable milestone payments to Licensor within thirty (30) days after receipt of an invoice from Licensor therefor; provided, however, in the event that the last of the milestone payments described in the table below becomes payable, the due date for Licensee to make payment to Licensor of such milestone payment will be the first anniversary of the payment of the $[***] milestone payment in the penultimate row of the table below.

Milestone Event	**Payment** (millions of Dollars)
Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $50 million in any consecutive 12-month period	$[***]
Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] in any consecutive 12-month period	$[***]
Upon the first time Royalty-Bearing Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] in any consecutive 12-month period	$[***]
Upon the first time Royalty-Bearing Sales by Licensee and its Sublicensees of the Product for all Indications reach $[***] in any consecutive 12-month period	$[***]
Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $[***] in any consecutive 12-month period	$[***]
Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $1.5 billion in any consecutive 12-month period	$[***]

8.3 **Royalties; Non-Royalty Commercialization Consideration.**

(a) ***Royalties***. In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, Licensee shall pay Licensor royalties on Net Sales of the Product by Licensee and any of its Sublicensees and Third Party Distributors in accordance with the rates set forth in the tables set forth below in this Section 8.3(a)(i).

Royalty-Bearing Net Sales in each Calendar Year (millions of Dollars)	**Royalty Rate**
That portion of Annual Net Sales greater than $0 and less than or equal to $500 million	28%
That portion of Annual Net Sales greater than $500 million and less than or equal to $1 billion	30%
That portion of Annual Net Sales greater than $1 billion	33%

(b) Third Party Royalties.

(i) *CPEX and Reprise*. Licensor will be responsible for payment of any amounts payable to CPEX and Reprise under the terms of the CPEX License Agreement and the Reprise License Agreement, respectively.

(ii) *Other Third Parties*.

(A) In the event that after the Effective Date Licensee reasonably determines that it is necessary or advisable for Licensee to obtain a license under any Patent Rights from any Third Party in order for Licensee (each a "Third Party License"; collectively, "Third Party Licenses"), its Sublicensees, and any Third Party Distributors to Commercialize the Product in the Field in any country in the Territory as contemplated by this Agreement, the Parties shall discuss the best course of action to resolve such potential license requirement, provided that such discussions shall not limit or delay Licensee's right to obtain any such Third Party Licenses.

(B) With respect to any such Third Party Licenses that Licensor reasonably agrees are necessary for Licensee to be able to Commercialize the Product in the Field in any country in the Territory, Licensee shall have the right to set off an amount equal to [***] percent ([***]%) of the aggregate of any and all payments required to be paid by Licensee to the licensors under such Third Party Licenses in respect of any Calendar Quarter against payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter; provided, however, that in no event shall the aggregate set off in any Calendar Quarter resulting from such payments in respect of such Third Party Licenses exceed an amount equal to [***] percent ([***%) of the royalty payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter.

(c) ***Royalty Term***. Licensee's obligation under Sections 8.3(a) to pay Licensor royalties on Net Sales of the Product in each country in Territory will apply to any and all sales or other dispositions of such the Product in such country made during the Term of this Agreement.

(d) ***Generic Product***. If, during the Royalty Term, one or more Third Parties is selling in any country in the Territory any product that is a Generic Product in relation to the Product being sold in such country by Licensee or any of its Sublicensees or Third Party Distributors, Licensee's royalty obligations under Section 8.3(a) for sales in such country of the Product shall be reduced as follows:

If the Generic TRxs-to-Total TRxs Percentage in such country during such Calendar Quarter is:	Licensee's royalty obligations under Section 8.3(a) shall be reduced by the Percentage Indicated Below
[***]% or greater	[***]%
[***]%; but less than [***]%	[***]%
[***]%; but less than [***]%	[***]%

8.4 **Reports and Payments**. During the Term of this Agreement following the First Commercial Sale of the Product by Licensee, its Sublicensees, or its Third Party Distributors, within five (5) Business Days after the filing by Licensee of each Form 10-K or Form 10-Q, Licensee shall pay to Licensor the royalty payments payable by Licensee for the Calendar Quarter preceding the Calendar Quarter in which such Form 10-K or 10-Q, as applicable, is filed, and shall provide a report showing, on a country-by-country basis:

(a) the net quantity of the Product sold, total gross sales, an itemized list of the deductions applied to total gross sales, and Net Sales of the Product sold in the Calendar Quarter in respect of which such report has been prepared;

(b) the calculation in Dollars of royalty payments due hereunder with respect to such Net Sales, including any deductions for any offsets in accordance with Section 8.3(b)(ii);

(c) withholding taxes on Net Sales, if any, required by Applicable Laws to be deducted with respect to such royalties; and

(d) the rate of exchange used by Licensee in determining the amount of Dollars payable hereunder.

If no royalty or other payment is due for any period hereunder, Licensee shall so report.

8.5 **Currency of Payment**. All payments to be made under this Agreement shall be made in Dollars by electronic funds transfer to such bank accounts as Licensor may designate from time to time. When Licensee or any of its Sublicensee of Third Party Distributors sells the Product for monies other than Dollars, Licensee will convert any non-Dollar currencies into Dollars with the exchange rate for the purchase of Dollars with such domestic currency as quoted by The Wall Street Journal, New York edition, at an average rate for the Calendar Quarter for which the payment is made.

8.6 ***Accounting***.

(a) Licensee shall determine Net Sales with respect to the Product sold using its standard accounting procedures, consistent with GAAP, as if the Product was a solely owned product of Licensee, except as specifically provided in this Agreement. In the case of amounts to be determined by Third Parties (for example, Net Sales by Sublicensees), such amounts shall be determined in accordance with generally accepted accounting principles in effect in the country in which such Third Party is engaged. Licensor and Licensee also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales. Licensor and Licensee agree that, where such changes are economically material to Licensor, adjustments shall be made to compensate Licensor in order to preserve the same economics as are reflected under this Agreement under Licensee's accounting procedures in effect prior to such change. Where the change is or would be material to Licensor, Licensee shall provide an explanation of the proposed change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.

(b) In the event of the payment or receipt of noncash consideration in connection with the performance of activities under this Agreement Licensee shall advise Licensor of such transaction, including without limitation Licensee's assessment of the fair market value of such noncash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by Licensor and Licensee in good faith.

8.7 **Withholding Tax**. Notwithstanding anything to the contrary herein, in the event that withholding taxes apply with respect to any amounts due from Licensee hereunder, Licensee shall be entitled to withhold from any payment due to Licensor under this Agreement any taxes that Licensee is required to pay and such withholding shall decrease by an equivalent amount the payment due to Licensor. Licensee shall provide Licensor with notification of any anticipated withholding requirements with as much advance notice as practicable and shall cooperate in good faith with Licensor to legally minimize such withholding taxes. Licensee will timely pay to the proper governmental authority the amount of any taxes withheld and will provide Licensor with an official tax certificate or other evidence of tax obligation, together with proof of payment from the relevant governmental authority sufficient to enable Licensor to claim such payment of taxes.

8.8 **Books and Records; Audit Request.**

(a) During the term of this Agreement and for three (3) years thereafter, Licensee shall keep and maintain, and shall cause each of its Affiliates, and Sublicensees, if any, to keep and maintain, at their respective regular places of business complete and accurate books, records, and accounts in accordance with GAAP, or other accounting standards mandated by the U.S. Securities and Exchange Commission if applicable to Licensee, in sufficient detail to reflect all amounts required to be paid under this Agreement, as well as any other books, records or accounts required to be maintained in connection with the Product under any Applicable Laws, necessary to permit the audits contemplated under Section 8.8(b). Prior to destroying any books, records or accounts which are material to the Parties' rights and obligations under this Agreement, Licensee must seek prior written consent from Licensor, which consent may not be unreasonably withheld.

(b) During the term of this Agreement and for three (3) years thereafter, Licensor shall have access to and the right to examine such relevant records and accounts that Licensee is required to maintain pursuant to Section 8.8(a) at Licensee's premises for the sole purpose of verifying the accuracy of any report or payment made under this Agreement in the three (3) preceding years; provided, however, that any such examination: (i) shall not occur more than once during each Calendar Year (except that if as a result of any audit pursuant to this Section 8.8(b), an error in favor of Licensee exceeding five percent (5%) of any payments previously reported as owed by Licensee to Licensor is discovered, the frequency of audits under this Section 8.10(b) shall not be so limited); (ii) shall be during normal business hours upon reasonable prior written notice which shall in no event be less than thirty (30) days; and (iii) shall not unreasonably interfere with Licensee's operations and activities. If Licensor desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to Licensee, to examine such records under conditions of confidentiality with respect thereto at least as stringent as those specified in Article 13. The expense of any such audit shall be borne by Licensor; provided, however, that, if an error of more than five percent (5%) in favor of Licensor is discovered as a result of such audit, then such expenses shall be paid by Licensee. If such accountant concludes that additional payment amounts were owed to Licensor during any period, Licensee shall pay such payment amount (including without limitation interest thereon from the date such amounts were payable) within thirty (30) days after the date Licensor delivers to Licensee such accountant's written report so concluding, unless Licensee notifies Licensor of any dispute regarding the audit. If such accountant concludes that Licensee has overpaid any amounts to Licensor during any period, in Licensor's discretion, Licensee may credit such amounts against future payments due Licensor or Licensor may pay such amounts (including without limitation interest thereon from the date such amounts were payable), unless Licensor notifies Licensee of any dispute regarding the audit. Any Information received by Licensor pursuant to this Section 8.10 shall be deemed to be Confidential Information of Licensee for purposes of Article 13.

8.9 **Blocked Currency**. If by Applicable Laws or fiscal policy of a particular country, conversion into Dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, royalties accrued in such country shall be paid to Licensor in the country in local currency by deposit in a local bank designated by Licensor for such deposit, unless Licensor and Licensee otherwise agree.

8.10 **Interest**. If Licensor does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Licensor from the due date until the date of payment at a rate equal to three month Dollar LIBOR Rate, as reported in the online edition of The Wall Street Journal as of Noon (New York Time) on such due date, or the maximum rate allowable by Applicable Laws, whichever is less.

8.11 **Transaction Expenses**. Licensee shall upon execution and delivery of this Agreement pay the documented reasonable fees and expenses of Licensor's advisors and counsel incurred by Licensor in structuring, negotiating, memorializing, and otherwise undertaking the transaction contemplated by this Agreement. Notwithstanding the foregoing, Licensee's obligation under this Section 8.11 shall be limited to an amount not to exceed $2,000,000.

9. INTELLECTUAL PROPERTY MATTERS.

9.1 **Existing Intellectual Property.**

(a) Other than as provided in this Agreement, neither Party grants any right, title, or interest in any Patent Right, information, or other intellectual property right Controlled by such Party to the other Party.

(b) Except as otherwise provided herein, Licensor shall be responsible for the preparation, filing, prosecution (including, without limitation, any interferences, inter partes proceedings, reissue proceedings, cancellations, oppositions, and reexaminations), and maintenance of any and all Licensed Serenity Patent Rights. Licensor shall consult with Licensee, and consider Licensee's comments, in good faith with respect to the preparation, filing, prosecution, and maintenance of any Licensed CPEX Patent Rights or Licensed Reprise Patent Rights to the extent that Licensor has the right, under any agreement with any applicable licensor, to file, prosecute, and maintain such Licensed Patent Rights.

(c) Licensee agrees and acknowledges that Licensor intends to continue to use, in Licensor's discretion, patent counsel currently retained by Licensor to prosecute and maintain the Licensed Serenity Patent Rights. Licensee shall execute, acknowledge and deliver any instruments, and to do all such other acts, as may be necessary or appropriate in order to enable such patent counsel to continue to prosecute and maintain such Licensed Serenity Patent Rights. The Parties shall reasonably consult with each other, and shall consider any comments from each other in good faith, with respect to the preparation, filing, prosecution, and maintenance of such Licensed Serenity Patent Rights and patent strategy for the Licensed Serenity Patent Rights. Licensee shall reimburse Licensor for all costs and expenses incurred by Licensor after the Effective Date in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights in the Territory, up to an amount not to exceed [***] Dollars
($[***]), which is the estimated cost set forth on Schedule 9.1(c). Licensor shall provide to Licensee copies of any papers relating to the filing, prosecution or maintenance of the Licensed Serenity Patent Rights promptly upon their being filed or received. Licensee shall not knowingly take any action during prosecution and maintenance of the Licensed Serenity Patent Rights.

(d) Licensor shall not knowingly permit any of the Licensed Serenity Patent Rights to be abandoned in any country in the Territory without Licensor first giving Licensee an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of a Licensed Serenity Patent Rights in any country in the Territory, Licensor will provide Licensee with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensee elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Licensed Serenity Patent Rights except that the role of Licensee and Licensor shall be reversed thereunder (except further that Licensee will continue to be responsible for all costs and expenses thereafter incurred in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights). Any such Serenity Patent Right that is subject to such election by Licensee shall otherwise continue to be subject to all of the terms and conditions of the Agreement in the same way as the other Licensed Serenity Patent Rights.

9.2 **Inventions by Licensee.**

(a) ***Disclosure***. Licensee shall promptly disclose to Licensor the invention of any Licensee Inventions.

(b) ***Ownership***. As between the Parties, all Licensee Inventions will be owned and Controlled by Licensee.

(c) ***Patent Filings***.

(i) Licensee, at its expense, will have sole discretion and responsibility to prepare, file, prosecute, and maintain any patent applications and patents claiming Licensee Inventions. The Parties' respective patent counsel shall meet no fewer than once per Calendar Year to discuss strategies for the preparation, filing, prosecution, and maintenance of any such patent applications and patents claiming Licensee Inventions. Licensee shall consider in good faith any comments provided by Licensor with respect to the foregoing. In the event of any dispute between Parties with respect to such strategies, either Party may notify the Alliance Managers for purposes of resolving such dispute; provided, however, that Licensee shall have the final decision-making authority with respect to any such dispute.

(ii) Licensee shall not knowingly permit any Patent Rights with claims to any Licensee Inventions to be abandoned in any country without Licensee first giving Licensor an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of any Patent Right claiming a Licensee Invention in any country, Licensee will provide Licensor with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensor elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Patent Right claiming such Licensee Invention except that the role of Licensee and Licensor shall be reversed thereunder.

9.3 **Infringement, Violation, or Misappropriation by Third Parties.**

(a) ***Notice***. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement, violation, or misappropriation by any Third Party of the Licensed Rights or the Sublicensed Rights of which it becomes aware, and following such notification, the Parties shall confer as to any response thereto. The notice shall set forth the facts of such infringement, violation, or misappropriation in reasonable detail.

(b) ***Response to Infringement, Violation, or Misappropriation by Third Parties***.

(i) If a Third Party is infringing, violating, or misappropriating, or either Party reasonably believes a Third Party may be infringing, violating, or misappropriating any Enforceable IP Right in any country in the Territory, Licensee shall have the first right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement, violation, or misappropriation by counsel of its own selection, at its expense. Licensor shall have the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense. To the extent required by Applicable Laws, Licensor agrees to be joined as a party plaintiff (with Licensor having the right to be represented, if it so desires, by counsel of its own selection and at its own expense) if necessary for Licensee to bring and prosecute such action or proceeding, and to give Licensee reasonable assistance and authority to bring and prosecute such action or proceeding. If Licensee fails to bring an action or proceeding within ninety (90) days after receiving or giving written notice pursuant to Section 9.3(a), then Licensor shall have the right, but not the obligation, to bring and control any such action by

counsel of its own selection, at its expense (with Licensee having the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense). To the extent required by Applicable Laws, Licensee agrees to be joined as a party plaintiff (with Licensee having the right to be represented, if it so desires, by counsel of its own selection and expense therein) if necessary for Licensor to bring and prosecute such action or proceeding, and to give Licensor reasonable assistance and authority to bring and prosecute such action or proceeding. No settlement of any such action or consent judgment or other voluntary final disposition which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may be entered into by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned.

(ii) Each Party shall share in any recoveries obtained in connection with any action or proceeding described in Section 9.3(b)(i) as follows:

(A) each Party's costs and expenses incurred in connection with bringing and prosecuting any such action or proceeding, including without limitation attorneys' fees, first shall be reimbursed from such recoveries, and if such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party, and

(B) if Licensee controlled such action or proceeding Licensee shall receive one hundred percent (100%) of such remaining recoveries, provided that such recoveries shall be deemed Net Sales for purposes of Section 8.3(a)(i); and if Licensor controlled such action or proceeding, each Party shall receive fifty percent (50%) of such remaining recoveries, provided that Licensee's portion shall not be deemed as Net Sales for purposes of Section 8.3(a)(i) in such case.

(c) ***Withdrawal***. If either Party brings an action or proceeding under Section 9.3(b)(i) and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of Section 9.3(b)(i).

(d) ***Oppositions by Parties***. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination, inter partes proceeding, or other attack upon the validity, title, or enforceability of any intellectual property right Controlled by a Third Party that Covers the Product in the Field in any country in the Territory, such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Each Party shall be entitled to separate representation in any such action by counsel of its own choice and at its own expense, and shall cooperate fully with the other Party. The costs of any such action shall be borne by the Party bringing the action, and such Party shall retain any recoveries obtained in connection therewith.

9.4 **Infringement of Third Party Rights.**

(a) ***Notice***. If the Exploitation of the Product pursuant to this Agreement results in a claim, action, suit, or proceeding that such activity infringes or misappropriates the intellectual property rights of a Third Party ("Third Party Infringement Claim"), the Party first

receiving notice thereof shall promptly notify in writing the other Party thereof. The notice shall set forth the facts of the Third Party Infringement Claim in reasonable detail.

(b) ***Litigation***.

(i) Licensee shall have the sole right, but not the obligation, to defend, at its expense, against any Third Party Infringement Claim. Licensee shall have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensee shall not settle any Third Party Infringement Claim that is subject to indemnification pursuant to Section 11.1 without the prior written consent of Licensor, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensor shall cooperate with Licensee, at Licensee's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensor's expense. Licensee will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim.

(ii) If Licensee decides not to commence a defense against any Third Party Infringement Claim pursuant to Section 9.4(b)(i), then Licensee will promptly notify Licensor of such decision in a timely manner so as to allow Licensor, who shall have the right, but not the obligation, to commence such a defense by counsel of its own selection, at its expense (with Licensee having the right to participate in such defense and be represented, if it so desires, by counsel of its own selection and at its own expense). Licensor shall thereupon have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensor shall not settle any Third Party Infringement Claim without the prior written consent of Licensee, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensee shall cooperate with Licensor, at Licensor's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensee's expense. Licensor will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim, subject to Section 11.1.

(iii) Notwithstanding any provisions set forth herein to the contrary, Licensor shall be responsible for continuing to manage, at Licensor's expense, that certain litigation with Ferring Pharmaceuticals that is described in Schedule 10.2. Notwithstanding the foregoing, any settlement of any such action or consent judgment or other voluntary final disposition with respect to the litigation with Ferring Pharmaceuticals described in Schedule 10.2, which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may not be entered into by Licensor without the prior written consent of the Licensee, which consent shall not be unreasonably withheld, delayed or conditioned.

(c) ***Oppositions by Third Parties***. If any patent, trademark, copyright, or other intellectual property right within the Licensed Rights or the Sublicensed Rights becomes after the Effective Date the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, inter partes proceeding, or other attack upon the validity, title, or enforceability thereof, then Licensee shall control such defense at its sole cost. Licensee shall permit Licensor to participate in the proceeding to the extent permissible under Applicable Laws, and to be represented by its own counsel in such proceeding, at Licensor's expense. If Licensee elects not to defend against such action with respect to

any such intellectual property right with the Licensed Rights or the Sublicensed Rights within ninety (90) days after first receiving notice or otherwise becoming aware of such action or proceeding, then Licensor shall have the right to assume defense of such Third Party action at its own expense. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the Parties' expenses in such action, and any remaining amounts shall be retained by the Party defending against such proceeding.

9.5 **Use of Licensed Serenity Trademark.**

(a) Licensee agrees and acknowledges that (i) as between the Parties, Licensor is and shall remain the owner of the Licensed Serenity Trademarks, and (ii) all of the goodwill associated with the Licensed Serenity Trademarks, in all countries of the world, and all uses thereof by Licensee, its Affiliates, sublicensees, and Third Party Distributors shall inure to the benefit of Licensor.

(b) Licensee will cooperate with Licensor for the purpose of protecting, preserving, registering, and enhancing the Licensed Serenity Trademarks and Licensor 's interest therein and in furtherance of such obligations, Licensee will promptly execute and deliver to Licensor all documents and instruments that Licensor, acting reasonably, determines are necessary or prudent from time to time. If and to the extent that Licensee, its Affiliates, sublicensees, or Third Party Distributors obtain any rights (other than the licenses granted herein) to the Licensed Serenity Trademarks in any country in the world, at the request of Licensor, Licensee shall immediately and automatically assign, and ensure that its Affiliates, sublicensees, and Third Party Distributors immediately and automatically assign, to Licensor all right, title and interest in and to the Licensed Serenity Trademarks, and all goodwill with respect thereto.

(c) Licensee will use the Licensed Serenity Trademarks (i) only in compliance with all Applicable Law and the express terms of this Agreement and the Serenity Trademark Standards, and (ii) not as part of any composite trademark in close proximity or in combination with any other trademark.

(d) Licensee agrees to conform, and to cause any of its Affiliates, sublicensees and Third Party Distributors to conform, the manner of their respective use of the Licensed Serenity Trademarks with the policies, specifications, directions, and standards for use thereof set forth in the Serenity Trademark Standards, and to maintain the quality standards of Licensor set forth in the Serenity Trademark Standards with respect to the Products sold. Except to the extent that any use of the Licensed Serenity Trademarks by Licensee and any of its Affiliates, sublicensees, and Third Party Distributors is not in accordance with the Serenity Trademarks Standards, Licensee shall not be required to submit to Licensor any materials bearing any Licensed Serenity Trademark for review and approval prior to the use thereof.

(e) To the extent Licensee desires to use any Licensed Serenity Trademark in a manner not expressly permitted under the Serenity Trademark Standards, Licensee will submit to Licensor for Licensor's review all packaging, advertising, brochures, and other material (including, without limitation, mockups or models thereof), that evidence such use. Within fifteen (15) calendar days after Licensor receives any such material, Licensor will provide Licensee with (i) approval of Licensee's proposed use of the Licensed Serenity or (ii) comments as to any revisions Licensor reasonably believes are necessary or advisable to achieve compliance with the Licensed Trademark Standards. In each case where Licensor provides any such comments, Licensor and Licensee will promptly

discuss and resolve whether any such revisions are necessary or advisable and, if determined to be so necessary or advisable, Licensee will make such revisions. From and after such approval of Licensor of such use, the Serenity Trademark Standards shall be amended or revised to reflect such approved use. {{

(f) All rights in and to any new version, translation, or arrangement of the Licensed Serenity Trademarks, or other change in the Licensed Serenity Trademarks created by Licensee, with Licensor's prior written consent or otherwise, will be and will remain the exclusive property of Licensor, and the provisions of this Agreement will apply to the same.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

10.1 **Mutual Representations and Warranties**. Licensor and Licensee (each, a "**Representing Party**") each hereby represents and warrants to each other, as of the Effective Date and except as otherwise set forth in Schedule 10.2 (in the case of Licensor) and Schedule 10.3 (the case of Licensee), that:

(a) such Representing Party is a corporation or limited liability company, as applicable, duly organized and subsisting under the laws of its jurisdiction of organization;

(b) such Representing Party has the power, authority, and legal right, and is free, to enter into this Agreement on behalf of itself and its Affiliates and to perform its respective obligations hereunder and to cause its Affiliates to perform their respective obligations hereunder;

(c) such Representing Party has the power, authority, and legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

(d) this Agreement constitutes a legal, valid, and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity;

(e) the execution and delivery of this Agreement and the performance of such Representing Party's and its Affiliates' obligations hereunder (i) have been duly authorized and approved by all necessary action by such Representing Party, and all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; (ii) do not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Representing Party, as applicable, in any material way; and (iii) do not, and will not, conflict with or otherwise interfere with in such a manner as to result in a violation, breach, or default under or require any consent that has not been obtained under any contract between such Representing Party and any Third Party;

(f) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other agreements that would prevent or impair such Representing Party's or any of its Affiliates' full and complete exercise of the terms and conditions of the Agreement;

(g) such Representing Party and its Affiliates shall at all times comply with all Applicable Laws relating or pertaining to their obligations under the Agreement;

(h) with respect to the services provided hereunder to the other Party, its Affiliates, and their respective employees, officers, contractors and agents who perform such services have the experience, capability, and resources to efficiently and skillfully perform the services, and shall perform, where applicable, all such services in a professional and workmanlike manner and in accordance with the generally accepted then-current standards, forms, procedures, and techniques established from time to time by the industry;

(i) all of such Representing Party's employees, officers, contractors, and consultants have executed agreements requiring assignment to such Representing Party of all inventions created by such persons in the course of their employment by such Representing Party and obligating each such employee, officer, contractor, and consultant to maintain and safeguard the confidentiality of (i) any information that is confidential to such Representing Party or (ii) any information that is confidential to any other Person and that such Representing Party is obligated to maintain and safeguard as confidential; and

(j) neither such Representing Party, nor any of its employees, officers, subcontractors, or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a.

10.2 **Additional Representations, Warranties, and Covenants of Licensor**. Licensor hereby represents, warrants, and covenants to Licensee, as of the Effective Date and except as otherwise set forth in Schedule 10.2, that:

(a) Licensor is entitled to grant the rights and licenses purported to be granted to Licensee under this Agreement, and to assign the rights purported to be assigned to Licensee under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Licensee the rights, licenses and sublicenses purported to be so granted in this Agreement;

(b) Licensor is the sole and exclusive owner of all right, title, and interest, in, to, and under the Licensed Rights and has the right under the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights to grant the sublicenses thereunder in accordance with Section 2.2;

(c) the Licensed Rights are free and clear of any liens, charges, encumbrances, or judgments, and Licensor has sufficient rights to grant the licenses and rights purported to be granted herein, free and clear of any security interests, claims, encumbrances, or charges of any kind;

(d) Licensor has not granted, and will not grant during the term of this Agreement, any right, option, license, or interest in or to any of the Licensed Rights that is in conflict with the rights assigned or granted to Licensee under this Agreement;

(e) there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending, or to Licensor's knowledge threatened by, against or involving Licensor, regarding the Licensed Rights, whether at law or in equity, before or by any Third Party, and Licensor

has not received any written communications alleging that it has violated, through the manufacture, Development, import, or other exploitation of the Product, any intellectual property rights of any Third Party;

(f) to Licensor's knowledge:

(i) the patents in the issued Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights are valid and enforceable; and

(ii) no Third Party has asserted that any of the Licensed Rights or the Sublicensed Rights is invalid or unenforceable;

(g) all applications, registrations, maintenance and renewal fees due in respect of any of the Licensed Serenity Patent Rights and, to Licensor's knowledge, the Licensed Reprise Patent Rights and the Licensed CPEX Patent Rights, have been paid and all documents and certificates required to be filed with the relevant agencies for the purpose of maintaining such Licensed Serenity Patent Rights, and to Licensor's knowledge, the Licensed Reprise Patent Rights and Licensed CPEX Patent Rights have been filed;

(h) none of the Licensed Serenity Patent Rights, the Licensed Serenity Know-How and, to Licensor's knowledge, none of the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights were developed with funding from any Governmental Authority such that any Governmental Authority has any march in rights or other rights to use the Licensed Serenity Patent Rights, the License Serenity Know-How, the Licensed Reprise Patent Rights, or the Licensed CPEX Patent Rights;

(i) to Licensor's knowledge, no Third Party has infringed or misappropriated any of the Licensed Rights or the Sublicensed Rights;

(j) all inventors of any inventions included within the Licensed Serenity Patent Rights and, to the knowledge of Licensor, the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights have assigned their entire right, title, and interest in and to such inventions and the corresponding patents and patent applications to Licensor, Reprise, or CPEX, as applicable, and have been listed as inventors in the Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights, as applicable;

(k) no agreements that Licensor or its Affiliates may have with any Third Party provide such Third Party with any rights of first offer, rights of first refusal, or any other rights to make, have made, use, conduct Clinical Studies for, sell, offer for sale, have sold, import, export, or otherwise Exploit the Product in the Field in the Territory or the right to use the Licensed Rights or the Sublicensed Rights in connection with the Exploitation of the Product in the Field in the Territory; and Licensor has received no notice from a Third Party of any suit, action, proceeding, or arbitration pending or threatened against it that the proposed terms and conditions of this Agreement, and the Parties' performance in accordance therewith, do or shall conflict or interfere with in a manner resulting in a breach or default under, or other violation of, any agreements that Licensor or its Affiliates may have with any Third Party;

(l) to Licensor's knowledge, (i) each of the CPEX License Agreement and the Reprise License Agreement is valid and enforceable in accordance with its terms, is in full force and effect, and there are no approvals or consents required to make it effective, (ii) Licensor has supplied Licensee with a true and correct copy of the CPEX License Agreement and the Reprise License Agreement , together with all amendments, waivers,

or other changes thereto, (iii) Licensor has performed all material obligations required to be performed by it in connection with the CPEX License Agreement and the Reprise License Agreement, (iv) Licensor shall not materially breach and is not in material breach of the CPEX License Agreement or the Reprise License Agreement, (v) Licensor is not in receipt of any claim of default, cure notice, or show cause notice under the CPEX License Agreement or the Reprise License Agreement, and (vi) there is no current material breach or anticipated material breach by any other party to the CPEX License Agreement or the Reprise License Agreement;

(m) (i) Licensor is the named sponsor of the First Approved NDA for the Product; and (ii) with respect to all Regulatory Documentation to obtain Regulatory Approvals for the Product in the Field: (A) the data, information and/or all other documents in Licensor's or its Affiliates submissions were, are and shall be free from fraud or material falsity, and neither Licensor nor its Affiliates has made any material misrepresentation or omission in connection with such data; (B) the Regulatory Approvals have not been and will not be obtained either through bribery or the payment of illegal gratuities by Licensor; (C) the data, information and/or all other documents in Licensor's or its Affiliates' submissions are, were and shall be accurate and reliable for purposes of supporting approval of the submissions; and (D) the Regulatory Approvals shall be obtained without illegal or unethical behavior of any kind by Licensor or its Affiliates; provided that Licensor shall not be deemed to be in breach of this Section 10.2(m) if the violation of this Section 10.2(m) results from the action or omission of Licensee of Licensee's Affiliates, Sublicensees, or contractors (other than Licensor);

(n) Licensor believes in good faith, based on the information set forth in Schedule 10.2(n), that FDA will consider amending or supplementing the First Approved NDA (or the related IND) in the manner described in Schedule 10.2(n); provided, however, that Licensor cannot assure that FDA will approve such amendment or supplement.

(o) except as expressly permitted hereunder, Licensor agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product; and

(p) other than the CPEX License Agreement, the Reprise License Agreement, the Renaissance Supply Agreements, and the other Third Party Supply Agreements, Licensor and/or its Affiliates have not entered into any agreements with any Third Party, pursuant to which any Third Party has granted to Licensor, or Licensor has granted to any Third Party, any rights to licenses to, in or under any of the Licensed Rights or the Sublicensed Rights or other intellectual property rights that relate to the Product, or relating to the manufacture of the Product.

10.3 **Additional Representations, Warranties, and Covenants of Licensee**. Licensee hereby represents, warrants, and covenants to Licensor, as of the Effective Date and except as otherwise stated in Schedule 10.3, that:

(a) if, during the term of this Agreement Licensee has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (i) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or will be under indictment under said Section 335a, then Licensee shall immediately notify Licensor in writing;

(b) as of the Effective Date, there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending or, to the knowledge of Licensee's senior management, threatened by, against Licensee regarding this Agreement, whether at law or in equity, before or by any Third Party; and Licensee shall provide notice of any of the foregoing to the extent it affects Licensee's performance of its obligations under this Agreement;

(c) except for information provided by Licensor, its Affiliates or Sublicensees: (i) the data and information in Licensee's submissions and modifications of Regulatory Documentation relating to the Product shall be free from fraud or material falsity; (ii) Regulatory Approvals for the Product hereafter obtained will not be obtained either through bribery or the payment of illegal gratuities by Licensee; (iii) the data and information in Licensee's submissions and modifications of any Regulatory Documentation shall be accurate and reliable; and (iv) any such the Regulatory Approvals will be obtained without illegal or unethical behavior of any kind by Licensee; provided that Licensee shall not be deemed to be in breach of this Section 10.3(c) if the violation of this Section 10.3(c) results from the action or omission of Licensor or its Affiliates, Sublicensees (other than Licensee), or contractors; and

(d) except as expressly permitted hereunder, Licensee agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iv) bring any action or proceeding or otherwise assert any claim under any Applicable Law in the event any licensee (or sublicensee or any entity or person acting on its behalf) initiates any proceeding or otherwise assert any claim in any court, administrative agency, or other forum with jurisdiction over such proceeding or claim, that any of the Licensed Rights or Sublicensed Rights are invalid, unenforceable, or not infringed, violated, or misappropriated. In the event that Licensee or any Affiliate or Sublicensee of Licensee initiates any proceeding or otherwise asserts any claim in violation of clause (iv) of this Section 10.3, and the result thereof is a final decision, ruling, holding, award, or other disposition to the effect that any of the Licensed Rights or Sublicensed Rights are valid, enforceable, or infringed, violated, or misappropriated, then each of the royalty rates set forth in the table in Section 8.3(a) will each be increased by [***] and the party initiating such proceeding or otherwise asserting such claim shall pay the attorneys' fees and expenses incurred by Licensor in defending against such proceeding or claim.

10.4 **Inaccuracies**. Without limiting either Party's rights and remedies at law, in equity or under this Agreement, if, at any point in time (not just at the times when the warranties are deemed

granted), either Party becomes aware of any inaccuracies in the foregoing warranties and representations, such Party shall promptly notify the other Party of such inaccuracies, with a detailed written explanation.

11. INDEMNIFICATION AND INSURANCE.

11.1 **Indemnification by Licensee**. Licensee shall defend, indemnify and hold harmless any Licensor Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensee and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensee of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensee or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensor); (d) the failure to comply with Applicable Laws by Licensee, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor); and (e) any allegation that personal injury or death, or any damage to any property, was caused or allegedly caused by a manufacturing defect in the Product manufactured by Licensee or for Licensee by Third Parties.

11.2 **Indemnification by Licensor**. Licensor shall defend, indemnify and hold harmless any Licensee Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensor and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensor's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensor of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensor or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensee); and (d) the failure to comply with Applicable Laws by Licensor, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor).

11.3 **Process for Indemnification**. A claim to which indemnification applies under Section 11.1 shall be referred to herein as an **"Indemnification Claim**". If a Licensor Indemnitee or Licensee Indemnitee (each being an "Indemnitee" for purposes of this Section 11.3) intends to claim indemnification under Section 11.1, such Indemnitee must notify Licensee or Licensor, as the case may be (each in such capacity of providing indemnification hereunder, the "Indemnitor"), in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that the Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitor and the Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this Section 11.2, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. An Indemnitee shall not settle or compromise any Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise any Indemnification Claim in any manner that

would have an adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. Each Indemnitee shall reasonably cooperate with the Indemnitor at the Licensor's expense and shall make available to the Licensee or Licensor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 13.

11.4 **Insurance**.

(a) At all times during the term of this Agreement and for five (5) years thereafter, Licensee shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $5,000,000 per occurrence/$10,000,000 aggregate (collectively, the "**Licensee Insurance Policies**"); (ii) include Licensor as "Additional Insured" under the Licensee Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensee will obtain such Licensee Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensee Insurance Policies shall be assumed by Licensee. The policy limits stated above do not limit the obligation of Licensee under this Agreement.

(b) At all times during the term of this Agreement and for five (5) years thereafter, Licensor, to the extent that it is engaged in any Development Activities hereunder, shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $1,000,000 per occurrence/$ 2,000,000 aggregate (collectively, the "**Licensor Insurance Policies**"); (ii) include Licensee as "Additional Insured" under the Licensor Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensor will obtain such Licensor Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensor Insurance Policies shall be assumed by Licensor. The policy limits stated above do not limit the obligation of Licensor under this Agreement

12. LIMITATION OF LIABILITY AND DISCLAIMER OF WARRANTY.

12.1 **LIMITATION OF LIABILITY**. EXCEPT FOR BREACH BY EITHER PARTY OF ARTICLE 13, AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR TO ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING FROM OR RELATING TO THIS AGREEMENT, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT, STATUTES, OR ANY OTHER LEGAL THEORY, AND WHETHER SUCH FIRST PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR NOT.

12.2 **DISCLAIMER OF WARRANTY**. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

13. CONFIDENTIALITY.

13.1 **Confidential Information, Defined; Exclusions.**

(a) ***Definition of Confidential Information***. The term "Confidential Information" means, with respect to a Disclosing Party, information and material, regardless of the form in which that information or material is constituted, any and all regulatory, technical, manufacturing, business, financial, operational, administrative, marketing or economic information, data, documents, designs, patents, materials, product samples, and Know-How asserted by such Disclosing Party as being confidential to it and disclosed by the Disclosing Party to the Receiving Party, whether orally, in writing, or in pictorial form in hard copy, electronic form or in any other form, in connection with the performance of

this Agreement by the Parties, marked in English, or otherwise identified, as confidential or proprietary or secret.

(b) ***Exclusions***. The term "Confidential Information" does not apply to any portion of information or materials that a Receiving Party can demonstrate by contemporaneous written records was: (i) known to the general public at the time of its disclosure to the Receiving Party, or thereafter became generally known to the general public, other than as a result of actions or omissions of the Receiving Party or anyone to whom the receiving Party disclosed such information or materials; (ii) known by the Receiving Party prior to the date of disclosure by the Disclosing Party; (iii) disclosed to the Receiving Party on an unrestricted basis from a source unrelated to the Disclosing Party and not under a duty of confidentiality to the Disclosing Party; or (iv) independently developed by the Receiving Party by personnel that did not have access to or use of Confidential Information of the Disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the Receiving Party.

13.2 **Degree of Care**. Each Party shall take Commercially Reasonable Efforts to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own information and materials of a similar confidential nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including without limitation all copies and derivations thereof, is and shall remain the sole and exclusive property of such Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than as permitted under this Agreement

13.3 **Required Disclosures**. The obligations of Sections 13.2 and 13.7 shall not apply to the extent that the Receiving Party:

(a) is required to disclose Confidential Information it receives pursuant to (i) an order of a court of competent jurisdiction, (ii) Applicable Laws, (iii) regulations or rules of a securities exchange, including without limitation as required in connection with a public offering of the Receiving Party's stock or to comply with regulations imposed by the United States Securities and Exchange Commission, NASDAQ, or stock exchange disclosure requirements, or (iv) requirement of a governmental agency for purposes of obtaining approval to test or market the Product; provided that, in the case of clauses (i) through (iv) of this subsection (a), the Receiving Party shall provide prior written notice thereof to the Disclosing Party and, where practicable, reasonable opportunity for the Disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefore in a reasonably timely manner, or

(b) discloses such Confidential Information to Affiliates, potential or actual acquirers, merger partners, external advisors, licensees, sublicensees, assignees, subcontractors, investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and each of the Parties' respective directors,

employees, contractors, and agents; provided that such any such person or entity listed in the first part of this subsection (b) agrees to confidentiality and nonuse obligations with respect thereto at least as stringent as those specified in Section 13.2.

13.4 **Permitted Disclosures**. At each Receiving Party's request, the Disclosing Party shall review and approve in good faith the use by the Receiving Party any packet of Confidential Information of the Disclosing Party that the Receiving Party proposes to disclose, under commercially reasonable confidentiality obligations that are less stringent than those specified in Section 13.2 to actual or potential investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and the Receiving Party's respective directors, employees, contractors, and agents for purposes of raising capital.

13.5 **Irreparable Injury**. The Parties acknowledge that either Party's breach of this Article 13 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach of this Article 13, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

13.6 **Return of Confidential Information**. Each Receiving Party shall return or destroy, at the Disclosing Party's instruction, all Confidential Information of the Disclosing Party in the Receiving Party's possession upon termination or expiration of this Agreement, except any Confidential Information that is necessary to allow the Receiving Party to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this Agreement.

13.7 **Public Disclosure**.

(a) The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form set forth on Exhibit 13.7 (the "Press Release").

(b) During the term of this Agreement, in all cases other than the announcement set forth in the Press Release, Licensor and Licensee shall submit to each other in a reasonably timely manner for review and approval all proposed press releases involving medical or scientific information, academic, scientific, and medical Publications and public presentations, including without limitation any and all abstracts, public presentations at congresses or scientific meetings or other public meetings, and any Publication manuscripts, relating to the Product, the Nocturia Indication, the PNE Indication and any Additional Indication that have not been previously publicly disclosed and that are not otherwise permitted to be disclosed under this Article 13. Such review and approval shall be conducted in a timely manner for the purposes of preserving intellectual property protection and determining whether any portion of the proposed publication or presentation containing the Confidential Information of either Party should be modified or deleted. Notwithstanding the foregoing and for clarity sake, this provision shall not apply for any disclosures or releases required by the SEC or any other Regulatory Authority, which such disclosures and releases will be subject to Section 13.3.

13.8 **Effect on Existing Confidentiality Agreement**. The provisions of this Article 13 do not supersede that certain letter agreement, dated April 3, 2017, between Licensor and Licensee.

14. TERM AND TERMINATION.

14.1 **Term**. The term of this Agreement shall commence as of the Effective Date and shall continue in effect until it is terminated as specifically provided in this Agreement.

14.2 **Termination for Material Breach**.

(a) If either Party (the "non-breaching Party") believes the other Party (the "alleged breaching party") is in material breach of any of such alleged breaching Party's obligations under this Agreement, the non-breaching Party may give notice of such breach to the alleged breaching Party, and the alleged breaching Party shall have sixty (60) days in which to remedy such material breach or establish that it is not in material breach hereunder. Subject to Section 14.2(b), if such alleged material breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the alleged breaching Party.

(b) If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the non-breaching Party pursuant to Section 14.2(a), and the alleged breaching Party provides notice to the non-breaching Party of such dispute within fifteen (15) days after receipt of such notice, the non-breaching Party shall not have the right to terminate this Agreement unless and until the existence of such material breach by the alleged breaching Party has been determined in accordance with the dispute resolution procedures set forth in Section 15.8 (each such termination delay, a "Toll Period") and the breaching Party fails to cure such default within sixty (60) days following such determination; provided that, if it is determined that such material breach occurred and such breach is not cured within such sixty (60) day period, then, for purposes of Section 14.4(c)(iii), this Agreement shall be deemed to have been terminated as of the date of delivery of notice of such breach under Section 14.2(a). During the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

14.3 **Termination upon Insolvency**. To the extent permitted under Applicable Laws, either Party may terminate this Agreement with respect to the other Party if, at any time, such other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party proposes a written agreement of composition or extension of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment for the benefit of its creditors.

14.4 **Termination upon Force Majeure**. Either Party may terminate this agreement due to a Force Majeure event pursuant to Section 15.13.

14.5 **Consequences of Expiration or Termination**.

(a) Upon termination of this Agreement by Licensor pursuant to Sections 14.2 or 14.3 or by either Party pursuant to Section 14.4,

(i) all of the licenses granted by Licensor to Licensee shall therewith immediately terminate and any sublicenses granted by Licensee thereunder will be subject to the provisions set forth in Section 2.4(f);

(ii) Licensee must assign and transfer to Licensor, and shall cause its Affiliates and Sublicensees to assign and transfer to Licensor, without additional compensation, all of their right, title, and interest in to, and under, subject to any licenses or sublicenses

granted by Licensee that expressly survive any such termination pursuant to Section 2.4(f), all clinical and related study data based on use of Products, all Regulatory Filings and Regulatory Approvals for Products in respect of each country in the Territory; and the Renaissance Supply Agreements.

(b) If at the time of any such termination of this Agreement by Licensor pursuant to Sections 14.2 or 14.3 Licensee has in its possession or under its control any inventory of the Product approved and allocated for sale in the Territory, Licensee shall for a period not to exceed six (6) months following the effective date of such termination be permitted to sell any such inventory of the Product in the Field in the Territory, and the licenses hereunder shall continue on a nonexclusive basis until all such units of the Product have been sold, provided that (A) the Product shall not be sold at a discount to a purchaser that is greater than the average discount provided to such purchaser for the Product during the twelve (12) month period preceding such termination and, in addition, such sales shall not result in the applicable wholesaler inventory levels for the Product exceeding the average levels for the twelve (12) month period preceding such termination, and (B) Licensee continues to pay, during the applicable Royalty Term, the applicable royalty and, if applicable, sales milestones, on resulting applicable Net Sales of Product in the Territory by it Licensee, its Sublicensees or any Third Party Distributors.

(c) Upon termination of this Agreement by Licensee pursuant to Section 14.2, Licensee shall continue to have the right to continue to exercise the licenses granted to it under Article 2, subject to termination of such right by Licensor for Licensee's material, uncured breach of the terms and conditions of this Agreement as it were still in effect and further subject to the payment of the milestone payments pursuant to Section 8.2 and royalty payments and other consideration pursuant to Section 8.3 due to Licensor; provided, however, that (i) in the event of any termination by Licensee pursuant to Section 14.2 the payment of milestone payments and/or royalty payments at Licensee's discretion may be fully reduced by the amount of damages suffered by Licensee due to such material breach by Licensor after determination of such amount by an independent third party with requisite expertise (the selection of which such third party will be agreed upon by the Parties), with any dispute as to the determination being subject to the dispute resolution process set forth in Section 15.8(b), and (ii) any termination by Licensee pursuant to Section 14.3 will be subject to Section 14.7.

(d) Upon termination of this Agreement by Licensee pursuant to Section 14.3, Licensee shall continue to have the right to continue to exercise the licenses granted to it under Article 2, subject to the payment of the milestone payments pursuant to Section 8.2 and royalty payments and other consideration pursuant to Section 8.3 due to Licensor; provided, however, that the provisions of this Agreement that survive any such termination shall continue to be subject to termination by Licensor for Licensee's material, uncured breach of the terms and conditions of this Agreement as it were still in effect.

14.6 **General Surviving Obligations**. The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Expiration or termination of this Agreement for any reason shall not (a) release either Party from any obligation that has accrued prior to the effective date of such expiration or termination (including without limitation the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such termination but

that are unpaid or become payable thereafter), (b) preclude either Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (c) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: Sections 7.7, 7.8, 9.1(a), 9.2(b), 9.5(a), and Articles 1 (to the extent that any term defined therein is used in any of the sections or articles specified in this list as surviving termination of this Agreement), 4 (to the extent Licensee continues to Commercialize Products in accordance with Sections 14.5(c) or 14.5(d)),) 8, 11, 12, 13, 14, and 15.

14.7 **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by either Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 61 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

15. MISCELLANEOUS.

15.1 **Agency**. Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer, or legal representative of the other Party for any purpose, except as expressly set forth herein. No Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Parties, nor shall either Party be entitled to pledge the credit of the other Parties in any way or hold itself out as having the authority to do so.

15.2 **Assignment**. Except as expressly provided in this Agreement, neither Party may assign any rights or delegate any duties under this Agreement to any Third Party without the prior written consent of the other Party; provided, however, that (a) Licensor may freely assign its right to receive any payments hereunder without such consent of Licensee, (b) in the case where either Party seeks to assign this Agreement as a whole to an Affiliate or to a Successor in connection with a Change of Control of such Party or of that part of such Party's business to which this Agreement relates, such consent shall not be unreasonably withheld, delayed, or conditioned, provided that such Party provides written notice to the other Party of such Change of Control and such Successor agrees in writing to be bound as such Party hereunder. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's Successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or transfer not in accordance with this Section 15.2 shall be null and void.

15.3 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.4 **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when personally delivered or sent by confirmed facsimile or email (with hard copy to follow); (b) one (1) Business Day after sent by reputable overnight express courier (charges prepaid); or (c) five (5) Business Days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, such notices to Licensor or Licensee shall be sent to the addresses indicated below:

If to Licensor, addressed to:

Serenity Pharmaceuticals, LLC
105 Hawk Court
Milford, PA 18327
Attention: Chief Executive Officer
With a copy to:
email: docsam122@gmail.com>
With a further copy to:
Mr. Alain Kodsi
email: alainkodsi@gmail.com

If to Licensee, addressed to:

Avadel Specialty Pharmaceuticals, LLC
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005
Attention: Chief Executive Officer
With a copy to: General Counsel

15.5 **Amendment**. No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.6 **Waiver**. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

15.7 **Counterparts; Electronic Delivery**. This Agreement may be executed simultaneously in two counterparts, either of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.8 **Governing Law; Dispute Resolution**.

(a) This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A. without regard to its or any other jurisdiction's choice of law rules that would result in the application of the laws of any jurisdiction other than the State of New York, U.S.A.

(b) Except as otherwise provided in this Agreement, in the event of any dispute, controversy, or claim ("**Dispute**") between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party providing such notice may, by written notice to the other Party refer such Dispute to the other Party for attempted resolution by good faith negotiation by the Chief Executive Officers or President of

Licensor and the Chief Executive Officer, President or an Executive Vice President within thirty (30) days after such notice is received. In the event that any such Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 15.8(c). Any Disputes of the type described in Section 3.2(i) shall first be subject to the dispute resolution mechanism set forth in Section 3.2(i) before being subject to this Section 15.8.

(c) In the event such officers of the Parties are not able to resolve any such Dispute, either Party may at any time after such thirty (30) day period submit such Dispute to be finally settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") in effect at the time of submission. The arbitration shall be heard and determined by three (3) arbitrators. Each such Party shall each appoint one arbitrator and the third arbitrator shall be selected by the two Party-appointed arbitrators, or, failing agreement within thirty (30) days following the date of receipt by the respondent of the claim, by the AAA. Such arbitration shall take place in New York, NY. The arbitration award so given shall be a final and binding determination of the dispute, shall be fully enforceable in any court of competent jurisdiction, and shall not include any damages expressly prohibited by Section 12.1. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the dispute resolution procedures set forth in this Section 15.8(c) are pending.

(d) Notwithstanding anything herein to the contrary, nothing in this Section 15.8 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, including in a court of law, if necessary to protect the interests of such Party. This Section 15.8 shall be specifically enforceable.

(e) Notwithstanding the foregoing, any disputes regarding the validity, scope or enforceability of Patent Rights or trademarks shall be submitted to a court of competent jurisdiction in the territory in which such rights apply.

15.9 **Hart-Scott-Rodino**. Licensee, at its expense, with the reasonable cooperation of Licensor, will be responsible for making any filing with the U.S. Federal Trade Commission ("FTC") in respect of this Agreement and the transaction contemplated hereby under Hart-Scott-Rodino Antitrust Improvements Act of 1976. This Agreement shall not become effective until the expiration of any applicable waiting period under such Act.

15.10 **Severability**. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

15.11 **Compliance with Applicable Laws**. Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder.

15.12 **Remedies**. The exercise of any remedies hereunder shall be cumulative and in addition to and not in limitation of any other remedies available to such Party at law or in equity.

15.13 **Force Majeure**. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of nature, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, or civil unrest ("Force Majeure"); provided that the affected Party promptly notifies the other Party and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. In the event any such Force Majeure event continues for three (3) months or more, the unaffected Party shall have the right to terminate this Agreement, effective as of the date of delivery of notice, which notice shall not be delivered prior to the end of such three (3) month period.

15.14 **Interpretation**. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.15 **Construction**. In construing this Agreement, unless expressly specified otherwise: (a) unless otherwise specifically provided, any references to Articles, Sections, Exhibits, Schedules, and Appendices are to articles in, sections of, and exhibits, schedules and appendices to, this Agreement; (b) except where the context otherwise requires, use of either gender includes the other gender and use of the singular includes the plural and vice versa; (c) headings and titles are for convenience only and do not affect the construction or interpretation of this Agreement; (d) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words; (e) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (f) except where the context otherwise requires, the word "or" is used in the inclusive sense; (g) all references to "dollars" or "$" herein shall mean US Dollars; (h) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (i) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, and (j) any reference herein to any person or entity shall be construed to include the person's or entity's successors and assigns,.

15.16 **Entire Agreement of the Parties**. This Agreement and the exhibits attached hereto constitute and contain the complete, final, and exclusive understanding and agreement of the Parties, and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including without limitation the Confidentiality Agreement, and neither Party shall be liable or bound to any other Party in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon either Party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall control.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives as set forth below:

LICENSOR:	**LICENSEE:**
SERENITY PHARMACEUTICALS, LLC	AVADEL SPECIALTY PHARMACEUTICALS **, LLC**
By: _____	By: _____
Name:	Name:
Title:	Title:
By: _____	
Name:	
Title:	

Exhibit 4.4
Commercialization Plan

[to be prepared in accordance with Article 4]

Exhibit 5.5

Manufacturing and Supply Plan

[to be prepared in accordance with Article 5]

Exhibit __
Development Plan

71

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

EXCLUSIVE LICENSE AND ASSIGNMENT AGREEMENT

CONFIDENTIAL TREATMENT REQUESTED
THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

Contents

Form of Press Release *(1)*

(1) *attached to this Agreement upon its execution*
(2) *to be drafted following execution of this Agreement*
(3) *to be provided separately*

Schedules (in the order in which they appear in the Agreement):

Exceptions to Licensor's Representations and Warranties
Exceptions to Licensee's Representations and Warranties

EXCLUSIVE LICENSE AND ASSIGNMENTS AGREEMENT

This Exclusive License and Assignments Agreement (this "Agreement") is made as of September 1, 2017, by and among SERENITY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensor"), with offices at 105 Hawk Court, Milford, PA 18327, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensee"), with offices at16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005. Licensor and Licensee are each sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Licensor has developed the Product (herein defined) for treating certain medical conditions characterized by abnormalities or disorders in voiding and other urinary functions, and the FDA (herein defined) has approved a New Drug Application (herein defined) for treating certain of these medical conditions (herein defined as the "First Approved NDA);

WHEREAS, Licensee is engaged in the business of the development, distribution, sale and marketing of pharmaceutical products;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to grant to Licensee, and Licensee desires to be so granted, an exclusive license and sublicense to the Licensed Rights (herein defined) and the Sublicensed Rights (herein defined), respectively, for the purpose of: (a) Commercializing (herein defined) Products in the Field (herein defined) throughout the Territory (herein defined) and (b) Developing (herein defined) and Commercializing the Product for the PNE Indication and Additional Indications (herein defined) in the Field and Territory;

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and to delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related regulatory obligations in respect of, the First Approved NDA and the related IND (herein defined); and

WHEREAS, on the terms and conditions provided in this Agreement, Licensor desires to assign and delegate to Licensee, and Licensee desires to be so assigned and delegated, all of Licensor's right, title, and interest in and to, and the related obligations under, the Renaissance Supply Agreements (herein defined),

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the Parties intending to be legally bound agree as follows:

1. DEFINITIONS.

When used in this Agreement each of the following terms whether used in the singular or plural shall have the following meanings.

1.1 "A/B Rated" means, (a) inside the United States, "therapeutically equivalent" as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations", and (b) outside the United States, such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law.

1.2 "Acceptance" and its correlative "Accepted" means with respect to an NDA submitted to the FDA, receipt by the sponsor thereof of written notice from the FDA that the FDA deems such NDA to be sufficiently complete for filing and filed by the FDA pursuant to 21 C.F.R. 314.101 and any regulation successor thereto.

1.3 "Additional Indications" means any other Indication for the Product in the Field in the Territory other than the PNE Indication.

1.4 "Adverse Drug Experience" has the meaning set forth in 21 CFR Sec. 314.80 and any regulation successor thereto.

1.5 "Affiliate" means any Person who, directly or indirectly through one or more intermediates, controls or is controlled by or is under common control with another Person, but only for so long as such relationship exists. For purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means the possession, directly or indirectly through one or more intermediates, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Such power will be deemed to exist in the case of ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, or status as a general partner in any partnership. The Parties acknowledge that, in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity.

1.6 "Agreement" has the meaning set forth in the Preamble.

1.7 "Alliance Manager" means, with respect to each of Licensor and Licensee, the individual designated by such Party in accordance with Section 3.2(h).

1.8 "Applicable Law" means, with respect to any action taken or omitted to be taken by a Party under this Agreement, the Laws in any country and any jurisdiction therein that are applicable to such action or omission.

1.9 "Bankruptcy Code" means the United States Bankruptcy Code, as amended and set forth in Title 11 of the United States Code.

1.10 "Branding Strategy" means the strategy, including messaging, for branding the Product for use in the Field in the Territory, to be set forth in the Commercialization Plans for each combination of Product and Indication.

1.11 "Business Day" means a day other than any Saturday, Sunday or other day on which banking institutions in New York, New York are required by Applicable Law to remain closed.

1.12 "Calendar Quarter" means each calendar quarter ending on the last day of each March, June, September and December during the Term of this Agreement; *provided, however,* that (a) the first Calendar Quarter of the Term of this Agreement will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.13 "Calendar Year" means each calendar year ending on December 31 of such year; *provided, however,* that (a) the first Calendar Year of the Term of this Agreement will extend from the Effective Date to and including December 31, 2017; and (b) the last Calendar Quarter of the term of this Agreement will end upon the expiration or termination of this Agreement.

1.14 "CFR" means the United States Code of Federal Regulations.

1.15 "Change of Control" means with respect to Licensee:

(a) Licensee enters into a merger, consolidation, stock sale or sale or transfer of all or substantially all of its assets to which this Agreement relates, or other similar transaction or series of transactions with a Third Party, unless, following such transaction or transactions, (i) the individuals and entities who were the beneficial owners of the outstanding voting securities of Licensee immediately prior to such transaction beneficially own, directly or indirectly, at least fifty percent (50%) of the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors or similar governing persons of the corporation or other entity resulting from such transaction ("Successor") in substantially the same proportions as their ownership immediately prior to such transaction of such outstanding voting securities, (ii) at least fifty percent (50%) of the members of the Board of Directors or similar governing body of the Successor were members of the Board of Directors of Licensee at the time of the execution of the initial agreement, or the action of the Board of Directors of Licensee, providing for such transaction, (iii) Licensee retains title ownership after the transaction or transactions to properties and assets (x) representing more than fifty percent (50%) of such Third Party's consolidated total assets or (y) from which more than fifty percent (50%) of such Third Party's consolidated operating income for its most recent fiscal year was derived, and (iv) Licensee is the surviving entity in such transaction or transactions; or

(b) any transaction or series of related transactions in which any Third Party or group of Third Parties acquires beneficial ownership of securities of Licensee representing more than fifty percent (50%) of the combined voting power of the then outstanding securities of Licensee.

Notwithstanding subsections (a) or (b), above, a stock sale to underwriters of a public or private offering of Licensee's capital stock shall not constitute a Change of Control.

1.16 "Clinical Study" means (a) a Phase 1 Clinical Study, a Phase 2 Clinical Study, a Phase 3 Clinical Study, (b) variations of such studies and/or trials (for example, a Phase 2/3 Clinical Study), as such terms are defined and understood by the FDA, and (c) such other tests and studies in human patients that are required by Applicable Law, or otherwise recommended by applicable Regulatory Authorities in the Territory, to obtain or maintain Regulatory Approvals, but excluding Post-Market Approval Studies not required to be conducted under an IND.

1.17 "CMC" means, as required by the context, the chemistry, manufacturing and controls processes applicable to the manufacture of a product or the section of an IND or NDA that contains information on such processes.

1.18 "Combination Product" means any product that comprises (a) the Compound and (b) at least one clinically active therapeutic, or prophylactic ingredient or component (whether packaged together or in the same formulation) that is not the Compound.

1.19 "Commercialize", "Commercializing" or "Commercialization" means, with respect to any drug product, any and all activities directed to using, launching, marketing, market researching, detailing, promoting, advertising, educating, importing, exporting, distributing, selling, offering for sale, post-market approval pharmacovigilance and safety reporting, legal, customer service, securing from both government agency payors and non-government third-party payors reimbursement of such drug product after Regulatory Approval has been obtained (including, without limitation, obtaining pricing and reimbursement approvals), regulatory compliance, planning with respect to each of the foregoing, and reporting. For clarity, "Commercialization" shall not include any activities related to clinical research or Development of Products or to Manufacturing of Products.

1.20 "Commercialization Activities" means any of the activities described in the definition of "Commercialize".

1.21 "Commercialization Plan" means, from time to time and with respect to any period during the Term, Licensee's plan then in effect for Commercializing the Product during such period.

1.22 "Commercially Reasonable Efforts" means, from to time to time with respect to the performance at such time of any Development, Commercialization or other obligation of a Party under this Agreement that expressly requires efforts characterized as such, the performance by such Party of such obligation by expending reasonable, diligent, good faith efforts to accomplish such obligation as a similarly situated pharmaceutical company would use to accomplish a similar obligation under similar circumstances through the exercise of reasonable business judgment, where the assessment of being similarly situated would be undertaken by reference to company size and financial position, competitive factors in the relevant market relating to the proprietary position of the relevant product in terms of market and profit potential, the safety and effectiveness profile of the relevant product, strategic value, and applicable regulatory matters; provided, that, with respect to the Development and Commercialization of the Compound or the Product, such efforts shall be substantially equivalent to those efforts and resources that a pharmaceutical company would generally devote to its own internally discovered compounds or products of similar market and profit potential, safety and effectiveness profile, strategic value, and regulatory matters at a similar stage in their development or life cycle, with respect to which it does not owe license payments, milestone payments, royalties or similar financial obligations to licensors or other Persons, and based on conditions then prevailing, with the goal of maximizing the revenue potential of such compounds or products. Commercially Reasonable Efforts shall be determined on a country by country basis.

1.23 "Compound" means "(a) the compound designated as Desmopressin (1-desamino-8-D-arginine vasopressin) and (b) any and all functionally equivalent analogues thereof having antidiuretic activity disclosed in a patent or patent application within the Patent Rights licensed and sublicensed hereunder.

1.24 "Confidential Information" has the meaning set forth in Section 13.1.

1.25 "Control" or "Controlled" means, with respect to any Know-How or Patent Right, the possession by a Party, whether by ownership, license, sublicense or otherwise (other than pursuant to a license granted under this Agreement), of the ability to grant the right to access

or use, or to grant a license or a sublicense under, or to grant the right to disclose or transfer, such Know-How or Patent Right, without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party. For clarity, the Patent Right or Know-How licensed to Licensee under this Agreement shall be deemed to be Controlled by Licensee.

1.26 "Cover", "Covered", or "Covering" means, (a) with respect to an issued patent, that, in the absence of a license granted to a Person under a Valid Claim included in such patent, the practice by such Person of an invention claimed in such Patent Right would infringe such Valid Claim, or (b) with respect to a patent application, that, in the absence of a license granted to a Person under a Valid Claim included in such patent application, the practice by such Person of an invention claimed in such patent application would infringe such Valid Claim if such patent application were to issue as a patent.

1.27 "CPEX" means CPEX Pharmaceuticals, Inc. (formerly Bentley Pharmaceuticals, Inc.), a corporation organized under the laws of Delaware.

1.28 "CPEX License Agreement" means that certain Development and License Agreement, dated February 4, 2008 and as amended March 31, 2010, by and among Licensor and CPEX.

1.29 "Detail" means a meeting (either in person or through live video conferencing) in respect of the Product (i) with one or more physicians and other persons included in other medical professional categories (where, in the case of group presentations, each such physician or other person participating in a group presentation shall be counted as a separate Detail), who are permitted under the Applicable Law of the country in which they work to prescribe the Product and (ii) in which key attributes of the Product are orally presented, but shall not include merely a reminder or a Sample or promotional material drop). When used as a verb, "Detail" and "Detailing" shall have correlative meanings.

1.30 "Develop" or "Development" means the undertaking of all activities relating to obtaining Regulatory Approval for a product and all Manufacturing Activities reasonably required for development of CMC processes. For the sake of clarity, such activities include preclinical testing, toxicology, formulation, Clinical Studies, and regulatory affairs required for Regulatory Approval, and activities relating to the manufacture of Products that relate to regulatory matters are included in the definition of Manufacturing.

1.31 "Development Activities" means any of the activities described in the definition of "Develop".

1.32 "Development Budget" means, for any Development Activities to be undertaken with respect to the Product, the PNE Indication and any Additional Indications, the detailed budget for all Development Costs for the Development Activities set forth in any Development Plan in respect of such Development Activities.

1.33 "Development Costs" means, in respect of the Development Activities described in any Development Plan, the following costs: (i) Out-of-Pocket Costs attributable to such Development Activities and (ii) FTE Costs of Licensee's internal personnel that are attributable or reasonably allocable to such Development Activities. Such costs shall be determined in accordance with GAAP.

1.34 "Development Plan" means, in respect of the Product, the PNE Indication and each Additional Indication, from time to time during the Term of this Agreement, any plan then in

effect for the conduct of Development Activities in respect thereof, and includes, without limitation, the Development Budget for such Development Activities.

1.35 "Disclosing Party" means, with respect to any disclosure by a Party of any of its Confidential Information to the other Party, the Party so disclosing such Confidential Information.

1.36 "Disposition" means any disposition by Licensee of any of its assets, including any direct or indirect sale, lease, exchange, transfer, contribution, license, spinoff, recapitalization, dividend, grant or other disposition, with or without value; provided, however, that any sale of inventory by a Licensee Change of Control Party in the ordinary course of business, an offering of debt or equity securities in a public financing, or any pledge of assets to secure acquisition debt financing on customary terms which would not involve the issuance of equity that would otherwise result in a Change of Control, shall not be deemed a Disposition hereunder.

1.37 "Dispute" has the meaning set forth in Section 15.8(b).

1.38 "Dollars" or "$" means U.S. dollars.

1.39 "Drug Master File" or "DMF" has the meaning set forth in 21 CFR Section 314.420 (and any regulation successor thereto).

1.40 [***].

1.41 "Effective Date" shall mean the later of: (i) the date of this Agreement set forth in the Preamble or (ii) the expiration of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

1.42 "Enforceable IP Right(s)" shall mean any Patent Rights, Trademarks, Copyrights, or other intellectual property rights within the Licensed Rights or the Sublicensed Rights that would be infringed by any Exploitation of any product in the Territory in the absence of a valid and enforceable license, sublicense, or other right to engage in such Exploitation.

1.43 "Exploit" and, with correlative meaning, "Exploitation", means to Develop, Commercialize, Manufacture, and otherwise exploit.

1.44 "FDA" means the United States Food and Drug Administration and any agency successor thereto.

1.45 "FDCA" means the United States Food, Drug and Cosmetic Act of 1938, as amended, and any law successor thereto.

1.46 "Field" means the use of the Product for the Treatment in humans and animals of medical conditions characterized by abnormalities or disorders in voiding and other urinary functions of a subject to control urination**.**

1.47 "First Approved NDA" means U.S. NDA #201656, dated and received by the FDA on February 4, 2016 and as thereafter amended, and approved by the FDA, as evidenced by that certain letter, signed March 3, 2017, from the FDA to Serenity.

1.48 "First Approved Product" means the Product that is the subject of the First Approved NDA.

1.49 "First Commercial Sale" means, with respect to the Product in each country in the Territory, the first sale in such country by Licensee or any Third Party Distributor for consumption or use. Sales or transfers of reasonable quantities of the Product for Clinical Study purposes or for compassionate or similar use, shall not be considered a first sale for consumption or use.

1.50 "First Position" means, with respect to the Detail of an applicable product, that the product is presented in such Detail before any other product, such that the average time spent on all Details in any Calendar Quarter during the First Position Period is approximately fifty (50%), excluding any Detail to a person or group of persons where for good reason Detailing of the Product should either not be made or, if made, made substantially shorter than such average.

1.51 "First Position Period" has the meaning set forth in Section 14.3(b).

1.52 "Force Majeure" has the meaning set forth in Section 15.12.

1.53 "FTE" means the hours of work devoted to or in support of Commercialization, Manufacture, or Development, as applicable, of the Product, in accordance with the applicable Commercialization Plan, Manufacturing Plan, or Development Plan, that is carried out by one or more employees, contract personnel or consultants of a Party, measured in accordance with such Party's normal time allocation practices from time to time. In no event shall an individual account for more than one FTE year in any Calendar Year.

1.54 "GAAP" means United States Generally Accepted Accounting Principles as applied in the United States.

1.55 "Generic Product" means, with respect to the Product, any product Commercialized by a Third Party in any country in the Territory, that meets the following criteria: (i) such product contains a Low Dosage formulation of a compound that is an active pharmaceutical ingredient in a product that is A/B Rated with respect to the Licensed Product (including, without limitation, any salt, free acid or base, hydrate, isotopic, deuterated, solvate, polymorphic, crystalline, or non-crystalline form of such Compound), and (ii) is A/B Rated with respect to the Product.

1.56 "Generic TRxs-to-Total TRxs Percentage" means, with respect to any Calendar Quarter during the Term of this Agreement in each country in the Territory, the quotient, expressed as a percentage, of (a) total TRxs for Generic Products during such Calendar Quarter in such country DIVIDED BY (b) the sum of total TRxs for Generic Products during such Calendar Quarter in such country PLUS total TRxs for Products during such Calendar Quarter in such country.

1.57 "Governmental Authority" means any legislative, executive, judicial, regulatory, or administrative unit of any governmental entity (multinational, foreign, federal, state, or local) or any department, commission, board, agency, bureau, ministry, official, arbitrator (public), or other similar body exercising executive, legislative, regulatory, administrative, or judicial authority or functions of or pertaining to government to perform any such functions.

1.58 "IND" means, with respect to any investigational product, an Investigational New Drug Application filed with the FDA under 21 CFR Part 312 (and any regulation successor thereto) or similar foreign application or submission in any country in the Territory for permission to conduct human clinical investigations of such investigational product.

1.59 "Indemnification Claim" has the meaning set forth in Section 11.2.

1.60 "Indication" shall mean any human disease or condition, and any subcategories thereof, or sign or symptom of a human disease or condition, and any subcategories thereof.

1.61 "Inventions" means any and all inventions made, conceived, or discovered solely by employees, independent contractors, or agents of either Party or their respective or jointly by

employees, independent contractors, or agents of each of the Parties or their respective Affiliates.

1.62 "Joint Steering Committee" or "JSC" means the committee formed by designees of Licensor and Licensee for the purpose of monitoring the Development, Commercialization, and Manufacture of the Product as contemplated by this Agreement and governed in accordance with Article 3.

1.63 "JSC Subcommittee" means any subcommittee established by the JSC in accordance with Article 3.

1.64 "Know-How" means any nonpublic information, ideas, data, inventions, works of authorship, trade secrets technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissues, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, and whether stored or transmitted in oral, documentary, electronic or any other form, including all Regulatory Documentation.

1.65 "Launch" means, with respect to the Product or any Generic Product for an Indication in a country in the Territory, the Product or such Generic Product first becoming available for commercial sale.

1.66 "Law" means any law, statute, rule, regulation, ordinance, regulatory guidance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision in each country in the Territory, including, without limitation, (a) the FDCA in the United States and counterparts thereof in each other country in the Territory, (b) good clinical practices and adverse event reporting requirements and all other rules, regulations and requirements of the FDA and Regulatory Authorities that are counterparts of the FDA, as applicable, (c) the Foreign Corrupt Practices Act of 1977, as amended, in the United States and any comparable laws in each other country in the Territory, and (d) all export control laws in any country in the Territory.

1.67 "LIBOR Rate" means, for any applicable interest period, the rate per annum equal to the average of the one month US Dollar Rate Intercontinental Exchange London Interbank Offered Rate, as published by Thomson Reuters (or, if Thomson Reuters does not publish quotations of such rate, another commercially available source providing quotations thereof as reasonably selected by agreement of the Parties), with the average determined by adding such rate for each day on which such rate is published during the applicable period, divided by the number of such days during such period. If such rate is not available at such time for any reason, then the rate for that interest period will be determined by such alternate method as reasonably selected by agreement of the Parties.

1.68 "Licensed CPEX Patent Rights" means the Patent Rights set forth in Exhibit 1.68.

1.69 "Licensed Reprise Know-How" means the Know-How licensed by Reprise to Serenity under the Reprise License Agreement.

1.70 "Licensed Reprise Patent Rights" means the Patent Rights set forth in Exhibit 1.70.

1.71 "Licensed Reprise Rights" means the Licensed Reprise Patent Rights and the Licensed Reprise Know-How.

1.72 "Licensed Rights" means the rights under the licenses granted by Licensor to Licensee in Sections 2.1(a),(b), and (c).

1.73 "Licensed Serenity Copyrights" means the copyrights set forth in Exhibit 1.73.

1.74 "Licensed Serenity Know-How" means the Know-How described in Exhibit 1.74.

1.75 "Licensed Serenity Patent Rights" means the Patent Rights in the issued patents and patent applications set forth in Exhibit 1.75.

1.76 "Licensed Serenity Trademarks" means the trademarks set forth in Exhibit 1.76.

1.77 "Licensee" has the meaning set forth in the Preamble.

1.78 "Licensee Change of Control Party" means Licensee or any Affiliate of Licensee to the extent Licensee or such Affiliate of Licensee, as applicable, is the subject of a Change of Control.

1.79 "Licensee Insurance Policies" has the meaning set forth in Section 11.3.

1.80 "Licensee Indemnitee(s)" means any of Licensee and its directors, officers, employees, agents, contractors and agent of Licensee and its Affiliates (including without limitation Avadel Pharmaceuticals plc).

1.81 "Licensee Inventions" means any and all Inventions with respect to the Product, Controlled by Licensee and not made, conceived, or discovered by any employees, independent contractors, or agents of Licensor or any of its Affiliates, contractors, or agents.

1.82 "Licensee's Sales and Marketing Force" means, from time to time, Licensee's sales and marketing personnel responsible for managing, coordinating and overseeing the Commercialization of the Product in the Field in the Territory.

1.83 "Licensor" has the meaning set forth in the Preamble.

1.84 "Licensor Indemnitee(s)" means any of Licensor and its directors, officers, employees, agents, contractors and agents of Licensor and its Affiliates (including, without limitation, Serenity).

1.85 "Long Term Care" or "LTC" means the provision of health care in skilled nursing and other long-term care and assisted living facilities.

1.86 "Losses" means, with respect to any Claim for which one Party as an Indemnitee hereunder seeks indemnification hereunder from the other Party as an Indemnitor hereunder, any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and reasonable attorneys' fees) of any kind payable to Third Parties (including attorneys for such Indemnitees) incurred by the Indemnitees and arising out of such Claim.

1.87 "Low Dosage" means, with respect to any product containing the Compound, that such product produces a peak blood concentration (measured as a Cmax) equal to or less than [***] per milliliter of blood plasma or serum ([***]), where "Cmax" means the maximum concentration of the Compound measured in blood plasma or serum following administration of the product and prior to a subsequent administration of the product."

1.88 "LTC Activities" means, for each combination of Product, Indication, and country in the Territory, (a) meetings (either in person or through live video conferencing), other than Details, with one or more physicians, administrators, and other medical or other professional categories identified in the Annual Commercialization Plan for the purpose of marketing and promoting such combination of Product and Indication to LTC organizations in such country and (b) activities connected with pricing, rebate and other contract-related negotiations, contracting, and processing and implementation of agreements with LTC organizations.

1.89 "Manufacture", "Manufacturing", or "Manufacturing Activities" means, as applicable, all activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, and storage of bulk and finished forms of bulk and finished forms of Products and/or any components thereof, including, without limitation, process and formulation development, process validation, stability testing, manufacturing scale-up, manufacture for preclinical and clinical studies and Commercialization, analytical development, product characterization, quality assurance and quality control development, testing and release, and any technical support activities that are necessary for Regulatory Approval and Commercialization of Products.

1.90 "Manufacturing and Supply Plan" means the plan attached as Exhibit 5.5 and relating to the manufacture by or for Licensee of quantities of the Product and subsequent supply thereof for Commercialization and Development Activities by Licensee, as such plan may be modified from time to time for the Territory.

1.91 "Marketing Authorization Application" or "MAA" means, with respect to any product and each country in the Territory, an application to the applicable Regulatory Authority for approval to commercially market and sell the product in such country. For the sake of clarity, this term (and its abbreviation) includes NDAs and sNDAs in the United States.

1.92 "New Drug Application" or "NDA" means, with respect to any product, the application referred to as such by FDA and that must be approved by FDA before such product can be commercially marketed and sold in the United States, and such term includes, without limitation, and, unless the context otherwise states to the contrary, any supplemental NDAs ("sNDAs"), each such application having the form and containing the substance specified by the FDA for such applications and supplemental applications.

1.93 "Net Sales" means, with respect to a given period of time, gross sales of the Product in such period to unrelated Third Parties in bona fide arm's length transactions, (excluding sales or dispositions for use in Clinical Studies or other scientific testing or reasonable quantities of samples, in each case for which Licensee and any such Third Party Distributors receive no revenue), less the following deductions which are actually incurred, allowed, paid, accrued or specifically allocated to such gross sales amounts of the Product and not separately invoiced:

(a) credits or allowances actually granted for damaged Product, returns or rejections of Product, price adjustments, and billing errors;

(b) governmental and other rebates (or equivalents thereof) granted to: managed health care organizations; pharmacy benefit managers (or equivalents thereof); federal, state/provincial, local and other governments, their agencies and purchasers and payors, including, without limitation, any state or federal Medicare, Medicaid or similar program); or trade customers;

(c) normal and customary trade, cash and quantity discounts, allowances and credits actually allowed and taken specifically with respect to sales of other dispositions of the Product;

(d) distribution services agreement fees allowed or paid to Third Party distributors;

(e) transportation costs, including without limitation insurance, for outbound freight related to delivery of the Product to the extent included in the gross amount invoiced;

(f) excise and sales taxes, tariffs, duties, value added taxes, and other taxes applied to the sale of the Product imposed upon and paid directly with respect to such sales or

(reduced by any refunds of such taxes deducted in the calculation of Net Sales for prior periods and, for the avoidance of doubt, no deduction shall be permitted for income, withholding, corporate or similar taxes); and

(g) any other items that reduce gross sales amounts as required by GAAP.

Transfers and sales of the Product between or among a Party and its Affiliates or Third Party Distributors shall be excluded from the computation of Net Sales, but the subsequent final sales of the Product to Third Parties by such Affiliates or Third Parties shall be included in the computation of Net Sales.

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. The deductions set forth above in this definition of Net Sales shall be determined in accordance with GAAP, as consistently applied by Licensee and such Third Party Distributors across all of their products. The amounts set forth in clauses (a) through (g) above shall only be deducted from gross invoiced sales where gross invoiced sales before deductions are non-discounted gross sales amounts.

In the event Licensee or such Third Party Distributors sell the Product together with other products to Third Parties in a particular country in the Territory and the price attributable to the Product is less than the average price of "arm's length" sales of the Product alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of "arm's length" sales of the Product alone), Net Sales for any such sales shall be the average price of "arm's length" sales by Licensee or Third Party Distributors, as applicable, of the Product alone and in the country during the reporting period in which such sales occur. If the average price of "arm's length" sale of the Product cannot be determined in any given country, the Net Sales will be determined by the value of the Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities. Any dispute as to the determination of fair market value that cannot be resolved through discussion between the Parties shall be determined in accordance with Section 3.2(i). Notwithstanding the foregoing, in the event the Product is sold as a Combination Product, for purposes of determining the royalties payable by Licensee to Licensor hereunder, Net Sales shall be calculated by the Net Sales for such Combination Product in a manner to be negotiated and agreed upon by Licensor and Licensee, reasonably and in good faith, prior to any sale of such Combination Product, which shall be based upon the respective fair market values of the active pharmaceutical ingredients in such Combination Product; provided that in no event shall the royalty rate payable by Licensee to Licensor for such Combination Product be greater than the royalty rate of the Product containing the Compound as the sole active ingredient.

1.94 "Noctiva Launch" shall mean the date the Noctiva Product has been supplied, to wholesalers, retail chains and pharmacy benefit managers and is widely available for commercial sale to patients.

1.95 "Noctiva Product" shall mean .83mcg or 1.66mcg desmopressin acetate nasal spray product.

1.96 "Nocturia Indication" means an Indication characterized by urination in a human aged 18 years or older wherein, during a defined period of such human's normal period of sleep at night, two or more non-incontinent urinary void(s) of any volume during such period of sleep, each such void following an initial period of sleep and, thereafter, followed by sleep or an attempt to sleep.

1.97 "Out-of-Pocket Costs" means the direct expenses paid or payable by Licensee to any Third Parties in respect of any Development Activities or Commercialization Activities, as applicable, performed for such Party (or its Affiliates) by such Third Party.

1.98 "Party" means Licensor or Licensee; "Parties" means Licensor and Licensee.

1.99 "Patent Rights" means, with respect to each country in the Territory (except as otherwise stated to be with respect to any country in or outside the Territory), (a) patent applications (including provisional applications) pending in such country, (b) any patents issuing in such country from such patent applications (including certificates of invention), (c) all patents and patent applications issued or pending, as applicable, in such country based on, corresponding to or claiming the priority date(s) of any of the foregoing, (d) rights in such country derived from any of (a), (b) or (c), including any substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations in part, reexaminations, renewals, revalidations, revivals, patents of addition, and (e) all patents and patent applications issued or pending, as applicable, in such country claiming overlapping priority therefrom.

1.100 "Person" means any individual, corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, or any other entity or body.

1.101 "Pharmacovigilance Agreement" means the pharmacovigilance agreement to be entered into by Parties, Third Party Distributors, and any Third Parties which such Third Parties are licensed or sublicensed to Commercialize the Product in countries outside the Territory.

1.102 "Phase 1 Clinical Study", with respect to any investigational drug product, means a human clinical study that provides for the introduction into humans of such investigational drug product and that is intended to initially evaluate the safety, tolerance or pharmacological effects of such investigational drug product in human subjects, or that is otherwise described in 21 CFR Sec 312.21 (a) or its foreign counterpart.

1.103 "Phase 2 Clinical Study" means a human clinical study that is intended to initially evaluate the dosing and effectiveness of the Product, and to further evaluate the safety of the Product, or that is otherwise described in 21 CFR Sec. 312.21(b) or its foreign counterpart.

1.104 "Phase 3 Clinical Study" means a human clinical study that is prospectively designed to demonstrate statistically whether the Product is safe and effective to control, mitigate, prevent, treat or cure a particular Indication in a manner sufficient to obtain Regulatory Approval to market the Product, or that is otherwise described in 21 CFR Sec. 312.21(c) or its foreign counterpart.

1.105 "PNE Indication" means the Primary Nocturnal Enuresis Indication and is characterized by the occurrence of one or more incontinent urinary voids occurring during sleep in a person under the age of eighteen (18) years.

1.106 "Post-Market Approval Study" means a human clinical study in respect of the Product for a specified Indication that is conducted under the Applicable Law of any country in the Territory after Regulatory Approval of the Product for such Indication has been obtained from the applicable Regulatory Authority in that country, and includes trials conducted (a) voluntarily for the purpose of enhancing marketing or scientific knowledge of such Indication or (b) at the request or requirement of the applicable Regulatory Authority.

1.107 "Product" means any product for a specific Indication within the Field that contains the Compound in any form, presentation, formulation and dosage form, and (a) is at any time during the Term of this Agreement Covered by a Licensed Serenity Patent Right, Licensed CPEX Patent Right, or Licensed Reprise Patent Right. For purposes of this Agreement, Net Sales of any such Product so Covered by any such Patent Right at any time during the Term of this Agreement will continue to be treated, from and after the time that the Product is no longer Covered by any Valid Claim of any such Patent Right, as a Product for purposes of calculating any payments to be made to Licensor under Article 8. For the sake of clarity, the term "Product" includes the First Approved Product.

1.108 "Product Regulatory Approvals and Documentation" means all Regulatory Approvals and Regulatory Documentation in respect of the Product and each country in the Territory (including, without limitation, the First Approved NDA and any INDs in respect of the Product open as of the Effective Date).

1.109 "Promotional Materials" means any printed or other materials bearing the name (trade name or generic name) used to promote the Product in any country in the Territory, including brochures, journal ads, selling aids, posters, reprints, video or audio tapes, press releases, Internet pages and websites, radio or television advertisements and textbooks.

1.110 "Publication" means any publication in a scientific journal, any abstract to be presented to any scientific audience, any presentation at any scientific conference, any other scientific presentation and any other oral, written or electronic disclosure directed to a scientific audience which pertains to the Product or the use of the Product.

1.111 "Receiving Party" means, with respect to the receipt by a Party of any Confidential Information from the other Party, the Party so receiving such Confidential Information.

1.112 "Regulatory Approval" means, with respect to a drug product and a specified country in the Territory, the act of the applicable Regulatory Authority in such country necessary for the marketing and commercial sale of such drug product in such country (including pricing and/or reimbursement approval in such country in which such pricing and/or reimbursement approval is required by Applicable Laws), including, without limitation, the approval of an NDA for the Product by the FDA and other regulatory agencies in the Territory.

1.113 "Regulatory Authority" means, in any country in the Territory, any applicable government regulatory authority involved in the granting of Regulatory Approval for the Product in such country or regulatory jurisdiction, including the FDA in the United States and counterparts thereof in other country in the Territory.

1.114 "Regulatory Documentation" means, with respect to the Product, all INDs, NDAs (including, without limitation, sNDAs), MAAs or other regulatory applications submitted to any Regulatory Authority, preclinical and clinical data and information, regulatory materials, drug dossiers, master files (including, without limitation, Drug Master Files), and any other reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Product, including, without limitation, those materials necessary to Develop, Manufacture, Commercialize and otherwise Exploit the Product, including, without limitation, any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database.

1.115 “Regulatory Exclusivity” means, with respect to a country, any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority with respect to the Product in such country, other than a Patent Right.

1.116 “Regulatory Rights Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee of the Product Regulatory Approvals and Documentation relating to the Commercialization and Development of Products in each country in the Territory, including, without limitation, U.S. IND 076667 and U.S. NDA 201656 (also referred to herein as the First Approved NDA), and the assumption by Licensee of all of the obligations under Applicable Law as the sponsor thereunder.

1.117 “Remedial Action” means any recall, market withdrawal, safety alert, corrective action or other regulatory action taken with respect to the Product by virtue of Applicable Laws.

1.118 “Renaissance” means Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC), a limited liability company organized under the laws of the State of Delaware.

1.119 “Renaissance Agreements” means (a) that certain Manufacturing Agreement, dated July 14, 2014, between Serenity and Renaissance, relating to the manufacture by Renaissance of Product and supply thereof to Serenity or any third party designated by Serenity and (b) that certain Quality Agreement, dated January 16, 2015, between Serenity and Renaissance, relating to compliance with current Good Manufacturing Practices guidances and directives applicable to the manufacture by Renaissance of Products.

1.120 “Renaissance Agreements Assignment and Assumption Agreement” means that certain agreement of even date herewith entered into by Licensor and Licensee, relating to the assignment by Licensor to Licensee and the assumption by Licensee of the Renaissance Agreements.

1.121 “Reprise” means Reprise Biopharmaceutics, LLC, a limited liability company organized under the laws of the State of New York.

1.122 “Reprise License Agreement” means that certain license agreement, effective as of May 28, 2017, by and between Reprise and Serenity, relating to the grant by Reprise to Serenity of an exclusive license under the patent rights and know-how specified therein.

1.123 “Right of Reference or Use” has the meaning set forth in 21 CFR Sec. 314.3(b) with respect to the United States, and any provisions equivalent thereto in the Applicable Laws of any other country in the Territory.

1.124 “Royalty Term” means, with respect to the Product and each country in the Territory, the period of time commencing on the date of First Commercial Sale by Licensee or its Sublicensees of the Product in such country and ending upon the termination of this Agreement in accordance with Article 14.

1.125 “Serenity” has the meaning set forth in the Preamble.

1.126 “Serenity Trademark Standards” means the set of policies, specifications, directions, and standards for use of the Licensed Serenity Trademarks to be prepared in accordance with Section 4.4 and to be attached hereto as Exhibit 1.124.

1.127 “Sublicensed Rights” has the meaning set forth in Section 2.2(b).

1.128 "Term" means the period commencing on Effective Date and ending upon the termination of this Agreement in accordance with Article 14.

1.129 "Territory" means the United States, Canada, and each of their respective territories and possessions.

1.130 "Third Party" means any Person other than the Parties and their Affiliates.

1.131 "Third Party Distributor" means any Third Party engaged and authorized by Licensee Party to distribute, import, market, promote and sell the Product in any country in the Territory.

1.132 "Third Party Infringement Claim" has the meaning set forth in Section 9.4(a).

1.133 "Third Party License(s)" has the meaning set forth in Section 8.3(b)(ii)(A).

1.134 "Third Party Supply Agreements" means the agreements originally executed by and between Serenity and the Third Parties named therein, relating to the manufacture and supply of certain components of the First Approved Product (including, without limitation, the applicable drug substance, ingredients for formulating the applicable drug product, and intranasal delivery device) and the manufacture and supply of the First Approved Product in finished form, including, the Renaissance Agreements and the other agreements set forth in Exhibit 1.134.

1.135 "Toll Period" has the meaning set forth in Section 14.2(b).

1.136 "TRx" shall mean total prescriptions of a product for a specified period.

1.137 "Treatment" (or, when required by the context, "Treat" or "Treats") means, with respect to an Indication, the diagnosis, prevention, palliation, amelioration, control, mitigation, treatment, cure, or prognosis of such Indication.

1.138 "Unexpected Adverse Drug Experience" has the meaning set forth in 21 CFR Section 314.80 and any regulation successor thereto.

1.139 "Valid Claim" means, with respect to a particular country in the Territory, a claim within an issued patent or patent application included in the Licensed Serenity Patent Rights, Licensed Reprise Patent Rights, or Licensed CPEX Patent Rights that has not expired, lapsed, or been abandoned, and that has not been held unenforceable, invalid, or been cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including without limitation through opposition, re-examination, reissue, or disclaimer.

2. LICENSES AND ASSIGNMENTS.

2.1 **Licenses of Patent Rights, Know-How, Trademark, and Copyrights.**

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Patent Rights and the Licensed Serenity Know-How, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (subject to Section 2.5, even as to Licensor) license to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory.

(b) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Trademarks, a

transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use the Licensed Serenity Trademarks to Commercialize the Product in the Field throughout the Territory.

(c) Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee under Licensor's right, title, and/or interest in or to the Licensed Serenity Copyrights, a transferable (subject to Section 15.2), sublicenseable (subject to Section 2.4), royalty-, fee- and milestone payment-bearing, exclusive (even as to Licensor) license to use, copy, publish, and distribute the content that is the subject of the Licensed Serenity Copyrights for the purpose of Commercializing the Product in the Field throughout the Territory.

(d) The license in, to, and under the Licensed Patents granted in Sections 2.1(a), (b) and (c) includes, without limitation,

(i) the right to sue for past and future infringement, violation, or misappropriation of any of such Licensed and any invention claimed therein and all applications for industrial property protection hereafter filed for any such invention, including, without limitation, all applications for patents, utility models, and designs which may be filed for any such invention in any country or countries in the Territory,

(ii) the right to file such applications in such countries in the Territory,

(iii) the right to claim for such applications the priority rights derived from the corresponding patent application under the patent laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and

(iv) all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for any such invention in any country or countries in the Territory and all extensions, renewals and reissues thereof.

2.2 **Grant of Sublicenses to Licensee.** Subject to the terms and conditions of this Agreement, the CPEX License Agreement, and the Reprise License Agreement, Licensor hereby grants Licensee under Licensor's rights in the Licensed CPEX Patent Rights and the Licensed Reprise Rights (collectively, the "Sublicensed Rights") a transferable (subject to Section 15.2), sublicenseable (subject to the terms of Section 2.4, and each of the CPEX License Agreement and the Reprise License Agreement, as applicable), royalty-, fee-, and milestone payment-bearing, exclusive (even as to Licensor) sublicense to make, have made, use and have used, offer to sell, sell and have sold, import and have imported, and to otherwise Commercialize the Product in the Field throughout the Territory.

2.3 **Assignments.**

(a) ***Assignment of Supply Agreement.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Renaissance Supply Agreement Assignment and Assumption Agreement.

(b) ***Assignment of Regulatory Rights.*** Simultaneously with the execution and delivery of this Agreement, the Parties will execute and deliver to each other the Regulatory Rights Assignment and Assumption Agreement.

2.4 **Sublicensing by Licensee.**

(a) Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant to Third Parties sublicenses under the license to the Licensed Rights granted to Licensee in Sections 2.1(a), (b) and (c) and the sublicense to the Sublicensed Rights granted to Licensee in Section 2.2; provided that Licensee hereby covenants that it will not grant any such sublicense unless (i) in the case of any such sublicense of the Licensed Rights or the Sublicensed Rights, Licensor has consented thereto, which such consent shall not be unreasonably withheld, conditioned or delayed, (ii) in the case of any such sublicense of the Sublicensed Rights, such sublicense complies with the terms and conditions set forth in the CPEX License Agreement or Reprise License Agreement, as applicable; and provided, further, that except for sublicenses granted in respect of Development and Commercialization of the Product in Canada, Licensee will not grant any such sublicenses during the first two (2) years immediately following the Effective Date.

(b) Licensee will be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.4.

(c) Each such sublicense granted by Licensee in accordance with this Section 2.4 will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of (i) this Agreement as are applicable to Licensee as licensee hereunder and (ii) the CPEX License Agreement and the Reprise License Agreement as are applicable to Licensee as a sublicensee thereunder.

(d) Licensee will provide Licensor with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(e) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement (except to the existence of any obligations to disclose such sublicense agreement to the licensors under CPEX License Agreement or the Reprise License Agreement, as applicable).

(f) Each such sublicense granted by Licensee will terminate immediately upon the termination of this Agreement, unless:

(i) such sublicensee is not in material breach of its obligations thereunder,

(ii) if this Agreement was terminated for Licensee's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensee within thirty (30) days after such termination; and

(iii) such sublicensee agrees in writing to be bound directly to (A) Licensor as licensee under the Licensed Rights and sublicensee under the Sublicensed Rights in accordance with the terms and conditions of this Agreement and (B) CPEX and Reprise in accordance with terms and conditions of the CPEX License Agreement and the Reprise License Agreement, respectively.

2.5 **Licenses Granted by Licensee to Serenity.**

(a) ***License for Development and Commercialization Activities.*** Subject to the terms and conditions of this Agreement Licensee hereby grants to Serenity and its Affiliates, under Licensee's rights in any and all intellectual property (including, without limitation, Know-

How and any Patent Rights, trademarks, and copyrights) with respect to the Product that Licensee or any of its Affiliates owns or otherwise controls by license or otherwise,

(i) an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to Develop, Commercialize, and Manufacture outside the Territory Products for any Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments;

(ii) in the event that Licensor engages, in accordance with Section 2.6, Section 6.2, Article 14, or otherwise under the terms and conditions of this Agreement, in any Development, Commercialization, or Manufacture of Products in the Territory for any Indications, an exclusive (even as to Licensee), sublicenseable (subject to Section 2.5(b)), transferable (subject to Section 15.2), sublicense to so Develop, Commercialize in the Territory, and Manufacture such Products for such Indications, which such sublicense (A) in the case of any such intellectual property not originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall bear royalties, fees, and/or milestone payments to be mutually agreed upon by the Parties and (B) in the case of any such intellectual property originally licensed, sublicensed, or assigned by Licensor to Licensee in accordance with this Agreement shall not bear any royalties, fees, or milestone payments; and

(iii) in the event that Licensor engages in any Development of Products in the Territory for any Indications in connection with any Development Activities contemplated by Article 6, a non-exclusive sublicense to Develop such Products for such Indications, which such sublicense shall not bear any royalties, fees, or milestone payments.

(b) Sublicensing by Licensor.

(i) Subject to the terms and conditions of this Agreement, Licensor shall have the right to grant to Third Parties sublicenses under the license granted to Licensor under Section 2.5(a); provided that Licensor hereby covenants that it will not grant any such sublicense unless Licensee has provided its consent, which consent shall not be unreasonably withheld or delayed and such sublicense complies with the terms and conditions set forth in this Agreement.

(ii) Licensor shall be solely responsible for the performance of any sublicensee under each such sublicense agreement granted in accordance with this Section 2.5(b).

(iii) Each sublicense agreement granted by Licensor in accordance with this Section 2.5(b) will be set forth in a sublicense agreement that includes provisions that obligate the sublicensee thereunder to abide by and be subject to all of the terms and conditions of this Agreement as are applicable to the intellectual property so licensed by Licensee to Licensor under Section 2.5(a).

(iv) Licensor will provide Licensee with a copy of each such executed sublicense agreement within ten (10) days after the execution and delivery thereof.

(v) The existence and any and all of the contents of any such executed sublicense agreement will be deemed to be Confidential Information of each Party under this Agreement.

(vi) Each such sublicense granted by Licensor in accordance with this Section 2.5(b) shall terminate immediately upon the termination of this Agreement, unless:

(A) such sublicensee is not in material breach of its obligations thereunder,

(B) if this Agreement was terminated for Licensor's material breach of the terms and conditions hereof, such sublicensee cures such material breach by Licensor within thirty (30) days after such termination; and

(C) sublicensee agrees in writing to be bound directly to Licensee as licensee under the intellectual property sublicensed under such sublicense.

(c) Right of Reference or Use.

(i) Licensee hereby grants to Licensor a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation (for purposes of this Section 2.5(c), "Licensee Regulatory Approvals and Regulatory Documentation") relating to the Compound and any Products in respect of which Licensee is the sponsor for purposes of:

(A) Licensor's Development, Commercialization, or Manufacture of Products outside the Territory and

(B) Licensor's Development, Commercialization, or Manufacture of Products for any Indications inside the Territory in the event that Licensor engages in any such Development, Commercialization, or Manufacture of Products in the Territory for such Indications in accordance with Section 2.6, Section 6.3, and/or Article 14, or otherwise under the terms and conditions of this Agreement.

(ii) The Parties agree that prior to any exercise by Licensor of the Right of Reference or Use granted by Licensee to Licensor under Section 2.5(c)(i), the Parties will mutually agree upon the amount and timing of one or more payments by Licensor to Licensee as consideration to Licensee for the grant of such Right of Reference or Use, which such payments shall be fair and reasonable in respect of the expenditures that Licensee incurs to obtain such Regulatory Approvals and Regulatory Documents and only payable in the event that such Regulatory Approvals and/or Regulatory Documents are referenced or used by Licensor to support a Regulatory Approval of the Product that is granted by the applicable Regulatory Authority.

(iii) The Parties agree that for purposes of Section 2.5(c)(ii),

(A) [***]; and

(B) to the extent Licensor licenses or sublicenses the Commercialization of any Products pursuant to any arrangement that becomes effective following the first anniversary of the Effective Date and in respect of which the applicable Regulatory Approval has been supported at least in part by any Regulatory Approvals or Regulatory Documents of Licensee that are referenced or used as contemplated by this Section 2.5(c), payments of such consideration in respect of any Calendar Quarter will not exceed more than [***] percent ([***]%) of

the consideration received by Licensor from any sublicensee of Licensor in respect of such Commercialization.

2.6 **Right of First Negotiation.** Licensee covenants and agrees that if at any time during the Royalty Term with respect to any country in the Territory, Licensee decides to seek to negotiate an agreement with any Third Party relating to the Commercialization of Generic Products in such country by such Third Party, Licensee will not enter into any such negotiations with any such Third Party before providing Licensor prior written notice thereof, whereupon Licensor will, upon written notice to Licensee within thirty (30) days after the receipt of such notice from Licensee, have the right to enter into good faith, exclusive negotiations with Licensee with respect to Licensor obtaining the right to so Commercialize in such country Generic Products, and further provided that as a condition to Licensee agreeing to grant Licensor any rights to so Commercialize any Generic Products for any Indications in any country in the Territory, Licensor must demonstrate that Licensor possesses or otherwise has access to the resources required to so Commercialize any such Generic Products and Licensor agrees not to otherwise Commercialize any Generic Products in the Territory. Notwithstanding anything to the contrary set forth herein, Licensee has the right to Develop and Commercialize Generic Products in any country in the Territory and the TRxs in respect of such Commercialization of Generic Products by Licensee will be included in TRxs of Generic Products for purposes of the definition of Royalty Term, provided that if Licensee Launches any such Generic Product prior to the Launch of a Generic Product in any country in the Territory prior to the Launch in such country of a Generic Product by a Third Party, then Licensee must obtain the written consent of Licensor prior to such Launch.

With respect to Products, Licensor from time to time may notify and demonstrate to Licensee that Licensor possesses or has access to the resources required for performing Commercialization Activities in respect of such Products in the Territory. Licensee agrees that upon demonstration that Licensor possesses or has access to such resources, Licensee will in good faith consider Licensor to perform such Commercialization Activities prior to negotiating an agreement with a Third Party related to such Commercialization Activities.

2.7 **No Implied Rights or Licenses.** No Party grants to the other Parties any rights or licenses in or to any intellectual property right or regulatory right whether by implication, estoppel, or otherwise, except to the extent expressly provided in this Agreement. Nothing in this Agreement shall in any manner limit the activities of Licensor or its Affiliates with respect to the Product outside the Territory.

3. JOINT STEERING COMMITTEE AND ALLIANCE MANAGERS.

3.1 **Generally.**

(a) ***Joint Steering Committee.*** Licensor and Licensee shall form the Joint Steering Committee. The JSC will have only such powers as are specifically delegated to it in this Agreement, and such powers shall be subject to the terms and conditions set forth in this Agreement.

(b) ***JSC Subcommittees.*** The JSC is hereby authorized to appoint one or more JSC Subcommittees to which the JSC may assign responsibility for specific matters (including, without limitation, matters arising with respect to Development, Commercialization, and Manufacturing. Each JSC Subcommittee will have only such powers as are specifically delegated to it by the JSC, and the delegation of any such

powers to any JSC Subcommittee shall be subject to the terms and conditions set forth in this Agreement.

(c) ***Limitation of Power of JSC and JSC Subcommittees.*** Without limiting the generality of Sections 3(a) and 3(b), neither the JSC nor any JSC Subcommittee shall have any power to amend this Agreement or bind or incur liability on behalf of either Party without such Party's express prior written authorization.

(d) ***Compliance with JSC and JSC Subcommittee Decisions.*** Each Party will comply with the decisions of the JSC and any JSC Subcommittee to the extent such decisions arise from the JSC or such JSC Subcommittee, as applicable, carrying out its powers and responsibilities as set forth in this Agreement and not otherwise inconsistent with the terms and conditions of this Agreement. Notwithstanding the foregoing, and is expressly set forth herein, Licensee shall have the sole and absolute right and discretion to decide matters related to the Commercialization, Manufacturing, or Development of the Product.

3.2 **Membership and Governance of JSC and JSC Subcommittees.**

(a) ***Membership.***

(i) The JSC will be comprised of six (6) members who, except as otherwise provided in clause (iii) of this Section 3.2(a), are employees of the Parties (each a "JSC Member"), with three (3) JSC Members designated by Licensor and three (3) JSC Members designated by Licensee.

(ii) Each JSC Subcommittee will be comprised of the total number of members (each a "JSC Subcommittee Member") as is designated by the JSC in forming such JSC Subcommittee, with the number of JSC Subcommittee Members appointed to such JSC Subcommittee from each Party to be designated by the JSC in forming such JSC Subcommittee. In determining the number of JSC Subcommittee Members to serve on any JSC Subcommittee formed by the JSC, the JSC will provide that the number of such JSC Subcommittee Members to be designated by each Party will be reasonable with respect to the experience and expertise of the human resources of each such Party in respect of the matters for which such JSC Subcommittee is responsible.

(iii) Each of Licensor and Licensee, upon prior written notice to the other Party, may (i) replace each person such Party has designated as a JSC Member or a JSC Subcommittee Member for any reason at any time, upon prior written notice to the other Party, (ii) designate a substitute for each person such Party has designated as a JSC Member or JSC Subcommittee Member, and (iii) appoint non-employees of such Party as JSC Members and JSC Subcommittee Members only upon the prior consent and approval of the other Party.

(b) ***Decision-Making.*** While the JSC and each JSC Subcommittee will seek to decide matters under their respective consideration by consensus of all of its members, Licensee reserves the right to decide each such matter in its sole and absolute discretion.

(c) ***Meetings.*** The JSC and each JSC Subcommittee will meet as agreed upon by the JSC Members or the applicable JSC Subcommittee Members, respectively, in person or by teleconference or video-teleconference; provided that the first meeting of the JSC

Committee or such JSC Subcommittee, as applicable, will be within ninety (90) days after the Effective Date.

(d) ***Observers.*** Except for matters in respect of which the JSC or any JSC Subcommittee needs to meet in executive session, the meetings of the JSC and any JSC Subcommittee may be attended by non-Member observers at the invitation of an executive officer of either Party (the "Inviting Party"), provided that (i) the Inviting Party provides reasonable prior notice of such invitation to the other Party, (ii) the other Party has consented to such invitation in advance of the applicable meeting, which such consent shall not be unreasonably withheld, delayed or conditioned and (iii) any such observer has agreed in writing to obligations to safeguard the confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations in Section 13.2.

(e) ***Chairperson.***

(i) *Of JSC*. At the first meeting of the JSC following the Effective Date and at the first meeting of the JSC in each calendar year beginning after the Effective Date, the JSC Members will select a chairperson to serve until such person's successor has been designated in accordance herewith. The chairperson of the JSC shall rotate annually between JSC Members designated by Licensor and those designated by Licensee. The first chairperson of the JSC shall be selected from the JSC Members designated by the Licensee.

(ii) *Of Each JSC Subcommittee*. Each JSC Subcommittee shall have a chairperson appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(f) ***Secretary.***

(i) *Of JSC*. The chairperson of the JSC shall designate a secretary of the JSC who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within thirty (30) days after each meeting of such committee setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JSC. Such minutes shall be effective only after being approved by both Parties. Definitive minutes of all committee meetings shall be finalized no later than sixty (60) days after the meeting to which the minutes pertain.

(ii) *Of Each JSC Subcommittee.* Each JSC Subcommittee shall have a secretary appointed in accordance with the directions of the JSC in establishing such JSC Subcommittee.

(g) ***Term of JSC and JSC Subcommittees.***

(i) The JSC shall continue to exist for the Term of this Agreement or upon its termination upon mutual agreement of the Parties.

(ii) Each JSC Subcommittee shall continue to exist for the term to be set forth by the JSC in establishing such JSC Subcommittee, but in no event for a period extending beyond the Term of this Agreement

(h) Alliance Managers.

(i) Each of Licensor and Licensee shall appoint an Alliance Manager, who shall be an individual authorized to act as such Party's point of contact for communications between and among the Parties relating to the Commercialization, Manufacturing and Supply, and any Development Activities contemplated by this Agreement. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. The Alliance Manager of a Party may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

(ii) Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between and among the Parties and within the JSC and each JSC Subcommittee.

(iii) Each Alliance Manager will also: (i) be the point of first referral in all matters of conflict resolution; (ii) identify and bring disputes to the attention of the JSC or the relevant JSC Subcommittee, as applicable, in a timely manner; (iii) plan and coordinate cooperative efforts and internal and external communications; and (iv) take responsibility for ensuring that governance activities, such as the conduct of required JSC and JSC Subcommittee meetings and production of meeting minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed

(i) Dispute Resolution.

(i) In the event that any dispute arises with respect to matters falling within the scope of the role and the powers and responsibilities of the JSC or any JSC Subcommittee as set forth in or contemplated by this Article 3 or elsewhere in this Agreement, then either Licensor or Licensee or any of the Members of such Committee may notify the Alliance Managers of such disputed matter.

(ii) The Alliance Managers shall discuss in good faith any such disputed matter referred to them in accordance with Section 3.2(i)(i). If the Alliance Managers are unable to resolve any such matter, either Licensor or Licensee may refer the matter to the Chief Executive Officer or President of Licensor and the Chief Executive Officer, President, or an Executive Vice President of Licensee, which such two individuals shall meet at an agreed location or by telephone to resolve the matter within twenty (20) days after the meeting at which such matter arose.

(iii) If such two officers of the Parties are unable to resolve the disputed matter so referred to them in accordance with Section 3.2(i)(ii) within an additional thirty (30) day period, then the following procedures shall apply:

(A) in the case of matters with respect to which Licensee is authorized hereunder to decide in its sole and absolute discretion, including, without limitation, any Commercialization or Manufacturing and Supply matter, Licensee shall have final decision-making rights with respect thereto and shall promptly provide written notice to Licensor of its final position regarding such matter and Licensor will comply with the position taken by Licensee on such matter unless compliance with such position would result in the incurrence of a direct material financial expenditure or imposition of some other non-financial

burdensome obligation upon Licensor that would be greater than would have been the case absent compliance with such position, which in such case shall be referred for dispute resolution under Section 15.8 and

(B) in the case of matters with respect to which Licensee is not authorized hereunder to decide such matters in its sole and absolute discretion, such matters shall be referred for dispute resolution under Section 15.8.

3.3 **Committee Oversight of Commercialization Activities.**

(a) ***Role.*** The JSC and any JSC Subcommittee established for the purpose of oversight of Commercialization Activities, will monitor, assess, and make recommendations to Licensee in respect of the Commercialization of the Product contemplated in Article 4 of this Agreement.

(b) ***Powers and Responsibilities.*** With respect to Product Commercialization Activities, the powers and responsibilities of the JSC and any JSC Subcommittee established for the purpose of oversight of such Commercialization Activities are limited to the matters set forth in this Section 3.3 and Article 4. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify, or waive compliance with this Agreement with respect to Commercialization Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Commercialization Plans for the Product and any Indications. Notwithstanding the foregoing, Licensee reserves the right to decide each such Commercialization matter in its sole and absolute discretion, including amending or modifying any Commercialization Plan.

(c) ***Annual Review of Commercialization Plan***. On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities will review, analyze, and comment on the Annual Commercialization Plan then in effect and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Commercialization Activities contemplated by the Annual Commercialization Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Commercialization Plan;

(ii) an assessment of whether the strategic objectives set forth in the Annual Commercialization Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(iii) the submission to Licensee of any recommended revisions to the Annual Commercialization Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

(d) ***Regulatory Exclusivity.*** The JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor the process of applying for and securing Regulatory Exclusivity that may be available under the applicable Law of countries in the Territory, including, without limitation, any data or market exclusivity periods such as those periods listed in the FDA's Orange Book. Each of Licensor and Licensee shall use Commercially Reasonable Efforts to cooperate with each other and to take such reasonable actions to obtain such Regulatory Exclusivity in each country in the Territory.

3.4 **Oversight of Manufacturing and Supply Activities.**

(a) ***Role.*** The JSC and any JSC Subcommittee responsible for oversight of Manufacturing and Supply Activities will monitor, assess, and make recommendations to Licensee in respect of the manufacture and supply of the Product as contemplated in Article 5 for purposes of Commercializing the Product for any Indications that are the subject of Regulatory Approvals and any Development Activities in respect of the Product for the PNE Indication, any Additional Indications and the Nocturia Indication throughout the Territory.

(b) ***Powers and Responsibilities.*** With respect to Product Manufacturing Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Manufacturing Activities are limited to the matters set forth in this Section 3.4 and Article 5. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Manufacturing Activities required to be undertaken by Licensee under this Agreement, including, without limitation, the Manufacturing and Supply Plan for the Product. Notwithstanding the foregoing, Licensee reserves the right to decide each such manufacturing and supply matter in its sole and absolute discretion, including amending or modifying any Manufacturing and Supply Plan.

(c) ***Annual Review of Manufacturing and Supply Plan.*** On an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC or any JSC Subcommittee responsible for oversight of Manufacturing Activities will review, analyze, and comment on the Manufacturing and Supply Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(i) an assessment of whether the Manufacturing Activities contemplated by the Manufacturing and Supply Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Manufacturing and Supply Plan; and

(ii) an assessment of whether the strategic objectives set forth in the Manufacturing and Supply Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties.

3.5 **Oversight of Development Activities.**

(a) ***Role.*** The JSC and any JSC Subcommittee responsible for oversight of any Development Activities contemplated in Article 6 of this Agreement will monitor such Development Activities. In this role the JSC or such JSC Subcommittee, as applicable, will (i) assist Licensee in overseeing any Development of, Clinical Studies for, and preparation and submission of Regulatory Documentation for obtaining Regulatory Approval of the Product contemplated by any Development Plan, including, without limitation, review of any relevant Regulatory Documents and Regulatory Documentation and (ii) provide a forum for sharing advice, progress, and results and documents, including, without limitation, relevant Clinical Study designs, protocols, study reports, and any other material information with respect to any such Development Activities.

(b) ***Powers and Responsibilities.*** With respect to any Product Development Activities, the powers and responsibilities of the JSC and any JSC Subcommittee responsible for oversight of such Development Activities are limited to the matters set forth in this Section 3.5 and Article 6. Neither the JSC nor any JSC Subcommittee shall have the power to amend, modify or waive compliance with this Agreement with respect to Development Activities, including, without limitation, any Development Plan in effect from time to time. Notwithstanding the foregoing, Licensee reserves the right to decide each such Development matter in its sole and absolute discretion, including amending or modifying any Development Plan.

(c) ***Annual Review of Development Plan.*** If Licensee determines to engage in any Product Development Activities in accordance with Article 6, on an annual basis, beginning in the first full Calendar Year following the Effective Date, no later than sixty (60) days before the end of such Calendar Year, the JSC and any JSC Committee responsible for oversight of Development Activities that Licensee may so determine to undertake in accordance with Article 6 will review, analyze, and comment on the Development Plan then in effect, and any revisions thereto proposed by Licensee or Licensor, which such review, analysis, and comment will include, without limitation:

(A) an assessment of whether the Development Activities contemplated by the Development Plan for the then current Calendar Year have been successfully undertaken and have achieved or are achieving the strategic objectives set forth in the Development Plan;

(B) an assessment of whether the strategic objectives set forth in the Development Plan, together with any revisions then proposed by Licensee or Licensor, continue to reflect the best interests of the Parties;

(C) the submission to Licensee of any recommended revisions to the Development Plan then in effect and any revisions then proposed by Licensee or Licensor, in order to reflect the aforementioned assessments.

4. COMMERCIALIZATION.

4.1 **Preparation and Scope of Commercialization Plan.**

(a) ***Preparation.*** Licensee agrees to prepare and provide to Licensor within one hundred twenty (120) days immediately following the Effective Date the initial Commercialization Plan.

(b) ***Scope.*** The Commercialization Plan for the Product in respect of the Nocturia Indication, PNE Indication and any Additional Indication will consist of a Pre-Launch Commercialization Plan, an Annual Commercialization Plan, and, in respect of the initial three-year period following the Effective Date, the three-year Commercialization Plan described below.

4.2 **Timing of Product Launches.** The initial Commercialization Plan will set forth the timing of the Launch of the Product in the United States for the Nocturia Indication. To the extent, Licensee or any sublicensee intends in accordance with Article 6 to engage in any Development Activities in order to (a) Commercialize the Product for the Nocturia Indication in Canada, the Commercialization Plan then in effect will be amended to include such Commercialization at such time and (b) Commercialize any Product for the PNE Indication and any Additional

Indication in either country in the Territory, the Commercialization Plan then in effect will be amended to include such Commercialization at such time.

4.3 **Diligent Commercialization of the Product in the Territory.**

(a) Licensee covenants that at all times during the Term of this Agreement it will use Commercially Reasonable Efforts to Commercialize the Product in each country in the Territory, including, without limitation, the making and implementation of decisions and allocation of Licensee's resources for the purpose of achieving the objectives set forth in the Commercialization Plan, which such objectives will include, without limitation, the placement of the Product in First Position in all Detailing of the Product with the Sales Representatives for the Product for the First Position Period achieving the timing and geographic extent of Detailing of the Product set forth in the Commercialization Plan, and the continued optimization of such Detailing to maximize Net Sales of the Product. Failure by Licensee to use Commercially Reasonable Efforts to Commercialize the Product will be deemed to be a material breach of this Agreement for purposes of Section 14.3.

(b) The term "First Position Period" means the four (4) year period commencing upon the Launch of the Product in the United States; *provided, however*, that if Licensee has not been the subject of a Change of Control prior to the end of such four-year period, the First Position Period shall be extended to the earlier of (x) the fifth (5^{th}) anniversary of the commencement thereof and (y) any such Change of Control; and *further, provided, however,* that if any such Change of Control occurs prior to the fourth (4^{th}) anniversary of the commencement of the First Position Period, then the party surviving such Change of Control will be obligated to continue Detailing of the Product in First Position until such fourth (4^{th}) anniversary and Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until the fifth (5^{th}) anniversary of the commencement of the First Position Period, and if such Change of Control occurs after the fourth (4^{th}) anniversary of such commencement of the First Position Period but before the fifth (5^{th}) such anniversary, then Licensee will use Commercially Reasonable Efforts to obtain the agreement of the party surviving such Change of Control to continue Detailing of the Product in First Position until such fifth (5^{th}) anniversary.

4.4 **Commercialization Plan and Budgets, Generally.**

(a) ***In General.*** Subject to the terms of this Agreement, the preparation of the Commercial Plan and any and all updates, revisions, amendments, and the like thereof will be the responsibility of Licensee, and Licensee will bear the expense of the preparation of the initial Commercial Plan and any and all updates, revisions, amendments and the like thereof. The Commercialization Plan for the Product for each Indication for which Regulatory Approval is obtained in each country in the Territory will include the following:

(i) prior to the Launch of a Product, a detailed Pre-Launch Commercialization Plan covering the period from the date such pre-Launch Commercialization Plan as approved by the JSC or the JSC Subcommittee responsible for oversight of Commercialization and adopted by Licensee (generally, upon commencement of the first Phase 3 Clinical Studies in respect of such combination through the end of the second (2^{nd}) full Calendar Year following Launch of the Product for such Indication in such country (the "Pre-Launch Commercialization Plan"), provided that the Pre-

Launch Commercialization Plan for the Product for the Nocturia Indication for the United States is set forth in the Commercialization Plan in Exhibit 4.4 to be attached hereto following its preparation and adoption in accordance with the provisions of this Agreement);

(ii) an annual Commercialization plan and budget for such Product (the "Annual Commercialization Plan") for each full Calendar Year following the end of the period of time covered in the Pre-Launch Commercialization Plan for such Product, each of which such annual Commercialization Plans shall be reviewed and analyzed by the JSC (or the JSC Subcommittee responsible for oversight of Commercialization) in accordance with Section 3.3(c)(ii);

(iii) a three-year Commercialization plan and budget (the "Long-Term Commercialization Plan") that sets forth the Branding Strategy for the Product for the initial three year period, the anticipated Commercialization programs and funding requirements for the Commercialization of the Product for such combination during such three-year period, and anticipated gross sales and Net Sales of the Product during each quarter in such three-year period, and which such Long-Term Commercialization Plan will be used to guide the formulation of the applicable Pre-Launch Commercialization Plan and the Annual Commercialization Plan for such Product.

(b) ***Content of Commercialization Plan, More Specifically.*** The Commercialization Plan will specify in detail the content of the Commercialization Activities contemplated hereby.

(c) ***Preparation of Serenity Trademark Standards.*** As part of the preparation of the initial Commercialization Plan, Licensee will prepare a proposed set of Serenity Trademark Standards for review and approval by the JSC (or the JSC Subcommittee responsible for Commercialization matters) in accordance with Section 3.3(b).

4.5 **Annual Commercialization and Pre-Launch Commercialization Plans.**

(a) ***Interim Updating Annual Commercialization Plan***. Each Annual Commercialization Plan shall be updated by Licensee as frequently as needed during a Calendar Year to take into account developments in the Commercialization of the Product for the applicable Indication and country.

(b) ***Pricing and Reimbursement Approvals.***

(i) Where pricing and reimbursement approvals are required for Commercialization of the Product in any country in the Territory, Licensee, will be responsible for obtaining such approvals in a timely manner, and shall consider in good faith any suggestions and comments from or on behalf of Licensor with respect thereto.

(ii) As part of its responsibility for oversight of Commercialization Activities, the JSC and any JSC Subcommittee responsible for oversight of Commercialization Activities shall review and comment on matters relating to pricing and reimbursement approvals in respect of the Product. Such review shall include review of any materials, presentations, documents, agendas, and other relevant information to be presented or followed in meetings and communications with Regulatory Authorities and third party payors to the extent the timing of such

meetings and communications reasonably allows for such review and the outcome of any such meetings.

(iii) Following any meetings or material communications with Regulatory Authorities and third party payors relating to pricing and reimbursement approvals, Licensee will provide to the members of the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities, copies of any materials, presentations, documents, agendas, and other relevant information to be presented or followed at such meetings, to the extent not previously provided to the members of the JSC or such JSC Subcommittee pursuant to clause (ii) of this Section 4.5(b), and a summary of the outcome of such meetings.

4.6 **Sales Training.**

As specified in the Commercialization Plan and in accordance with dates specified therein, Licensee, at its expense, will develop a sales training plan and sales training materials for the Product for the Nocturia Indication in the United States and, if Licensee determines to Develop, directly or indirectly through a sublicensee, the Product for the Nocturia Indication in Canada, a sales training plan and sales training materials therefor. The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities, as applicable, will review such training materials and make recommendations for any revisions and updates thereto as the JSC or such JSC Subcommittee, as applicable, may deem appropriate. Thereafter, Licensee, at its expense, will train its Sales Representatives in accordance with such sales training plan and sales training materials in sufficient time to ensure that the Sales Representatives are fully trained prior to the date specified in the Commercialization Plan for the Launch of the Product for the Nocturia Indication in the United States and, if applicable, Canada.

4.7 **Advertising and Promotional Materials and Promotional Policies**.

(a) ***Tools, Materials, and Samples.***

(i) Licensee, at its expense, and in accordance with the Commercialization Plan, will develop all advertising and promotional tools and materials relating to the Commercialization of the Product in the Territory.

(ii) The JSC or the JSC Subcommittee responsible for oversight of Commercialization Activities shall monitor Licensee's use of such tools and materials.

(b) ***Use of Promotional Materials by Sales Representatives.*** Licensee agrees that:

(i) it will instruct its Sales Representatives to use, and will use Commercially Reasonable Efforts to train and monitor its Sales Representatives to ensure that such Sales Representatives use, only promotional materials, the Product Samples, and literature approved for use under this Section 4.6 for the promotion of the Product in the Territory;

(ii) any promotional material, promotional literature, and the Product Samples supplied to it shall not be misbranded, changed, altered or adulterated by it or any of its agents in any way prior to their distribution or use by such Party or its Sales Representatives; and

(iii) it will instruct its Sales Representatives to do, and will use Commercially Reasonable Efforts to train its Sales Representatives to do, and will establish

appropriate internal systems, policies and procedures for the monitoring of its Sales Representatives with the goal of ensuring that such personnel do, the following:

(A) limit claims of efficacy and safety for the Product to those that are (1) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of the Product in any respect from those claims of efficacy and safety that are contained in, the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (2) consistent with Applicable Law, and (C) consistent with the Product labeling approved by the FDA and other Regulatory Authorities;

(B) (1) refrain from making any changes in promotional materials and literature provided in accordance with this Section 4.6, and (2) use promotional materials, literature, and Samples within the Territory only in a manner that is consistent with (I) the then effective Pre-Launch Commercialization Plan and Annual Commercialization Plans and Budgets, (II) applicable Law and (III) the Product labeling approved by the FDA or other applicable Regulatory Authorities; (3) promote the Product in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, such as the FDA Guidance for Industry-Supported Scientific and Educational Activities; the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals; the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers; the Accreditation Council for Continuing Medical Education Standards for Commercial Support of Continuing Medical Education; the American Medical Association Gifts to Physicians From Industry Guidelines; the Pharmaceutical Marketing Research Group Guidelines on market research activities; the Prescription Drug Marketing Act of 1987, as amended, and the rules, regulations and guidelines promulgated thereunder; federal, state and local agencies and all “fraud and abuse”, and consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti- Kickback Law (42 USC Sec 1320a-7b(b)) and the “Safe Harbor Regulations” which are found at 42 CFR Sec 1001_952 et seq.; the U.S. Foreign Corrupt Practices Act (and foreign equivalents); the U.S. Physician Payments Sunshine Act of 2010; and, to the extent not inconsistent with the foregoing, such Party’s policies communicated in writing to its Sales Representatives in accordance with this Article 4; and (4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any government, or of any agency or instrumentality of any government, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of the Product.

(c) Detailing.

(i) Licensee will use Commercially Reasonable Efforts to Detail the Product in accordance with the Commercialization Plan.

(ii) All written, electronic and visual communications provided by Licensee to its Sales Representatives Detailing the Product regarding Product strategy, positioning, Regulatory Approval, or selling messages for use by such personnel in Detailing the Product will be subject to being monitored by the JSC or the JSC Subcommittee responsible for oversight of Commercialization.

(d) ***Medical Education Activities.*** Funding for Medical Education Activities for the Product in the Territory will be set forth in the applicable Annual Commercialization Plan.

(e) ***Direct-to-Consumer Advertising.*** In each country in the Territory, Licensee will observe any and all Applicable Law relating to direct-to-consumer advertising for the Product in such country.

(f) ***Obligations in Respect of Product Samples.***

(i) Licensee will: (i) maintain an investigation, corrective and preventive action program for the handling of Product Samples in accordance with its internal policies and procedures; (ii) maintain monitoring and auditing programs capable of detecting losses, potential diversion and falsification of records related to Product Samples; (iii) implement processes for the inventory, distribution reconciliation and storage of Product Samples; (iv) review with the JSC its practices with respect to its contacts and communications with Regulatory Authorities with respect to matters relating to the Product Samples; and (v) administer the Product Samples program described in any applicable Annual Commercialization Plan in accordance with such standard operating procedures for product sampling that comply with "best practices" in the pharmaceutical industry.

(ii) Licensee will be responsible for compliance with Applicable Law with respect to its Product Samples program.

4.8 **Sales and Distribution.** Licensee will be responsible for warehousing and distributing in the Territory the Product and will perform related distribution activities. Licensee will also be solely responsible for handling all returns, recalls (in accordance with Section 4.11), order processing, invoicing and collection, distribution and inventory and receivables.

4.9 **Sales Representatives**.

The following provisions shall apply to each Party's Sales Representatives in the Territory:

(a) Licensee will use Commercially Reasonable Efforts to ensure that it has the appropriate number of Sales Representatives and managers to Commercialize the Product.

(b) Except as otherwise provided in this Article 4, Licensee's Sales Representatives will be full-time employees of Licensee or its Affiliates or an individual acting as an independent contractor as permitted below.

(c) Licensee may engage individuals as independent contractors to provide the Details to be provided by it in a country in the Territory and may use such independent contractors as Sales Representatives for the Product in a country in the Territory. Licensee will inform the JSC or any JSC Subcommittee responsible for oversight of Commercialization Activities of the extent to which Licensee engages such independent contractors for purposes of Detailing.

(d) Licensee will be responsible for the compliance by its independent contractors engaged pursuant to this section with applicable terms and conditions of this Agreement and shall be jointly and severally liable with any independent contractors who serve as Licensee's Sales Representatives for any breach of this Agreement or failure by independent contractors to perform such delegated duties (as well as for any breach by such independent contractors of its agreement with Licensee), and shall use Commercially Reasonable Efforts to cause such independent contractor to perform his, her or its services as a Sales Representative in compliance with the provisions of this Agreement. All compensation, reimbursement of costs and other payments to be made to any of such independent contractors shall be solely a matter between Licensee and such independent contractor.

(e) Licensee may from time to time use part-time employee Sales Representatives to sell the Product on behalf of Licensee in a country to the extent that such use is consistent with Licensee's practice in such country with respect to the majority of its other pharmaceutical products.

(f) Licensee will use Commercially Reasonable Efforts to provide full training (both general and Product-specific training) to its Sales Representatives, to deploy such number of Sales Representatives as may be necessary to fulfill its duties to Commercialize the Product and, consistent with its normal business practices, to minimize turnover of its Sales Representatives Detailing the Product and to cause its Sales Representatives to adhere to the sales call plan included in the Annual Commercialization Plan. Licensee will establish reasonable qualifications and experience levels (measured in years of experience selling or promoting ethical pharmaceutical products to health care professionals with actual prescribing authority) for Sales Representatives, and Licensee will use Commercially Reasonable Efforts to provide Sales Representatives that meet such qualifications and experience levels. Unless the JSC establishes a different time, within forty-five (45) days after the end of each Year, Licensee will provide Licensor and the JSC with a report with respect to the number of its Sales Representatives assigned to the promotion of the Product and the length of time each such Sales Representative has been assigned to the promotion of the Product to the extent not previously provided to the JSC.

(g) In the event that information comes to Licensor's attention that provides it a reasonable basis to believe that Licensee's Sales Representatives may have (i) violated any Applicable Law, or (ii) failed to provide satisfactory service or to comply with this Agreement, Licensor will have the right to request that Licensee immediately assess the performance of such individual, and to exercise any other rights or remedies available to Licensor under this Agreement, at law or in equity. Licensee will promptly use Commercially Reasonable Efforts to evaluate and resolve such issue in accordance with its policies or as it may otherwise deem appropriate, will (to the extent permitted by Applicable Law) keep Licensor informed of the progress of, and information learned during, its evaluation, and within fifteen (15) Business Days after Licensor first brought such information to Licensee's attention will provide Licensor, to the extent possible in compliance with Applicable Law, with a reasonably detailed written report summarizing any steps taken toward resolution of the matter.

(h) Licensee will comply with all Applicable Laws, rules and regulations applicable to the hiring, employment, and discharge of its Sales Representatives and its employees involved in marketing and promoting the Product. Licensee represents to Licensor that

Licensee is an equal opportunity employer and does not discriminate against any person because of race, color, creed, age, sex, or national origin.

(i) Licensee will be responsible for any failure of its Sales Representatives or employees to comply with the terms of this Agreement.

(j) Licensee will be solely responsible and liable for all probationary and termination actions taken by it with respect to its Sales Representatives, as well as for the formulation, content, and for the dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its Sales Representatives.

(k) Licensee shall in its sole discretion have the right to determine the configuration of its sales force(s) including, the geographical assignments of its Sales Representatives.

4.10 **Incentive Plans for Sales Representatives**. Licensee, in its sole discretion, will establish and implement a target bonus or sales incentive program whereunder Licensee's Sales Representatives are compensated for their efforts with respect to the Product in a manner consistent with such Party's other programs for similar products (and taking into consideration the commercial life cycle of the Product). All such programs shall be in compliance with all Applicable Law.

4.11 **Product Claims**. Licensee will not, and will cause each of its Sublicensees, contractors, and other agents not to, make any medical or promotional claim for the Product beyond the scope of the relevant Regulatory Approvals then in effect for the Product; provided, that Licensee may, subject to Section 13.7, distribute any information concerning the Product or its use, including scientific articles, reference publications and healthcare economic information, in accordance with Applicable Law**.**

4.12 **Recalls and Withdrawals.**

(a) Following consultation between Licensee and Licensor (or its designee), Licensee shall have final decision-making authority with respect to any recall or withdrawal of the Product from any market.

(b) The costs of any such recall or withdrawal will be borne by Licensee.

(c) In the event of any recall or withdrawal, Licensee shall implement any necessary action, with assistance from Licensor as reasonably requested by Licensee.

5. MANUFACTURE AND SUPPLY OF PRODUCTS.

5.1 **Manufacture and Supply of the Product, Generally.** Licensee will be responsible for the manufacture and supply of the Product for Commercialization and any Development.

5.2 **Scope of Manufacturing and Supply Plan.** In accordance with Article 5, the Manufacturing and Supply Plan for the Product in respect of the Nocturia Indication, the PNE Indication and any Additional Indication will address manufacturing and supply requirements for both the Commercialization Activities and any Development Activities contemplated by this Agreement.

5.3 **Existing Inventory.** Upon request of the Licensee, Licensor agrees to sell to Licensee at Licensor's cost, any and all inventory of Product, both in bulk drug and finished product form, existing as of the Effective Date. Licensee will make payment for any such inventory of Product requested by Licensee in two equal installments each at the time Licensee makes it first and second royalty payments to Licensee, respectively, in accordance with Article 8.

5.4 **Manufacturing for Licensor.** Licensee agrees that following any written request from Licensor during or after the Term of this Agreement, Licensee will within sixty (60) days after the date of such request, will use Commercially Reasonable Efforts to enter into an agreement with Licensor (which shall be transferable and sublicensable by Licensor to the same extent as contemplated in Section 2.5 in respect of sublicenses granted under this Agreement by Licensee to Licensor) containing fair and reasonable terms and conditions to be negotiated by Licensor and Licensee pursuant to which Licensee will designate under each of the Third Party Supply Agreements (and any successor agreements thereto and additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof) Licensor (and any transferee, sublicensee, or subcontractor of Licensor) as a party for which the applicable Third Party under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements) will manufacture and supply Products thereunder on terms and conditions no less favorable to Licensor as those applicable to Licensee under such Third Party Supply Agreement (and any such successor agreements and any such additional agreements), subject to the agreement of such Third Party. Licensor acknowledges and agrees that any use of such Product so manufactured and supplied will only be used by Licensor for purposes not in conflict with Licensee's rights under this Agreement. With respect to any such additional agreements entered into by Licensee relating to the manufacture and supply of Products and any components thereof, Licensee will use Commercially Reasonable Efforts to cause to be included in such additional agreements provisions that so allow Licensee to so designate Licensor (and any transferee, sublicensee, or subcontractor of Licensor) to so obtain Products and any components thereof in accordance with this Section 5.3.

5.5 **Manufacturing and Supply Plan.** The Manufacturing and Supply Plan for the First Approved Product will be set forth in Exhibit 5.5 to be attached to this Agreement. The JSC or any JSC Subcommittee responsible for reviewing, assessing, and revising this Plan in accordance with Section 3.4(c), including, without limitation, such revision as are necessary to address Development and Commercialization of Products for the Nocturia Indication in Canada, the PNE Indication and any Additional Indications in the United States and/or Canada.

6. DEVELOPMENT ACTIVITIES BY LICENSEE.

6.1 **Determination by Licensee to Engage in Development Activities.**

(a) Within one hundred eighty (180) days immediately following the Effective Date, Licensee will provide written notice to Licensor of Licensee's decision to undertake Development of the Product for the Nocturia Indication in Canada and the PNE Indication in the United States and/or Canada. For any such Indication and country in respect of which Licensee timely provides such notice of its decision to undertake Development of the Product, Licensor and Licensee hereby agree to engage in good faith negotiations in respect of the consideration to be received by Licensor from Licensee from the Commercialization of the Product for the Indication and the country for which Regulatory Approval is obtained as a result of such Development, including, without limitation, consideration in the form of licensing fees, development and commercialization milestone payments, and royalties. Upon mutual agreement of the Parties, such time period which Licensee must provide its written notice of its decision pursuant to this Section 6.1 may be extended.

(b) As part of the process by which Licensee determines whether to engage in Development of the Product for the Nocturia Indication in Canada and the PNE Indication and any Additional Indications in the United States and/or Canada, the Parties will engage in

good faith discussions as to Development Activities that Licensor can undertake to support and collaborate with Licensee with respect to Licensee's undertaking of such Development.

6.2 **Development Plan.** In respect of any Development of the Product specified in Section 6.1 that Licensee decides to undertake in accordance with Section 6.1, Licensee shall include with the notice specified in Section 6.1 a copy of the initial Development Plan in respect of such Development, which such Development Plan will describe the Development Activities necessary or advisable to obtain Regulatory Approvals of the Product for the Nocturia Indication in Canada and/or the PNE Indication and in the United States and/or Canada, as the case may be.

6.3 **Licensor's Rights to Develop and Commercialize.** For the PNE Indication in either country in the Territory and the Nocturia Indication in Canada in respect of which Licensee does not decide in accordance with Section 6.1 to undertake Development, Licensor has the right, as contemplated by Section 2.5(c), to engage in such Development and the Commercialization of the Product for such Indication and country for which Regulatory Approval is obtained as a result of such Development. To the extent that Licensor engages in any such Development Activities and Commercialization Activities under this Section 6.3, Licensor will keep Licensee informed thereof. To the extent that Licensee believes in good faith that such Commercialization Activities by Licensor would compete with the Commercialization of the Product by Licensee contemplated by this Agreement, the Parties will discuss such matter in good faith and seek to agree upon such measures as are reasonable to minimize any adverse impact of such Commercialization Activities by Licensor on such Commercialization of the Product in the Territory by Licensee.

7. REGULATORY MATTERS.

7.1 **Ownership of Product Regulatory Approvals and Documentation.** Licensee shall own all Product Regulatory Approvals and Documentation in respect of each country in the Territory.

7.2 **Conduct and Management of Regulatory Activities.** Licensee will use its Commercially Reasonable Efforts:

(a) to maintain the First Approved NDA in the United States;

(b) to obtain Regulatory Approval for the Product for the Nocturia Indication in each other country in the Territory in accordance with the Development Plan;

and

(c) to obtain Regulatory Approval for the Product for the PNE Indication in each country in the Territory in accordance with the Development Plan.

Any breach by Licensee of its obligations under Section 7.2(a) shall be deemed to be a material breach of this Agreement for purposes of Article 14.

7.3 **Transfer to Licensee of Product Regulatory Approvals and Documentation.** Following the transfer to Licensee of ownership of the Product Regulatory Approvals and Documentation in each such country in the Territory pursuant to Section 2.3(b),

(a) Licensee or its designee shall be the owner of any and all Product Regulatory Approvals and Documentation in each such country in the Territory, subject to the Right of Reference or Use hereby granted by Licensee to Licensor in Section 2.5(c) for purposes of Development and Commercialization of Products outside the Territory;

(b) Except for the Development and Commercialization of Products by Licensor in the Territory pursuant to Section 6.3, Licensee shall have the responsibility, at its expense, for all regulatory activities (including, without limitation, Development Activities undertaken to support obtaining or maintaining Regulatory Approvals) and interactions relating to the Product in each country in the Territory, including without limitation preparing, obtaining, and maintaining Regulatory Approvals in each country in the Territory and all substantive interactions with such Regulatory Authorities relating thereto; and

(c) Licensee shall determine, in its sole discretion, the content of all such submissions and of all correspondence with Regulatory Authorities relating to the Product in the Territory.

(d) To the extent Licensor has not undertaken any Product Development Activities in the Territory under Section 2.5(c), Section 2.6, Section 6.1 and/or Article 14, Licensor hereby grants to Licensee a Right of Reference or Use in all Regulatory Approvals and Regulatory Documentation in respect of the Compound and any Products in respect of which Licensor is the sponsor for purposes of Licensee's Development and Commercialization of Products in the Field and in the Territory. In consideration of such grant, Licensee will make one or more payments to Licensor determined in accordance with the same provisions set forth in clauses (ii) and (iii) in Section 2.5(c) in respect of Licensee's grant of the Right of Reference or Use set forth in clause (i) of Section 2.5(c).

7.4 **Regulatory Documentation for Generic Products.**

(a) Each Party shall deliver written notice to the other Party of any notice it receives as to the submission, filing, or approval of an application, including, without limitation, an Abbreviated New Drug Application in the United States or the equivalent thereof in any other country in the Territory, in respect of a Generic Product within three (3) days after receipt or such notice thereof.

(b) Licensee shall have the sole right to respond to each such application, provided that Licensee shall consult with Licensor regarding any such application and the response thereto.

7.5 **Audits.** Licensor will have the continuing right during the Term of this Agreement, upon reasonable prior written notice to Licensee, to inspect, audit, and investigate any facilities, equipment, record-keeping procedures, and records utilized by Licensee and its subcontractors in connection with the Manufacture and Commercialization of the Product and any Development (including, without limitation, the conduct of Clinical Studies) of the Product.

7.6 **Regulatory Authority Communications Received by a Party.**

(a) Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection, or communication by or from any Person, including, without limitation, any Regulatory Authority in any country in the Territory, that may affect the safety or efficacy claims of the Product, have a material adverse effect on the Commercialization of the Product, or that otherwise suggests the Product may be in violation of Applicable Laws in such country.

(b) Upon receipt of such information described in Section 7.7(a), the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for Licensee to take at Licensee's expense.

(c) Each Party shall keep the other Party informed, in a timely manner consistent with the reporting requirements of Regulatory Authorities, of notification of any action by any Regulatory Authority, or notification or other information that the Party receives (directly or indirectly) from any such Regulatory Authority, and provide to such other Party copies of all documents, if any, it received from such Regulatory Authority.

(d) Each Party will provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to in this Section 7.7.

7.7 **Adverse Event Reporting and Safety Data Exchange.**

(a) Licensee shall be responsible, at Licensee's expense, in each country in the Territory for the monitoring of all clinical experiences, post-marketing experiences, and filing of all required reports with respect to the Product.

(b) Licensor shall transfer to Licensee the patient database, including without limitation the databases, in their entirety, containing pharmacokinetic, pharmacodynamic, efficacy, and safety information, developed in connection with the conduct of Clinical Studies for the Product under U.S. IND 076667, and all information relating thereto, in the format requested by Licensee. Licensor shall have the right to retain a copy of any and all such information transferred to Licensee.

(c) Each Party shall (i) notify the other Party immediately, but in no event later than three (3) Business Days, after becoming aware of any information concerning any complaint involving the possible failure of Product to meet any requirement of Applicable Laws, and any Unexpected Adverse Drug Experience or other serious or unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidents associated with the distribution or use of the Product and (ii) with respect to adverse events, comply with the provisions of this Section 7.7, and the applicable agreements described herein. Specific details regarding the exchange and management of information relating to adverse events related to the use of the Product shall be delineated and product labeling personnel of each Party shall work in good faith together during such time to negotiate an agreement that:

(i) identifies which safety information shall be exchanged, which shall include without limitation all adverse events for any Indication or condition;

(ii) identifies when such information shall be exchanged (which SAE information shall be provided within two (2) Business Days after notification of such SAE);

(iii) provides that Licensee shall (i) have regulatory reporting responsibilities, (ii) manage the global safety database, (iii) be obligated to obtain follow-up information on incomplete safety reports, (iv) review the literature for safety report information, and (v) prepare required periodic safety updates;

(iv) sets forth the roles and responsibilities of the Parties related to review and approval of safety information for inclusion in the Product labeling; provided that Licensee shall have the final decision-making authority with respect to any disputes regarding such activities with respect to Product in accordance with the terms and conditions hereof;

(v) identifies any other details required to appropriately manage safety information for the Product; and

(vi) as soon as reasonably practicable following the Effective Date, but in no event later than sixty (60) days thereafter Licensor and Licensee will agree upon the terms and conditions of the Pharmacovigilance Agreement and will thereupon execute and deliver to the other Party a copy of such Agreement.

7.8 **Remedial Actions.**

(a) Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Product in the Field may be subject to a Remedial Action.

(b) The Parties will assist each other in gathering and evaluating such information as is required to determine the necessity of conducting a Remedial Action with respect to the Product in the Field in the Territory; *provided, however,* that Licensee shall have sole responsibility for collecting information from its customers in the Territory, including, without limitation, customer complaints, in accordance with the terms and conditions hereof.

(c) Each Party will maintain adequate records to permit the Parties to trace the manufacture of the Product in the Field and the distribution and use of the Product in the Field. In the event Licensee determines that any Remedial Action with respect to the Product in the Field in the Territory should be commenced or Remedial Action is required by any Governmental Authority having jurisdiction over the matter, Licensee will control and coordinate all efforts necessary to conduct such Remedial Action, provided that Licensee shall consult with Licensor or its designee regarding any such Remedial Action.

(d) The cost and expense of a Remedial Action (including the Parties' reasonable costs and expenses in conducting such Remedial Action, but excluding claims described in Article 10) shall be allocated as follows:

(i) If such Remedial Action is due to Licensee's gross negligence or willful misconduct, material breach of this Agreement, or material violation of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensee;

(ii) if and to the extent that such Remedial Action is due to Licensor's gross negligence or willful misconduct, Licensor's material breach of this Agreement, or Licensor's material breach of or substantial noncompliance with any Law, but only to the extent such Remedial Action is due thereto, such costs and expenses shall be borne and paid by Licensor; and

(iii) if and to the extent that such Remedial Action is due to reasons other than as set forth in Sections 7.8(d)(i) and (ii), then: (A) Licensor shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensor, as Licensor's predecessor in interest; and (B) except for the Development and Commercialization of Product in the Territory by Licensor pursuant to Section 6.3, Licensee shall bear and pay the costs and expenses incurred by the Parties in connection with a Remedial Action with respect to any lots of the Product subject to such Remedial Action that were manufactured by or for Licensee

and its contractors; *provided, however,* that nothing in this Section 7.8(d)(iii) is intended to limit or supersede any obligation that Renaissance may have in respect of any such lots of the Product subject to such Remedial Action.

8. PAYMENT OBLIGATIONS.

8.1 **Initial Fee.** In consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall pay to Licensor a one-time, nonrefundable, non-creditable initial fee of Fifty Million Dollars ($50,000,000) on the Effective Date.

8.2 **Milestone Payments.**

(a) ***Launch Milestone Payment.*** Licensee shall notify Licensor promptly of the date of the Noctiva Launch, but in no event later than twenty (20) days thereafter. In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall pay to Licensor a one-time, nonrefundable, non-creditable payment of Twenty Million Dollars ($20,000,000) in respect of such Noctiva Launch on the earlier to occur of: (i) the thirtieth (30^{th}) day immediately following the date of the Noctiva Launch and (ii) June 30, 2018. Such payment shall not require Licensor to provide any invoice in respect thereof.

Tier One Commercialization Milestone Payments. Licensee shall notify Licensor promptly, but in no event later than thirty (30) days, after the first achievement of the relevant sales milestone for the Product as set forth in the table below in this Section 8.2(b). In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, and the assignments by Licensor to Licensee in accordance with Section 2.3, Licensee shall make the following one-time, nonrefundable, non-creditable milestone payments to Licensor within thirty (30) days after receipt of an invoice from Licensor therefor.

	Milestone Event	Payment (millions of Dollars)
(i)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $50 million on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$[***]
(ii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$[***]
(iii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $[***] on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$[***]
(iv)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications in the aggregate reach $200 million on a cumulative basis beginning with the first dollar of Royalty-Bearing Net Sales	$[***]

(b) ***Tier Two Commercialization Milestone Payments.*** Licensee shall notify Licensor promptly, but in no event later than thirty (30) days, after the first achievement of the relevant sales milestone for the Product as set forth in the table below in this Section 8.2(c). In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, [and the assignments by Licensor to Licensee in accordance with Section 2.3,] Licensee shall make the following one-time, nonrefundable, non-creditable milestone payments to Licensor within thirty (30) days after receipt of an invoice from Licensor therefor; provided, however, in the event that the last of the milestone payments described in the table below becomes payable, the due date for Licensee to make payment to Licensor of such milestone payment will be the first anniversary of the payment of the $[***] milestone payment in the penultimate row of the table below.

	Milestone Event	Payment (millions of Dollars)
(i)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $300 million in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$[***]
(ii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $[***] in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$[***]
(iii)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $ [***] in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$[***]
(iv)	Upon the first time Royalty-Bearing Net Sales by Licensee and its Sublicensees of the Product for all Indications reach $ 1.5 billion in any consecutive 12-month period beginning after achievement of milestone (iv) described in Section 8.2(b)	$[***]

(c) ***Change of Control Payment.*** If a Change of Control occurs, simultaneously with the consummation of such Change of Control, Licensee shall pay to Licensor the amount of [***] Dollars ($[***]) less the sum of the following allocable portions of any of the milestone payments described in Section 8.2(b) that are paid to Licensor prior to such Change of Control:

(i) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (i) of the table in Section 8.2(b);

(ii) [***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (ii) of the table in Section 8.2(b);

(iii)[***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (iii) of the table in Section 8.2(b); and

(iv)[***] Dollars ($[***]) of the [***] Dollars ($[***]) set forth in item (iv) of the table in Section 8.2(b).

For the sake of clarity, in respect of any occurrence of a Change of Control (x) in no event shall any payment by Licensee to Licensor under this Section 8.3(c) in respect of such Change of Control exceed $[***], (y) each Tier One Milestone Payment that is not paid to Licensor prior to such Change of Control, less the allocable portion of the amount of such Tier One Milestone Payment paid to Licensor pursuant to this Section 8.3(c), shall survive such Change of Control, and (z) the Tier Two Milestone payment obligations shall survive such Change of Control.

8.3 **Royalties; Non-Royalty Commercialization Consideration.**

(a) ***Royalties.*** In further consideration of the license and sublicense granted by Licensor to Licensee in accordance with Sections 2.1 and 2.2, respectively, Licensee shall pay Licensor royalties on Net Sales of the Product by Licensee and any of its Sublicensees and Third Party Distributors in accordance with the rates set forth in the tables set forth below in this Section 8.3(a)(i).

Royalty-Bearing Net Sales in each Calendar Year (millions of Dollars)	**Royalty Rate**
That portion of Annual Net Sales greater than $0 and less than or equal to $ 500 million	28%
That portion of Annual Net Sales greater than $ 500 million and less than or equal to $ 1 billion	30%
That portion of Annual Net Sales greater than $ 1 billion	33%

(b) ***Third Party Royalties.***

(i) *CPEX and Reprise.* Licensor will be responsible for payment of any amounts payable to CPEX and Reprise under the terms of the CPEX License Agreement and the Reprise License Agreement, respectively.

(ii) *Other Third Parties.*

(A) In the event that after the Effective Date Licensee reasonably determines that it is necessary or advisable for Licensee to obtain a license under any Patent Rights from any Third Party in order for Licensee (each a "Third Party License"; collectively, "Third Party Licenses"), its Sublicensees, and any Third Party Distributors to Commercialize the Product in the Field in any country in the Territory as contemplated by this Agreement, the Parties shall discuss the best course of action to resolve such potential license requirement, provided that such discussions shall not limit or delay Licensee's right to obtain any such Third Party Licenses.

(B) With respect to any such Third Party Licenses that Licensor reasonably agrees are necessary for Licensee to be able to Commercialize the Product in the Field in any country in the Territory, Licensee shall have the right to set off an amount equal to [***] percent ([***]%) of the aggregate of any and all payments required to be paid by Licensee to the licensors under such Third Party Licenses in respect of any Calendar Quarter against payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter; *provided, however,* that in no event shall the aggregate set off in any Calendar Quarter resulting from such payments in respect of such Third Party Licenses exceed an amount equal to [***] percent ([***]%) of the royalty payments otherwise payable to Licensor under Section 8.3(a) in respect of such Calendar Quarter.

(c) ***Royalty Term.*** Licensee's obligation under Sections 8.3(a) to pay Licensor royalties on Net Sales of the Product in each country in Territory will apply to any and all sales or other dispositions of such the Product in such country made during the Term of this Agreement.

(d) ***Generic Product.*** If, during the Royalty Term, one or more Third Parties is selling in any country in the Territory any product that is a Generic Product in relation to the Product being sold in such country by Licensee or any of its Sublicensees or Third Party Distributors, Licensee's royalty obligations under Section 8.3(a) for sales in such country of the Product shall be reduced as follows:

If the Generic TRxs-to-Total TRxs Percentage in such country during such Calendar Quarter is:	Licensee's royalty obligations under Section 8.3(a) shall be reduced by the Percentage Indicated Below
[***]% or greater	[***]%
[***]%; but less than [***]%	[***]%
[***]%; but less than [***]%	[***]%

8.4 **Reports and Payments.** During the Term of this Agreement following the First Commercial Sale of the Product by Licensee, its Sublicensees, or its Third Party Distributors, within five (5) Business Days after the filing by Licensee of each Form 10-K or Form 10-Q, Licensee shall pay to Licensor the royalty payments payable by Licensee for the Calendar Quarter preceding the Calendar Quarter in which such Form 10-K or 10-Q, as applicable, is filed, and shall provide a report showing, on a country-by-country basis:

(a) the net quantity of the Product sold, total gross sales, an itemized list of the deductions applied to total gross sales, and Net Sales of the Product sold in the Calendar Quarter in respect of which such report has been prepared;

(b) the calculation in Dollars of royalty payments due hereunder with respect to such Net Sales, including any deductions for any offsets in accordance with Section 8.3(b)(ii);

(c) withholding taxes on Net Sales, if any, required by Applicable Laws to be deducted with respect to such royalties; and

(d) the rate of exchange used by Licensee in determining the amount of Dollars payable hereunder.

If no royalty or other payment is due for any period hereunder, Licensee shall so report.

Currency of Payment. All payments to be made under this Agreement shall be made in Dollars by electronic funds transfer to such bank accounts as Licensor may designate from time to time. When Licensee or any of its Sublicensee of Third Party Distributors sells the Product for monies other than Dollars, Licensee will convert any non-Dollar currencies into Dollars with the exchange rate for the purchase of Dollars with such domestic currency as quoted by The Wall Street Journal, New York edition, at an average rate for the Calendar Quarter for which the payment is made.

8.5 **Accounting.**

(a) Licensee shall determine Net Sales with respect to the Product sold using its standard accounting procedures, consistent with GAAP, as if the Product was a solely owned product of Licensee, except as specifically provided in this Agreement. In the case of amounts to be determined by Third Parties (for example, Net Sales by Sublicensees), such amounts shall be determined in accordance with generally accepted accounting principles in effect in the country in which such Third Party is engaged. Licensor and Licensee also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales. Licensor and Licensee agree that, where such changes are economically material to Licensor, adjustments shall be made to compensate Licensor in order to preserve the same economics as are reflected under this Agreement under Licensee's accounting procedures in effect prior to such change. Where the change is or would be material to Licensor, Licensee shall provide an explanation of the proposed change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.

(b) In the event of the payment or receipt of noncash consideration in connection with the performance of activities under this Agreement Licensee shall advise Licensor of such transaction, including without limitation Licensee's assessment of the fair market value of such noncash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by Licensor and Licensee in good faith.

(c) **Withholding Tax.** Notwithstanding anything to the contrary herein, in the event that withholding taxes apply with respect to any amounts due from Licensee hereunder, Licensee shall be entitled to withhold from any payment due to Licensor under this Agreement any taxes that Licensee is required to pay and such withholding shall decrease by an equivalent amount the payment due to Licensor. Licensee shall provide Licensor with notification of any anticipated withholding requirements with as much advance notice as practicable and shall cooperate in good faith with Licensor to legally minimize such withholding taxes. Licensee will timely pay to the proper governmental authority the amount of any taxes withheld and will provide Licensor with an official tax certificate or other evidence of tax obligation, together with proof of payment from the relevant governmental authority sufficient to enable Licensor to claim such payment of taxes.

8.6 **Books and Records; Audit Request.**

(a) During the term of this Agreement and for three (3) years thereafter, Licensee shall keep and maintain, and shall cause each of its Affiliates, and Sublicensees, if any, to keep and maintain, at their respective regular places of business complete and accurate books, records, and accounts in accordance with GAAP, or other accounting standards mandated by the U.S. Securities and Exchange Commission if applicable to Licensee, in sufficient detail to reflect all amounts required to be paid under this Agreement, as well as any other books, records or accounts required to be maintained in connection with the Product under any Applicable Laws, necessary to permit the audits contemplated under Section 8.8(b). Prior to destroying any books, records or accounts which are material to the Parties' rights and obligations under this Agreement, Licensee must seek prior written consent from Licensor, which consent may not be unreasonably withheld.

(b) During the term of this Agreement and for three (3) years thereafter, Licensor shall have access to and the right to examine such relevant records and accounts that Licensee is required to maintain pursuant to Section 8.8(a) at Licensee's premises for the sole purpose of verifying the accuracy of any report or payment made under this Agreement in the three (3) preceding years; *provided, however,* that any such examination: (i) shall not occur more than once during each Calendar Year (except that if as a result of any audit pursuant to this Section 8.8(b), an error in favor of Licensee exceeding five percent (5%) of any payments previously reported as owed by Licensee to Licensor is discovered, the frequency of audits under this Section 8.10(b) shall not be so limited); (ii) shall be during normal business hours upon reasonable prior written notice which shall in no event be less than thirty (30) days; and (iii) shall not unreasonably interfere with Licensee's operations and activities. If Licensor desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to Licensee, to examine such records under conditions of confidentiality with respect thereto at least as stringent as those specified in Article 13. The expense of any such audit shall be borne by Licensor; *provided, however,* that, if an error of more than five percent (5%) in favor of Licensor is discovered as a result of such audit, then such expenses shall be paid by Licensee. If such accountant concludes that additional payment amounts were owed to Licensor during any period, Licensee shall pay such payment amount (including without limitation interest thereon from the date such amounts were payable) within thirty (30) days after the date Licensor delivers to Licensee such accountant's written report so concluding, unless Licensee notifies Licensor of any dispute regarding the audit. If such accountant concludes that Licensee has overpaid any amounts to Licensor during any period, in Licensor's discretion, Licensee may credit such amounts against future payments due Licensor or Licensor may pay such amounts (including without limitation interest thereon from the date such amounts were payable), unless Licensor notifies Licensee of any dispute regarding the audit. Any Information received by Licensor pursuant to this Section 8.10 shall be deemed to be Confidential Information of Licensee for purposes of Article 13.

8.7 **Blocked Currency.** If by Applicable Laws or fiscal policy of a particular country, conversion into Dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, royalties accrued in such country shall be paid to Licensor in the country in local currency by deposit in a local bank designated by Licensor for such deposit, unless Licensor and Licensee otherwise agree.

8.8 **Interest.** If Licensor does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Licensor from the due date until the date of payment at a rate equal to three month Dollar LIBOR Rate, as reported in the online edition of The Wall Street Journal as of Noon (New York Time) on such due date, or the maximum rate allowable by Applicable Laws, whichever is less.

8.9 **Transaction Expenses.** Licensee shall upon execution and delivery of this Agreement pay the documented reasonable fees and expenses of Licensor's advisors and counsel incurred by Licensor in structuring, negotiating, memorializing, and otherwise undertaking the transaction contemplated by this Agreement. Notwithstanding the foregoing, Licensee's obligation under this Section 8.11 shall be limited to an amount not to exceed $2,000,000.

9. INTELLECTUAL PROPERTY MATTERS.

9.1 **Existing Intellectual Property.**

(a) Other than as provided in this Agreement, neither Party grants any right, title, or interest in any Patent Right, information, or other intellectual property right Controlled by such Party to the other Party.

(b) Except as otherwise provided herein, Licensor shall be responsible for the preparation, filing, prosecution (including, without limitation, any interferences, inter partes proceedings, reissue proceedings, cancellations, oppositions, and reexaminations), and maintenance of any and all Licensed Serenity Patent Rights. Licensor shall consult with Licensee, and consider Licensee's comments, in good faith with respect to the preparation, filing, prosecution, and maintenance of any Licensed CPEX Patent Rights or Licensed Reprise Patent Rights to the extent that Licensor has the right, under any agreement with any applicable licensor, to file, prosecute, and maintain such Licensed Patent Rights.

(c) Licensee agrees and acknowledges that Licensor intends to continue to use, in Licensor's discretion, patent counsel currently retained by Licensor to prosecute and maintain the Licensed Serenity Patent Rights. Licensee shall execute, acknowledge and deliver any instruments, and to do all such other acts, as may be necessary or appropriate in order to enable such patent counsel to continue to prosecute and maintain such Licensed Serenity Patent Rights. The Parties shall reasonably consult with each other, and shall consider any comments from each other in good faith, with respect to the preparation, filing, prosecution, and maintenance of such Licensed Serenity Patent Rights and patent strategy for the Licensed Serenity Patent Rights. Licensee shall reimburse Licensor for all costs and expenses incurred by Licensor after the Effective Date in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights in the Territory, up to an amount not to exceed [***] Dollars ($[***]), which is the estimated cost set forth on Schedule 9.1(c)**.** Licensor shall provide to Licensee copies of any papers relating to the filing, prosecution or maintenance of the Licensed Serenity Patent Rights promptly upon their being filed or received. Licensee shall not knowingly take any action during prosecution and maintenance of the Licensed Serenity Patent Rights.

(d) Licensor shall not knowingly permit any of the Licensed Serenity Patent Rights to be abandoned in any country in the Territory without Licensor first giving Licensee an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of a Licensed Serenity Patent Rights in any country in the Territory, Licensor will provide Licensee with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensee elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Licensed Serenity Patent Rights except that the role of Licensee and Licensor shall be reversed thereunder (except further that Licensee will continue to be responsible for all costs and expenses thereafter incurred in the preparation, filing, prosecution, and maintenance of any Licensed Serenity Patent Rights). Any such Serenity Patent Right that is subject to such election by Licensee shall otherwise continue to be subject to all of the terms and conditions of the Agreement in the same way as the other Licensed Serenity Patent Rights.

9.2 **Inventions by Licensee.**

(a) ***Disclosure.*** Licensee shall promptly disclose to Licensor the invention of any Licensee Inventions.

(b) ***Ownership.*** As between the Parties, all Licensee Inventions will be owned and Controlled by Licensee.

(c) ***Patent Filings.***

(i) Licensee, at its expense, will have sole discretion and responsibility to prepare, file, prosecute, and maintain any patent applications and patents claiming Licensee Inventions. The Parties' respective patent counsel shall meet no fewer than once per Calendar Year to discuss strategies for the preparation, filing, prosecution, and maintenance of any such patent applications and patents claiming Licensee Inventions. Licensee shall consider in good faith any comments provided by Licensor with respect to the foregoing. In the event of any dispute between Parties with respect to such strategies, either Party may notify the Alliance Managers for purposes of resolving such dispute; *provided, however,* that Licensee shall have the final decision-making authority with respect to any such dispute.

(ii) Licensee shall not knowingly permit any Patent Rights with claims to any Licensee Inventions to be abandoned in any country without Licensee first giving Licensor an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. In the event that Licensee decides not to continue the prosecution or maintenance of any Patent Right claiming a Licensee Invention in any country, Licensee will provide Licensor with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In the event that Licensor elects to assume responsibility for such prosecution and maintenance within thirty (30) days of Licensor's notice, Section 9.1(c) shall thereafter apply to such Patent Right claiming such Licensee Invention except that the role of Licensee and Licensor shall be reversed thereunder.

9.3 **Infringement, Violation, or Misappropriation by Third Parties.**

(a) ***Notice.*** Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement, violation, or misappropriation by any Third Party of the Licensed Rights or the Sublicensed Rights of which it becomes aware, and following such notification, the Parties shall confer as to any response thereto. The notice shall set forth the facts of such infringement, violation, or misappropriation in reasonable detail.

(b) ***Response to Infringement, Violation, or Misappropriation by Third Parties.***

(i) If a Third Party is infringing, violating, or misappropriating, or either Party reasonably believes a Third Party may be infringing, violating, or misappropriating any Enforceable IP Right in any country in the Territory, Licensee shall have the first right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to such infringement, violation, or misappropriation by counsel of its own selection, at its expense. Licensor shall have the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense. To the extent required by Applicable Laws, Licensor agrees to be joined as a party plaintiff (with Licensor having the right to be represented, if it so desires, by counsel of its own selection and at its own expense) if necessary for Licensee to bring and prosecute such action or proceeding, and to give Licensee reasonable assistance and authority to bring and prosecute such action or proceeding. If Licensee fails to bring an action or proceeding within ninety (90) days after receiving or giving written notice pursuant to Section 9.3(a), then Licensor

shall have the right, but not the obligation, to bring and control any such action by counsel of its own selection, at its expense (with Licensee having the right to participate in such action and be represented, if it so desires, by counsel of its own selection and at its own expense). To the extent required by Applicable Laws, Licensee agrees to be joined as a party plaintiff (with Licensee having the right to be represented, if it so desires, by counsel of its own selection and expense therein) if necessary for Licensor to bring and prosecute such action or proceeding, and to give Licensor reasonable assistance and authority to bring and prosecute such action or proceeding. No settlement of any such action or consent judgment or other voluntary final disposition which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may be entered into by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned.

(ii) Each Party shall share in any recoveries obtained in connection with any action or proceeding described in Section 9.3(b)(i) as follows:

(A) each Party's costs and expenses incurred in connection with bringing and prosecuting any such action or proceeding, including without limitation attorneys' fees, first shall be reimbursed from such recoveries, and if such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party, and

(B) if Licensee controlled such action or proceeding Licensee shall receive one hundred percent (100%) of such remaining recoveries, provided that such recoveries shall be deemed Net Sales for purposes of Section 8.3(a)(i); and if Licensor controlled such action or proceeding, each Party shall receive fifty percent (50%) of such remaining recoveries, provided that Licensee's portion shall not be deemed as Net Sales for purposes of Section 8.3(a)(i) in such case.

(c) ***Withdrawal.*** If either Party brings an action or proceeding under Section 9.3(b)(i) and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of Section 9.3(b)(i).

(d) ***Oppositions by Parties.*** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination, inter partes proceeding, or other attack upon the validity, title, or enforceability of any intellectual property right Controlled by a Third Party that Covers the Product in the Field in any country in the Territory, such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Each Party shall be entitled to separate representation in any such action by counsel of its own choice and at its own expense, and shall cooperate fully with the other Party. The costs of any such action shall be borne by the Party bringing the action, and such Party shall retain any recoveries obtained in connection therewith.

9.4 **Infringement of Third Party Rights.**

(a) ***Notice.*** If the Exploitation of the Product pursuant to this Agreement results in a claim, action, suit, or proceeding that such activity infringes or misappropriates the intellectual

property rights of a Third Party (**"Third Party Infringement Claim"**), the Party first receiving notice thereof shall promptly notify in writing the other Party thereof. The notice shall set forth the facts of the Third Party Infringement Claim in reasonable detail.

(b) Litigation.

(i) Licensee shall have the sole right, but not the obligation, to defend, at its expense, against any Third Party Infringement Claim. Licensee shall have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensee shall not settle any Third Party Infringement Claim that is subject to indemnification pursuant to Section 11.1 without the prior written consent of Licensor, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensor shall cooperate with Licensee, at Licensee's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensor's expense. Licensee will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim.

(ii) If Licensee decides not to commence a defense against any Third Party Infringement Claim pursuant to Section 9.4(b)(i), then Licensee will promptly notify Licensor of such decision in a timely manner so as to allow Licensor, who shall have the right, but not the obligation, to commence such a defense by counsel of its own selection, at its expense (with Licensee having the right to participate in such defense and be represented, if it so desires, by counsel of its own selection and at its own expense). Licensor shall thereupon have full control over the defense and settlement of such Third Party Infringement Claim, provided that Licensor shall not settle any Third Party Infringement Claim without the prior written consent of Licensee, which consent shall not be unreasonably withheld, delayed, or conditioned. Licensee shall cooperate with Licensor, at Licensor's expense and reasonable request, in such defense and shall have the right to be represented by counsel of its own choice, at Licensee's expense. Licensor will pay any losses incurred in defense or settlement of, or imposed pursuant to settlement of or judgment on, such Third Party Infringement Claim, subject to Section 11.1.

(iii) Notwithstanding any provisions set forth herein to the contrary, Licensor shall be responsible for continuing to manage, at Licensor's expense, that certain litigation with Ferring Pharmaceuticals that is described in Schedule 10.2. Notwithstanding the foregoing, any settlement of any such action or consent judgment or other voluntary final disposition with respect to the litigation with Ferring Pharmaceuticals described in Schedule 10.2, which restricts the scope, or adversely affects the enforceability, of an Enforceable IP Right may not be entered into by Licensor without the prior written consent of the Licensee, which consent shall not be unreasonably withheld, delayed or conditioned.

(c) Oppositions by Third Parties. If any patent, trademark, copyright, or other intellectual property right within the Licensed Rights or the Sublicensed Rights becomes after the Effective Date the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, inter partes proceeding, or other attack upon the validity, title, or enforceability thereof, then Licensee shall control such defense at its sole cost. Licensee shall permit Licensor to participate in the proceeding to the extent permissible under

Applicable Laws, and to be represented by its own counsel in such proceeding, at Licensor's expense. If Licensee elects not to defend against such action with respect to any such intellectual property right with the Licensed Rights or the Sublicensed Rights within ninety (90) days after first receiving notice or otherwise becoming aware of such action or proceeding, then Licensor shall have the right to assume defense of such Third Party action at its own expense. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the Parties' expenses in such action, and any remaining amounts shall be retained by the Party defending against such proceeding.

9.5 **Use of Licensed Serenity Trademark.**

(a) Licensee agrees and acknowledges that (i) as between the Parties, Licensor is and shall remain the owner of the Licensed Serenity Trademarks, and (ii) all of the goodwill associated with the Licensed Serenity Trademarks, in all countries of the world, and all uses thereof by Licensee, its Affiliates, sublicensees, and Third Party Distributors shall inure to the benefit of Licensor.

(b) Licensee will cooperate with Licensor for the purpose of protecting, preserving, registering, and enhancing the Licensed Serenity Trademarks and Licensor 's interest therein and in furtherance of such obligations, Licensee will promptly execute and deliver to Licensor all documents and instruments that Licensor, acting reasonably, determines are necessary or prudent from time to time. If and to the extent that Licensee, its Affiliates, sublicensees, or Third Party Distributors obtain any rights (other than the licenses granted herein) to the Licensed Serenity Trademarks in any country in the world, at the request of Licensor, Licensee shall immediately and automatically assign, and ensure that its Affiliates, sublicensees, and Third Party Distributors immediately and automatically assign, to Licensor all right, title and interest in and to the Licensed Serenity Trademarks, and all goodwill with respect thereto.

(c) Licensee will use the Licensed Serenity Trademarks (i) only in compliance with all Applicable Law and the express terms of this Agreement and the Serenity Trademark Standards, and (ii) not as part of any composite trademark in close proximity or in combination with any other trademark.

(d) Licensee agrees to conform, and to cause any of its Affiliates, sublicensees and Third Party Distributors to conform, the manner of their respective use of the Licensed Serenity Trademarks with the policies, specifications, directions, and standards for use thereof set forth in the Serenity Trademark Standards, and to maintain the quality standards of Licensor set forth in the Serenity Trademark Standards with respect to the Products sold. Except to the extent that any use of the Licensed Serenity Trademarks by Licensee and any of its Affiliates, sublicensees, and Third Party Distributors is not in accordance with the Serenity Trademarks Standards, Licensee shall not be required to submit to Licensor any materials bearing any Licensed Serenity Trademark for review and approval prior to the use thereof.

(e) To the extent Licensee desires to use any Licensed Serenity Trademark in a manner not expressly permitted under the Serenity Trademark Standards, Licensee will submit to Licensor for Licensor's review all packaging, advertising, brochures, and other material (including, without limitation, mockups or models thereof), that evidence such use. Within fifteen (15) calendar days after Licensor receives any such material, Licensor will provide Licensee with (i) approval of Licensee's proposed use of the Licensed Serenity or (ii) comments as to any revisions Licensor reasonably believes are necessary or

advisable to achieve compliance with the Licensed Trademark Standards. In each case where Licensor provides any such comments, Licensor and Licensee will promptly discuss and resolve whether any such revisions are necessary or advisable and, if determined to be so necessary or advisable, Licensee will make such revisions. From and after such approval of Licensor of such use, the Serenity Trademark Standards shall be amended or revised to reflect such approved use.

(f) All rights in and to any new version, translation, or arrangement of the Licensed Serenity Trademarks, or other change in the Licensed Serenity Trademarks created by Licensee, with Licensor's prior written consent or otherwise, will be and will remain the exclusive property of Licensor, and the provisions of this Agreement will apply to the same.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

10.1 **Mutual Representations and Warranties.** Licensor and Licensee (each, a **"Representing Party"**) each hereby represents and warrants to each other, as of the Effective Date and except as otherwise set forth in Schedule 10.2 (in the case of Licensor) and Schedule 10.3 (the case of Licensee), that:

(a) such Representing Party is a corporation or limited liability company, as applicable, duly organized and subsisting under the laws of its jurisdiction of organization;

(b) such Representing Party has the power, authority, and legal right, and is free, to enter into this Agreement on behalf of itself and its Affiliates and to perform its respective obligations hereunder and to cause its Affiliates to perform their respective obligations hereunder;

(c) such Representing Party has the power, authority, and legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement;

(d) this Agreement constitutes a legal, valid, and binding obligation of such Representing Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity;

(e) the execution and delivery of this Agreement and the performance of such Representing Party's and its Affiliates' obligations hereunder (i) have been duly authorized and approved by all necessary action by such Representing Party, and all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained by such Representing Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; (ii) do not conflict with or violate any requirement of Applicable Laws or any provision of the articles of incorporation, bylaws, limited partnership agreement, or any similar instrument of such Representing Party, as applicable, in any material way; and (iii) do not, and will not, conflict with or otherwise interfere with in such a manner as to result in a violation, breach, or default under or require any consent that has not been obtained under any contract between such Representing Party and any Third Party;

(f) there are no, and shall be no, liens, conveyances, mortgages, assignments, encumbrances, or other agreements that would prevent or impair such Representing Party's or any of its Affiliates' full and complete exercise of the terms and conditions of the Agreement;

(g) such Representing Party and its Affiliates shall at all times comply with all Applicable Laws relating or pertaining to their obligations under the Agreement;

(h) with respect to the services provided hereunder to the other Party, its Affiliates, and their respective employees, officers, contractors and agents who perform such services have the experience, capability, and resources to efficiently and skillfully perform the services, and shall perform, where applicable, all such services in a professional and workmanlike manner and in accordance with the generally accepted then-current standards, forms, procedures, and techniques established from time to time by the industry;

(i) all of such Representing Party's employees, officers, contractors, and consultants have executed agreements requiring assignment to such Representing Party of all inventions created by such persons in the course of their employment by such Representing Party and obligating each such employee, officer, contractor, and consultant to maintain and safeguard the confidentiality of (i) any information that is confidential to such Representing Party or (ii) any information that is confidential to any other Person and that such Representing Party is obligated to maintain and safeguard as confidential; and

(j) neither such Representing Party, nor any of its employees, officers, subcontractors, or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a.

10.2 **Additional Representations, Warranties, and Covenants of Licensor.** Licensor hereby represents, warrants, and covenants to Licensee, as of the Effective Date and except as otherwise set forth in Schedule 10.2, that:

(a) Licensor is entitled to grant the rights and licenses purported to be granted to Licensee under this Agreement, and to assign the rights purported to be assigned to Licensee under this Agreement, and is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency, that restricts it from granting to Licensee the rights, licenses and sublicenses purported to be so granted in this Agreement;

(b) Licensor is the sole and exclusive owner of all right, title, and interest, in, to, and under the Licensed Rights and has the right under the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights to grant the sublicenses thereunder in accordance with Section 2.2;

(c) the Licensed Rights are free and clear of any liens, charges, encumbrances, or judgments, and Licensor has sufficient rights to grant the licenses and rights purported to be granted herein, free and clear of any security interests, claims, encumbrances, or charges of any kind;

(d) Licensor has not granted, and will not grant during the term of this Agreement, any right, option, license, or interest in or to any of the Licensed Rights that is in conflict with the rights assigned or granted to Licensee under this Agreement;

(e) there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending, or to Licensor's knowledge threatened by, against or involving Licensor, regarding the Licensed Rights, whether at law or in equity, before or by any Third Party, and Licensor has not received any written communications alleging that it has violated, through the manufacture, Development, import, or other exploitation of the Product, any intellectual property rights of any Third Party;

(f) to Licensor's knowledge:

(i) the patents in the issued Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights are valid and enforceable; and

(ii) no Third Party has asserted that any of the Licensed Rights or the Sublicensed Rights is invalid or unenforceable;

(g) all applications, registrations, maintenance and renewal fees due in respect of any of the Licensed Serenity Patent Rights and, to Licensor's knowledge, the Licensed Reprise Patent Rights and the Licensed CPEX Patent Rights, have been paid and all documents and certificates required to be filed with the relevant agencies for the purpose of maintaining such Licensed Serenity Patent Rights, and to Licensor's knowledge, the Licensed Reprise Patent Rights and Licensed CPEX Patent Rights have been filed;

(h) none of the Licensed Serenity Patent Rights, the Licensed Serenity Know-How and, to Licensor's knowledge, none of the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights were developed with funding from any Governmental Authority such that any Governmental Authority has any march in rights or other rights to use the Licensed Serenity Patent Rights, the License Serenity Know-How, the Licensed Reprise Patent Rights, or the Licensed CPEX Patent Rights;

(i) to Licensor's knowledge, no Third Party has infringed or misappropriated any of the Licensed Rights or the Sublicensed Rights;

(j) all inventors of any inventions included within the Licensed Serenity Patent Rights and, to the knowledge of Licensor, the Licensed CPEX Patent Rights and the Licensed Reprise Patent Rights have assigned their entire right, title, and interest in and to such inventions and the corresponding patents and patent applications to Licensor, Reprise, or CPEX, as applicable, and have been listed as inventors in the Licensed Serenity Patent Rights, the Licensed CPEX Patent Rights, and the Licensed Reprise Patent Rights, as applicable;

(k) no agreements that Licensor or its Affiliates may have with any Third Party provide such Third Party with any rights of first offer, rights of first refusal, or any other rights to make, have made, use, conduct Clinical Studies for, sell, offer for sale, have sold, import, export, or otherwise Exploit the Product in the Field in the Territory or the right to use the Licensed Rights or the Sublicensed Rights in connection with the Exploitation of the Product in the Field in the Territory; and Licensor has received no notice from a Third Party of any suit, action, proceeding, or arbitration pending or threatened against it that the proposed terms and conditions of this Agreement, and the Parties' performance in accordance therewith, do or shall conflict or interfere with in a manner resulting in a breach or default under, or other violation of, any agreements that Licensor or its Affiliates may have with any Third Party;

(l) to Licensor's knowledge, (i) each of the CPEX License Agreement and the Reprise License Agreement is valid and enforceable in accordance with its terms, is in full force and effect, and there are no approvals or consents required to make it effective, (ii) Licensor has supplied Licensee with a true and correct copy of the CPEX License Agreement and the Reprise License Agreement , together with all amendments, waivers, or other changes thereto, (iii) Licensor has performed all material obligations required to be performed by it in connection with the CPEX License Agreement and the Reprise License Agreement, (iv) Licensor shall not materially breach and is not in material breach of the CPEX License Agreement or the Reprise License Agreement, (v) Licensor is not in receipt of any claim of default, cure notice, or show cause notice under the CPEX License Agreement or the Reprise License Agreement, and (vi) there is no current material breach or anticipated material breach by any other party to the CPEX License Agreement or the Reprise License Agreement;

(m) (i) Licensor is the named sponsor of the First Approved NDA for the Product; and (ii) with respect to all Regulatory Documentation to obtain Regulatory Approvals for the Product in the Field: (A) the data, information and/or all other documents in Licensor's or its Affiliates submissions were, are and shall be free from fraud or material falsity, and neither Licensor nor its Affiliates has made any material misrepresentation or omission in connection with such data; (B) the Regulatory Approvals have not been and will not be obtained either through bribery or the payment of illegal gratuities by Licensor; (C) the data, information and/or all other documents in Licensor's or its Affiliates' submissions are, were and shall be accurate and reliable for purposes of supporting approval of the submissions; and (D) the Regulatory Approvals shall be obtained without illegal or unethical behavior of any kind by Licensor or its Affiliates; provided that Licensor shall not be deemed to be in breach of this Section 10.2(m) if the violation of this Section 10.2(m) results from the action or omission of Licensee of Licensee's Affiliates, Sublicensees, or contractors (other than Licensor);

(n) Licensor believes in good faith, based on the information set forth in Schedule 10.2(n), that FDA will consider amending or supplementing the First Approved NDA (or the related IND) in the manner described in Schedule 10.2(n); *provided, however,* that Licensor cannot assure that FDA will approve such amendment or supplement.

(o) except as expressly permitted hereunder, Licensor agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product; and

(p) other than the CPEX License Agreement, the Reprise License Agreement, the Renaissance Supply Agreements, and the other Third Party Supply Agreements, Licensor and/or its Affiliates have not entered into any agreements with any Third Party, pursuant to which any Third Party has granted to Licensor, or Licensor has granted to any Third Party, any rights to licenses to, in or under any of the Licensed Rights or the Sublicensed

Rights or other intellectual property rights that relate to the Product, or relating to the manufacture of the Product.

10.3 **Additional Representations, Warranties, and Covenants of Licensee.** Licensee hereby represents, warrants, and covenants to Licensor, as of the Effective Date and except as otherwise stated in Schedule 10.3, that:

(a) if, during the term of this Agreement Licensee has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (i) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a, or (ii) is or will be under indictment under said Section 335a, then Licensee shall immediately notify Licensor in writing;

(b) as of the Effective Date, there is no legal, administrative, arbitration, or other proceeding, suit, claim, or action of any nature, judgment, decree, decision, injunction, writ, or order pending or, to the knowledge of Licensee's senior management, threatened by, against Licensee regarding this Agreement, whether at law or in equity, before or by any Third Party; and Licensee shall provide notice of any of the foregoing to the extent it affects Licensee's performance of its obligations under this Agreement;

(c) except for information provided by Licensor, its Affiliates or Sublicensees: (i) the data and information in Licensee's submissions and modifications of Regulatory Documentation relating to the Product shall be free from fraud or material falsity; (ii) Regulatory Approvals for the Product hereafter obtained will not be obtained either through bribery or the payment of illegal gratuities by Licensee; (iii) the data and information in Licensee's submissions and modifications of any Regulatory Documentation shall be accurate and reliable; and (iv) any such the Regulatory Approvals will be obtained without illegal or unethical behavior of any kind by Licensee; provided that Licensee shall not be deemed to be in breach of this Section 10.3(c) if the violation of this Section 10.3(c) results from the action or omission of Licensor or its Affiliates, Sublicensees (other than Licensee), or contractors; and

(d) except as expressly permitted hereunder, Licensee agrees not to, and agrees to cause its Affiliates and Sublicensees not to (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Licensed Rights, the Sublicensed Rights, or any Regulatory Approvals and Documentation in respect of the Product, (ii) grant in any manner any license or other right, title or interest in or to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to any of the Licensed Rights, the Sublicensed Rights, or the Regulatory Approvals and Documentation in respect of the Product, or (iv) bring any action or proceeding or otherwise assert any claim under any Applicable Law in the event any licensee (or sublicensee or any entity or person acting on its behalf) initiates any proceeding or otherwise assert any claim in any court, administrative agency, or other forum with jurisdiction over such proceeding or claim, that any of the Licensed Rights or Sublicensed Rights are invalid, unenforceable, or not infringed, violated, or misappropriated. In the event that Licensee or any Affiliate or Sublicensee of Licensee initiates any proceeding or otherwise asserts any claim in violation of clause (iv) of this Section 10.3, and the result thereof is a final decision, ruling, holding, award, or other disposition to the effect that any of the Licensed Rights or Sublicensed Rights are valid, enforceable, or infringed, violated, or misappropriated,

then each of the royalty rates set forth in the table in Section 8.3(a) will each be increased by [***] and the party initiating such proceeding or otherwise asserting such claim shall pay the attorneys' fees and expenses incurred by Licensor in defending against such proceeding or claim.

10.4 **Inaccuracies.** Without limiting either Party's rights and remedies at law, in equity or under this Agreement, if, at any point in time (not just at the times when the warranties are deemed granted), either Party becomes aware of any inaccuracies in the foregoing warranties and representations, such Party shall promptly notify the other Party of such inaccuracies, with a detailed written explanation.

11. INDEMNIFICATION AND INSURANCE.

11.1 **Indemnification by Licensee.** Licensee shall defend, indemnify and hold harmless any Licensor Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensee and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensee of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensee or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensor); (d) the failure to comply with Applicable Laws by Licensee, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor); and (e) any allegation that personal injury or death, or any damage to any property, was caused or allegedly caused by a manufacturing defect in the Product manufactured by Licensee or for Licensee by Third Parties.

11.2 **Indemnification by Licensor.** Licensor shall defend, indemnify and hold harmless any Licensee Indemnitee from and against any and all Losses arising out of a claim by a Third Party arising out of, resulting from or relating to: (a) the gross negligence or willful misconduct of Licensor and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensor's performance of its obligations or exercise of its rights under this Agreement; (b) any material breach by Licensor of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) any Development Activities and Commercialization Activities in respect of the Product, undertaken by Licensor or any of its Affiliates, Sublicensees, agents, and contractors (other than Licensee); and (d) the failure to comply with Applicable Laws by Licensor, or any of its Affiliates, Sublicensees, agents, or contractors (other than Licensor).

11.3 **Process for Indemnification.** A claim to which indemnification applies under Section 11.1 shall be referred to herein as an **"Indemnification Claim"**. If a Licensor Indemnitee or Licensee Indemnitee (each being an "Indemnitee" for purposes of this Section 11.3) intends to claim indemnification under Section 11.1, such Indemnitee must notify Licensee or Licensor, as the case may be (each in such capacity of providing indemnification hereunder, the "Indemnitor"), in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that the Indemnitee

shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitor and the Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this Section 11.2, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. An Indemnitee shall not settle or compromise any Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise any Indemnification Claim in any manner that would have an adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. Each Indemnitee shall reasonably cooperate with the Indemnitor at the Licensor's expense and shall make available to the Licensee or Licensor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 13.

11.4 **Insurance.**

(a) At all times during the term of this Agreement and for five (5) years thereafter, Licensee shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $5,000,000 per occurrence/$10,000,000 aggregate (collectively, the **"Licensee Insurance Policies"**); (ii) include Licensor as "Additional Insured" under the Licensee Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensee will obtain such Licensee Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensee Insurance Policies shall be assumed by Licensee. The policy limits stated above do not limit the obligation of Licensee under this Agreement.

(b) At all times during the term of this Agreement and for five (5) years thereafter, Licensor, to the extent that it is engaged in any Development Activities hereunder, shall at its sole cost: (i) maintain Commercial General Liability, including without limitation product liability insurance (including without limitation bodily injury and property damage coverage) including coverages of: (A) products and completed operations; (B) premises – operations; and (C) broad form contractual liability at limits not less than $1,000,000 per occurrence/$ 2,000,000 aggregate (collectively, the **"Licensor Insurance Policies"**); (ii) include Licensee as "Additional Insured" under the Licensor Insurance Policies; and (iii) provide Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day notice of cancellation, non-renewal or material change. Licensor will obtain such Licensor Insurance Policies from insurers having A.M. Best's Ratings of–A - VII or equivalent. Any and all deductibles in such Licensor Insurance Policies shall be assumed by Licensor. The policy limits stated above do not limit the obligation of Licensor under this Agreement,

12. LIMITATION OF LIABILITY AND DISCLAIMER OF WARRANTY.

12.1 **LIMITATION OF LIABILITY.** EXCEPT FOR BREACH BY EITHER PARTY OF ARTICLE 13, AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY

OR TO ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS OR OTHER ECONOMIC LOSS) ARISING FROM OR RELATING TO THIS AGREEMENT, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT, STATUTES, OR ANY OTHER LEGAL THEORY, AND WHETHER SUCH FIRST PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR NOT.

12.2 **DISCLAIMER OF WARRANTY.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

13. CONFIDENTIALITY.

13.1 **Confidential Information, Defined; Exclusions.**

(a) ***Definition of Confidential Information.*** The term “Confidential Information” means, with respect to a Disclosing Party, information and material, regardless of the form in which that information or material is constituted, any and all regulatory, technical, manufacturing, business, financial, operational, administrative, marketing or economic information, data, documents, designs, patents, materials, product samples, and Know-How asserted by such Disclosing Party as being confidential to it and disclosed by the Disclosing Party to the Receiving Party, whether orally, in writing, or in pictorial form in hard copy, electronic form or in any other form, in connection with the performance of this Agreement by the Parties, marked in English, or otherwise identified, as confidential or proprietary or secret.

(b) ***Exclusions.*** The term “Confidential Information” does not apply to any portion of information or materials that a Receiving Party can demonstrate by contemporaneous written records was: (i) known to the general public at the time of its disclosure to the Receiving Party, or thereafter became generally known to the general public, other than as a result of actions or omissions of the Receiving Party or anyone to whom the receiving Party disclosed such information or materials; (ii) known by the Receiving Party prior to the date of disclosure by the Disclosing Party; (iii) disclosed to the Receiving Party on an unrestricted basis from a source unrelated to the Disclosing Party and not under a duty of confidentiality to the Disclosing Party; or (iv) independently developed by the Receiving Party by personnel that did not have access to or use of Confidential Information of the Disclosing Party. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or known to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation thereof are published or known to the general public or are in the rightful possession of the Receiving Party.

13.2 **Degree of Care.** Each Party shall take Commercially Reasonable Efforts to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own information and materials of a

similar confidential nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including without limitation all copies and derivations thereof, is and shall remain the sole and exclusive property of such Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than as permitted under this Agreement.

13.3 **Required Disclosures.** The obligations of Sections 13.2 and 13.7 shall not apply to the extent that the Receiving Party:

(a) is required to disclose Confidential Information it receives pursuant to (i) an order of a court of competent jurisdiction, (ii) Applicable Laws, (iii) regulations or rules of a securities exchange, including without limitation as required in connection with a public offering of the Receiving Party's stock or to comply with regulations imposed by the United States Securities and Exchange Commission, NASDAQ, or stock exchange disclosure requirements, or (iv) requirement of a governmental agency for purposes of obtaining approval to test or market the Product; provided that, in the case of clauses (i) through (iv) of this subsection (a), the Receiving Party shall provide prior written notice thereof to the Disclosing Party and, where practicable, reasonable opportunity for the Disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefore in a reasonably timely manner, or

(b) discloses such Confidential Information to Affiliates, potential or actual acquirers, merger partners, external advisors, licensees, sublicensees, assignees, subcontractors, investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and each of the Parties' respective directors, employees, contractors, and agents; provided that such any such person or entity listed in the first part of this subsection (b) agrees to confidentiality and nonuse obligations with respect thereto at least as stringent as those specified in Section 13.2.

13.4 **Permitted Disclosures.** At each Receiving Party's request, the Disclosing Party shall review and approve in good faith the use by the Receiving Party any packet of Confidential Information of the Disclosing Party that the Receiving Party proposes to disclose, under commercially reasonable confidentiality obligations that are less stringent than those specified in Section 13.2 to actual or potential investment bankers, investors, lenders, venture capital firms, investment bankers, or other potential financial partners, and their and the Receiving Party's respective directors, employees, contractors, and agents for purposes of raising capital.

13.5 **Irreparable Injury.** The Parties acknowledge that either Party's breach of this Article 13 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach of this Article 13, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

13.6 **Return of Confidential Information.** Each Receiving Party shall return or destroy, at the Disclosing Party's instruction, all Confidential Information of the Disclosing Party in the Receiving Party's possession upon termination or expiration of this Agreement, except any Confidential Information that is necessary to allow the Receiving Party to perform or enjoy any of its rights or obligations that expressly survive the termination or expiration of this Agreement.

13.7 **Public Disclosure.**

(a) The Parties agree that the initial public announcement of the execution of this Agreement shall be in the form set forth on Exhibit 13.7 (the **"Press Release"**).

(b) During the term of this Agreement, in all cases other than the announcement set forth in the Press Release, Licensor and Licensee shall submit to each other in a reasonably timely manner for review and approval all proposed press releases involving medical or scientific information, academic, scientific, and medical Publications and public presentations, including without limitation any and all abstracts, public presentations at congresses or scientific meetings or other public meetings, and any Publication manuscripts, relating to the Product, the Nocturia Indication, the PNE Indication and any Additional Indication that have not been previously publicly disclosed and that are not otherwise permitted to be disclosed under this Article 13. Such review and approval shall be conducted in a timely manner for the purposes of preserving intellectual property protection and determining whether any portion of the proposed publication or presentation containing the Confidential Information of either Party should be modified or deleted. Notwithstanding the foregoing and for clarity sake, this provision shall not apply for any disclosures or releases required by the SEC or any other Regulatory Authority, which such disclosures and releases will be subject to Section 13.3.

(c) **Effect on Existing Confidentiality Agreement.** The provisions of this Article 13 do not supersede that certain letter agreement, dated April 3, 2017, between Licensor and Licensee.

14. TERM AND TERMINATION.

14.1 **Term.** The term of this Agreement shall commence as of the Effective Date and shall continue in effect until it is terminated as specifically provided in this Agreement.

14.2 **Termination for Material Breach.**

(a) If either Party (the "non-breaching Party") believes the other Party (the "alleged breaching party") is in material breach of any of such alleged breaching Party's obligations under this Agreement, the non-breaching Party may give notice of such breach to the alleged breaching Party, and the alleged breaching Party shall have sixty (60) days in which to remedy such material breach or establish that it is not in material breach hereunder. Subject to Section 14.2(b), if such alleged material breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the alleged breaching Party.

(b) If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the non-breaching Party pursuant to Section 14.2(a), and the alleged breaching Party provides notice to the non-breaching Party of such dispute within fifteen (15) days after receipt of such notice, the non-breaching Party shall not have the right to terminate this Agreement unless and until the existence of such material breach by the alleged breaching Party has been determined in accordance with the dispute resolution procedures set forth in Section 15.8 (each such termination delay, a **"Toll Period"**) and the breaching Party fails to cure such default within sixty (60) days following such determination; provided that, if it is determined that such material breach occurred and such breach is not cured within such sixty (60) day period, then, for

purposes of Section 14.4(c)(iii), this Agreement shall be deemed to have been terminated as of the date of delivery of notice of such breach under Section 14.2(a). During the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

14.3 **Termination upon Insolvency.** To the extent permitted under Applicable Laws, either Party may terminate this Agreement with respect to the other Party if, at any time, such other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party proposes a written agreement of composition or extension of its debts, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment for the benefit of its creditors.

14.4 **Termination upon Force Majeure.** Either Party may terminate this agreement due to a Force Majeure event pursuant to Section 15.13.

14.5 **Consequences of Expiration or Termination.**

(a) Upon termination of this Agreement by either Party pursuant to Sections 14.2, 14.3, or 14.4,

(i) all of the licenses granted by Licensor to Licensee shall therewith immediately terminate and any sublicenses granted by Licensee thereunder will be subject to the provisions set forth in Section 2.4(f);

(ii) Licensee must assign and transfer to Licensor, and shall cause its Affiliates and Sublicensees to assign and transfer to Licensor, without additional compensation, all of their right, title, and interest in to, and under, subject to any licenses or sublicenses granted by Licensee that expressly survive any such termination pursuant to Section 2.4(f), all clinical and related study data based on use of Products, all Regulatory Filings and Regulatory Approvals for Products in respect of each country in the Territory; and the Renaissance Supply Agreements.

(b) If at the time of any such termination of this Agreement by Licensor pursuant to Sections 14.2 or 14.3 Licensee has in its possession or under its control any inventory of the Product approved and allocated for sale in the Territory, Licensee shall for a period not to exceed six (6) months following the effective date of such termination be permitted to sell any such inventory of the Product in the Field in the Territory, and the licenses hereunder shall continue on a nonexclusive basis until all such units of the Product have been sold, provided that (A) the Product shall not be sold at a discount to a purchaser that is greater than the average discount provided to such purchaser for the Product during the twelve (12) month period preceding such termination and, in addition, such sales shall not result in the applicable wholesaler inventory levels for the Product exceeding the average levels for the twelve (12) month period preceding such termination, and (B) Licensee continues to pay, during the applicable Royalty Term, the applicable royalty and, if applicable, sales milestones, on resulting applicable Net Sales of Product in the Territory by it Licensee, its Sublicensees or any Third Party Distributors.

(c) In the event of a material breach of this Agreement by Licensor that is not successfully disputed or cured by Licensor in accordance with Section 14.2(b), Licensee may elect to terminate this Agreement or continue the Agreement; provided, that in the event Licensee elects to continue the Agreement in lieu of terminating the Agreement in accordance with Section 14.2, Licensee will have the right in its discretion to fully reduce the royalty payments or milestone payments required under Article 8 by the amount of damages suffered by Licensee due to such material breach by Licensor, which such amount will be determined by an independent third party with requisite expertise and agreed upon by the Parties, with any dispute as to the determination being subject to the dispute resolution process set forth in Section 15.8(b).

(d) In the event of the insolvency or bankruptcy of Licensor that gives rise to Licensee's right to terminate this Agreement in accordance with Section 14.3, Licensee may elect to terminate this Agreement or continue the Agreement (subject, to the extent applicable, Section 14.7).

14.6 **General Surviving Obligations.** The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Expiration or termination of this Agreement for any reason shall not (a) release either Party from any obligation that has accrued prior to the effective date of such expiration or termination (including without limitation the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such termination but that are unpaid or become payable thereafter), (b) preclude either Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (c) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: Sections 7.7, 7.8, 9.1(a), 9.2(b), 9.5(a), and Articles 1 (to the extent that any term defined therein is used in any of the sections or articles specified in this list as surviving termination of this Agreement), 8, 11, 12, 13, 14, and 15.

14.7 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by either Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 61 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

15. MISCELLANEOUS.

15.1 **Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer, or legal representative of the other Party for any purpose, except as expressly set forth herein. No Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Parties, nor shall either Party be entitled to pledge the credit of the other Parties in any way or hold itself out as having the authority to do so.

15.2 **Assignment.** Except as expressly provided in this Agreement, neither Party may assign any rights or delegate any duties under this Agreement to any Third Party without the prior written consent of the other Party; provided, however, that (a) Licensor may freely assign its right to receive any payments hereunder without such consent of Licensee, (b) in the case where either Party seeks to assign this Agreement as a whole to an Affiliate or to a Successor in connection with a Change of Control of such Party or of that part of such Party's business to which this Agreement relates, such consent shall not be unreasonably withheld, delayed, or conditioned, provided that such Party provides written notice to the other Party of such Change of Control and such Successor agrees in writing to be bound as such Party hereunder. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's Successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or transfer not in accordance with this Section 15.2 shall be null and void.

15.3 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.4 **Notices.** All notices and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when personally delivered or sent by confirmed facsimile or email (with hard copy to follow); (b) one (1) Business Day after sent by reputable overnight express courier (charges prepaid); or (c) five (5) Business Days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, such notices to Licensor or Licensee shall be sent to the addresses indicated below:

If to Licensor, addressed to:

Serenity Pharmaceuticals, LLC
105 Hawk Court
Milford, PA 18327
Attention: Chief Executive Officer
With a copy to:
email: docsam122@gmail.com>

With a further copy to:
Mr. Alain Kodsi
email: alainkodsi@gmail.com

If to Licensee, addressed to:

Avadel Specialty Pharmaceuticals, LLC
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005
Attention: Chief Executive Officer
With a copy to: General Counsel

15.5 **Amendment.** No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.6 **Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

15.7 **Counterparts; Electronic Delivery.** This Agreement may be executed simultaneously in two counterparts, either of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.8 **Governing Law; Dispute Resolution.**

(a) This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A. without regard to its or any other jurisdiction's choice of law rules that would result in the application of the laws of any jurisdiction other than the State of New York, U.S.A.

(b) Except as otherwise provided in this Agreement, in the event of any dispute, controversy, or claim (**"Dispute"**) between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party providing such notice may, by written notice to the other Party refer such Dispute to the other Party for attempted resolution by good faith negotiation by the Chief Executive Officers or President of Licensor and the Chief Executive Officer, President or an Executive Vice President within thirty (30) days after such notice is received. In the event that any such Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 15.8(c). Any Disputes of the type described in Section 3.2(i) shall first be subject to the dispute resolution mechanism set forth in Section 3.2(i) before being subject to this Section 15.8.

(c) In the event such officers of the Parties are not able to resolve any such Dispute, either Party may at any time after such thirty (30) day period submit such Dispute to be finally settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association (**"AAA"**) in effect at the time of submission. The arbitration shall be heard and determined by three (3) arbitrators. Each such Party shall each appoint one arbitrator and the third arbitrator shall be selected by the two Party-appointed arbitrators, or, failing agreement within thirty (30) days following the date of receipt by the respondent of the claim, by the AAA. Such arbitration shall take place in New York, NY. The arbitration award so given shall be a final and binding determination of the dispute, shall be fully enforceable in any court of competent jurisdiction, and shall not include any damages expressly prohibited by Section 12.1. The Parties agree that all applicable statutes of limitation and time-based defenses (such as

estoppel and laches) shall be tolled while the dispute resolution procedures set forth in this Section 15.8(c) are pending.

(d) Notwithstanding anything herein to the contrary, nothing in this Section 15.8 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, including in a court of law, if necessary to protect the interests of such Party. This Section 15.8 shall be specifically enforceable.

(e) Notwithstanding the foregoing, any disputes regarding the validity, scope or enforceability of Patent Rights or trademarks shall be submitted to a court of competent jurisdiction in the territory in which such rights apply.

15.9 **Hart-Scott-Rodino.** Licensee, at its expense, with the reasonable cooperation of Licensor, will be responsible for making any filing with the U.S. Federal Trade Commission ("FTC") in respect of this Agreement and the transaction contemplated hereby under Hart-Scott-Rodino Antitrust Improvements Act of 1976. This Agreement shall not become effective until the expiration of any applicable waiting period under such Act.

15.10 **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

15.11 **Compliance with Applicable Laws.** Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder.

15.12 **Remedies.** The exercise of any remedies hereunder shall be cumulative and in addition to and not in limitation of any other remedies available to such Party at law or in equity.

15.13 **Force Majeure**. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of nature, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, or civil unrest (**"Force Majeure"**); provided that the affected Party promptly notifies the other Party and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. In the event any such Force Majeure event continues for three (3) months or more, the unaffected Party shall have the right to terminate this Agreement, effective as of the date of delivery of notice, which notice shall not be delivered prior to the end of such three (3) month period.

15.14 **Interpretation**. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.15 **Construction**. In construing this Agreement, unless expressly specified otherwise: (a) unless otherwise specifically provided, any references to Articles, Sections, Exhibits, Schedules, and Appendices are to articles in, sections of, and exhibits, schedules and appendices to, this Agreement; (b) except where the context otherwise requires, use of either gender includes the

other gender and use of the singular includes the plural and vice versa; (c) headings and titles are for convenience only and do not affect the construction or interpretation of this Agreement; (d) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words; (e) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (f) except where the context otherwise requires, the word "or" is used in the inclusive sense; (g) all references to "dollars" or "$" herein shall mean US Dollars; (h) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (i) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, and (j) any reference herein to any person or entity shall be construed to include the person's or entity's successors and assigns.

15.16 **Entire Agreement of the Parties**. This Agreement and the exhibits attached hereto constitute and contain the complete, final, and exclusive understanding and agreement of the Parties, and cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including without limitation the Confidentiality Agreement, and neither Party shall be liable or bound to any other Party in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon either Party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided herein. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall control.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date set forth in the first paragraph hereof by their duly authorized representatives as set forth below:

LICENSOR:
SERENITY PHARMACEUTICALS, LLC

By: /s/ Samuel Herschkowitz, M.D.
Name: Samuel Herschkowitz, M.D.
Title: Chief Executive Officer

By: /s/ Alain Kodsi
Name: Alain Kodsi
Title: President

LICENSEE:
AVADEL SPECIALTY PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson

Name: Michael S. Anderson
Title: Chief Executive Officer

Exhibit 4.4
Commercialization Plan

[to be prepared in accordance with Article 4]

Exhibit 5.5
Manufacturing and Supply Plan

[to be prepared in accordance with Article 5]

Exhibit __
Development Plan

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

CONFIDENTIAL TREATMENT REQUESTED
THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

MANUFACTURING AGREEMENT

DPT LAKEWOOD, LLC

AND

SERENITY PHARMACEUTICALS

Table of Contents

This Manufacturing Agreement (the "Agreement") is made as of this 14th day of July, 2014 (the "Effective Date") by and between Serenity Pharmaceuticals, a corporation organized under the laws of the State of Delaware with its principal place of business at 105 Hawk Court, Milford, Pennsylvania 18337 (hereinafter referred to as "SERENITY") and DPT Lakewood LLC, a corporation organized under the laws of the State of Delaware with a place of business at 1200 Paco Way, Lakewood, New Jersey, 08701, individually and on behalf of its Affiliates (hereinafter collectively referred to as "DPT"). SERENITY and DPT shall hereinafter be individually referred to as a "Party" and collectively as the "Parties."

WITNESSETH:

WHEREAS, SERENITY is engaged in the distribution and sale of certain pharmaceutical products; and

WHEREAS, DPT owns and has a broad spectrum of technologies for the development, formulation, testing, control, manufacture, filling and distribution of pharmaceutical products; and

WHEREAS, SERENITY desires DPT to manufacture and sell the Products hereinafter defined to SERENITY, and SERENITY and DPT desire to enter into this Agreement governing the supply of the Products upon the terms and conditions contained herein; and

WHEREAS, SERENITY has entered into a global agreement with Allergan Sales, LLC, a Delaware limited liability company with its principal place of business at 2525 Dupont Drive, Irvine, California 92612 ("Allergan") relating to development and commercialization of Products; and

WHEREAS, DPT has entered into a separate Capacity Guaranty Agreement with Allergan (as an intended beneficiary of this Agreement) dated as July 14, 2014, for the purchase of certain equipment for use in conjunction with the manufacturing of the Products (the "Capacity Guaranty Agreement"), attached hereto as "Exhibit 1" and incorporated herein.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter expressed, the Parties agree as follows:

I - DEFINITIONS

1.1 Act

"Act" means the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder.

1.2 Affiliate

"Affiliate" means any corporation or non-corporate business entity which Controls is Controlled by, or is under common Control of a Party. "Control" or "Controlled" shall mean (1) ownership by one entity, directly or indirectly, beneficially or legally, of at least fifty percent (50%) of the voting stock of another entity (or such lesser percentage which is the maximum allowed to be owned by an entity in a particular jurisdiction); or (2) the power of one entity to direct the management or policies of another entity, by contract or otherwise.

1.3 Calendar Year

"Calendar Year" means any period during the term commencing on January 1 and ending on December 31st of such year.

1.4 GMP

"cGMP" or "cGMPs" or "current Good Manufacturing Practices" means all the current standards and requirements relating to the manufacturing, processing, packing, and holding of bulk products, finished pharmaceutical products, and components thereof, including (a) Eudralex Volume 4: EU Guidelines to Good Manufacturing Practice for Human and Veterinary Use; (b) Code of Federal Regulations (CFR) 21, Parts 210 and 211; and (c) additional regulatory authority documents or regulations that replace, amend, modify, supplement, supplant or complement any of the foregoing.

1.5 Capacity Guaranty Agreement

"Capacity Guaranty Agreement" means the Capacity Guaranty Agreement between DTP and Allergan, dated July 14, 2014, that sets forth DPT's obligations to meet capacity requirements for the manufacture and supply of the Product.

1.6 Facilities

"Facilities" means DPT's manufacturing facilities at 1200 Paco Way, Lakewood, New Jersey, 08701.

1.7 FDA

"FDA" means the United States Food and Drug Administration, or any successor entity thereto.

1.8 Forecasted Needs

"Forecasted Needs" means SERENITY's estimate of Products to be ordered from DPT for each of the eighteen (18) months following the month in which such estimate is provided.

1.9 Label, Labeled, or Labeling

"Label", "Labeled", or "Labeling" means all labels and other written, printed, or graphic matter upon: (i) Product or any container or wrapper utilized with Product or (ii) any written material accompanying Product.

1.10 Launch Year

"Launch Year" means a period of a variable number of months commencing on the first day of the month following the initial invoicing of Product which has been commercially manufactured by DPT in accordance with the terms and conditions of this Agreement and ending on December 31 of the year of the initial invoicing.

1.11 Manufacturing Fee

"Manufacturing Fee" means the fee paid by SERENITY to DPT for services required to manufacture and package Products. The Manufacturing Fee is quoted in single final Product unit increments (i.e. by the bottle or tube). The Manufacturing Fee shall include services for incoming inspection and release of materials, compounding of bulk materials, packaging Product, performing semi-annual Media Fill Runs (as defined below), in-process bioburden test of bulk phases, sterility testing, testing Product for release, making Product ready for shipment, and minimum product documentation (one copy of Certificate of Analysis, and Certificate of Compliance .

The Manufacturing Fee does not include, without limitation, any research and development support, package engineering studies, validation support, extraordinary FDA audit support, or additional laboratory testing performed by an outside testing laboratory or testing beyond that are required in the Specifications (as defined in Schedule C). These services are in addition to the Manufacturing Fee and shall be billed by the hour at DPT's then-prevailing R&D hourly rate, or such other rate mutually agreed to by the Parties, in accordance with a separate development agreement. In addition, the Manufacturing Fee does not include warehousing or distribution of Product, any materials costs or costs associated with establishing or manufacturing new materials such as art charges, die costs, plate costs, and packaging equipment change parts.

1.12 Materials Fee

"Materials Fee" is quoted in single final Product unit increments and is defined as DPT's Standard Cost ("Standard Cost" is the average actual cost to DPT of all raw materials, components, packaging materials, plus incoming freight, scrap/yield loss adjustments and any other recurring costs directly attributable to acquiring the material) plus a mark-up of [***]% for administration and carrying costs.

Materials Fee does not include costs associated with establishing, testing or manufacturing components or new materials such as reference standards, reagents, art charges, die costs, mold or tooling costs, plate costs, and packaging equipment change parts. With the exception of items that are not ordinary and customary, DPT will obtain prior written approval from SERENITY before making any financial commitment on SERENITY's behalf. These items will be invoiced to SERENITY at DPT's cost on a net thirty (30) basis and SERENITY agrees to reimburse DPT for any such SERENITY-authorized expenditure made on SERENITY's behalf.

1.13 Material Safety Data Sheet

"Material Safety Data Sheet" ("MSDS") means written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration, or any successor entity thereto.

1.14 Media Fill Run

"Media Fill Run" means an evaluation run conducted with media to test the sterility of the manufacturing process in accordance with the applicable Specifications and current FDA and EU Aseptic Processing guidance.

1.15 Packaging

"Packaging" means all primary containers, cartons, shipping cases, inserts or any other like material used in packaging, or accompanying, Product.

1.16 Product(s)

"Product(s)" means the finished product(s) to be manufactured and supplied by DPT to SERENITY for commercial distribution under purchase order(s) issued under this Agreement and as more specifically detailed in Schedule A attached hereto and incorporated herein as an integral part of this Agreement, and which shall be packaged with SERENITY-approved Labeling and in accordance with the Specifications.

1.17 Quality Agreement

"Quality Agreement" has the meaning as set forth in Paragraph 6.6.

1.18 Specifications

"Specifications" means the Product specifications referenced in Schedule C which may be amended from time-to-time. The Specifications shall also include all necessary test protocols/methods, packaging and Labeling specifications, engineering change requests or orders (ECR/ECO), bills of material and other documentation required to describe, control, and assure the quality of the manufacture of the Product regardless of whether the foregoing is included as a part of Schedule C.

1.19 Territory

"Territory" means the European Union and United States of America including its commonwealths, territories and possessions listed on Schedule B as long as the Product and DPT are approved for such region(s). Countries may be added or removed from time to time by amendment to this Agreement by written consent of both Parties.

II - PRODUCT MANUFACTURE AND SUPPLY

2.1 Manufacture and Purchase

Subject to the terms and conditions of this Agreement, DPT agrees that it will exclusively manufacture the Products for, and sell to, SERENITY, and SERENITY agrees that it will exclusively purchase from DPT, one hundred percent (100%) of SERENITY's requirements of the Products in the Territory. SERENITY shall pay DPT for Products according to Paragraph 2.9 below. DPT shall manufacture Products in accordance with the Specifications or pursuant to exceptions approved by SERENITY in writing, and in sufficient quantity to meet SERENITY's Forecasted Needs for the duration of this Agreement.

In the event that DPT is not approved as a manufacturer in any region of the Territory or is not able to meet SERENITY's anticipated demand as reflected in SERENITY's Forecasted Needs, and in accordance with acceptable modification range as indicated in Paragraph 2.5 below, SERENITY shall have the right to purchase the Products from an alternate manufacturer required to support the region of the Territory for which DPT is not approved and/or the quantities of the Forecasted Needs DPT is not able to supply.

During the life of manufacturing exclusivity, DPT will not produce competitive products that use a combination of nasal spray, associated excipient and desmopressin for specific use in nocturia.

2.2 Supply of Materials

(a) Materials Supplied by DPT

DPT shall be responsible for supply of all materials, at the expense of SERENITY including all other commodities necessary for the manufacture of Products. All DPT supplied materials ("DPT Materials") will be billed to SERENITY on the respective invoice for Product, into which the DPT supplied materials was converted, as part of the Materials Fee, and in addition to the Manufacturing Fee, all in accordance with the provisions of Paragraph 2.8 below. To the extent that SERENITY provides materials it shall be in accordance with Paragraph 2.2 (b) below.

(b) Materials Supplied by SERENITY

Although it is the mutual intent for DPT to supply all materials upon commercialization of Products, if SERENITY elects to supply any material for manufacture of Products as set forth under this Section, SERENITY shall notify DPT, in writing, specifying which materials it will supply. SERENITY shall provide DPT with said materials ("SERENITY Materials") at SERENITY's expense along with Certificates of Analysis and MSDS sheets relating to same, at a minimum of forty-five (45) days prior to DPT's scheduled production of Product requiring said SERENITY Materials and in sufficient amounts for DPT's manufacture of Product but not to exceed quantities necessary to support four (4) months of the most recently supplied Forecasted Needs or the minimum order quantity whichever is greater. SERENITY Materials in excess of these amounts shall be either subject to storage fees or returned to SERENITY. All SERENITY Material shall be shipped to DPT freight prepaid. In the event SERENITY ships or causes to ship such SERENITY Material freight collect, DPT shall invoice SERENITY for the cost of the freight plus a reasonable administrative fee which invoice shall be paid promptly upon receipt. DPT is hereby authorized by SERENITY to return any portion of SERENITY Material for which no future production is planned. SERENITY shall be responsible for the quality of all SERENITY Materials. SERENITY shall be responsible for the payment of all personal property and other taxes incident to the storage of SERENITY Material at DPT. For each lot of SERENITY Materials supplied by SERENITY, DPT shall perform the quality control and inspection tests as agreed to in the Specifications and/or the Quality Agreement unless SERENITY has made arrangements in writing for pre-approved SERENITY Material. DPT shall have the right to reject any pre-approved SERENITY Material which does not meet the Specifications in accordance with paragraph 2.3 below.

(c) Material Inventory

DPT warrants that it will maintain, for the benefit of SERENITY, complete and accurate records of the inventory of all SERENITY Materials and DPT Materials. If requested by SERENITY, DPT will provide to SERENITY a monthly report of ending monthly inventory balance of such SERENITY Materials and DPT Materials stored at DPT's Facilities and any other facilities at which such materials are stored by DPT. This reporting will be supplied exclusively on DPT forms. DPT shall use SERENITY

Materials and DPT Materials (that are unique to Products) only to manufacture and supply Products under this Agreement, and shall not use these materials for any other purpose. All SERENITY Materials and DPT Materials, while in DPT's custody or control, shall be held at DPT's risk, shall be kept insured by DPT at DPT's expense in an amount equal to or greater than the replacement cost. SERENITY Materials shall be subject to removal at SERENITY's written request, in which event DPT shall prepare such materials for shipment and redeliver to SERENITY, at SERENITY's cost and expense, in substantially the same condition as originally received by DPT.

(d) Packaging and Labeling

SERENITY shall provide DPT with Specifications (including art proofs) for Packaging and Labeling, and subject to pre-approval from SERENITY on a case-by-case basis, DPT shall purchase, at the expense of SERENITY, Packaging and Labeling in accordance with the Specifications.

(e) Additional Charges

SERENITY shall be responsible for any additional charges (including, but not limited to, items such as brokerage fees, courier expenses, duty fees payable, etc.) that are incurred in the procurement of any materials and/or Packaging and Labeling components as detailed in the immediately preceding sub-sections (a), (b) and (d); required for the manufacture of the Products, irrespective of which Party to the Agreement is responsible for supplying such items.

2.3 Materials Testing

All materials and packaging supplies shall, when received by DPT, be submitted to analysis and evaluation in accordance with DPT's SOP's to determine whether or not said materials meet the Specifications. The cost of all such analyses and evaluations shall be borne by DPT. DPT agrees to maintain and, if necessary, make available records of all such analyses and evaluations.

2.4 Material Safety Data Sheets

Prior to DPT's receipt and testing, and as a condition precedent of any testing or formulation work by DPT pursuant to this Agreement, SERENITY shall provide MSDS to OPT for finished Products and all components necessary for the manufacture of Products. Any components or Products requiring disposal shall be presumed hazardous unless otherwise provided in the MSDS information provided.

2.5 Commencement of Manufacturing of Products

No later than four (4) months prior to the commercialization of Products, SERENITY agrees to notify DPT of its delivery requirements, including firm orders for same, for such four (4) months and shall provide its Forecasted Needs for the first Calendar Year in order to ensure timely delivery of Product for initial sales and marketing.

2.6 Purchase Orders

(a) Purchase of Products

SERENITY agrees to purchase from DPT all Products manufactured for SERENITY by DPT in accordance with SERENITY's purchase orders or the binding portion of Forecasted Needs to the extent such Products meet the Specifications or exceptions approved by SERENITY in writing. Products shall be ordered by SERENITY by the issuance of separate, pre-numbered purchase orders in increments of full batches.

(b) Forecasted Needs

SERENITY shall provide DPT with a written, non-binding eighteen (18) month projection with specific data as to its Forecasted Needs. Such Forecasted Needs shall be updated by SERENITY monthly on or before the 10th day of each calendar month on a rolling eighteen (18) month basis. It is understood and agreed that with respect to all Forecasted Needs issued to DPT by SERENITY pursuant to the terms hereof, the forecast for the first four (4) months thereof shall constitute a firm order for Products, regardless of receipt of SERENITY's actual purchase order. Thereafter, SERENITY shall provide OPT with a purchase order on or before the 10th day of each calendar month. DPT may produce Product up to thirty (30) days prior to the requested delivery date in order to accommodate fluctuations in production demands. The remaining fourteen (14) months of the Forecasted Needs shall be utilized by DPT for purposes of production planning. DPT shall attempt to minimize the material inventory purchased on behalf of SERENITY. Certain materials, however, may have long lead times and/or require a minimum order quantity. The Parties agree that the Long Lead Time Quantity (as defined below) is greater than the quantity needed to support up to six (6) months of SERENITY's Forecasted Needs. At least ninety (90) days prior to first commercial production, SERENITY and DPT will mutually agree on what components or materials are designated as "Long Lead Time Items" and what the lead time is for each Long Lead Time Item, as well as the quantity of each Long Lead Time Item that DPT must purchase to support SERENITY's Forecasted Needs ("Long Lead Time Quantity").

DPT shall notify Serenity and obtain SERENITY's prior written approval for any orders of chemical and packaging components in excess of the Long Lead Time Quantity. DPT agrees to provide Serenity, in writing, minimum order quantities for chemical and packaging components. Should SERENITY subsequently reduce its Forecasted Needs, SERENITY will be financially responsible for any material purchased by DPT on SERENITY's behalf in accordance with this Section. Any such material which is subsequently rendered in excess of that required to support up to six (6) months of SERENITY's Forecasted Needs may be subject to storage and inventory caring fees. DPT will require a deposit for such materials as well as any mutually agreed upon safety stock carried on behalf of SERENITY.

(c) Time of Issuance

SERENITY shall issue written purchase orders for Products to DPT at least one hundred twenty (120) days prior to the requested delivery dates (the "Lead Time") if the requirements are at or below [***] percent ([***]%)) of the applicable Forecasted Needs, and at least [***] ([***]) days prior to the requested delivery dates if the requirements exceed the Forecasted Needs by more than [***] percent ([***]%), subject to material lead time and the timely availability of materials prior to production. However, DPT

agrees to use commercially reasonable efforts to deliver increase in requirements greater than [***]% within the Lead Time.

(d) Contents of Purchase Orders

SERENITY's purchase orders shall designate the desired quantities of Products, price, delivery terms, delivery dates and destinations, and purchase order number for billing purposes. This Agreement allows for up to three (3) shipping destinations per batch of Product. Additional destinations can be accommodated for a shipping preparation fee to be negotiated by DPT and SERENITY.

(e) Minimum Purchase Requirements following FDA approval

SERENITY shall be required to purchase a minimum quantity of Product per Calendar Year commencing with the Launch Year. For clarity purposes, the term "Unit" shall be defined as one vial equipped with Aptar pump device which includes the Product. The Units produced in validation batches that are commercialized, shall be counted toward such minimum purchase requirements (for example, but without limitation, Units produced in validation batches that are commercialized in the period beginning on January 1 and ending on December 31 shall be counted toward the minimum purchase requirement for such period, and any Units produced in validation batches that are commercialized in any Calendar Year thereafter shall be counted toward the minimum purchase requirement for such Calendar Year). In the event that SERENITY fails to purchase the agreed upon minimum requirements in a given Calendar Year, SERENITY agrees to pay DPT the Unit shortfall at the agreed upon Manufacturing Fee in accordance with Schedule A. For the avoidance of doubt, for Products that are ordered in accordance of this Agreement and are scheduled to be delivered with a specified delivery date within the same Calendar Year in which the order was placed, the quantity shall be counted towards the minimum purchase requirements for that applicable Calendar Year regardless if the Products were actually made or delivered during that Calendar Year and will not be counted for the following Calendar Year when the Products are actually delivered.

Calendar Years	**Minimum Purchase (Units)**
Launch Year (Year 1)	[***]
Year 2	[***]
Year 3	[***]
Year 4	[***]
Year 5	[***]
Year 6	[***]

Notwithstanding the foregoing, SERENITY's obligation to purchase the minimum quantities of Product under this Section is conditioned upon DPT supplying SERENITY with Products pursuant to the warranties and Lead Time obligations under this Agreement.

2.7 Delayed Delivery

In the event that any delivery of the Product is anticipated to be late, DPT will promptly notify SERENITY of the circumstances for the delay. DPT will make a reasonable effort to minimize the delay. At the request of SERENITY, subject to SERENITY'S obligation under Paragraph 2.2(b) to make available to DPT SERENITY Materials timely, DPT agrees to assume the burden of bearing additional costs associated with overtime production and premium freight for corrective action as a result of delays caused by events under the span of control of DPT.

2.8 Rejected Products

(a) Rejection of Product by SERENITY

SERENITY may reject any Product which fails to meet the Specifications ("Rejected Product"). SERENITY shall, within sixty (60) days after its receipt of any shipment of Product and related Certificate of Analysis of Product batch (as described in paragraph 6.1 hereof), notify DPT in writing of any claim relating to rejected Product batch and, failing such notification, shall be deemed to have accepted such Product batch; provided, however, SERENITY may reject all of a given lot or batch of Product if a statistical sample does not meet the Specifications. Such notice to DPT shall specify why the Product batch failed to perform to Specifications. SERENITY shall grant to DPT the right to inspect or test said Product batch. All Products shall be submitted to inspection and evaluation in accordance with DPT's SOP's to determine whether or not said Products meet the Specifications. SERENITY's inspection and/or acceptance of Product shall not relieve DPT of any obligations or warranties under this Agreement.

(b) Replacement of Rejected Product

As to any Rejected Product pursuant to paragraph 2.7(a) above, DPT shall, without prejudice to any of SERENITY's other rights, promptly replace such Rejected Product (in an agreed upon batch order quantity, but in no event less than full batch increments). If requested, DPT shall make arrangements with SERENITY for the return or disposal of Rejected Product.

(c) Responsibility for Costs

For the initial three (3) commercial batches and all validation batches of a Product produced by DPT, or in the event a Rejected Product is due to SERENITY supplied information, formulations or materials, SERENITY shall bear one hundred percent (100%) of all costs directly related to and invoiced for Rejected Product including cost of destruction of the Rejected Product, which shall be conducted by SERENITY in accordance with all Applicable Laws (as defined below). Upon the completion of all necessary validation batches and the first three (3) commercial batches, and in the event a validated Product is rejected due to DPT's failure to comply with applicable written procedures and such failure renders the Product unmarketable, DPT shall bear one hundred percent (100%) of the manufacturing fees, costs of all materials supplied by DPT and costs of destruction. In the event a validated Product does not meet final Specifications and results in a Rejected Product, but such failure is not due to either SERENITY supplied information or DPT's failure to follow written procedures, SERENITY shall bear all Materials Fees with DPT bearing all Manufacturing Fees related to Rejected Product, and with destruction to be paid by SERENITY. Destruction of Rejected Product shall be in accordance with all Applicable Laws and the Party

conducting the destruction shall, subject to paragraph 11.7, indemnify, defend and hold harmless the other Party hereto for any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees) resulting from any third party claims made or suits brought against such Party to the extent arising from the other Party's failure to dispose of such Product in accordance with such laws and regulations.

(d) Resolution of Conflict

In the event of a conflict between the test results of DPT and the test results of SERENITY with respect to any shipment of Product batch, a sample of such Product batch shall be submitted by DPT to an independent laboratory or recognized industry expert acceptable to both Parties for testing against the Specifications utilizing the methods set out in the Specifications and/or Quality Agreement. The fees and expenses of such laboratory testing shall be borne entirely by the Party against whom such laboratory's findings are made. If results from the independent laboratory are inconclusive, final resolution will be settled in accordance with paragraph 13.6 (b) below.

(e) Recalled Product

In the event (i) any government authority issues a request, directive or administrative order that Product be recalled, or (ii) a court of competent jurisdiction orders a Product recalled, or (iii) SERENITY reasonably declares any recall of, or field corrective action to, any Product supplied to SERENITY under this Agreement, DPT agrees to cooperate with SERENITY in connection with any such recall. In the event such recall results from the breach of DPT's warranties under this Agreement, DPT shall be responsible for the administrative expenses of the recall as well as for the cost of replacing the recalled Product. In the event the recall results from the breach of SERENITY's warranties under this Agreement, SERENITY shall be responsible for all of the expenses of the recall. For the purposes of this Agreement, administrative expenses of the recall shall be the expenses of notification and return (but not destruction) of the recalled Product; including any reasonable out-of-pocket costs incurred by the Parties in connection with any corrective action. Notwithstanding anything contained herein to the contrary, DPT's liability for administrative expenses under this paragraph 2.7 shall not exceed [***] dollars ($[***]) per incident; provided, however, this monetary limitation shall not apply to DPT's indemnity obligations under Section Xl.

2.9 Product Price

(a) Manufacturing Fees

The initial Manufacturing Fees to be paid by SERENITY to DPT are listed in Schedule A. The Parties hereto agree that the Manufacturing Fees set out in Schedule A shall be effective through [***]. Effective [***] through [***], the inflation adjustment will be [***] percent ([***]%) less than PPI (or zero if PPI is less than [***] percent ([***]%)), and to the extent that annual Units in a Calendar Year exceed [***] Units, such PPI increase for that Calendar Year shall be waived. However, in the event that during this period the annual Units exceed [***] Units and PPI exceeds [***] percent ([***]%) percent, then pricing during this period will be adjusted by the amount in excess of [***] percent ([***]%).

Effective [***] the Manufacturing Fees shall be re-negotiated, in good faith, at the beginning of each Calendar Year. If the Parties are unable to agree on a re-negotiated price at least thirty (30) days prior to the start of a new twelve (12) month period, then this Agreement, effective the first day of January of the new twelve (12) month period, shall continue in force with prices being adjusted to reflect the change in the most recently published monthly Producer Price Index for Pharmaceutical Preparation Manufacturing PCU 325412, issued by the Bureau of Labor Statistics, US Department of Labor ("PPI") in July of the preceding year as compared to the same month of the year prior thereto until such time as to when price negotiation can be completed.
(For example: If in July [***] the PPI is 548.3 and in the previous year ([***]) the PPI was 530.5, the difference would be 17.8 (548.3-530.5 = 17.8). Then the 17.8 would be divided by 530.5 resulting in a PPI increase of 3.4% in year [***]).

Prices for new Products or new Product sizes, new batch sizes or product configuration changes not initially included in Schedule A, shall be negotiated and DPT and COMPANY shall arrive at a mutual agreement with respect to prices at the time said new Products or new Product sizes are added to Schedule A.

(b) Materials Fees

The Materials Fee to be paid by SERENITY to DPT shall be listed in Schedule A within one hundred twenty (120) days of commencement of the initial commercial products of the applicable Product. The Materials Fee will be adjusted once annually at the beginning of each Calendar Year and Schedule A shall be amended accordingly based on changes in DPT's standard costs for materials. In the event, however, the cost of a material increases during any Calendar Year greater than [***] percent ([***]%), DPT may promptly upon the effective date of such increase adjust its invoice price for said material to SERENITY to compensate for the increase.

Material Fees for new Products or new Product sizes, new batch sizes or product configuration changes not initially be included in Schedule A and shall be established at the time prior to first production.

2.10 Payment

Payment of undisputed amounts for all deliveries of Product and services shall be made in U.S. Dollars (USD), net thirty (30) days after the date of SERENITY's receipt of the applicable invoice. Invoices shall be generated upon shipment of Product from DPT. Total invoice price shall be equal to the quantity of Product times the Total Price per unit effective on the date of Product release, as listed in Schedule A. If SERENITY disputes any portion of an invoice received DPT, then SERENITY shall so notify DPT in writing of the disputed amounts and shall pay the undisputed amounts as set forth above in this paragraph 2.10, and the Parties shall use good faith efforts to reconcile the disputed amounts as soon as practicable.

Payments shall be made by certified check, via wire transfer or through other instrument accepted by DPT. Fund transfers by wire should be made to the following (this information may be updated in writing from time to time without requiring an amendment to this Agreement):

Account Name:
Account Number:
Bank Name:
ABA Routing Number:
SWIFT Code (US$)
Bank Location:
Contact:

2.11 Late Payment

A late fee of [***] percent ([***]) of total invoice can be added each month for late payments; provided, however, no such interest shall be due or payable unless and until DPT provides written notice to SERENITY of the non-payment and SERENITY fails to cure such non-payment within five (5) business days following SERENITY's receipt of said notice. In the event SERENITY's account is more than thirty (30) days past due with respect to undisputed amounts, and SERENITY fails to cure any non-payment within five (5) business days following receipt of written notice thereof, DPT, at its sole discretion, has the right to discontinue SERENITY's credit on future orders and to put a hold on any production or shipment of Product. Such hold on production or shipment shall not constitute a breach of this Agreement by DPT. In the event credit is discontinued, a one hundred percent (100%) material deposit paid by SERENITY to DPT may be required prior to DPT ordering materials. In addition, a fifty percent (50%) Manufacturing Fee deposit may be required prior to DPT manufacturing any Product and the balance of the invoice must be paid in full prior to shipment.

2.12 Disposal Costs

DPT reserves the right to invoice SERENITY for all disposal costs, related to manufacture of the Products, unless the disposal relates to a Rejected Product caused by the failure of DPT to follow established written procedures or any of the terms and conditions of this Agreement.

III - SHIPMENT AND RISK OF LOSS

3.1 Supply Chain Security and Shipment

DPT shall have in place a comprehensive and effective security program related to the security of the Products while in DPT's control. DPT shall ensure that physical security for the Products is maintained at all times at its Facilities until such time that the Products are transferred to an authorized freight handler. DPT shall take all necessary steps to prevent unauthorized tampering with the Products. Shipment of Product shall be in accordance with SERENITY instructions, provided that shipment is made in accordance with all relevant statutory requirements. Product will be shipped to SERENITY or its designee immediately upon release, freight collect. At SERENITY's request, DPT may hold Product in DPT's warehouse for a storage fee. Product held at DPT will be subject to payment as if the product was shipped in accordance with paragraph 2.10 above. If SERENITY requests DPT to make any miscellaneous small shipments of Product, material, or other items on SERENITY's behalf, SERENITY agrees to reimburse DPT for any shipping charges incurred.

3.2 Delivery Terms

The delivery terms of the Products detailed in Schedule A hereof shall be Ex Works ("EXW" Incoterms 2010) DPT's plant of manufacture). Title to, and risk of loss for, Product, shall transfer from DPT to SERENITY when DPT makes Products available to SERENITY at its plant of manufacture. SERENITY shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.

3.3 Claims

The weights, tares and tests affixed by DPT's invoice shall govern unless established to be incorrect. Claims relating to quantity, weight and loss or damage to any Product sold under this Agreement, which can be reasonably detected upon visual inspection of the delivered Products, shall be waived by SERENITY unless made within sixty (60) days of receipt of Product by SERENITY.

IV — FACILITIES AND CAPACITY GUARANTY

4.1 Facilities

DPT will be solely responsible for all cost and activities required for the construction, validation and qualification of the Facilities for the manufacture and supply of Product in accordance with Schedule D.

4.2 Capacity Guaranty

DPT shall, at DPT's sole cost and expense, be responsible for all activities, including, but not limited to, the purchase, installation, validation, qualification and maintenance of the equipment required to ensure that DPT can meet up to [***] ([***]) the Forecasted Needs for the manufacture and supply of Product subject to, and as further defined in, the Capacity Guaranty Agreement provided that the [***] ([***]) Forecasted Needs are equally spread throughout a Calendar Year and do not exceed [***] Units per year in Calendar Years 1 through 4, [***] Units in Calendar Year 5, and [***] Units in Calendar Year 6. However, the Parties further agree to review and discuss in good faith the Forecasted Needs on an annual basis and adjust (increase or decrease) the maximum Units for a given Calendar Year or Years, if warranted, based on historical Units manufactured and Forecasted Needs required to support projected sales demand. Upon execution, the Capacity Guaranty Agreement shall be attached hereto as Exhibit 1 and shall be incorporated herein.

V - TERM AND TERMINATION

5.1 Term

The initial term of this Agreement shall commence on the Effective Date hereof and will continue until December 31 of the sixth (6th) Calendar Year following the Launch Year, unless sooner terminated pursuant to paragraph 5.2 below. This Agreement may thereafter be extended upon the mutual written agreement of the Parties.

5.2 Termination

This Agreement may be terminated at any time upon the occurrence of either of the following events:

(a) This Agreement may be terminated by SERENITY upon written notice to DPT in the event SERENITY does not obtain FDA approvals for Product by December 31, 2017. In such event, the Minimum Purchase Requirement set forth herein will not apply, and neither Party will have any further obligations to the other Party under this Agreement.

(b) The failure of either Party to comply with its obligations herein, which failure is not remedied within sixty (60) days after written notice thereof.

(c) Notice by either Party to the other upon the insolvency or bankruptcy of the other Party.

(d) SERENITY reserves the right to terminate this Agreement in a reasonable amount of time with regard to an individual Product or in whole if SERENITY has been given notice by the regulatory authority that Product is no longer viable due to non-approval of Product. Such termination will absolve SERENITY of its obligations hereunder without penalty.

5.3 Payment on Termination

In the event of the termination or cancellation of this Agreement for any reason, and without prejudice to any other rights and remedies available to DPT hereunder, SERENITY agrees to reimburse DPT the Materials Fee directly ordered for the manufacture of Products based on SERENITY's Forecasted Needs as well as for work-in-process and finished Products per the terms of this Agreement.

5.4 Survival

Termination of this Agreement under paragraph 5.2 or due to expiration or cancellation shall not relieve either Party of obligations or liability for breaches of this Agreement incurred prior to or in connection with termination, expiration or cancellation. Sections VII, VIII, X, XI and XII hereof, along with any other provision of this Agreement that by its terms would survive expiration or termination shall survive the expiration or termination of this Agreement for any reason.

VI - CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE

6.1 Certificates of Analysis

DPT shall test each lot of Product purchased pursuant to this Agreement before delivery to SERENITY. Each Certificate of Analysis shall set forth the items tested, specifications and test results for each lot delivered. DPT shall send one (1) Certificate of Analysis to SERENITY at the time of the release of Product. Extraordinary reporting or documentation, outside this Agreement, may be subject to an additional charge by DPT.

6.2 Stability Testing

It is the mutual intent of the Parties to conduct the necessary inter-laboratory qualifications for DPT to be approved by the FDA to conduct stability testing. In the event that DPT is qualified and approved, SERENITY agrees that DPT shall perform its standard stability test program as defined in DPT's SOP's or as separately agreed to in accordance with a Change Control Request ("CCR") for each of the Products contained herein. DPT shall bill SERENITY for these costs under the Project Protocol (as defined below). SERENITY shall receive a copy of DPT's Annual

Product Review for each Product as long as DPT is continuing to produce such Product for SERENITY and for as long as SERENITY's account is current. If SERENITY elects to perform its own stability testing on Product, SERENITY agrees to provide DPT with a copy of the results from such testing on an annual basis.

6.3 Validation Work or Additional Testing

It is understood by the Parties hereto that the responsibility for any validation work shall be the sole responsibility of SERENITY. The Parties agree that for any validation work or additional testing in connection with the Product, DPT and SERENITY shall enter into a specific written Project Protocol establishing methodology and pricing for such services (the "Project Protocol"). It is understood between the Parties hereto that if DPT is required by regulatory authority to perform validation studies or additional testing in order to legitimately continue to engage in the manufacture of the Product for SERENITY and DPT and SERENITY cannot reach an agreement on a written Project Protocol, then DPT shall be under no obligation to continue the manufacture of the Product affected by said regulation.

6.4 FDA Inspection

DPT shall advise SERENITY if an authorized agent of the FDA or other governmental agency visits DPT's manufacturing facility and requests or requires information or changes which specifically pertain to the Products. If requested or required by DPT or the FDA, SERENITY will be invited on-site to participate during such inspection. Otherwise, DPT agrees to keep SERENITY updated on the status of the audit and will consult with SERENITY where appropriate. To the extent permitted, DPT shall provide SERENITY with copies of any and all inspection reports from the FDA regarding the manufacture of the Product within five (5) working days of receipt of such reports. DPT warrants and agrees that it will correct, at its own expense and within a reasonable amount of time from the date of notification, all deficiencies and/or non-conformances found in the facilities, equipment, processes or procedures during an FDA inspection; and that it will correct or issue a plan, including timetable, to correct all such deficiencies and/or non-conformances; provided, however, DPT shall not be responsible for deficiencies related to the Product itself or any of the Specifications or protocols approved by SERENITY. The plan will be provided to SERENITY within no more than thirty (30) days of completion of the inspection. Notwithstanding anything contained herein to the contrary, in the event the forgoing deficiencies and/or non-conformance were the direct result of new laws or regulations which came into effect after the Effective Date hereof and directly impact the manufacturing of Products, and to the extent any corrective action to address such deficiencies and/or non-compliance with regard to only Products will result in a significant cost increase or capital investment ("Cost of New Law"), the Parties agree to negotiate in good faith how the costs associated with making such corrections to the facilities, equipment, processes and/or procedures as it pertains to the Products should be allocated between the Parties. Should the Parties fail to reach an agreement on how to apportion the Costs of New Law between DPT and SERENITY, either Party may terminate this Agreement upon ninety (90) days written notice to the other Party without recourse. In the case where this Agreement is so terminated as set forth in this Section, SERENITY will be obligated to pay DPT for all outstanding invoices, expenses and/or work-in-progress.

6.5 Regulatory Filings

SERENITY agrees to provide DPT with copies of any sections of NDA's, ANDA's, 510(k)'s or other regulatory filings applicable to the Products manufactured and/or tested by DPT, and copies of any changes in or updates of same as they, from time to time, hereafter occur. All such materials and information shall be considered SERENITY Confidential Information, subject to Section X.

6.6 Quality Agreement

Prior to manufacturing the first batch of Product, or upon such other timing as the Parties may mutually agree upon, the Parties shall execute an agreement specifying the roles and responsibilities of the Parties with respect to quality assurance/quality control activities in a form mutually agreeable to both Parties and which, unless the Parties otherwise agree, shall be consistent with this Agreement (the "Quality Agreement"). In the event of any conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement shall control.

VII - WARRANTIES

7.1 Conformity with Specifications

DPT warrants that all Products sold pursuant to this Agreement will have been manufactured in accordance with the Specifications for the release of the Product or pursuant to exceptions approved by SERENITY at the time of manufacture.

7.2 Compliance with the Act

SERENITY shall bear sole responsibility for the validity of all test methods and appropriateness of all Specifications. In addition, SERENITY shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. SERENITY further warrants that it has obtained any and all necessary approvals from all applicable regulatory agencies necessary to manufacture and distribute all Products under this Agreement.

7.3 Conformity with regulations and cGMPs

Subject to the provisions set forth in paragraph 7.2 and 7.4 hereof, DPT warrants that during the term of this Agreement, DPT will comply with cGMPs, and all Products shall have been manufactured by DPT in compliance with applicable laws, regulations, regulatory requirements ("Applicable Laws") and cGMPs in the Territories as that term is defined in those Territories. DPT further warrants that its Facilities at which manufacturing of the Products shall occur: (a) are in good standing with the FDA and other applicable governmental agencies in the Territory; (b) are fully compliant with cGMPs and that all employees working on the Product whose responsibilities involve work which must be performed under cGMP standards have been properly trained; (c) hold all necessary licenses and permits from local, state, Federal, and other governmental authorities required for the manufacture and testing of the Product and that all such licenses and permits are in full force and effect. DPT is not aware of the existence of any outstanding violations of any such licenses or permits and warrants that no proceeding is pending or, to the knowledge of DPT, threatened, seeking the revocation or limitation of any such licenses or permits.

7.4 Compliance of Packaging and Labeling with Laws and Regulations

SERENITY warrants that all Labeling copy and artwork approved, designated or supplied by SERENITY shall be in compliance with all Applicable Laws . Compliance with all federal, state, and local laws and regulations concerning Packaging and Labeling shall be the sole responsibility of SERENITY, provided that DPT purchases such Packaging and Labeling as provided in paragraph 2.2(c) hereof. SERENITY hereby represents and warrants to DPT that all SERENITY designated formulas, components and artwork related to the Product do not violate or infringe any U.S. patent (or any foreign counterparts thereof), copyright or trademark laws, and agrees, subject to paragraph 11.7, to indemnify, defend and hold harmless DPT, its employees, officers, directors and representatives for all costs, damages and expense (including reasonable attorney's fees) arising out of any suit or action brought or threatened by a third party against DPT based upon any such claim of infringement; provided, however, SERENITY will have no obligation under this paragraph or otherwise with respect to any infringement claim based upon any modification of such formulas, components and/or artwork that are not authorized by SERENITY.

7.5 Access to DPT's Facilities

SERENITY shall have access to DPT's facilities at a mutually agreeable time for the sole purpose of auditing DPT's compliance with current Good Manufacturing Practices, the Act and this Agreement (including the Quality Agreement). Such access shall in no way give SERENITY the right to any of DPT's confidential or proprietary information. Further, such audits shall normally be limited to every twelve (12) months and three (3) employees, which may include employees of Allergan, who are subject to the same requirements of confidentiality as SERENITY. DPT warrants and agrees that it will correct, at its own expense and within a reasonable amount of time from the date of notification, the agreed to deficiencies and/or non-conformances found during a SERENITY audit. DPT shall use reasonable efforts to issue an approved plan, including timetable, to correct all deficiencies and/or non-conformances within no more than thirty (30) days of such notification.

7.6 Disclaimer

DPT AND SERENITY MAKE NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, LABELING OR PACKAGING, EXCEPT AS DETAILED HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY LOSS OF REVENUES OR PROFITS, LOSS OF USE, BUSINESS INTERRUPTION, COST OF COVER, OR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OR CLAIMS AGAINST EITHER PARTY OR ITS CUSTOMERS BY ANY THIRD PARTY, WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. DPT's LIABILITY UNDER THIS AGREEMENT FOR DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, RESTITUTION, WILL NOT EXCEED [***] **DOLLARS ($**[***]**). SERENITY's LIABILITY UNDER THIS AGREEMENT FOR DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, RESTITUTION, WILL NOT EXCEED** [***] **DOLLARS ($**[***]**).**

VIII - FORCE MAJEURE

Failure of either Party to perform its obligations under this Agreement shall not subject such Party to any liability to the other if such failure is caused by acts such as, but not limited to, acts of God, acts of terrorism, fires, explosion, flood, drought, war, riot, sabotage, embargo, strikes, compliance with any court order or regulation of any government entity acting with color of right or by any other cause beyond the reasonable control of the Parties, whether or not foreseeable.

IX — CHANGES TO PROCESS OR PRODUCT

9.1 Changes by SERENITY

If SERENITY at any time requests a change to Product and DPT agrees such change is reasonable with regard to Product manufacture; (I) such change shall be incorporated within the Master Batch Record and/or Specifications via a written CCR reviewed and agreed upon by both DPT and SERENITY; (ii) The Parties shall adjust the price of Product, if necessary, and Schedule A shall be amended accordingly; and (iii) SERENITY shall pay DPT for the costs associated with such change including, but not limited to, any additional development or validation work required, charged at DPT's then-prevailing R&D rates.

9.2 Changes by DPT

DPT agrees that any changes developed by DPT, which may be incorporated into the Product shall require the written approval of SERENITY via a CCR prior to such incorporation. At the time of such incorporation, such changes shall become part of the Specifications. It is also agreed that any regulatory filings incident to any such change shall be the sole responsibility of SERENITY.

9.3 Changes by Regulatory Authorities

The Parties agree that any changes required by regulatory authority, shall be incorporated into the Product as evidenced by the written approval of SERENITY via a CCR prior to such incorporation. At the time of such incorporation, such changes shall become part of the Specifications. If DPT is required by regulatory authority to perform validation studies for purposes of validating new manufacturing process or new material and finished Product assay procedures with respect to Product in order to continue to engage in the manufacture of said Product for SERENITY, such studies shall be conducted in accordance with Paragraph 6.3 herein. Any costs to DPT resulting from the operation of this paragraph shall be reimbursed by SERENITY.

9.4 Obsolete Inventory

Any SERENITY-specific inventory including, but not limited to, materials, expired materials, work-in-process, and Products rendered obsolete as a result of formula, artwork or packaging changes requested by SERENITY or by changes required by regulatory authority shall be reimbursed to DPT by SERENITY at DPT's Materials Fee. At such time and unless otherwise instructed by SERENITY agreed by DPT, DPT will ship the obsolete inventory to SERENITY for destruction by SERENITY. SERENITY shall bear one hundred percent (100%) of all shipping and destruction costs related to said obsolete inventory. The destruction shall be in accordance with all Applicable Laws and SERENITY shall, subject to Paragraph 11.7, indemnify, defend and

hold harmless DPT for any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees) resulting from any third party claims made or suits brought against DPT to the extent arising from SERENITY's failure to dispose of such inventory in accordance with such laws and regulations. SERENITY shall also provide DPT with all manifests and other applicable evidence of proper destruction as may be requested by DPT or required by Applicable Law. DPT shall provide written notification to SERENITY of its intent to dispose and or store obsolete inventory. If DPT does not receive disposition instructions from SERENITY within thirty (30) days from date of notification, obsolete inventory remaining at DPT's facilities shall be subject to a deposit covering the standard cost of the obsolete inventory and storage fees and or destruction at DPT's discretion.

X - CONFIDENTIAL INFORMATION

10.1 Confidential Information

(a) Obligations of Confidentiality

All confidential information furnished by SERENITY to DPT, or by OPT to SERENITY, during the term of this Agreement, relating to the subject matter hereof, shall be kept confidential by the Party receiving said confidential information, except for purposes authorized by this Agreement, and shall not be disclosed to any person or firm, unless previously authorized in writing to do so, for a period of not less than five (5) years following the date of disclosure. The Party receiving said confidential information may, however, disclose the same to its responsible officers and employees who require said information for the purposes contemplated by this Agreement, provided that said officers and employees shall have assumed like obligations of confidentiality. It is understood that all confidential information provided by either Party shall be identified or marked as such. Any oral communications which are to be considered confidential shall be reduced to writing and identified as confidential within thirty (30) days after disclosure. Notwithstanding the foregoing, any information disclosed by a Party that the other Party knows or has reason to know is confidential, trade secret or proprietary information of the disclosing Party, shall be treated as confidential information hereunder regardless of whether such information is identified, marked or confirmed in writing as confidential.

(b) Exceptions

Any other provisions hereof to the contrary notwithstanding, it is expressly understood and agreed by the Parties hereto that the obligations of confidence and nonuse herein assumed shall not apply to any information which:

(1) Is at the time of disclosure or thereafter so becomes a part of the public domain; or

(2) Was otherwise in the receiving Party's lawful possession prior to disclosure as shown by its written record; or

(3) Is hereafter disclosed to the receiving Party by a third party purporting not to be in violation of an obligation of confidentiality to the disclosing Party relative to said information; or

(4) Is by mutual agreement of the Parties hereto released from a confidential status; or

(5) Is required to be disclosed pursuant to regulatory or legal requirements.

(c) DPT Business Model

SERENITY acknowledges that as a contract manufacturing organization, DPT's business involves the application of its expertise, technology and know-how to numerous pharmaceutical and other products and that DPT retains the right (subject to its obligations under the applicable confidentiality provision or agreement and its exclusivity restrictions hereunder) to apply such expertise, technology and know-how to a variety of products or services.

10.2 Trademarks and Trade Names

(a) Each Party hereby acknowledges that it does not have, and shall not acquire any interest in any of the other Party's trademarks or trade names unless otherwise expressly agreed.

(b) Each Party agrees not to use any trade names or trademarks of the other Party, except as specifically authorized by the other Party in writing both as to the names or marks which may be used and as to the manner and prominence of use.

XI — INDEMNIFICATION

11.1 Indemnification by DPT

Subject to paragraph 7.6 above, DPT will indemnify, defend and hold SERENITY harmless against any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees) resulting from any third party claims made or suits brought against SERENITY to the extent arising from DPT's breach of this Agreement, including without limitation, its warranties set forth in Section VII hereof, and/or the negligence or willful misconduct of DPT, its officers, directors, employees, agents or other representatives in connection with this Agreement. Notwithstanding the foregoing, under no circumstances shall DPT have any responsibility for product liability or personal injury claims of such third parties which arise from the sale, distribution or any use of Product which meets the Specifications or otherwise covered by SERENITY's indemnity obligations under this Agreement.

11.2 Insurance by DPT

While this Agreement is in full force and effect DPT shall maintain in full force and effect and for a period of two (2) years following termination, if written on a claims made basis: commercial general liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury in an amount not less than Ten Million ($10,000,000) dollars per occurrence with an annual aggregate amount of not less than Ten Million ($10,000,000) dollars; products liability coverage and contractual liability coverage in an amount not less than Ten Million ($10,000,000) dollars per occurrence with an annual aggregate amount of not less than Ten Million ($10,000,000) dollars; workers compensation insurance in accordance with applicable statutory requirements, and employers liability insurance coverage of One Million ($1,000,000) per accident/disease/injury. The limits required may be satisfied through a

combination of both primary and excess casualty programs. Evidence of insurance coverage will be in the form of a Certificate of Insurance which shall name SERENITY as an additional insured. Concurrent with the execution of this Agreement, DPT shall provide evidence of the foregoing insurance coverage to SERENITY.

11.3 Indemnification by SERENITY

SERENITY will indemnify, defend and hold DPT harmless against any and all liability, damage, loss, cost or expense (including reasonable attorney's fees) resulting from any third party claims made or suits brought against DPT which are related to the breach of any of SERENITY's warranties provided for herein or which arise out of the promotion, distribution, use, testing or sales of Products, including, without limitation, any claims, express, implied or statutory, made as to the efficacy, safety, or use to be made of Products, and claims made by reason of any Product Labeling or any Packaging containing Product (provided such packaging and Labeling was purchased by DPT as provided in paragraph 2.2(c) hereof), unless such liability, damage, loss or expense is caused by the breach of DPT's warranties under Section VII hereof or otherwise covered by DPT's indemnity obligations under this Agreement.

11.4 Insurance by SERENITY

While this Agreement is in full force and effect SERENITY shall maintain in full force and effect and for a period of five (5) years following termination if written on a claims made basis: commercial general liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury in an amount not less than Ten Million ($10,000,000) dollars per occurrence with an annual aggregate amount of not less than Ten Million ($10,000,000) dollars; products liability coverage and contractual liability for the indemnity provided under this contract coverage in an amount not less than Ten Million ($10,000,000) dollars per occurrence with an annual aggregate amount of not less than Ten Million ($10,000,000) dollars. Such evidence of insurance coverage can be in the form of the original policy or a Certificate of Insurance which shall name DPT as an additional insured. Concurrent with the execution of this Agreement, SERENITY shall provide evidence of the foregoing insurance coverage to:

DPT Laboratories, Ltd.
Attention: Legal Department
318 McCullough Ave.
San Antonio, TX 78215
(210) 476-8100

11.5 Stacking of Insurance

Neither SERENITY nor DPT intend for their respective insurance policies to stack on top of each other. To that end, both Parties agree that if a loss is incurred: for which DPT has an obligation under Paragraph 11.1 to indemnify SERENITY hereunder, DPT's policies will be triggered and DPT will defend SERENITY under the additional insured endorsement, Furthermore, if a loss is incurred for which Serenity has an obligation under Paragraph 11.3 to indemnify DPT hereunder, then SERENITY's policies will be triggered and SERENITY will defend DPT under the additional insured endorsement.

11.6 Patent and Other Intellectual Property Rights

(a) by SERENITY

SERENITY shall indemnify, defend and hold DPT harmless from all costs, damages and expense (including reasonable attorney's fees) arising out of any suit or action brought or threatened by a third party against DPT based upon a claim that Products, as manufactured in compliance with the Specifications, or the use of the Product names and any other trademarks, trade names, or trade dress used by SERENITY in connection with Products, infringes any U.S. patent (or any foreign counterparts thereof) or other proprietary rights of a third party.

(b) by DPT

DPT shall indemnify, defend and hold SERENITY harmless from all costs, damages and expense (including reasonable attorney's fees) arising out of any suit or action brought by a third party against SERENITY based upon a claim that any process or technical data furnished and utilized by DPT infringes any U.S. patent (or any foreign counterparts thereof) or other proprietary rights.

11.7 Conditions of Indemnification

If either Party expects to seek indemnification from the other under this Agreement, it shall (a) promptly give notice to the other Party of any such claim or suit threatened, made or filed against it which forms the basis for such claim of indemnification (except that failure to timely provide such notice will relieve the other Party of its obligations only to the extent the other Party is materially prejudiced as a direct result of such delay), (b) give the other Party sole control over the defense thereof and any related settlement negotiations, and (c) cooperate fully with the other Party, at the other Party's expense, in the defense of all such claims or suits. Notwithstanding the foregoing, the Party seeking indemnification may participate at its own expense in the defense and any settlement discussions, and will have the right to approve any settlement agreement that involves an admission of fault by such Party or imposes non-monetary obligations on such Party; provided, however, that such approval will not be unreasonably withheld.

XII - GENERAL PROVISIONS

12.1 Notices

Any notices permitted or required by this Agreement shall be sent by certified or registered mail with a copy by fax and shall be effective the earlier of the date received or three (3) days after deposit in the U.S. mail, if sent and addressed as follows or to such other address as may be designated by either Party in writing:

If to DPT:
DPT Lakewood, LLC
c/o: DPT Laboratories, Ltd.
Attention: President
318 McCullough Ave.
San Antonio, Texas 78215
Fax: (210) 227-6132
with a copy to the General Counsel's Office

If to SERENITY:
Serenity Pharmaceuticals
Attention: Alain Kodsi
105 Hawk Court

Milford, Pennsylvania
Fax: 845-639-1703; 570-296-4247

With copies to: Allergan Sales, LLC
Attention: V.P., Global Sourcing & Procurement
2525 Dupont Drive
Irvine, California 92612
Fax: 714-246-5598

Allergan Sales, LLC
Attention: General Counsel
2525 Dupont Drive
Irvine, California 92612
Fax: 714-246-6995

12.2 Entire Agreement; Amendment

The Parties hereto acknowledge that this Agreement, Capacity Guaranty Agreement and Quality Agreement sets forth the entire agreement and understanding of the Parties and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof, and shall supersede any conflicting portions of DPT's quotation, acknowledgment and invoice forms and SERENITY's Purchase Order and other written forms. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by the Party against whom enforcement is sought. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.

12.3 Waiver

No waiver by either Party of any default shall be effective unless in writing, nor shall any such waiver operate as a waiver of any other default or of the same default on a future occasion.

12.4 Obligations to Third Parties

Each Party warrants and represents that proceeding herein is not inconsistent with any contractual obligations express or implied, undertaken with any third party.

12.5 Assignment and Subcontracting

This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the Parties and may not be assigned or transferred by either Party without the prior written consent of the other, which consent will not be unreasonably withheld. No such assignment shall release the original Party hereto from its duties and obligations under this Agreement. Notwithstanding anything contained herein to the contrary, the Parties acknowledge and agree that SERENITY may assign or otherwise transfer this Agreement to Allergan (or any Affiliate of Allergan), and upon any such assignment or transfer, Allergan may assign or transfer this Agreement to an Affiliate or a successor to that area of its business to which this Agreement is related with DPT's approval, which consent shall not be unreasonably withheld.

DPT will not subcontract or otherwise delegate any of its obligations under this Agreement without SERENITY's express prior written consent on a case-by-case basis, which consent shall

not be unreasonably withheld. Upon receipt of such consent, before allowing any subcontractor to begin performing services hereunder, DPT will enter into a binding written agreement with such subcontractor that protects SERENITY's (and Allergan's) rights and interests to at least the same degree as this Agreement. DPT will be responsible for the direction and coordination of the services of each subcontractor and SERENITY will have no obligation to pay any subcontractor directly.

12.6 Third Party Beneficiary

Subject to Section 12.5 above and upon assignment of this Agreement to Allergan, the Parties acknowledge and agree that Allergan shall have the right to enforce this Agreement directly against DPT as if Allergan was "SERENITY" hereunder. Notwithstanding the foregoing to the contrary, the Parties acknowledge and agree that Allergan, with or without the foregoing assignment, shall have the right to enforce the Capacity Guaranty Agreement, as it relates to the equipment, against DPT as set forth in that agreement.

12.7 Governing Law and Arbitration

(a) Governing Law

The validity, interpretation and effect of this Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts of law provisions contained therein.

(b) Arbitration

(i) **ANY DISPUTE, CLAIM OR CONTROVERSY ARISING FROM OR RELATED IN ANY WAY TO THIS AGREEMENT OR THE INTERPRETATION, APPLICATION, BREACH, TERMINATION OR VALIDITY THEREOF, INCLUDING ANY CLAIM OF INDUCEMENT OF THIS AGREEMENT BY FRAUD OR OTHERWISE, WILL BE SUBMITTED FOR RESOLUTION TO ARBITRATION PURSUANT TO THE COMMERCIAL ARBITRATION RULES THEN PERTAINING OF THE CENTER FOR PUBLIC RESOURCES ("CPR"), EXCEPT WHERE THOSE RULES CONFLICT WITH THESE PROVISIONS, IN WHICH CASE THESE PROVISIONS CONTROL. SUCH ARBITRATION SHALL BE HELD IN DELAWARE**.

(ii) The panel shall consist of three arbitrators chosen from the CPR Panels of Distinguished Neutrals each of whom is a lawyer specializing in business litigation with at least 15 years' experience with a law firm of over 25 lawyers or was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than $5 million, and the aggregate damages sought by the counterclaimant are stated to be less than $5 million, and neither side seeks equitable relief, then a single arbitrator shall be chosen, having the same qualifications and experience specified above.

(iii) The Parties agree to cooperate (1) to obtain selection of the arbitrator(s) within 30 days of initiation of the arbitration, (2) to meet with the arbitrator(s) within 30 days of selection and (3) to agree at that meeting or before upon procedures for

discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than 9 months after selection of the arbitrator(s) and in the award being rendered within 60 days of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within 20 days after the conclusion of the hearings. In the event no such agreement is reached, the CPR will select arbitrator(s), allowing appropriate strikes for reasons of conflict or other cause and three peremptory challenges for each side. The arbitrator(s) shall set a date for the hearing, commit to the rendering of the award within 60 days of the conclusion of the evidence at the hearing, or of any post-hearing briefing (which briefing will be completed by both sides in no more than 20 days after the conclusion of the hearings), and provide for discovery according to these time limits, giving recognition to the understanding of the Parties hereto that they contemplate reasonable discovery, including document demands and depositions, but that such discovery be limited so that the time limits specified herein may be met without undue difficulty. In no event will the arbitrator(s) allow either side to obtain more than a total of 40 hours of deposition testimony from all witnesses, including both fact and expert witnesses. In the event multiple hearing days are required, they will be scheduled consecutively to the greatest extent possible.

(iv) The arbitrator(s) shall render an opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either Party.

(v) To the extent possible, the arbitration hearings and award will be maintained in confidence.

(vi) Any court of competent jurisdiction may enter judgment upon any award. In the event the panel's award exceeds $5 million in monetary damages or includes or consists of equitable relief, then the court shall vacate, modify or correct any award where the arbitrators' findings of fact are clearly erroneous, and/or where the arbitrators' conclusions of law are erroneous; in other words, it will undertake the same review as if it were a federal appellate court reviewing a district court's findings of fact and conclusions of law rendered after a bench trial. An award for less than $5 million in damages and not including equitable relief may be vacated, modified or corrected only upon the grounds specified in the Federal Arbitration Act.

(vii) Each Party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration.

(viii) **EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY**.

(ix) The Parties covenant that they will participate in the arbitration in good faith, and that they will share equally in its costs.

(c) Mediation

(i) **ANY DISPUTE, CONTROVERSY OR CLAIM ARISING OUT OF OR RELATED TO THIS AGREEMENT, OR THE INTERPRETATION, APPLICATION, BREACH, TERMINATION OR VALIDITY THEREOF, INCLUDING ANY CLAIM OF INDUCEMENT BY FRAUD OR OTHERWISE, WHICH CLAIM WOULD, BUT FOR THIS PROVISION, BE SUBMITTED TO ARBITRATION SHALL, BEFORE SUBMISSION TO ARBITRATION, FIRST BE MEDIATED THROUGH NON-BINDING MEDIATION. SUCH MEDIATION SHALL BE HELD IN DELAWARE AND SHALL BE ATTENDED BY A SENIOR EXECUTIVE WITH AUTHORITY TO RESOLVE THE DISPUTE FROM EACH OF THE OPERATING COMPANIES THAT ARE PARTIES**.

(ii) After written notice of any dispute or controversy arising out of or related to the Agreement, or the interpretation, application, breach, termination or validity thereof and Written Demand for Mediation (the "Written Demand for Mediation"), the Parties shall promptly confer within seven (7) days in an effort to select a mediator by mutual agreement. In the absence of such an agreement within thirty (30) days of the date of the Written Demand for Mediation by either of the Parties, the mediator shall be selected by the Party making the demand for mediation. In the event that the Party that has not made the Written Demand for Mediation refuses to participate in the mediation process for any reason, or mediation is not scheduled within sixty (60) days of the Written Demand for Mediation for any reason, then the part that made the Written Demand for Mediation shall have the absolute right to proceed to arbitration pursuant to paragraph 13.7(b) of this Agreement.

(iii) The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than 45 days after initiation. Under no circumstances shall the commencement of arbitration under Section 12.7(b) above be delayed more than 45 days by the mediation process specified herein.

(iv) Each Party agrees to toll all applicable statutes of limitation during the mediation process and not to use the period or pendency of the mediation to disadvantage the other Party procedurally or otherwise. No statements made by either side during the mediation may be used by the other during any subsequent arbitration.

(v) Each Party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.

(d) Legal Fees

The provisions of this paragraph 12.7 may be enforced by any Court of competent jurisdiction, and the Party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including attorneys' fees, to be paid by the Party against whom enforcement is ordered.

12.8 Severability

In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be deemed modified and will be interpreted to accomplish the objectives of such provision to the greatest extent possible under Applicable Law without invalidating any other provision hereof.

12.9 Headings, Interpretation

The headings used in this Agreement are for convenience only and are not a part of this Agreement.

12.10 Counterparts

This Agreement may be executed by electronic transmission (e.g. fax, email/scan) in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same original.

12.11 Independent Contractor

In performing its services hereunder, DPT shall act as an independent contractor.

12.12 Export/Import Laws and Regulations

This Agreement is subject to any restrictions concerning the import or export of Product, active pharmaceutical ingredient, chemical or packaging components (or related technical information or data) to or from the United States as well as the laws and regulations of any other country involved in the import or export of such Product, active pharmaceutical ingredient, chemical or packaging components (or related technical information or data).

SERENITY acknowledges that it shall be solely and exclusively responsible for the preparation of all import and export documentation and compliance with all import and export laws of the United States as well as the laws and regulations of any other country involved in the import or export of such Product, active pharmaceutical ingredient, chemical or packaging components (or related technical information or data); except as otherwise agreed by the Parties in writing. Subject to Paragraph 11.7, SERENITY shall indemnify, defend and hold harmless DPT for any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees) resulting from any third party claims made or suits brought against DPT to the extent arising from any breach by SERENITY of its obligations under this provision. SERENITY shall be the importer or exporter of record for all such import or export activities. SERENITY shall cooperate with DPT as reasonably necessary to permit DPT to comply with the laws and regulations of the United States and any other country relating to the control of import or export of Product, active pharmaceutical ingredient, chemical or packaging components (or related technical information or data).

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly authorized officers as of the date first above written.

Serenity Pharmaceuticals **DPT Lakewood, LLC**

By:	/s/ Samuel Herschkowitz, M.D.	By:	/s/ Paul Josephs
	Samuel Herschkowitz, M.D.		Paul Josephs
Its:	Chief Executive Officer	Its:	Sr. VP, Sales, Marketing & Corp. Dev.

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

Schedule A

PRODUCT DESCRIPTION, PRICE (in U.S. Dollars)

PRODUCT DESCRIPTION

[***]

PRODUCT AND PRICE

Volume of unit of Products per Calendar Year	Manufacturing Fee per unit of Product
Less than or equal to [***]	$[***]
Greater than [***] and less than or equal to [***]	$[***]
Greater than [***] and less than or equal to [***]	$[***]
Greater than [***]	$[***]

Pricing above reflects pricing for Product produced in the new [***] manufacturing suite and utilizing the [***] filler referenced in the Capacity Guaranty Agreement.

In the event that DPT is not approved for testing of Products, pricing will be reduced by $[***] per unit until such time that DPT is approved and assumes responsibility for testing.

For clarity, units of Product produced in validation batches that are commercialized shall count for purposes of determining the tiered prices only in the Calendar Year in which the Product is produced.

Parties agree to discuss and establish pricing two months prior to the Calendar Year. In the initial Calendar Year, pricing will be established at the lowest volume tier. Thereafter, Parties agree to establish pricing two months prior to each Calendar Year and will assess the prior Calendar Year's actual units produced and scheduled to be delivered in the applicable Calendar Year as well as the Forecasted Needs in selecting the appropriate volume tier pricing to be effective on January 1. Parties agree to review and reset volume tier pricing, if required, mid-year based on actual units shipped in accordance with this Agreement in combination with Forecasted Needs for the remaining months in the Calendar Year. Parties agree to review and issue a "true-up" payment two times per year in the event that DPT has either undercharged or over charged based on a change in tier level price. For example, If DPT charged SERENITY tier pricing of $[***] and SERENITY's actual units for the year were [***]. DPT would pay SERENITY $[***].

Schedule B

Territory

1. United States of America including its commonwealths, territories and possessions
2. European Union

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

Schedule C

Specifications

The Parties acknowledge and agree that the following specifications are subject to revision based on FDA requirements.

[***]

Storage Condition	Number of Months		
	[***]		
	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Storage Condition	Number of Months		
	[***]		
	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Specifications for Release and Stability

Test	Specification	Reporting Requirements
Appearance	[***]	Record Actual Individual Observations
Physical Appearance of DP Container Closure System	[***]	Record Actual Individual Observations
PH	[***]	Individual: X.X Min: X.X Max: X.X Mean: X.X %RSD: X.X
Osmolality	[***]	Individual: XX MM: XX Max: XX Mean: XX %RSD: X.X
Identification	[***]	Individual: X.XX Min: X.XX Max: X.XX Mean: XXX %RSD: X.X
Assay and Uncharacterized Formulation Related Peaks	[***]	Assay Individual: XX.X Min: XX.X Max: XX.X Mean: XX.X %RSD: X.X Uncharacterized Formulation Related Peaks Individual: XX.XX Mean: XX.XX

Test	Specification	Reporting Requirements
CPD Content	[***]	Individual: XX Min: XX Max: XX Mean: XX %RSD: X.X
Particle Size Distribution	[***]	[***] Individual: X.X Min: X.X Max: X.X Mean: X.X %RSD: X.X
Spray Content Uniformity	[***]	Beginning of Life and End of Life Desmopressin/ Actuation (.11g/mL) Individual: X.XXX Min: X.XXX Max: X.XXX Mean: X.X %RSD: X.X % Label Claim Individual: XX Min: XX Max: XX Mean: XX %RSD: X.X
Priming	Report Results	Individual X.X
Droplet Size Distribution by Laser Diffraction	[***]	[***], Percentage of Droplets <10 m Individual: X.X Min: X.X Max: X.X Mean: X.X %RSD: XX
Assay Content Uniformity and Uncharacterized Formulation Related Peaks	[***]	Assay Individual: XX.X Min: XX.X Max: XX.X Mean: XX.X %RSD: X.X Uncharacterized Formulation Related Peaks Individual: XX.XX Mean: XX.XX
Pump Delivery (n=9 bottles, Tier1 3 bottles, 10 shots per bottle through bottle life. Tier2 6 additional bottles, 10 shots per bottle through bottle life)	[***]	Individual: X.X Min: X.X Max: X.X Mean: X.X %RSD: X.X
Net Content	[***]	Individual: X.XX Min: X.XX Max: X.XX Mean: X.XX %RSD: X.X
Foreign Particulate Matter	[***]	Individual:XX Min: XX Max: XX Mean: XX RSD: XX

Test	Specification	Reporting Requirements
Weight Loss	[***]	Individual: XX.X MM: XX.X Max: XX.X Mean: XX.X %RSD: XX.X
Spray Pattern	[***]	Individual: X.X MM: X.X Max: X.X Mean: XX %RSD: X.X
Plume GeometJy	[***]	Angle: X.X Width: X.X
Bacterial Endotoxins	[***]	XX EU/mL
Sterility	[***]	Meets Requirement (No Growth)
	[***]	Meets Requirement (No Growth)

Reporting

A Certificate of Analysis will be issued at each stability interval with individual, mean and %RSD data. Min, Max and Mean data will be presented in the stability tables only.

Schedule D

Facilities

DPT will build-out and construct at its Facilities certain improvements for use as a manufacturing suite ("the Manufacturing Suite") for the manufacture and supply of Products. The Manufacturing Suite shall use best engineering practices, and meet local site standards, guidelines and regulatory requirements. The Manufacturing Suite will facilitate proper process flow, people flow, maintenance and cleaning, prevent cross-contamination, and will have provisions to prevent entrance of unauthorized people in accordance with cGMPs.

The "critical" area of the Manufacturing Suite where the sterilized drug product, containers, and closures are exposed to environmental conditions will be designed to be classified as [***]. The area of the Manufacturing Suite immediately adjacent to the aseptic processing line will meet, at a minimum, [***] standards under dynamic conditions.

Clean area control parameters will be supported by microbiological and particle data obtained during qualification studies. Conformance to standards will occur with an aseptic processing facility monitoring program, a routine monitoring and maintenance program. A changeover and cleaning procedure will be in place to prevent cross-contamination between products.

Exhibit 1
Capacity Guaranty Agreement

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

RENAISSANCE AGREEMENTS ASSIGNMENT AND ASSUMPTION AGREEMENT

This Renaissance Agreements Assignment and Assumption Agreement (this "Agreement") is made as of September 1, 2017 by and between SERENITY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensor"), with offices at 105 Hawk Court, Milford, PA 18327, and AVADEL SPECIALTY PHARMACEUTICALS, LLC, a limited liability company organized under the laws of Delaware ("Licensee"), with offices at16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005. Assignor and Assignee are each sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Assignor and Assignee are parties to that certain Exclusive License and Assignment Agreement of even date herewith (the "ELAA Agreement") relating to the Product (as defined in the ELAA Agreement);

WHEREAS, Assignor is party to (a) that certain Manufacturing Agreement, dated July 14, 2014 (the "Manufacturing Agreement"), between Assignor and Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC; "Renaissance"), relating to the manufacture and supply by Renaissance of the Product and (b) that certain Quality Agreement, dated January 16, 2015 (the "Quality Agreement"; together with the Manufacturing Agreement, the "Renaissance Agreements"), between Assignor and Renaissance, relating to compliance with current Good Manufacturing Practices applicable to the manufacture by Renaissance of the Product;

WHEREAS, in accordance with ELAA Agreement, Assignor and Assignee have agreed to enter into this Agreement for the purpose of Assignor assigning to Assignee the Renaissance Agreements and Assignee assuming Assignor's obligations under the Renaissance Agreements;

NOW, THEREFORE, in consideration of the foregoing, the covenants and agreement set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1.Assignment and Assumption.

(a) Effective as of the Effective Date (as defined in the ELAA Agreement), Assignor does hereby unconditionally and irrevocably transfer, convey, assign, and deliver to Assignee, its successors and assigns, all of Assignor's right, title and interest in, to and under the Renaissance Agreements;

(b) Effective as of the Effective Date, Assignee hereby unconditionally and irrevocably accepts the transfer, conveyance, assignment, and delivery of such rights, title and interest in, to and under the Renaissance Agreements; and

(c) Effective as of the Effective Date, Assignee hereby unconditionally and irrevocably accepts the delegation by Assignor of the Renaissance Agreements and assumes and agrees to perform all such delegated obligations, duties, liabilities and commitments of Assignor under the Renaissance Agreements and to be bound to the terms thereof.

2. Re-Assignment Upon Termination of ELAA Agreement.

(a) Upon termination of the ELAA Agreement, Assignee will, within ten (10) days after such termination is effective, assign and transfer to Assignor, without additional consideration, all of Assignee's right, title, and interest in the Renaissance Agreements.

[Next Page is Signature Page]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date set forth in the first paragraph hereof by their duly authorized representatives as set forth below:

ASSIGNOR:
SERENITY PHARMACEUTICALS, LLC
By: /s/ Samuel Herschkowitz, M.D.
Name: Samuel Herschkowitz, M.D.
Title: Chief Executive Officer

ASSIGNEE:
AVADEL SPECIALTY PHARMACEUTICALS, LLC
By: Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

Master Manufacturing Services Agreement

PATHEON UK LIMITED

&

ÉCLAT PHARMACEUTICALS L.L.C

November 8, 2012

MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the "**Agreement**") made as of the 8th day of November 2012 ("Effective Date")

BETWEEN:

PATHEON UK LIMITED, a company incorporated in England & Wales (registered number 3764421) with registered office at Kingfisher Drive, Covingham, Swindon, Wiltshire SN35BZ, United Kingdom **("Patheon"),** and

ÉCLAT PHARMACEUTICALS, L.L.C., a company incorporated in **Delaware (USA)** whose principal place of business is at 699 Trade Center Blvd., Suite A, Chesterfield, MO 63005 USA **("Éclat").**

WHEREAS, Éclat and Patheon have previously entered into Product Development Agreements for the development of certain Éclat-owned Products by Patheon;

WHEREAS, Patheon has the ability and know how to manufacture such Products in its facilities and are operated and maintained at all times in accordance with all applicable regulatory laws and regulations; and WHEREAS, the parties wish to enter into this Agreement where Patheon agrees to exclusively manufacture the Products for Éclat and Éclat agrees to purchase the Products on an exclusive basis from Patheon in accordance with the terms of this Agreement.

THEREFORE, 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 Éclat or any Affiliate of Éclat, 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 at a Patheon or any Affiliate of 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 shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"Active Materials", "Active Pharmaceutical Ingredients" or "API" means the materials listed in Schedule ED of a Product Agreement hereto;

“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 the purposes of this definition, “control” means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation.

“Annual Report” means the annual report as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2) or relevant update;

“Annual Product Review Report” means the annual product review report as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e) or relevant update;

“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 hereto;

“Applicable Laws” means (i) with respect to Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) with respect to Éclat and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed and marketed as such are agreed and understood by the parties in this Agreement;

“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;

“Bill Back Items” means the expenses in respect of all third-party supplier fees for the purchase of columns, standards, tooling, PAPR or PPE suits (where applicable), RFID tags and supporting equipment and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

“Business Day” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United Kingdom or in the United States or in the country where the Manufacturing Site is located;

“cGMPs” means current good manufacturing practices as described in: (a) Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations; and (b) EC Directive 2003/94/EC, together with the latest FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

“Components” means, collectively, all packaging components, raw materials and ingredients (including labels, product inserts and other labelling for the Products), required to be used in order to produce the Products in accordance with the Specifications, other than the Active Materials;

“Confidentiality Agreement” means the agreement relating to the non-disclosure of confidential information entered into between Éclat and Patheon Inc., dated 16 November 2010 which shall apply to all confidential information about the parties and the Services to be conducted under this Contract and such Confidentiality Agreement is deemed to be incorporated herein by reference;

“Deficiency Notice” shall have the meaning ascribed thereto in Section 6.1(a); **“EMEA”** means the European Medicines Agency;

“FDA” means the United States government department known as the Food and Drug Administration and any successor agency having substantially the same function;

“Firm Orders” has the meaning specified in Section 5.1(b);

“Initial Set Exchange Rate” means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the billing currency into the Patheon Manufacturing Site local currency, calculated as the daily average interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com `The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“Intellectual Property” includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs; trade secrets and know how;

“Invention” means information relating to 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 in connection with 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;

“Manufacturing Services” means the manufacturing, quality control, quality assurance and stability testing, packaging and related services, as contemplated in this Agreement, required to produce Products from Active Materials and Components;

“Manufacturing Services Based Intellectual Property” means Intellectual Property generated or derived by Patheon in the course of performing any Manufacturing Services or otherwise generated or derived by Patheon in connection with the conduct of its business which Intellectual Property is not specific to, or dependent upon, Éclat ‘s Active Material or Product including, without

limitation, Inventions and Intellectual Property which may have application to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems beyond the specific requirements of the Product(s);

"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" mean all Components, Bill Back Items and other materials used in the manufacture of the Product other than Active Materials;

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

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

"Price" means the price measured in US$ to be charged by Patheon regarding Product manufactured and supplied hereunder as delivered to Éclat or its designee, and is comprised of the fees for the Manufacturing Services, and the costs for Components, Bill Back Items and Materials and handling charges which Price is fully described in Schedule B of a Product Agreement;

"Product(s)" means the products listed in Schedule A of a Product Agreement;

"Product Agreement" means the agreement between Patheon or an Affiliate of Patheon and Éclat or an Affiliate of Éclat issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon or an Affiliate of Patheon will perform Manufacturing Services at a particular Manufacturing Site;

Product Development Agreement(s) means the agreements entered into between Patheon and Éclat for the development of the Products listed in Schedule A to a Product Agreement;

"Quality Agreement" means the agreement attached hereto as Exhibit C;

"Regulatory Authority" means the FDA, EMEA or any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"Reset Date" means, with reference to any particular Year, November 1st of the immediately preceding Year;

"Set Exchange Rate" means the exchange rate to convert one unit of the billing currency into the Patheon Manufacturing Site local currency for each Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com 'The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"Specifications" means the file, for each Product, which was developed by Patheon and Éclat and approved by Éclat and is owned by Éclat and provided to Patheon in accordance with the procedures listed in Schedule A of a Product Agreement hereto and which contains documents relating to such 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 relating to the 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 Patheon or Éclat in accordance with the terms of this Agreement or the Product Development Agreements; all such updates, amendments and revisions will require approval by Éclat.

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

"Territory" means the world unless otherwise identified in a Product Agreement.

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

"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 shall mean a calendar year.

1.4 Interpretation.

(a) The division of this Agreement into Articles, sections, subsections, an Appendix (including Schedules), and Exhibits and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Exhibit refers to the specified Section, Appendix or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section, Appendix, Exhibit or the provision hereof.

(b) Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.

1.5 Appendix 1 and Exhibits.

Appendix 1 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	Batch Numbering and Expiration Dates
Exhibit B	Technical Dispute Resolution
Exhibit C	Commercial Quality Agreement
Exhibit D	Shipping Logistics Protocol
Exhibit E	Quarterly Active Materials Inventory Report
Exhibit F	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Exhibit G	Exclusive Components Purchasing Summary

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

(a) Patheon shall provide the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C in order to produce Products for Éclat. Schedule B to a Product Agreement sets forth in detail cost items that are included in the Price for Products and those cost items excluded from the Price that are subject to additional fees to be paid by Éclat.

(b) Subject always to clause 13.6, and unless otherwise stated in a Product Agreement, Patheon may change the Manufacturing Site for the Products only upon providing Éclat with a twelve (12) month written notice and obtaining the prior written consent of Éclat, such consent not to be unreasonably withheld. Éclat may reasonably withhold consent for the change in Manufacturing Site until Patheon provides Éclat with sufficient quantity of Product(s) to ensure an uninterrupted supply to the market. Other than for Neostigmine and Phenylephrine, which are subject to the provisions of the relevant Product Agreement, in the event that Patheon changes the Manufacturing Site of a Product for reasons solely at Patheon's election, specifically a decision taken by Patheon to close the then current Manufacturing Site for the Product, Patheon shall be solely responsible for all its costs and expenses associated with the change in Manufacturing Site, including all tech transfer costs, and Patheon shall not increase the Price it charges Éclat for the Products solely as a result of the change in Manufacturing Site.

(c) If Manufacturing Services under a Product Agreement have not commenced within 12 months of the date of execution of this Agreement Patheon reserves the right to amend the fees set out in Schedules B and C to a Product Agreement.

(d) Patheon shall manufacture Products only for Éclat and only in response to and in compliance with purchase orders based on Firm Orders delivered by Éclat to Patheon.

(e) Patheon shall be the exclusive manufacturer of Products offered for sale by Éclat in the Territory.

(f) In providing the Manufacturing Services, Patheon and Éclat agree that:

(i) Conversion of Active Materials and Components. Patheon shall convert Active Materials and Components into Products;

(ii) Quality Control and Quality Assurance. Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Éclat shall be the responsibility of Patheon's quality assurance group. Patheon shall perform its batch review and release responsibilities in accordance with standard, operating procedures. Each time Patheon ships Products to Éclat or its designee, it shall provide to Éclat a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Éclat will have sole responsibility for the release of Products from Patheon to Éclat or its designee and to the market.

(iii) Components. Patheon shall purchase and test all Components (with the exception of those that are supplied by Éclat) at Patheon's expense and as specified by the Specifications.

(iv) Stability Testing. Subject to the provisions of the Product Development Agreement(s), Patheon shall 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 specified in Schedule C to a Product Agreement. No changes shall be made to these testing protocols without prior written approval from Éclat. In the event of a confirmed stability test failure, Patheon will notify Éclat within one Business Day, after which Patheon and Éclat shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure, including which party shall bear the cost of such investigation; provided that Patheon shall not be liable for any such costs unless there has been a failure by it to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws. Patheon will procure the provision of any and, all data and results relating to the stability testing upon request by Éclat.

(v) Packaging. Patheon shall pack the Products as set out in the Specifications. Éclat shall be responsible for the cost of artwork development. Patheon shall make arrangements for and implement the imprinting of batch numbers and expiration dates for each Product shipped. Such batch numbers and expiration dates shall be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for batch numbering and expiration dates is detailed in Exhibit A hereto. Éclat may, in its sole discretion, make changes to labels, product inserts and other packaging for the Products, which changes shall be submitted by Éclat to all applicable governmental agencies and other third parties responsible for the approval of the Products. Éclat shall be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name shall not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon expressly consents to such use of its name in writing.

(vi) Active Materials and Éclat Supplied Components Importing. At least forty-five (45) days prior to the scheduled production date, Éclat shall furnish to Patheon at the Manufacturing Site, DDP (Incoterms 2010), the Active Materials, free of charge in such quantities as are necessary to enable Patheon to manufacture the desired quantities of Product on the requested delivery date. If such Active Materials are not received forty-five (45) days in advance, Patheon will be entitled to delay shipments of Product caused by the re-scheduling of production; provided, however, that, Patheon shall be entitled to delay shipments until such later date as agreed to by the parties, but not to exceed thirty (30) days beyond the calculated re-scheduled date. All shipment of Active Material shall be accompanied by certificate(s) of analysis from the Active Material manufacturer Éclat, confirming the identity, purity and compliance with the Active Material specifications.

(vii) Bill Back Items. Bill Back Items shall be charged to Éclat at Patheon's cost plus the agreed upon handling fee of 10%.

(viii) Product Rejection for Finished Product Specification Failure. Internal process specifications shall be defined and mutually agreed upon. If Patheon manufactures Product in accordance with the agreed upon process specifications and a batch or portion of batch of Product does not meet a Finished Product Specification, Éclat shall pay Patheon the applicable fee per unit for such nonconforming Product.

2.2 Active Material Yield

(a) Reporting. Patheon will give Éclat a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in Exhibit E, 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.

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 and, for certainty, 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 6.1 or 6.2), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within sixty (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 **F** 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:

Quantity Converted during the Year x 100%

Quantity Dispensed during the Year

After Patheon has produced a minimum of ten (10) commercial production batches of Product and has produced commercial production batches for at least six (6) months at the Manufacturing Site (collectively, the **"Target Yield Determination Batches"),** the Parties will mutually agree on the target yield for the Product at the Manufacturing Site (each, a **"Target Yield").**

(b) Shortfall Calculation. If the Actual Annual Yield falls more than five percent (5%) below the respective Target Yield in a Year, then the shortfall for the Year (the **"Shortfall")** will be calculated as follows:

Shortfall = [(Target Yield — 5%) — AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Patheon will credit Éclat's account for the amount of the Shortfall not later than sixty (60) days after the end of the Year. Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit F. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2 in relation to such Product Agreement will be paid to Éclat. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) Maximum Credit. For the first ten (10) commercial production batches of Product under a Product Agreement, Patheon shall have no liability pursuant to this clause 2.2.. Thereafter, 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.

(e) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

ARTICLE 3

ÉCLAT'S OBLIGATIONS

3.1 Payment.

Pursuant to the terms of this Agreement, Éclat shall pay Patheon for the provision of the Manufacturing Services and related Materials according to the Prices specified in Schedules B and C to a Product Agreement (such fees being subject to adjustment in accordance with the terms hereof).

3.2 Active Materials.

Éclat shall at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(e) (vi)) in sufficient quantities and at such times to facilitate the provision of the Manufacturing Services by Patheon. The Active Materials shall be held by Patheon on behalf of Éclat on the terms and subject to the conditions herein contained. Title to the Active Materials shall at all times belong to and remain the property of Éclat. Any Active Materials received by Patheon shall only be used by Patheon to provide the Manufacturing Services. Patheon's liability with respect to any lost or damaged Active Materials shall be as set forth in Section 10.2(a).

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The Prices for the Products for the first Year are listed in Schedule B to a Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments - Annual or Year over Year Price Adjustments.

The Prices for the Products during any Year following the first Year of this Agreement shall be determined in accordance with the following:

(a) Manufacturing Costs. Effective at the beginning of each Year of this Agreement, Patheon shall be entitled to an adjustment to the Manufacturing Services fees in respect of the Products to reflect inflation, which adjustment shall be based on the increase in the Consumer Price Index in September of the preceding Year compared to the same month of the Year prior to that, unless the parties otherwise agree in writing;

(b) Annual Forecast. To the extent that Patheon determines that the projections contained in the rolling forecast provided pursuant to Section 5.1(a) necessitate that an adjustment be made to the Manufacturing Services fees in respect of any Product for such Year, then Patheon shall be entitled to an appropriate price adjustment to pass on the increase in the cost of providing the Manufacturing Services which is attributable to the changes in the rolling forecast projections.

(c) Component Costs. To the extent that there is a year over year increase in Component costs in respect of any Product for such Year, then Patheon shall be entitled to an appropriate Price adjustment to pass through the increase in the cost of such Components. In the event that there is a year over year decrease in Component Costs, then such decreases shall be borne equally by the Parties.

(d) Adjustments Due to Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for an Italian Manufacturing Site invoiced in USD) is set forth in Exhibit H.

(e) Pricing Basis. Éclat acknowledges that the Price in respect of a Product in any Year is quoted based upon the Minimum Run Quantity and Annual Volume per Product specified in Schedule B to a Product Agreement or thereafter specified in the forecast provided pursuant to clause (b) of this Section 4.2 for the Year and is subject to change if the specified Minimum Run Quantity changes or if the Annual Volume is not met. For greater certainty, if Patheon and Éclat agree that the Minimum Run

Quantity in respect of a Product shall be reduced whether as a result of a decrease in estimated annual volume or otherwise and, as a result of such reduction, Patheon's costs to perform the Manufacturing Services and acquire the Materials relating to such Product increase on a per unit basis, then Patheon shall be entitled to an increase in the Price in respect of such Product by an amount sufficient to absorb those increases.

In connection with a Price adjustment pursuant to clause (a) of this Section 4.2, Patheon shall deliver to Éclat on or about the first quarter of each Year, a statement outlining the percentage increase in the Consumer Price Index upon which such price adjustment is based. The adjusted prices shall be effective as of January 1st of the same Year in which the adjustment is required. In connection with all Price adjustments pursuant to clause (b) of this Section 4.2, Patheon shall deliver to Éclat by not later than the end of October a revised Schedule B to the Product Agreement in draft form and such information reasonably sufficient to demonstrate that a Price adjustment is justified. Upon delivery of such required Price adjustment information pursuant to clause (b) herein, each of Éclat and Patheon shall forthwith use all reasonable efforts acting in good faith to agree on a revised Price for the Products and Schedule B to the Product Agreement shall be amended accordingly. Such revised Price shall be effective with respect to any Product delivered after the end of the then current Year. In connection with, a Price adjustment pursuant to clause (c) of this section 4.2, Patheon shall deliver to Éclat documentation demonstrating the increase in the Component Cost.

4.3 Price Adjustments — Within the Current Year.

During any Year of this Agreement, the Prices set out in Schedule B to a Product Agreement shall be subject to adjustment in accordance with the following:

(a) Extraordinary Increases in Component Costs. If at any time market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon shall be entitled to an adjustment to the Price in respect of any affected Product to compensate it for such increased Component costs. For the purposes of this clause (b), changes materially greater than normal forecasted increases shall be considered to have occurred if: (i) the cost of a Component increases by 10% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by 5% of the total Component costs for such Product upon which the most recent fee quote was based. To the extent that Component costs have been previously adjusted pursuant to clause (c) of Section 4.2 or this clause (b) to reflect an increase in the cost of one or more Components, the adjustments provided for in (i) and (ii) above shall operate based on the costs attributed to such Component (or Components) at the time the last of such adjustments were made.

In connection with a Price adjustment pursuant to this Section 4.3, Patheon shall deliver to Éclat a revised Schedule B to the Product Agreement and such budgetary pricing information, adjusted Component costs or other documentation reasonably sufficient to demonstrate that a Price adjustment is justified, provided that Patheon shall have no obligation to provide any supporting documents to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers. Upon delivery of such required documents, each of Éclat and Patheon shall forthwith use all reasonable efforts to agree on a revised Price for each affected Product and Schedule B to the Product Agreement shall be amended accordingly.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by Éclat will only be implemented following a technical and cost review by Patheon and are subject to Éclat and Patheon reaching agreement as to revisions, if any, to the Prices specified in Schedules B or C to a Product Agreement necessitated by any such amendment. Amendments to the Specifications and the Quality Agreement requested by Patheon will only be implemented following the approval of Éclat, such approval not to be unreasonably withheld. If Éclat accepts a proposed Price change, the proposed change in the Specifications shall be implemented, and the Price change shall become effective only with respect to those orders of Products that are manufactured in accordance with the revised Specifications. In addition, Éclat agrees to purchase, at Patheon's cost therefor (including all costs incurred by Patheon in connection with the purchase and handling of such Inventory), all Inventory utilized under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or in accordance with Section 5.2, to the extent that such Inventory can no longer be utilized 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 in accordance with Section 5.2 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by Éclat.

4.5 Multi-Country Packaging Requirements.

If and when Éclat decides that it wishes to have Patheon provide manufacturing services in respect of the Product for countries where the Product is not being currently marketed, then Éclat shall inform Patheon of the packaging requirements for each new country and Patheon shall prepare a quotation for consideration by Éclat of the additional Component costs, if any, and the changeover fees for the Product destined for each such new country. The agreed additional packaging requirements and related packaging costs and change over fees shall be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling Forecasts. Concurrent with the execution of this Agreement, Éclat shall provide Patheon with a written non-binding 12 month forecast of the volume of each Product that Éclat then anticipates will be required to be produced and delivered to Éclat or its designee during each month of that 12 month period. Such forecast will be updated by Éclat monthly on or before

the 10th day of each calendar month on a rolling 12 month basis and updated forthwith upon Éclat determining that the volumes contemplated in the most recent of such forecasts has changed by more than 20%.

The most recent 12 month forecast shall prevail.

(b) Firm Orders. The first three (3) months and five (5) days of the initial rolling forecast shall constitute a firm written order in the form of a purchase order or otherwise **("Firm Order")** on the part of the Éclat to purchase and, when accepted by Patheon, for Patheon to supply the quantity of the Product. Thereafter, on or before the 10th day of each calendar month, Éclat shall issue Firm Orders for Manufacturing Services in respect of the Products to be produced and delivered to Éclat on a date not less than three (3) months from the first day of the calendar month immediately following the date that the Firm Order is submitted. Such Firm Orders submitted to Patheon shall specify Éclat's Manufacturing Services purchase order number, quantities by Product type, monthly delivery schedule and any other elements necessary to ensure the timely production and shipment of the Products. The quantities of Products ordered in such written orders shall be firm and binding on Éclat and shall not be subject to reduction by Éclat.

(c) Three Year Forecast. On or before the 10th day of June of each Year, Éclat shall provide Patheon with a written non-binding three-year forecast (broken down by quarters for the second and third years of the forecast) of the volume of each Product Éclat then anticipates will be required to be produced and delivered to Éclat during the three-year period.

5.2 Reliance by Patheon.

(a) Éclat understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted pursuant to Sections 5.1(a) and (b) in ordering or procuring the ordering the Components required to meet such Firm Orders. In addition, Éclat understands that to ensure an orderly supply of such Components, it may be desirable for Patheon to purchase such Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Éclat. Accordingly, Éclat authorizes Patheon to purchase Components in order to satisfy the Manufacturing Services requirements for Products for the first six (6) months contemplated in the most recent forecast provided by Éclat pursuant to Section 5.1(a) and agrees that Patheon may make such other purchases of Components to meet Manufacturing Services requirements during such longer periods as may be agreed to in writing from time to time by Éclat at the request of Patheon or Éclat. If Components ordered by Patheon pursuant to Firm Orders or this Section 5.2 are not included in finished Products manufactured for Éclat within six (6) months after the forecasted month in respect of which such purchases have been made (or such longer period as the parties may agree) or if such Components have expired during such period, then Éclat shall pay to Patheon its costs therefor (including all costs incurred by Patheon in connection with the purchase and handling of such Components); provided, however, that in the event such Components are incorporated into Products subsequently manufactured for Éclat. or into third party products manufactured by Patheon for a third party, Éclat will receive credit for any costs of such Components previously paid to Patheon by Éclat.

(b) Patheon shall provide Éclat, initially upon execution of a Product Agreement and thereafter on an annual basis, with a listing of all Components which are unique to Éclat, which Patheon anticipates purchasing or being required to be purchased pursuant to the terms of this Agreement (in accordance with rolling forecasts and Firm Orders as per Section 5.1(a) and (b)) in the form as set out in Exhibit G (the **"Exclusive Component Purchasing Summary").** The Exclusive Components Purchasing Summary shall indicate which Components have a limited shelf-life and which are subject to minimum order quantities as specified by the supplier. Subject to the provisions of subsection (a) above, Éclat shall be liable for the costs of all Components purchased by Patheon for use under this Agreement not used to perform Manufacturing Services prior to the expiry of the Component's shelf life. Reimbursement from Éclat shall be due, where applicable, within 30 days of notification from Patheon that said Component has expired. Patheon shall not be obligated to provide specific pricing information regarding any Component which is subject to confidentiality obligations between Patheon and its supplier.

5.3 Minimum Orders.

Éclat may only order Manufacturing Services in respect of batches of Products in multiples of the Minimum Run Quantities as set out in Schedule B to a Product Agreement.

5.4 Shipments.

Shipments of Products shall be made in accordance with Exhibit D unless otherwise mutually agreed. Subject to Patheon's limitation of liability set out in section 10.2, risk of loss or of damage to Products shall remain with Patheon until the Products are loaded onto the carrier's vehicle for shipment at the EXW (Incoterms 2010) shipping point at which time risk of loss or damage shall transfer to Éclat. Patheon shall, in accordance with Éclat's instructions and as agent for Éclat, (i) arrange for shipping to be paid by Éclat and (ii) at Éclat's risk and expense, obtain any export licence or other official authorization necessary to export the Products. Éclat shall arrange for insurance and shall 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.

5.5 Invoices and Payment.

Invoices shall be sent by fax or email to such fax number or email address as may be provided by Éclat in writing from time to time. Invoices will be sent at the time the Product is manufactured and released by Patheon or its Affiliate to Éclat. Patheon shall also submit to Éclat, with each shipment of Products, a duplicate copy of the invoice covering such shipment. Patheon shall also provide Éclat with an invoice covering any Inventory or Components which are to be purchased by Patheon pursuant to the terms of this Agreement. Each such invoice shall, to the extent applicable, identify Éclat's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by Éclat. Éclat

shall pay all such invoices within thirty (30) days of the date thereof. Interest on past due accounts will accrue at one percent (1%) per month or part thereof.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Éclat has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs or Applicable Laws without invalidating any remainder of such shipment. Éclat shall inspect the Products manufactured by Patheon upon receipt thereof and shall give Patheon written notice (a **"Deficiency Notice")** of all claims for Products that deviate from the Specifications, cGMPs and Applicable Laws within thirty (30) days after Éclat's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within thirty (30) days after discovery thereof by Éclat, but in no event after the expiration date of the Product). Should Éclat fail to provide Patheon with the Deficiency Notice within the applicable 30—day period, then the delivery shall be deemed to have been accepted by Éclat on the 30th day after delivery or discovery, as applicable. Except as set out in Section 6.3, Patheon shall have no liability for any deviations for which it has not received notice within the applicable 30-day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon shall have ten (10) days to advise Éclat by notice in writing that it disagrees with the contents of such Deficiency Notice. If Éclat and Patheon fail to agree within ten (10) days after Patheon's notice to Éclat as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs or Applicable Laws, then the parties shall mutually select an independent laboratory to evaluate if the Products deviate from the Specifications or cGMPs. Such evaluation shall be binding on the parties, and if such evaluation certifies that any Products deviate from the Specifications or cGMPs, Éclat may reject those Products in the manner contemplated in this Section 6.1. In that event the evaluation costs will be borne by Patheon, otherwise Éclat will be responsible for the evaluation costs. If such evaluation does not so certify in respect of any such Products, then Éclat shall be deemed to have accepted delivery of such Products on the 40th day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the 40th day after discovery thereof by Éclat, but in no event after the expiration date of the Product).

(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon shall be dealt with as may reasonably be agreed to by the parties.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Éclat shall each maintain such records as may be necessary to permit a Recall of any Products delivered to Éclat or customers of Éclat. Each party shall promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products and/or which might result in the Recall or seizure of the Products. Upon receiving any such notice or upon any such discovery, each party shall cease and desist from further shipments of such Products 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, shall be made and implemented by Éclat. **"Recall"** shall mean any action (i) by Éclat to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall shall also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. In the event (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) Éclat determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Éclat, having regard to all applicable laws and regulations.

(c) Product Returns. Éclat shall have the responsibility for handling Éclat returns of the Products. Patheon shall provide Éclat with such assistance as Éclat may reasonably require to handle such returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. In the event Éclat rejects Products in accordance with Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, Patheon will credit Éclat's account for Patheon's invoice price for such defective Products. If Éclat shall have previously paid for such defective Products, Patheon shall promptly, at Éclat's election, either: (i) refund the invoice price for such defective Products; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) provide a replacement of such Products with conforming Products as soon as reasonably possible without Éclat being liable for payment therefor under Section 3.1, contingent upon the receipt by Patheon from Éclat of all Active Materials required for the manufacture of such replacement Products. 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 Product. To the extent that a Recall or return results from, or arises out of, a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, Patheon shall be responsible for the documented out-of-pocket expenses of such Recall or return and shall use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Éclat of all Active Materials required for the manufacture of such replacement Products. For the avoidance of doubt, save that 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, Patheon shall not be liable, under any circumstances, for the loss or reimbursement therefor of Active Materials. In the event that Patheon is unable to replace the Recalled or returned Products (except where such inability results from a failure to, receive the required Active Materials), then Éclat may request Patheon to reimburse Éclat for the price that Éclat paid to Patheon for Manufacturing Services in respect of the affected Products. In all other circumstances, Recalls, returns or other corrective actions shall be made at Éclat's cost and expense.

(c) Product Claims. Except as provided in Sections 6.3(a) and (b) above, neither Patheon nor its Affiliates shall be liable nor have any responsibility for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, **"Product Claims").** For greater certainty, neither Patheon nor its Affiliates shall have any obligation for any Product Claims to the extent such Product Claim (i) is caused by deficiencies with respect to the Specifications, the safety, efficacy or marketability of the Products 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, (iii) results from a defect in the Active Materials or Components supplied by Éclat that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after such Product is shipped by Patheon pursuant to Section 5.4, (v) is due to packaging or labelling defects or omissions for which Patheon have no responsibility, (vi) is due to any unascertainable reason despite Patheon or its Affiliates having provided the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, or (vii) is due to any other breach by Éclat of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Éclat shall not dispose of any damaged, defective, returned or Recalled Products in relation to which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Éclat to return such Products to Patheon or its Affiliate. Patheon shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Products in relation to which it bears responsibility under Section 6.3 hereof. In all other circumstances, Éclat shall bear the cost of disposition, including all applicable fees for Manufacturing Services, with respect to any damaged, defective, returned or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Éclat shall have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon or its Affiliates from Éclat's customers, healthcare providers or patients shall be promptly referred to Éclat. Patheon shall co-operate or procure the co-operation of its Affiliate as reasonably required to allow Éclat to determine the cause of and resolve any such questions and complaints. Such assistance shall, include follow-up investigations, including testing. In addition, Patheon shall provide Éclat with all mutually agreed upon information that will enable Éclat to respond properly to questions or complaints relating to the Products as provided in the Quality Agreement. Unless it is determined that the cause of any such complaint resulted from a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws, all costs incurred in respect of this Section 6.5 shall be borne by Éclat.

6.6 Sole Remedy

Except for the indemnity provided 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 shall be Éclat's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall 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, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding such Products if in the opinion of that party's counsel, such communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation; provided, however, that unless in the reasonable opinion of its counsel there is a legal prohibition against doing so, such party shall permit the other party to accompany and take part in any communications with the agency, and to receive copies of all such communications from the agency.

7.3 Records and Accounting by Patheon.

Patheon shall keep records of the manufacture, testing and shipping of the Products, and retain samples of such Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be retained for a period of one year following the date of Product expiry, or longer if required by law at which time Éclat will be contacted concerning the delivery and destruction of such documents and/or Products. Éclat is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Éclat.

7.4 Inspection.

Éclat may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, provided a Patheon representative is present during any such inspection.

7.5 Access.

Patheon will provide Éclat with reasonable access at mutually agreeable times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled or shipped to permit Éclat to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs and Applicable Laws. But, with the exception of "for-cause" audits, Éclat will be limited each Year to one cGMP-type audit, lasting no more than two (2) days, and involving no more than two (2) auditors. Éclat may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of $5,000 for each additional audit day and $1,000 per audit day for each additional auditor. The right of access provided in this Section 7.5 will not include a right to access or inspect Patheon or its Affiliate's financial records.

7.6 Notification of Regulatory Inspections.

Patheon shall notify Éclat within one (1) Business Day of any inspections by any governmental agency specifically involving the Products, including the manufacturing of the Products. Patheon shall also notify Éclat within one (1) Business Day of receipt of any form 483's or immediately by telephone in the event of a warning letter or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products. Patheon shall also notify Éclat within one (1) Business Day of notices or requests for information or other communications related to the Products.

7.7 Reports.

Patheon will procure the supply on an annual basis (and at Éclat's expense) all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing and storage), that Éclat reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Éclat is required to file with the FDA.

7.8 FDA Filings

(a) Regulatory Authority. Éclat shall have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be Éclat-PUK MSA required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Unless required by law or regulation, Patheon shall not directly communicate with the FDA regarding the Product without the prior written consent of Éclat. Patheon shall assist Éclat, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. At least twenty-one (21) calendar days prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon or its Affiliates, Éclat shall provide Patheon with a copy of the documents incorporating such data so as to give Patheon the opportunity to verify the accuracy and regulatory validity of such documents as they relate to Patheon or its Affiliate's generated data.

(c) Verification of CMC. At least twenty-one (21) calendar days prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Éclat shall provide Patheon with a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. Such disclosure shall permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform pursuant to this Agreement. Éclat shall provide Patheon with copies of all FDA filings at the time of submission which contain CMC information regarding the Product.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information provided by Éclat in accordance with paragraphs (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "Deficiencies"), Patheon shall notify Éclat in writing of such Deficiencies. The parties shall work together to have such Deficiencies resolved prior to any pre-approval inspection.

(e) Éclat Responsibility. For clarity, the Parties agree that in reviewing the documents referred to in paragraph (b) 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 shall not assume any responsibility for the accuracy of any application for receipt of an approval by a regulatory authority. Éclat is solely responsible for the preparation and filing of the application for approval by the regulatory authorities and any relevant costs shall be borne by Éclat.

(f) Inspection by Regulatory Authorities. If Éclat does not provide Patheon with the documents requested pursuant to paragraph (b) above within the time stipulated in these paragraphs and if Patheon reasonably believes that Patheon's standing with a regulatory authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the regulatory authority until such time as Patheon has reviewed the requested documents and is satisfied with their contents.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement shall become effective as of the Effective Date and shall continue until such time as there are no Product Agreements in effect.

The term of each Product Agreement will be stated within said Product Agreement

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice in circumstances 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 60 days following receipt of a written notice (the "Remediation Period") of said breach that expressly states that it is a notice under this Section 8.2(a) (a "Breach Notice"). The aggrieved party's right to terminate this Agreement or a Product Agreement pursuant to this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (in circumstances where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party shall be deemed to have waived the breach of the representation, warranty or obligation described in the Breach Notice.

(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 in the event that: (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 such other party; or (iii) this Agreement or a Product Agreement is assigned by such other party for the benefit of creditors.

(c) Éclat may terminate this Agreement or a Product Agreement as to any Product upon thirty (30) days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents Éclat from importing, exporting, purchasing or selling such Product. However, in such event Éclat will make any payment due to Patheon under clause 4 above for the then current Year in addition to any other obligations Éclat may have in the event of termination under Section 8.4 below.

(d) Patheon may terminate this Agreement or a Product Agreement upon six (6) months' prior written notice if Éclat assigns pursuant to 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 Éclat or (ii) a competitor of Patheon; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations because for example it has failed to settle accounts on time or otherwise shown a willingness not to, or inability to, fulfill its contractual obligations on time or at all.

8.3 Product Discontinuation.

Éclat shall provide at least six (6) months' advance notice if it intends to no longer order Manufacturing Services for a Product due to that Product's discontinuance in the market.

8.4 Obligations on Termination.

If a Product Agreement is completed, expires or is terminated in whole or in part for any reason, then (in addition to any other remedies Patheon may have in the event of default by Éclat):

(a) Éclat shall take delivery of and pay for all undelivered Products that are manufactured and/or packaged pursuant to a Firm Order, at the price in effect at the time the Firm Order was placed;

(b) Éclat shall purchase, at Patheon's cost (including all costs incurred by Patheon in connection with the purchase and handling of such Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given;

(c) Éclat shall satisfy the purchase price payable pursuant to Patheon's orders with suppliers of Components unique to, or specifically purchased for, Éclat's product(s), provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;

(d) Patheon shall return to Éclat all unused Active Materials (with shipping and related expenses, if any, to be borne by Éclat); and

(e) Éclat acknowledges that no competitor of Patheon shall be permitted access to the Manufacturing Site.

(f) Éclat shall make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within ten (10) Business Days, all of Éclat's Components, Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, Equipment or other moveable property owned by Éclat, related to the Product Agreement and located at Patheon's site or that is otherwise under Patheon's care and control ("Éclat Property"). Éclat shall pay to Patheon a thirty dollar ($30.00) per square foot per month storage fee for all Éclat Property remaining at Patheon's site(s) after the tenth (10th) Business Day following the completion, termination or expiration of the Product Agreement and will assume any third party storage charges invoiced to Patheon regarding any such Éclat Property. Patheon will invoice Éclat for such storage charges according to the provisions of section 5.5 of this Agreement.

Any termination or expiration of a Product Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under the Product Agreement. For greater certainty, termination of a Product Agreement for any reason shall not affect the obligations and

responsibilities of the parties which are explicitly or impliedly intended to survive termination or expiry of the Product Agreement (as stated in this Agreement or said Product Agreement) and such provisions shall survive any termination.

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 Éclat Warranties.

Éclat covenants, represents and warrants that:

9.2.1 **Non-Infringement.**

(a) the Specifications for each of the Products are its or its Affiliate's property and that Éclat may lawfully disclose the Specifications to Patheon;

(b) any Intellectual Property, other than Patheon Intellectual Property, utilized by Patheon in connection with the provision of the Manufacturing Services according to the Specifications (i) is Éclat's or its Affiliate's unencumbered property, (ii) may be lawfully used as directed by Éclat, and (iii) such use does not knowingly infringe and will not knowingly infringe any Third Party Rights after having made due and careful enquiries;

(c) the provision of the Manufacturing Services by Patheon in respect of any Product pursuant to this Agreement or any Product Agreement or use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or under any Product Agreement does not and will not infringe any Third Party Rights;

(d) there are no actions or other legal proceedings, the subject of which is the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use or other disposition of any Product made in accordance with the Specifications;

9.2.2 **Quality and Compliance.**

(a) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws; and

(b) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in the Territory where appropriate regulatory authorization has been granted, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption.

(c) Éclat represents and warrants that, on the date of receipt by Patheon, the API will conform to the specifications for the API that Éclat has provided to Patheon. Éclat further warrants 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.

(a) Patheon warrants that it shall perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws.

(b) Patheon warrants that all Product shipped to Éclat or its designee shall be free and clear of all liens, security interests and other encumbrances.

(c) Patheon represent and warrants Éclat its employees, officers agents and representatives and the facilities used to manufacture the Products are and shall at all times during the term of this Agreement remain properly qualified under and in compliance with all applicable laws, rules and regulations to the extent required in order for Patheon to fulfill its obligations under this Agreement.

(d) Patheon shall maintain quality assurance procedures in accordance with Applicable Laws.

(e) Patheon warrants that any Manufacturing Services Based Intellectual Property utilized by Patheon in connection with the provision of the Manufacturing Services (i) is Patheon's unencumbered property, (ii) may be lawfully used as used by Patheon or its Affiliates, and (iii) such use does not knowingly infringe and will not knowingly infringe any Third Party Rights after having made due and careful enquiries.

(f) Patheon warrants that it shall be liable to Éclat for any Manufacturing Services it subcontracts to its Affiliates not in accordance with this Agreement.

(g) All Materials sourced by Patheon shall be sold to Éclat with, and only with, such warranty as Patheon receives from its supplier for said Materials. Patheon makes no further warranty of any kind, express or implied, in relation to said Materials.

9.4 Debarred Persons.

Patheon covenants that it will not, in the performance of its obligations under this Agreement, use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee 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 Federal Food, Drug, and Cosmetic Act (United States).

9.5 Permits.

Éclat shall be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals in respect of the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon shall maintain at all relevant times all governmental permits, licenses, approval, and authorities to the extent required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

PATHEON AND ÉCLAT MAKE NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

UNDER NO CIRCUMSTANCES WHATSOEVER SHALL 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) FOR ANY OTHER LIABILITY, DAMAGE, COSTS OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

10.2 Limitation of Liability.

(a) 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 TO A PRODUCT AGREEMENT.

(b) Maximum Liability. PATHEON'S MAXIMUM LIABILITY TO ÉCLAT UNDER THIS AGREEMENT OR ANY PRODUCT AGREEMENT FOR ANY REASON WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY LIABILITY ARISING UNDER ARTICLE 6 OR SECTION 10.3 HEREOF OR RESULTING FROM ANY AND ALL BREACHES OF ITS REPRESENTATIONS, WARRANTIES, OR ANY OTHER OBLIGATIONS UNDER THIS AGREEMENT OR ANY PRODUCT AGREEMENT WILL NOT EXCEED ON A PER PRODUCT BASIS 25% OF THE TOTAL REVENUES TO PATHEON UNDER THE APPLICABLE PRODUCT AGREEMENT IN THE YEAR IN WHICH THE CLAIM AROSE.

(c)

(d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement or any Product Agreement shall act to exclude or limit either party's liability for personal injury, death or fraudulent misrepresentation caused by the negligence of either party.

10.3 Indemnification by Patheon.

Subject to Sections 10.1 and 10.2, Patheon agrees to defend, indemnify and hold Éclat, its officers, employees and agents harmless against any and 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 any claim of personal injury or property damage to the extent that such injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs and Applicable Laws except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the negligence or wrongful act(s) of Éclat, its officers, employees or agents or Affiliates.

In the event of a claim, Éclat shall: (a) promptly notify Patheon of any such claim; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with Patheon in the defence of such claim; (d) permit Patheon to control the defence and settlement of such claim, all at Patheon's cost and expense.

10.4 Indemnification by Éclat.

Subject to Sections 10.1 and 10.2, Éclat agrees to defend, indemnify and hold Patheon, its Affiliates, its officers, employees and agents harmless against any and 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 any claim of infringement or alleged infringement of any Third Party Rights in respect of the Products, or any portion thereof, and/or any claim of personal injury or property damage to the extent that such injury or damage is the result of a breach of this Agreement or Product Agreement by Éclat, including, without

limitation, any representation or warranty contained herein, except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees or agents.

In the event of a claim, Patheon shall: (a) promptly notify Éclat of any such claims; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with Éclat in the defence of such claim; (d) permit Éclat to control the defence and settlement of such claim, all at Éclat's cost and expense.

10.5 Reasonable Allocation of Risk.

The provisions of this Agreement (including, without limitation, this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the parties respectively expect to derive from the Products, and that Patheon, in its fees for the provision of the Manufacturing Services, has not accepted a greater degree of the risks arising from the manufacture, distribution and use of the Products, based on the fact that Éclat has developed and holds the marketing approval for the Products and requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and that Éclat and not Patheon is in a position to inform and advise potential users of the Products as to the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

The provisions of the Confidentiality Agreement shall apply to all confidential information disclosed by the parties under this Agreement or any Product Agreement, which agreement remains in effect in accordance with its terms; provided, however, that in the event the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement or any Product Agreement, the terms of the Confidentiality Agreement shall continue to govern the parties' obligations of confidentiality with respect to any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement or Product Agreement, as though such agreement remained in full force and effect.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

In the event of any dispute arising out of or in connection with this Agreement or any Product Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute), the parties shall first try to solve it amicably. In this regard, any party may send a notice of dispute to the other, and each party shall appoint, within ten (10) Business Days from receipt of such notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If these representatives fail to solve the matter within one month from their appointment, or if a party fails to appoint a representative within the ten (10) Business Day period set forth above, such dispute shall immediately be referred to the Chief Operating Officer (or such other officer as he/she may designate) of each party who will meet and discuss as necessary in order to try to solve 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 13.16.

12.2 Technical Dispute Resolution.

In the event of a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) 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 or any Product Agreement (a "Technical Dispute"), the parties shall make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party shall, as soon as practicable and in any event no later than ten (10) Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite such meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within thirty (30) Business Days of such written request, the Technical Dispute shall, at the request of either party, be referred for determination to an expert in accordance with the provisions of Exhibit B. In the event that the parties cannot agree whether a dispute is a Technical Dispute, Section 12.1 shall prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution pursuant to the applicable marketing approval for such Products shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement nor any Product Agreement (including Exhibit B (Technical Dispute Resolution)) shall 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 this Agreement, Éclat hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Éclat's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use and sale of Éclat's Product that is the subject of the Manufacturing Services, shall be the exclusive property of Éclat.

(c) All Manufacturing Services Based Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services shall be the exclusive property of Patheon; Patheon hereby grants to Éclat a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license of the Manufacturing Services Based Intellectual Property used to manufacture the Product(s) which Éclat may use for the manufacture of the Product(s).

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

(e) Either party shall give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by such party.

13.2 Intellectual Property.

Subject to Section 13.1, all Intellectual Property of Éclat shall be owned by Éclat and all Intellectual Property of Patheon shall be owned by Patheon. Neither party has, nor shall it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party shall 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 shall 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 two (2) years thereafter, which insurance shall afford limits of not less than (i) $5,000,000 for each occurrence for personal injury or property damage liability; and (ii) $5,000,000 in the aggregate per annum with respect to product and completed operations liability. If requested each party will provide the other with 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 shall further provide for a minimum of thirty (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 on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

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

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Éclat, this consent not to be unreasonably withheld. But Patheon, with Éclat's written consent may arrange for subcontractors to perform specific testing services arising under any Product Agreement. Further it is specifically agreed that Patheon may subcontract any part of the Services to any of its Affiliates.

(b) Subject to Section 8.2(d), Éclat may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon; provided, however, that Éclat shall give prior written notice of any assignment to Patheon, any assignee shall covenant in writing with Patheon to be bound by the terms of this Agreement and any Product Agreement and Éclat shall remain liable hereunder. Any partial assignment will be subject to a cost review of the assigned Products by Patheon and is subject to assignee and Patheon reaching agreement as to revisions, if any, to the fees, failing such agreement, Patheon may terminate this Agreement or any Product Agreement on twelve (12) months' prior written notice to the assignee.

(c) Notwithstanding 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, provided that such assignee executes an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder. Any additional costs arising solely from the assignment to a successor or to a purchaser of all or substantially all of its business shall be for assignor's account.

13.7 Force Majeure.

Neither party shall be liable for the failure to perform its obligations under this Agreement or any Product Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to, strikes or

other labour disturbances or lockouts but only to the extent they are beyond such party's reasonable control, 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 shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance. Neither party shall 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 this Agreement through a further Product Agreement and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by amendments to Schedules A, B, C and D of the Product Agreement as applicable.

13.9 Notices.

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

If to Éclat:

Éclat Pharmaceuticals, LLC. 699 Trade Center Blvd., Suite A, Chesterfield, MO 63005

Attention: Chris Keith
Facsimile No.: 636-449-1850
Email address: ckeith@Éclatpharma.com

If to Patheon:

Patheon UK Limited. Kingfisher Drive, Covingham, Swindon, Wiltshire, SN3 5BZ. United Kingdom

Attention: Site Director
CC: Legal Counsel
Facsimile No.: +44 (0)1793 501081

with a copy to the relevant Patheon Affiliate (if relevant) named as a subcontractor of Patheon in the relevant Product Agreement at the address stated in paragraph 6 of said Product Agreement.

or to such other addresses, telecopier or facsimile numbers or electronic mail addresses provided to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopier, facsimile or electronic mail shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability.

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

13.11 Entire Agreement.

This Agreement, together with the applicable Product Agreement, Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to 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 shall be this Agreement, the Product Agreement the Quality Agreement and the Confidentiality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Éclat 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 Éclat or Patheon to object to such terms, provisions, or conditions unless such document specifically refers to this Agreement or the applicable Product Agreement and is signed by (the authorised representatives of) both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement or any Product Agreement shall 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 or any Product Agreement may be executed in two or more counterparts, by original or facsimile signature or by "pdf" signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.15 Use of Éclat Name.

Patheon shall not make any use of Éclat's name, trademarks or logo or any variations thereof, alone or in connection with any other word or words, without the prior written consent of Éclat, which consent shall not be unreasonably withheld. Notwithstanding the above, Éclat agrees that Patheon may include Éclat's name and logo in lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services only upon the prior written consent of Éclat.

13.16 Governing Law.

This Agreement and, unless otherwise agreed by the parties, any Product Agreement shall be construed and enforced in accordance with the laws of England and the parties hereby irrevocably submit to the exclusive jurisdiction of the English courts for all matters related to this Agreement or any Product Agreement. The 1980 UN Convention on Contracts for the International Sale of Goods and all and any amendments, additions, or further enactments thereof are expressly excluded and shall not apply to this Agreement or any Product Agreement.

SIGNED BY THE PARTIES

PATHEON UK LIMITED	**ÉCLAT PHARMACEUTICALS, L.L.C.**
By: /s/ Geoff Glass	By: /s/ Michael S. Anderson .
Name: Geoff Glass	Name: Michael S. Anderson
Title: Executive Vice President	Title: Chief Executive Officer
Date: 11/19/2012	Date: __

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 [insert date] between Patheon UK Limited and Éclat Pharmaceuticals, L.L.0 (the "Master Agreement"), and is entered into [insert effective date] (the "Effective Date"), between Patheon [applicable Patheon Affiliate], a corporation existing under the laws of [applicable founding jurisdiction for Patheon Affiliate], having a principal place of business at [Patheon Affiliate address] ("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. **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. **Territory:** (insert the description of the Territory here)
6. **Manufacturing Site:** (Insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
7. **Inflation Index:** (if different from Section under Section 4.2(a) of the Master Agreement)

8. **Product Term:** [FOR SERVICES PERFORMED IN THE UK] tbc

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

10. **Change of Manufacturing Site:** (if any variation to clause 2.1b))

11. **Modifications to the Master Agreement:** (if applicable under Section 1.2 of the Master Agreement)

12. **Exchange rate mechanism.** TBC

13. **Quality Agreement.** Copy of the relevant Quality Agreement to be attached hereto.

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

PATHEON *[applicable Patheon Affiliate]*

By: __

Name: __

Title: __

[CLIENT]

By: __

Name: __

Title: __

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

Specifications

Prior to the commencement of commercial manufacturing of Product under this Agreement Éclat shall provide Patheon with originally executed copies of the FDA/EMEA approved Specifications. If the Specifications provided are subsequently amended, then Éclat shall provide Patheon with revised and originally executed copies of such revised Specifications. Upon acceptance of the revised Specifications, Patheon shall provide Éclat with a signed and dated receipt evidencing such acceptance of the revised Specifications by Patheon.

SCHEDULE B

MINIMUM RUN QUANTITY, ANNUAL VOLUME AND PRICE

Product	Minimum Run Quantity	Annual Volume	Price (per unit)
	batch		

Batch size = _____ litres approximately _____ units

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

- Product manufactured and packaged under the Agreement
- Standard certificate of analysis (“COA”)
- Standard certificate of compliance (“COC”)
- GMP required retention samples
- Copies of deviation reports
- Batch Production Records (“BPR”)/Lot Packaging Records (“LPR”) copies for validation batches, first ten (10) commercial batches and one (1) commercial batch per Year thereafter
- One label copy change per Year
- BPR/LPR changes **[one change per Year]**
- Common HPLC/GC columns, reagents and lab supplies
- Copy of the Annual Product Review Report
- Product Approval Inspection (“PAI”) and copy of FDA Report
- Simple, routine statistical review
- Storage of Production Test Record (“PTR”) batches and other experimental batches for three (3) months
- Storage of registration batches and other experimental batches for two (2) years or until Product approval, whichever comes first
- Routine sampling and analysis as part of Product manufacture and release
- Warehousing of equipment, raw materials, API and finished goods for normal commercial supply
- Release testing of the API

SCHEDULE C

STABILITY TESTING & VALIDATION ACTIVITIES IF APPLICABLE

Patheon and Éclat shall agree in writing on any stability testing to be performed by Patheon in connection with the Products. Such agreement shall specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Éclat in connection with such testing shall be $_____ per test point per condition.

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
	•

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Éclat’s actual cost for Active Materials not to exceed $_____ per kilogram

MAXIMUM CREDIT VALUE

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

PRODUCT	MAXIMUM CREDIT VALUE
	15% of the annual value of this Product Agreement

EXHIBIT A

BATCH NUMBERING AND EXPIRATION DATES

Each batch of the Product manufactured by Patheon will bear a unique lot number using Patheon batch numbering system. This number will appear on all documents relating to the particular batch of Product and shall identify the date of manufacture for the batch of Product.

Patheon will calculate the expiration date for the Product for each batch by adding the expiration period of the Product supplied by Éclat to the date of Manufacture of each batch.

EXHIBIT B

TECHNICAL DISPUTE RESOLUTION

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

1. **Appointment of Expert**. Within ten (10) Business Days after a party requests pursuant to Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties shall 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 such ten (10) Business Day period, or in the event of disclosure of a conflict by an expert pursuant to paragraph 2 hereof which results in the parties not confirming the appointment of such expert, then the parties will proceed to action in a competent court.

2. **Conflicts of Interest**. Any person appointed as an expert shall be entitled to act and continue to act as such notwithstanding that 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 provided that before accepting such appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses any such interest or duty and the parties shall after such disclosure have confirmed his appointment.

3. **Not Arbitrator**. No expert shall be deemed to be an arbitrator and the provisions of any applicable statute (foreign or domestic) and the law relating to arbitration shall not apply to any such expert or the expert's determination or the procedure by which the expert reaches his determination to be made pursuant to this EXHIBIT B.

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

(a) Timing. The expert shall 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 such 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 forty-five (45) Business Days (or such other date as the parties and the expert may agree) after receipt of all information requested by him pursuant to paragraph 4(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to provide to any expert all such evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they shall disclose promptly and in any event within fifteen (15) Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint such 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 shall 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 shall 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 shall thereupon cease for the purposes of determining the matter at issue between the parties save that if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then such a decision shall have effect and the proposed appointment of the new expert shall be withdrawn.

(e) Final and Binding. The determination of the expert shall, save in the event of fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party shall bear its own costs in connection with 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 shall be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution pursuant to the applicable marketing approval for such Products shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement (including this EXHIBIT B) shall 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 C

QUALITY AGREEMENT

EXHIBIT D

SHIPPING LOGISTICS PROTOCOL

Shipping shall be carried out under the following terms and conditions: Exports of Products from Europe to the United States

1. Shipping terms shall be EXW (as such term is defined in INCOTERMS 2010), the Manufacturing Site.

2. Éclat, as the importer of record into the United States, shall advise Patheon prior to export of the Products from Europe of Éclat's designated customs broker and freight forwarder to enable Patheon to complete all applicable shipping documentation.

EXHIBIT E

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: **ÉCLAT PHARMACEUTICALS, L.L.C**

FROM: **PATHEON UK LIMITED.**

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

Reporting quarter:	_	kg	
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 during quarter: (A + C — B)	_	kg	
Quantity Converted during quarter: (total Active Materials in Products produced and not rejected, recalled or returned)	_	kg	

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

PATHEON UK LIMITED. DATE: _____

Per: _____
Name:
Title:

EXHIBIT F

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

TO: **ÉCLAT PHARMACEUTICALS, L.L.C**

FROM: **PATHEON UK LIMITED.**

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

Reporting Year ending:	__	kg	
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 during Year: (A + C — B)	__	kg	(D)
Quantity Converted during Year: (total Active Materials in Products produced and not rejected, recalled or returned)	__	kg	(E)
Active Materials Credit Value:	£	/kg	(F)
Target Yield:	__ %		(G)
Actual Annual Yield: ((E/D)* 100)	__ %		(H)
Shortfall: (((G — 5) - H)/100)* F* D	__ (if a negative number, insert zero)		(I)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of £_____.

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

DATE: _____

Per: _____
Name:
Title:

EXHIBIT G

EXCLUSIVE COMPONENTS PURCHASING SUMMARY

EXHIBIT H

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(d)

Historical Exchange Rates: Results

Conversion Table: EUR to USD (Interbank rate)

Time period: 10/01/11 to 09/30/12.

Average (365 days): 1.224 – "Set Exchange Rate"

SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate: 1.200 EUR/USD
Set Exchange Rate: 1.224 EUR/USD

Initial Price: 3.59
Revised Price (FX): 3.70 (Material price and PPI adjustments)

Calculation:

[Revised Price (After FX)] = [Revised Price (Before FX)] X [Initial Exchange Rate] / [Set Exchange Rate]

= 3.70 X [1.200 / 1.224]

= 3.627

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Anderson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

/s/ Michael S. Anderson

Michael S. Anderson

Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael F. Kanan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc:

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

/s/ Michael F. Kanan

Michael F. Kanan

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 2017 (the "Report"), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 9, 2017

/s/ Michael S. Anderson

Michael S. Anderson

Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 2017 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 9, 2017

/s/ Michael F. Kanan

Michael F. Kanan

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