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  
TABLE OF CONTENTS  
1  
I - DEFINITIONS  
3  
1.1  
ACT  
3  
1.2  
AFFILIATE  
3  
1.3  
CALENDAR YEAR  
3  
1.4  
cGMP  
4  
1.5  
CAPACITY GUARANTY AGREEMENT  
4  
1.6  
FACILITIES  
4  
1.7  
FDA  
4  
1.8  
FORECASTED NEEDS  
4  
1.9  
LABEL, LABELED, OR LABELING  
4  
1.10  
LAUNCH YEAR  
4  
1.11  
MANUFACTURING FEE  
4  
1.12  
MATERIALS FEE  
5  
1.13  
MATERIAL SAFETY DATA SHEET  
5  
1.14  
MEDIA FILL RUN  
5  
1.15  
PACKAGING  
5  
1.16  
PRODUCT(S)  
6  
1.17  
QUALITY AGREEMENT  
6  
1.18  
SPECIFICATIONS  
6  
1.19  
TERRITORY  
6  
II - PRODUCT MANUFACTURE AND SUPPLY  
6  
2.1  
MANUFACTURE AND PURCHASE  
6  
2.2  
SUPPLY OF MATERIALS  
7  
  
i  
  
  
2.3  
MATERIALS TESTING  
8  
2.4  
MATERIAL SAFETY DATA SHEETS  
8  
2.5  
COMMENCEMENT OF MANUFACTURING OF PRODUCTS  
9  
2.6  
PURCHASE ORDERS  
9  
2.7  
DELAYED DELIVERY  
11  
2.8  
REJECTED PRODUCTS  
11  
2.9  
PRODUCT PRICE  
13  
2.10  
PAYMENT  
14  
2.11  
LATE PAYMENT  
15  
2.12  
DISPOSAL COSTS  
15  
III - SHIPMENT AND RISK OF LOSS  
15  
3,1  
SUPPLY CHAIN SECURITY AND SHIPMENT  
15  
3.2  
DELIVERY TERMS  
16  
3.3  
CLAIMS  
16  
IV - FACILITIES AND CAPACITY GUARANTY  
16  
4.1  
FACILITIES  
16  
4.2  
CAPACITY GUARANTY  
16  
V - TERM AND TERMINATION  
16  
5.1  
TERM  
16  
5.2  
TERMINATION  
17  
5.3  
PAYMENT ON TERMINATION  
17  
5.4  
SURVIVAL  
17  
VI - CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE  
17  
6.1  
CERTIFICATES OF ANALYSIS  
17  
6.2  
STABILITY TESTING  
18  
6.3  
VALIDATION WORK OR ADDITIONAL TESTING  
18  
6.4  
FDA INSPECTION  
18  
6.5  
REGULATORY FILINGS  
19  
6.6  
QUALITY AGREEMENT  
19  
VII - WARRANTIES  
19  
7.1  
CONFORMITY WITH SPECIFICATIONS  
19  
7.2  
COMPLIANCE WITH THE ACT  
19  
7.3  
CONFORMITY WITH REGULATIONS AND CGMPS  
20  
7.4  
COMPLIANCE OF PACKAGING AND LABELING WITH LAWS AND REGULATIONS  
20  
7.5  
ACCESS TO DPT'S FACILITIES  
20  
7.6  
DISCLAIMER  
21  
VIII - FORCE MAJEURE  
21  
IX - CHANGES TO PROCESS OR PRODUCT  
21  
9.1  
CHANGES BY SERENITY  
21  
9.2  
CHANGES BY DPT  
22  
9.3  
CHANGES BY REGULATORY AUTHORITIES  
22  
9.4  
OBSOLETE INVENTORY  
22  
  
ii  
  
  
X - CONFIDENTIAL INFORMATION  
22  
10.1  
CONFIDENTIAL INFORMATION  
22  
10.2  
TRADEMARKS AND TRADE NAMES  
24  
XI - INDEMNIFICATION  
24  
11.1  
INDEMNIFICATION BY DPT  
24  
11.2  
INSURANCE BY DPT  
24  
11.3  
INDEMNIFICATION BY SERENITY  
24  
11.4  
INSURANCE BY SERENITY  
25  
11.5  
STACKING OF INSURANCE  
25  
11.6  
PATENT AND OTHER INTELLECTUAL PROPERTY RIGHTS  
25  
11.7  
CONDITIONS OF INDEMNIFICATION  
26  
XII - GENERAL PROVISIONS  
26  
12.1  
NOTICES  
26  
12.2  
ENTIRE AGREEMENT; AMENDMENT  
27  
12.3  
WAIVER  
77  
12.4  
OBLIGATIONS TO THIRD PARTIES  
27  
12.5  
ASSIGNMENT AND SUBCONTRACTING  
27  
12.6  
THIRD PARTY BENEFICIARY  
 28  
12.7  
GOVERNING LAW AND ARBITRATION  
28  
12.8  
SEVERABILITY  
31  
12.9  
HEADINGS, INTERPRETATION  
31  
12.10  
COUNTERPARTS  
31  
12.11  
INDEPENDENT CONTRACTOR  
31  
12.12  
EXPORT/IMPORT LAWS AND REGULATIONS  
31  
  
  
  
iii  
  
  
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 000 Xxxx Xxxxx, Xxxxxxx, Xxxxxxxxxxxx 00000 (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 0000 Xxxx Xxx, Xxxxxxxx, Xxx Xxxxxx, 00000, 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 0000 Xxxxxx Xxxxx, Xxxxxx, Xxxxxxxxxx 00000 ("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  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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 0000 Xxxx Xxx, Xxxxxxxx, Xxx Xxxxxx, 00000.  
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  
  
2  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
"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 xxxx-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  
  
3  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
"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.  
  
4  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
5  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
6  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
7  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
8  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
9  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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 ([\*\*\*]%).  
  
10  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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):  
  
11  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
12  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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:  
  
13  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
(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 xxxx SERENITY for these costs under the Project Protocol (as defined below). SERENITY shall receive a copy of DPT's Annual  
  
14  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
15  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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.  
  
16  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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 ($[\*\*\*]). SERENITY's LIABILITY UNDER THIS AGREEMENT FOR DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, RESTITUTION, WILL NOT EXCEED [\*\*\*] DOLLARS ($[\*\*\*]).  
  
17  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
18  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
19  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
(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  
  
20  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
000 XxXxxxxxxx Xxx.  
Xxx Xxxxxxx, XX 00000  
(000) 000-0000  
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  
  
21  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
(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  
000 XxXxxxxxxx Xxx.  
Xxx Xxxxxxx, Xxxxx 00000  
Fax: (000) 000-0000  
with a copy to the General Counsel's Office  
If to SERENITY:  
Serenity Pharmaceuticals  
Attention: Xxxxx Xxxxx  
000 Xxxx Xxxxx  
  
22  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
Milford, Pennsylvania  
Fax: 000-000-0000; 000-000-0000  
With copies to:  
Allergan Sales, LLC  
Attention: V.P., Global Sourcing & Procurement  
0000 Xxxxxx Xxxxx  
Xxxxxx, Xxxxxxxxxx 00000  
Fax: 000-000-0000  
Allergan Sales, LLC  
Attention: General Counsel  
0000 Xxxxxx Xxxxx  
Xxxxxx, Xxxxxxxxxx 00000  
Fax: 000-000-0000  
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  
  
23  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
24  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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.  
  
25  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
(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.  
  
26  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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]  
  
  
27  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
  
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/ Xxxxxx Xxxxxxxxxxxx, M.D.  
By:  
/s/ Xxxx Xxxxxxx  
 Xxxxxx Xxxxxxxxxxxx, M.D.  
 Xxxx Xxxxxxx  
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 $[\*\*\*].  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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.  
  
  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
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.  
  
  
  
Serenity Pharmaceuticals CONFIDENTIAL  
Manufacturing Agreement  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]  
  
  
Exhibit 1  
Capacity Guaranty Agreement  
  
[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]