Exhibit 10.2  
Confidential Materials omitted and filed separately with the  
Securities and Exchange Commission. Double asterisks denote omissions.  
  
COMMERCIAL MANUFACTURING AGREEMENT  
THIS MANUFACTURING AGREEMENT (the “Agreement”) is made and entered into this 18th day of September, 2015 (the “Effective Date”), by and between AAIPharma Services Corp., having a place of business at 0000 Xxxxxxxxxx Xxxx Xxxxx, Xxxxxxxxxx, XX 00000 (“AAIPharma”) and Marathon Pharmaceuticals, LLC having a place of business at 0000 Xxxxxx Xxxx., Xxxxx 000, Xxxxxxxxxx, XX 00000 XXX (“Company”). AAIPharma and Company, as used herein, may be referred to, collectively, as “Parties” and individually as a “Party”.  
Recitals  
WHEREAS, subject to the terms and conditions contained in this Agreement, Company desires to engage the services of AAIPharma to Manufacture the Products (each as defined below) for subsequent commercial distribution by Company.  
WHEREAS, AAIPharma is willing to undertake such Manufacture for Company according to the terms and conditions provided for in this Agreement.  
NOW, THEREFORE, for and in consideration of the foregoing premises and of the mutual covenants of the Parties hereinafter set forth, the Parties hereto agree as follows:  
ARTICLE 1  
DEFINITIONS  
The following words, terms and phrases, when used herein, shall have the following respective meanings:  
1.1 “AAIPharma” shall have the meaning set forth in the preamble.  
1.2 “AAIPharma Indemnified Parties” shall have the meaning set forth in Section 8.2.  
1.3 “Act” shall mean the United States Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended from time to time, and the regulations promulgated thereunder.  
1.4 “API” shall mean the active pharmaceutical ingredient with respect to each Product.  
1.5 “Applicable Law(s)” shall have the meaning set forth in Section 3.3.  
1.6 “Batch” shall mean a specific quantity of material produced in a contiguous process or series of processes that is expected to be homogeneous within specified limits. The Batch size for each Product is set forth in Exhibit A attached hereto and incorporated herein by reference.  
  
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1.7 “cGMP” or “GMP” shall mean the recognized pharmaceutical regulations and requirements of regulatory authorities such as those defined by the U.S. FDA’s regulations at 21CFR Parts 210 and 211, those defined by Eudralex, “The Rules Governing Medicinal Products in the European Union,” and specifically Volume 4, “Guidelines for Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use” and applicable Annexes (Directives 2001/83/EC and amendments including Directives 2003/94/EC dated October 2003 and 2004/27/EC dated March 2004 and/or others that may be appropriate for the particular project) and as may be amended from time to time.  
1.8 “Commercialize” or “Commercialization” shall mean, with respect to a Product, the marketing, promotion, sale and distribution of such Product.  
1.9 “Company” shall have the meaning set forth in the preamble.  
1.10 “Company Indemnified Parties” shall have the meaning set forth in Section 8.1.  
1.11 “Firm Commitment” shall have the meaning set forth in Section 4.1.  
1.12 “Firm Forecast” shall have the meaning set forth in Section 4.1.  
1.13 “Firm Order” shall have the meaning set forth in Section 4.2(b).  
1.14 “Indemnification Claim” shall have the meaning set forth in Section 8.3(a).  
1.15 “Initial Term” shall have the meaning set forth in Section 9.1.  
1.16 “Launch” means, with respect to a Product, the first commercial product shipped from AAIPharma’s site.  
1.17 “Long-Term Forecast” shall have the meaning set forth in Section 4.1.  
1.18 “Losses” shall have the meaning set forth in Section 8.1.  
1.19 “Manufacture”/“Manufacturing” shall mean the manufacture, processing, packaging, labeling (subject to Section 3.7), quality control and testing of the Products performed prior to their delivery by AA1 Pharma in accordance with the terms of this Agreement.  
1.20 “Marketing Authorizations” shall mean the United States new drug application or abbreviated new drug application, as applicable, for the Product(s).  
1.21 “Master Batch Record” shall mean the batch record as mutually agreed upon by the Parties.  
1.22 “Material Change” shall have the meaning set forth in Section 3.3.  
1.23 “Minimum Order Requirement” shall have the meaning set forth in Section 4.2(a).  
1.24 “Product(s)” shall mean those products described in Exhibit A, as the same may be amended from time to time upon mutual agreement of the Parties; provided, however, that no product  
  
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shall become a Product until such time as AAIPharma has successfully completed the registration batches for such product to Company’s reasonable satisfaction.  
1.25 “Purchase Prices” shall have the meaning set forth in Section 5.1.  
1.26 “Quality Agreement” shall have the meaning set forth in Section 6.5.  
1.27 “Raw Materials” shall mean any excipient and component materials used to Manufacture the Products, but excluding the API.  
1.28 “Raw Material Costs” shall have the meaning set forth in Section 5.2.  
1.29 “Recall” shall have the meaning set forth in Section 6.4(b).  
1.30 “Release To The Client” shall mean AAIPharma has: i) manufactured and/or packaged and/or labeled the Product according to the Master Batch Record; ii) fulfilled its testing/analytical obligations as further set forth herein; and iii) all manufacturing and testing services performed by AAIPharma have been reviewed and approved by AAIPharma’s Quality department.  
1.31 “Renewal Period” shall have the meaning set forth in Section 9.1.  
1.32 “Services” shall mean certain pharmaceutical development services in addition to manufacturing services including, for example, analytical method development and analysis, stability services, clinical packaging, validation services, quality assurance and regulatory consulting provided by AAIPharma.  
1.33 “Specifications” shall mean the specifications for the Products agreed upon by the Parties and included in the Master Batch Record, an example of which is set forth in Exhibit B attached hereto and incorporated herein by reference.  
1.34 “Term” shall have the meaning set forth in Section 9.1.  
1.35 “Territory” shall mean the United States, its territories and possessions.  
ARTICLE 2  
LICENSE GRANT TO AAIPHARMA TO MANUFACTURE PRODUCT  
2.1 Grant. Company hereby grants to AAIPharma during the Term of this Agreement, on a Product-by-Product basis, a nonexclusive, royalty-free right to Manufacture the Products in the Territory and to use any and all of Company’s licenses, trademarks, regulatory data and/or technical information, know how and Confidential Information of Company related to the Products for the purpose of AAIPharma carrying out its obligations hereunder, subject to the conditions of this Agreement.  
2.2 Marketing Authorizations. Company shall maintain the Marketing Authorizations in full force and effect at all times. Upon request by Company, AAIPharma shall use commercially reasonable efforts to assist Company in connection therewith; provided that, in exchange, Company will pay AAIPharma its standard fees and expenses therefor.  
  
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ARTICLE 3  
MANUFACTURING  
3.1 Engagement.  
(a) During the Term of this Agreement and subject to the terms and conditions set forth herein, Company agrees to exclusively purchase from AAIPharma, and AAIPharma agrees to exclusively manufacture and supply, one hundred percent (100%) of Company’s requirements for each Product for Commercialization in the Territory. Notwithstanding the foregoing, Company shall be entitled, at its sole cost and expense, to qualify other manufacturer(s) to manufacture Products solely for the purpose of such manufacturer(s) supplying Company with quantities of Product that AAIPharma is unable to supply (i) in breach of this Agreement, or (ii) during events of force majeure. Following the Initial Term, AAIPharma may notify Company if such exclusivity commitment would prevent AAIPharma from providing services to a third party. The Parties shall negotiate in good faith mutually acceptable revised terms including but not limited to termination of exclusivity or compensation to AAIPharma for the lost opportunity to provide services to such third party. If the Parties fail to agree on terms within [\*\*] days of such notification, either Party shall have the right to terminate this Agreement effective eighteen (18) months following the [\*\*] day negotiation period.  
(b) Notwithstanding the foregoing, to the extent Company intends to Commercialize a Product in a jurisdiction outside the Territory, for purposes of such Product only, the term “Territory” shall be expanded to include such jurisdiction provided that AAIPharma agrees in writing and AAIPharma is or becomes compliant with all laws, regulations and other legal and industry requirements applicable to the Manufacture of such Product for subsequent Commercialization of such Product in such jurisdiction. In the event AAIPharma is unwilling or unable to supply Product to a jurisdiction outside the Territory that Company intends to Commercialize, then Company may qualify other manufacturer(s) to manufacture Product solely for that jurisdiction outside the Territory and Company’s obligation to purchase Product exclusively from AAIPharma shall be waived for that jurisdiction.  
3.2 Manufacture of Commercial Drug Product. Subject to the terms and conditions contained herein, AAIPharma shall Manufacture, hold, handle and prepare for shipment all Product Manufactured pursuant to this Agreement (a) in accordance with this Agreement and the Quality Agreement, and (b) in material compliance with cGMP applicable to the Manufacturing of the Product to be Commercialized in the Territory.  
3.3 AAIPharma Changes to Manufacturing Process. Except as required by applicable federal, state, provincial or local law and/or respective regulations as established by the FDA and/or other regulatory authority (collectively, “Applicable Law(s)”), or cGMP, AAIPharma shall not Materially Change the Manufacturing process of a Product or change the facility where a Product is Manufactured that requires a change to a Marketing Authorization without the prior written consent of Company, which consent shall not be unreasonably withheld or delayed. AAIPharma shall notify Company of all material changes, including Material Changes required by  
  
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Applicable Law, as soon as practicable after AAIPharma learns of such change. A “Material Change” is one that requires a submission to the FDA, EU, or other applicable regulatory authority.  
3.4 Company Requested Changes. Company shall inform AAIPharma in writing of any proposed modifications to the Specifications or the Manufacturing process. Any proposed change shall require AAIPharma’s prior written consent, which consent shall not be unreasonably withheld or delayed. AAIPharma shall make changes it agrees to as promptly as practicable; provided, however, that such changes comply with Applicable Law, cGMP and the Marketing Authorizations.  
3.5 Costs of Changes. Unless otherwise agreed by the Parties, any and all direct costs associated with changes requested by AAIPharma and changes required by Applicable Law that apply generally to AAIPharma’s facility where the applicable Manufacturing occurs shall be borne by AAIPharma; provided however, in the event Applicable Law imposes a registration fee (such as GDUFA) or similar fee on AAIPharma’s cGMP facilities, and the fee relates to AAIPharma’s services hereunder, the Parties shall determine in good faith an equitable portion of such fee to be paid by Company. Unless otherwise agreed by the Parties, any and all direct costs associated with all other changes, including, without limitation, changes requested by Company, changes required by Applicable Laws that apply specifically to a Product, and changes required by a change to a Marketing Authorization, shall be borne by Company (collectively, the “Other Changes”). If the change is an Other Change, (i) the Purchase Prices shall be adjusted by the change in AAIPharma’s cost of Manufacture of the Product caused by such Other Change, plus an amount necessary to maintain AAIPharma’s profit margin on such, and (ii) Company shall reimburse AAIPharma for costs, expenses or losses associated with write-offs, obsolescence and/or destruction of any work in process or finished inventory resulting from any such Other Change.  
3.6 Notification and Approval of Changes. Company shall have sole responsibility for obtaining any and all necessary regulatory approvals from the relevant regulatory agencies in the Territory for changes to the Specifications and the Marketing Authorizations and for reporting any changes to such Specifications and the Marketing Authorizations to the relevant regulatory agencies in the Territory as appropriate. Upon request by Company, AAIPharma shall use commercially reasonable efforts to assist Company in obtaining any such approvals; provided that Company will pay AAIPharma its standard fees and expenses therefor.  
3.7 Labeling. Company shall be responsible for the labeling to be used on each Product and the packaging thereof, including any changes to such labels; provided that Company shall ensure that all such labeling complies with Applicable Laws. AAIPharma shall use the specified labeling (and only such labeling) on the Products, and shall not use such labeling on any other product. Any Company-directed change to a Product label shall be implemented by AAIPharma as soon as reasonably practicable following AAIPharma’s receipt of written notification of such label changes. Company shall reimburse AAIPharma for costs incurred in connection with any such label changes, including without limitation, the costs of obsolescence of goods-in-process, packaging materials  
  
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and supplies and finished goods not suitable for Commercializing in the Territory due to such label changes.  
3.8 Finished Product Release. AAIPharma will provide Company with manufacturing documents as are necessary for Company to release each lot of Product for human use. Company shall be responsible for the final release of Product for human use.  
3.9 Raw Materials and API. AAIPharma shall purchase at its own expense and for its own account all Raw Materials, packaging components and other items of any nature whatsoever that AAIPharma may use to Manufacture the Products. Except as otherwise agreed to between the Parties, all right, title and interest in and to these items, and in and to all work-in-process incorporating these items, shall remain the sole property of AAIPharma until Products incorporating such items are delivered for shipment to Company. However, the total cost of changing the source and/or type of Raw Materials shall be at the sole cost of Company. Company shall supply to AAIPharma at its own expense and for its own account all API to be used in the Manufacture of Products hereunder, and such API shall remain the sole property of Company. AAIPharma shall have no liability for lost or damaged API unless caused by its negligence or intentional misconduct. If such losses, in an annual reconciliation, lead to actual yields below [\*\*] percent ([\*\*]%) of theoretical, AAIPharma shall issue a credit to Company for the lesser of (a) an amount equal to Company’s then current replacement cost of the API, or (b) the amount AAIPharma would have charged Company for the amount of Product the lost quantity of API would have yielded. As such, if Company desires to insure its API, Company should do so under its own appropriate insurance policy. Company shall provide AAIPharma with documentation of its API cost at least annually on or before the anniversary of the Effective Date.  
ARTICLE 4  
FORECASTS, ORDERS, DELIVERY AND ACCEPTANCE  
4.1 Forecasting. Company shall provide to AAIPharma a written good faith forecast estimating Company’s quarterly requirements (broken out on a month-to-month basis) of each Product for each of the first [\*\*] calendar quarters during the Term at least [\*\*] months prior to Launch of each Product. In addition, within [\*\*] weeks after the start of each quarter (i.e. [\*\*]) during the Term, Company shall provide AAI Pharma with an updated rolling [\*\*] month forecast estimating Company’s requirements (broken out on a month-to-month basis) of the Product that shall cover the succeeding [\*\*] calendar month period (or the period until the expiration of the Term, if shorter) (each such forecast, a “Long-Term Forecast”). Except as set forth in Sections 4.2(a) and 4.2(b), the Long-Term Forecast shall not be binding on either Party, but for the first [\*\*] calendar months of a Long-Term Forecast, which shall be a “Firm Commitment” with respect to the Product, and but for the [\*\*] calendar months of a Long-Term Forecast, which shall be a “Firm Forecast” with respect to the Product.  
  
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4.2 Firm Commitments.  
(a) Each Firm Commitment shall be a binding commitment for the quantities of each Product forecast for the first [\*\*] calendar months of the Long-Term Forecast. The quantity of each Product specified in any Firm Commitment for delivery to, and purchase by, Company in any calendar quarter shall not be less than [\*\*] percent ([\*\*]%) of the quantities forecasted for such quantities when it was the applicable Firm Forecast (the “Minimum Order Requirement”).  
(b) With respect to each Firm Commitment, Company shall submit to AAIPharma binding written purchase orders (a “Firm Order”) no later than [\*\*] days prior to the requested delivery dates confirming the quantity of each Product ordered (which shall be in full Batch quantities), the requested delivery dates, and such other information as AAIPharma may find reasonably necessary to Manufacture the ordered Products. AAIPharma will confirm the requested delivery dates within [\*\*] business days of receipt of a Firm Order.  
(c) If Company fails to order and purchase the Minimum Order Requirement, then within [\*\*] days following the end of the quarter in which the Minimum Order Requirement was not met, Company shall pay to AAIPharma the difference between: (i) the Purchase Price for the applicable Minimum Order Requirement, and (ii) the Purchase Price that was paid by Company for the quantity ordered.  
Furthermore, Company agrees that purchases may be made by AAIPharma of the Raw Materials, packaging components and other items to satisfy the production requirements for the Long-Term Forecast. In such circumstances, if such Raw Materials, packaging components and other items are not included in finished Products purchased by Company within [\*\*] months after such purchases have been made (or such longer period as the Parties may have agreed to), Company will pay to AAIPharma its costs thereof and, in the event such Materials are incorporated into Products subsequently purchased by Company, Company will receive credit for any of such costs previously paid to AAIPharma by Company.  
(d) AAIPharma shall Manufacture and prepare for shipment the quantity of a Product specified in the Firm Commitment and related purchase orders. Notwithstanding the foregoing, with respect to a Product, in no event shall AAIPharma be required in any calendar quarter to deliver more than [\*\*] percent ([\*\*]%) of the quantities in the applicable Firm Forecast, but AAIPharma shall use its commercially reasonable and good faith efforts to deliver quantities in excess of [\*\*]% of the applicable Firm Forecast. The Firm Commitments shall be made available for shipment in accordance with Section 4.4.  
4.3 Changes in Orders. AAIPharma shall exercise its commercially reasonable efforts to comply with any proposed amendments to accepted Firm Orders that Company may request, but AAIPharma shall not be liable in any way for its inability to do so. Firm Orders may be amended only by mutual agreement of the Parties and such amendments shall not affect the Minimum Order Requirement.  
  
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4.4 Delivery. AAIPharma shall use commercially reasonable efforts to make Product available for shipment within [\*\*] business days of the delivery date requested in the applicable Firm Order. Company shall pay all crating, skidding, rigging, customs, freight, shipping, insurance and common carrier charges on all shipments in connection with Company’s chosen method of shipment of the Product. All Product(s) shall be shipped EX WORKS (Incoterms 2010) AAIPharma’s manufacturing facility. Title and risk of loss of Product shall pass to Company at the time the Products are placed on AAIPharma’s loading dock at Company’s disposal, not cleared for export and not loaded on any collecting vehicle. Company shall be responsible for arranging the shipment of the Product(s) from AAIPharma’s manufacturing facility to its final destination (and storage charges shall be imposed [\*\*] days after notice to Company that Product is available for shipment); provided, however, that Company must provide AAIPharma with reasonable evidence (e.g. a copy of the current DEA registration for the destination, when applicable) that such destination is authorized to handle the Product. Notwithstanding anything to the contrary in this Agreement, Company acknowledges and agrees that AAIPharma shall have no obligation to release Product for shipment to any destination for which Company has not provided adequate evidence of authorization as required in this Section 4.4. AAIPharma shall not be liable to Company for Product which is damaged or lost while in possession of a common carrier, and it shall be Company’s responsibility to recover any and all damage directly from such common carrier.  
4.5 Inspection, Acceptance and Rejection of Delivered Products.  
(a) Company will have [\*\*] days from receipt by Company to inspect and test Products for noncompliance with the applicable Specifications (the “Inspection Period”).  
(b) Except as provided in Section 4.5(c), Company shall give written notice if it intends to reject a Batch(es) of Product(s) - for not complying with the Specifications - within [\*\*] days after the Inspection Period expires; otherwise such Batch(es) shall be deemed accepted.  
(c) If, after the Inspection Period, Company first discovers that a Batch(es) of Product(s) do not comply with the applicable Specifications, then Company shall so notify AAIPharma if it intends to reject such Batch(es) within [\*\*] days after such discovery; otherwise such Batch(es) shall be deemed accepted. AAIPharma will only be responsible for Batch(es) of Product(s) rejected after the Inspection Period solely to the extent that AAIPharma is responsible for said non-conformity.  
(d) Notwithstanding anything to the contrary herein, AAIPharma shall not be responsible for damages to Product during shipment, and in no event shall AAIPharma be responsible for noncompliance with Specifications for Product that met Specifications at time of Release To The Client or from non-conformities that result from a deficiency or change in the API utilized in such Batch(es) of Product(s) or a defect in the Specifications for the Products.  
(e) In the event that Company rejects Product(s) as provided in this Agreement, AAIPharma shall use commercially reasonable efforts (but within [\*\*] days after AAIPharma’s receipt of Company’s notice of noncompliance) to replace the defective Product(s) or give notice  
  
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that it disagrees with the rejection. If Company and AAIPharma do not agree whether the Product(s) failed to meet applicable Specifications at the time of Release To The Client, such Products shall be submitted for testing to an independent laboratory or other authority of national reputation acceptable to both Parties for the purpose of determining the results. Any determination by such authority shall be final and binding upon the Parties hereto. If Company’s rejection is substantiated by the authority, AAIPharma shall pay the expenses associated with such analyses; otherwise Company shall pay such expenses and purchase the Product.  
4.6 Non-Conforming Product(s). Notwithstanding any other provisions of this Agreement, Company agrees, if so requested by AAIPharma, to return to AAIPharma any Product(s) that fail to meet Specifications or otherwise to dispose of such Product(s) as AAIPharma may direct, each at AAIPharma’s expense.  
ARTICLE 5  
PRICE, TERMS OF PAYMENT  
5.1 Purchase of Product(s). The initial prices to be paid for the Products by Company to AAIPharma shall be set forth in Exhibit A attached hereto and incorporated herein by reference (the “Purchase Prices”). The Purchase Prices are in United States dollars, and are exclusive of applicable taxes. Company shall be responsible for the payment of any and all taxes applicable to the Products and Services described herein.  
5.2 Price Change; Notice. AAIPharma may increase the Purchase Prices during the Term by [\*\*]. Upon request by Company, AAIPharma shall provide reasonable documentation that reflects the increase in cost of Raw Material Costs. AAIPharma shall provide written notification of any annual increase in the Purchase Prices prior to the January 1st effective date of the increase in Purchase Prices, or as increases in the cost of Raw Materials occur, as applicable.  
5.3 Invoices. AAIPharma shall provide invoices to Company for the Product(s) upon each Release To The Client (e.g. finished bulk, finished packaged, or finished packaged and labeled), and Company shall pay each such invoice, in United States dollars, within [\*\*] days after the date of each invoice regardless of when or whether Company has arranged for shipment of the Product(s) to its final destination. Company shall make no setoff or deduction of any kind from any payments due to AAIPharma unless Company receives written authorization from AAIPharma authorizing such setoff or deduction. Undisputed invoice balances not remitted within [\*\*] days of the date of each invoice shall be subject to a [\*\*] percent ([\*\*]%) per month interest charge. Should any part of the invoice be in dispute, Company shall pay the balance of the undisputed amount according to the terms and conditions described herein while said dispute is being resolved. Should payment of undisputed amounts not be received within [\*\*] days of invoice date, and after [\*\*] days notice to Company, the payment shall be deemed in default and AAIPharma reserves the right to cease all work and pursue collection activities. In the event of default in payment, Company shall be responsible for all collection fees and expenses incurred by AAIPharma, including reasonable attorney’s fees.  
  
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ARTICLE 6  
REGULATORY MATTERS; RECORDS  
6.1 Annual Review and Stability Testing. If listed in Exhibit A, AAIPharma will conduct an annual product review for the Products and upon completion of such review will forward a copy to Company. The Parties agree that AAIPharma’s Manufacturing process and the Purchase Prices do not include stability testing or any other work not specifically set forth herein or in an Exhibit hereto. Stability testing services and other services shall be provided at the then current AAIPharma rates for such services.  
6.2 Access to AAIPharma’s Facilities by Company Representatives for Quality Audit. During regular business hours and mutually agreed upon times, Company may review the records of AAIPharma and observe the manufacturing processes relating to the Services performed and expenses incurred to assure compliance with all provisions of this Agreement. Such review must be completed in not more than [\*\*] business days and shall be offered to Company by AAIPharma [\*\*] and may be more pursuant to cause. Subsequent reviews during the same calendar year or such reviews that cannot be completed in [\*\*] business days will be at Company’s sole cost and expense, at AAIPharma’s then current rates. Company shall also be provided an invoice for any incidental expenses AAIPharma incurs resulting from such review. Company’s rights in this Section 6.2 shall be subject to compliance with AAIPharma’s reasonable measures for purposes of confidentiality, safety, and security, and will be further subject to Company’s compliance with AAIPharma’s premises rules that are generally applicable to all persons at AAIPharma’s facilities. Should Company utilize one or more third party(ies) in exercising its rights in this paragraph, Company certifies that such party(ies) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required of Company hereunder and such third party(ies) shall be subject to any and all conditions upon Company’s rights that are set forth in this Section.  
6.3 Inspections by Governmental or Regulatory Authority. AAIPharma shall be responsible for handling and responding to any FDA or other governmental body inspections or inquiries received by Company or AAIPharma regarding the Manufacturing of any Product during the Term. In cases where AAIPharma is required to provide significant Company or Product specific support to such inspections or inquiries, Company agrees to pay AAIPharma for the time required at the then current AAIPharma regulatory support rate. Each Party shall promptly notify the other regarding any such inquiries and provide the other Party copies of any pertinent correspondence from such authorities related to the Product or Services covered in this Agreement. AAIPharma shall provide to Company and any governmental body any information reasonably requested by Company and/or such governmental body concerning any governmental inspection related to any Product (with all information provided to Company being subject to the confidentiality provisions in Section 10.1 herein and with AAIPharma being able to redact any information provided to Company to remove third party confidential information that does not relate to the Products). AAIPharma agrees to notify Company of any regulatory inspection specific to one or more of the Products and shall allow Company to send a representative to the site being audited, however participation in the audit will be at the sole discretion of AAIPharma. Company agrees to fully  
  
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cooperate with and assist as requested by AAIPharma in fulfilling the obligations pursuant to this Section 6.3.  
6.4 Complaints, Recalls, and Insurance  
(a) Complaints. Product complaints received by Company with respect to Product Manufactured by AAIPharma hereunder shall be faxed to AAIPharma within [\*\*] business days after receipt to:  
AAIPharma Services Corp.  
Attention: Corporate Quality  
0000 Xxxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxx, XX 00000  
Facsimile No.: [\*\*]  
As more fully described in the Quality Agreement, AAIPharma shall investigate all complaints directly associated with the Manufacture of Product(s) and shall provide an update every [\*\*] days and a report to Company regarding its investigation and any conclusions. Company shall investigate all other complaints associated with the Product(s).  
(b) Recall Procedures. In the event that a recall, withdrawal or field correction of any Product (a “Recall”) is initiated, whether by a statutory or regulatory authority in any jurisdiction or by Company, AAIPharma shall reimburse Company for all costs and expenses incurred in procuring or complying with the requirements of such Recall to the extent that such Recall is initiated as a result of AAIPharma’s breach of this Agreement (which shall include but not be limited to AAIPharma’s noncompliance or nonconformity with the Specifications, GMP, or any Applicable Laws), intentional misconduct, negligence, or defective manufacturing, processing, testing, packing, or storage of Product prior to delivery to Company, and, in addition, AAIPharma shall refund to Company an amount equal to the cost of all API supplied to AAIPharma and incorporated into the recalled Product; but not more than the cost of the Batch(es) or portion of a Batch, prorated. Company shall be responsible for all other costs and expenses associated with a Recall. AAIPharma shall reasonably cooperate with Company in connection with any Recall.  
(c) Insurance. At all times while this Agreement is in effect and for [\*\*] years thereafter, AAIPharma and Company shall each:  
i  
maintain general liability insurance (including, without limitation, product liability insurance, liability for property damage, personal injury and contractual liability) with Products/Professional at limits not less than $[\*\*] per occurrence/$[\*\*] aggregate;  
ii  
maintain Workers’ Compensation as required by all applicable laws and Employer’s Liability coverage with a limit of not less than $[\*\*]; and  
  
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iii  
provide, within [\*\*] days of the other Party’s request, Certificates of Insurance verifying insurance limits agreed upon as well as a [\*\*] day Notice of Cancellation or Non-Renewal.  
AAIPharma and Company shall each obtain all the insurance policies described in clauses 6.4(c)(i) and (ii) from insurers having A.M. Best ratings of A-VII or higher.  
Company shall, at its own cost and expense, obtain and maintain in full force and effect during the Term of this Agreement All Risk Property Insurance, including transit coverage, in an amount equal to full replacement value covering Company’s property while it is at AAIPharma’s facilities or in transit to or from AAIPharma’s facilities. Company shall obtain a waiver from any insurance carrier with whom Company carries All Risk Property Insurance releasing its subrogation rights against AAIPharma. Company shall not seek reimbursement for any property claim, or portion thereof, that is not fully recovered from Company’s All Risk Property Insurance policy.  
6.5 Quality Agreement. The Parties intend to enter into a quality agreement acceptable to both Parties (the “Quality Agreement”) as soon as practicable after the Effective Date. The Quality Agreement will detail the quality and regulatory obligations and responsibilities of the Parties with respect to the Products to the extent these obligations and responsibilities are not fully covered in this Agreement; provided, however, that in the event of conflict between the terms of this Agreement and the Quality Agreement, (i) the provisions of the Quality Agreement will prevail with respect to all matters pertaining to, or governed by, GMP and (ii) in all other respects, the provisions of this Agreement will prevail.  
ARTICLE 7  
REPRESENTATIONS AND WARRANTIES  
7.1 Representations and Warranties of AAIPharma. AAIPharma hereby represents and warrants as follows:  
(a) As of Release To The Client, all Product(s) delivered to Company during the Term of this Agreement: (i) shall have been Manufactured by AAIPharma in material compliance with this Agreement, the Quality Agreement, the Marketing Authorizations and cGMP, in each case, as in effect at the time of Manufacture, (ii) assuming compliance by Company with Section 3.7, shall not be adulterated or misbranded within the meaning of the Act, and (iii) shall not have been Manufactured by AAIPharma in violation of any Applicable Law in any material respect.  
(b) Upon delivery, AAIPharma shall convey good title to all Product(s) so delivered to Company.  
(c) The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby are within AAIPharma’s powers and have been duly authorized by all necessary action on the part of AAIPharma. This Agreement has been duly executed and delivered by AAIPharma and constitutes legal, valid and binding obligations of AAIPharma, enforceable against AAIPharma in accordance with its terms.  
  
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(d) The execution, delivery and performance by AAIPharma of this Agreement does not and will not (i) contravene or conflict with the organizational documents of AAIPharma Services Corp., (ii) contravene or conflict with or constitute a violation of any Applicable Laws, or (iii) breach or constitute a default under the provisions of any material contract, agreement or instrument to which it is a party or by which it is bound.  
(e) AAIPharma is not debarred and has not and shall not knowingly and intentionally use in any capacity the services of any third person debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992.  
EXCEPT AS SET FORTH IN THIS SECTION 7.1, AAIPHARMA MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AND SPECIFICALLY DISCLAIMS ALL SUCH REPRESENTATIONS AND WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, INFRINGEMENT, TITLE OR FITNESS FOR A PARTICULAR PURPOSE OR USE.  
7.2 Representations and Warranties of Company. Company hereby represents and warrants as follows:  
(a) The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby are within Company’s powers and have been duly authorized by all necessary action on the part of Company. This Agreement has been duly executed and delivered by Company and constitutes legal, valid and binding obligations of Company, enforceable against Company in accordance with its terms.  
(b) The execution, delivery and performance by Company of this Agreement does not and will not (i) contravene or conflict with the organizational documents of Company, (ii) contravene or conflict with or constitute a violation of any Applicable Laws, or (iii) breach or constitute a default under the provisions of any material contract, agreement or instrument to which it is a party or by which it is bound.  
(c) Company shall comply in all material respects with all Applicable Laws relating to its Commercialization of the Product(s).  
(d) To the extent that Company supplies any Raw Materials, or API, or other information to AAIPharma (including packaging and labeling requirements) or engages in manufacturing with respect to any of the Products (either directly or indirectly through a third party), all such Raw Materials, API or other information and formulas will comply with the Specifications and applicable laws, including GMP.  
(e) Company represents that to the best of its knowledge, the manufacture or the sale of the Products does not and will not infringe any third party intellectual property rights or other rights and that it is not aware of any patents existing in the Territory in which Company markets or distributes such Products relating in any manner to the Products or any use, method, activity or  
  
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application relating thereto which could adversely impact upon or prevent AAIPharma from Manufacturing the Products as contemplated by the terms hereof.  
ARTICLE 8  
INDEMNIFICATION  
8.1 By AAIPharma. AAIPharma hereby indemnifies Company and its directors, officers, employees, Affiliates, stockholders, agents, attorneys, representatives, successors and Permitted Assigns (collectively, the “Company Indemnified Parties”) against and agrees to hold each of them harmless from any and all product liability claims associated with the Products, losses, liabilities, obligations, damages, costs and expenses (“Losses”) incurred by any Company Indemnified Party as a result of third party claims, actions or proceedings (collectively, “Third Party Claims”) to the extent based upon, attributable to or resulting from: (a) any material misrepresentation or material breach of warranty made by AAIPharma in this Agreement, (b) any material breach of any covenant or agreement made or to be performed by AAIPharma pursuant to this Agreement, and (c) the negligence or willful misconduct by an AAIPharma Indemnified Party in connection with this Agreement; except in each case, to the extent such Losses are attributable to Company’s material breach of this Agreement or arising from the negligence or willful misconduct of Company.  
8.2 By Company. Company hereby indemnifies AAIPharma and its directors, officers, employees, Affiliates, stockholders, agents, attorneys, representatives, successors and assigns (collectively, the “AAIPharma Indemnified Parties”) against and agrees to hold each of them harmless from any and all Third Party Claims, including Losses incurred by any AAIPharma Indemnified Party to the extent based upon, attributable to or resulting from the performance of this Agreement and Services hereunder by AAIPharma (including, without limitation, any products liability claims related to Company products) other than for Losses for which AAIPharma is obligated to indemnify the Company Indemnified Parties under Section 8.1 above.  
8.3 Indemnification Procedures.  
(a) The indemnified Party shall give the indemnifying Party prompt notice of any such claim or lawsuit (“Indemnification Claim”) (including a copy thereof) served upon it and shall fully cooperate with the indemnifying Party and its legal representatives in the investigation of any matter the subject of indemnification. The indemnifying Party may enter into a settlement agreement with a claimant but shall not admit liability to a claimant without the prior written permission of the party or parties seeking indemnification, which permission shall not be unreasonably withheld.  
(b) The failure of the indemnified Party to give reasonably prompt notice of any Indemnification Claim shall not release, waive or otherwise affect the indemnifying Party’s obligations with respect thereto except to the extent that the indemnifying Party can demonstrate actual loss and prejudice as a result of such failure.  
8.4 Limitation on Liability. Except as set forth in Section 8.6 (Exceptions), neither Party shall be liable, whether in contract, tort (including negligence) or otherwise, for any punitive,  
  
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special, indirect, incidental, consequential or exemplary damages (including lost profit or business interruption even if notified in advance of such possibility) arising out of or pertaining to the subject matter of this Agreement.  
8.5 Aggregate Cap. Except as set forth in Section 8.6 (Exceptions), the total aggregate liability of either Party to the other Party arising out of this Agreement shall be limited to the total amounts paid and payable by Company to AAIPharma under this Agreement during the twelve (12) months preceding the event in question. Such liability cap amount does not alter each Party’s insurance obligations under Section 6.4(c) (Insurance).  
8.6 Exceptions. Sections 8.4 (Limitation on Liability) and 8.5 (Aggregate Cap) shall not apply to the following: (a) a Party’s obligations to indemnify the other for Claims under Sections 8.1 and 8.2 (Indemnification); or (b) damages due to a Party’s breach of its confidentiality obligations or claims for infringement of proprietary rights.  
ARTICLE 9  
TERM AND TERMINATION  
9.1 Term of the Agreement. Unless earlier terminated in accordance with this Article 9, this Agreement shall take effect and commence on the Effective Date and continue in effect, on a Product-by-Product basis, for five (5) years following Launch of a particular Product (the “Initial Term”). In addition, after the expiration of the Initial Term with respect to a particular Product, this Agreement will automatically renew with respect to such Product for consecutive two (2) year terms (each, a “Renewal Period”) unless either of the Parties terminates this Agreement with respect to such Product at the end of the applicable Initial Term or any applicable Renewal Period by providing the other Party with written notice, in the case of Company, at least twelve (12) months, and in the case of AAIPharma, at least eighteen (18) months, prior to the end of the applicable Initial Term or applicable Renewal Period. The Initial Term and all Renewal Periods for each Product shall be collectively referred to herein as the “Term” for such Product.  
9.2 Termination. Notwithstanding Section 9.1 herein, this Agreement may be terminated as follows:  
(a) immediately upon the delivery of written notice by one Party, if the other Party materially breaches any of the provisions of this Agreement and such breach is not cured within [\*\*] calendar days after receipt of written notice identifying such breach (or if cure has been commenced during such period, if it is not diligently prosecuted to completion); or  
(b) immediately upon the delivery of written notice by one Party, if the other Party has been unable to perform its obligations hereunder for one hundred twenty (120) calendar days by reason of force majeure (as defined in Section 12.11).  
(c) either Party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of  
  
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bankruptcy is filed in any court of competent jurisdiction by such other Party; (iii) ceases or threatens to cease to carry on business, or (iv) this Agreement is assigned by such other Party for the benefit of creditors.  
(d) Company may terminate this Agreement as to any Product upon forty-five (45) days’ written notice in the event that any governmental agency takes any action, or raises any objection, that prevents Company from importing, exporting, purchasing or selling such Product.  
(e) Company may at any time unilaterally terminate this Agreement only with respect to an individual Product if: (i) such individual Product is withdrawn from the market; (ii) Company divests, out-licenses or otherwise disposes of such individual Product to a party other than an Affiliate of Company; provided, however, for greater certainty, that this Subsection 9.2(e) shall not entitle Company to terminate this Agreement in whole or in part in connection with a sale or other disposition of all or substantially of its interest in the Products as a whole or any significant portion thereof; or (iii) such individual Product is found to infringe a third party’s Intellectual Property.  
Company shall provide to AAIPharma not less than twelve (12) months’ advance written notice of such partial termination of this Agreement except where it results from either a market withdrawal at the mandate of a competent authority having jurisdiction or an infringement as in Subsection 9.2(e)(iii) above, in which cases the termination can be effective immediately; provided, however, in respect of Subsection 9.2(e)(ii), Company may provide less than the twelve months advance notice if the acquiring party agrees in writing to purchase the particular individual Product from AAIPharma for the balance of the notice period on the same terms and conditions as contained herein.  
Any termination pursuant to this Section 9.2 may be effected with respect to this entire Agreement or with respect to any individual Product or Products, at the discretion of the terminating Party, and shall be effected by delivering written notice of such termination to the other Party and shall be effective upon the date of such written notice unless a later date is specified in such written notice.  
9.3 Effect of Termination. Upon termination or expiration of this Agreement, in its entirety or with respect to any particular Product(s):  
(a) Cessation of Activities. Except as provided in Section 9.3(c), AAIPharma shall stop the Manufacturing of Products; each Party shall return to the other any Confidential Information of such other Party concerning the Product(s) subject to such termination or expiration.  
(b) Payment of Minimum Order Requirement; Company to Take Product. In the event of termination by AAIPharma pursuant to Section 9.2(a), (b), or (c) above, Company shall pay AAIPharma any balance remaining of the Minimum Order Requirement in the same manner as set forth in Section 4.2(c) in the case of a failure to order and purchase the Minimum Order Requirement in any calendar quarter. Company shall, at its option and with respect to any Products that are subject to termination, be permitted to take delivery for any Raw Materials, work-in-process (at AAIPharma’s material costs) or finished Product (at prices then in effect under this Agreement).  
  
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(c) Firm Orders. If this Agreement is terminated by Company pursuant to Section 9.2(a), at Company’s option, Firm Orders with respect to the Product(s) not yet started shall be cancelled, or, if requested by Company in writing, AAIPharma will, with respect to the Product(s) subject to such termination, complete or cause the completion of the Manufacturing of any work-in-process that is subject to a valid and effective Firm Order on the date on which the termination is effective. Once such work-in-process is completed, the resulting Product(s) shall be shipped in accordance with Company’s Firm Orders and paid for by Company in accordance with Section 5.3.  
9.4 Survival. The Parties agree that the following provisions shall survive the termination of this Agreement; the definitions of Article 1 to the extent such Definitions pertain to terms in surviving provisions, Sections 4.5, 4.6, 6.4, and Articles 5, 7, 8, 9, 10, 11 and 12.  
ARTICLE 10  
CONFIDENTIALITY AND PUBLIC DISCLOSURE  
10.1 AAIPharma will hold in strict confidence, and shall not disclose to any third party without Company’s prior written consent, all proprietary or confidential information concerning Product, API and all materials and information provided by Company (collectively, “Company Information”). AAIPharma further agrees that it shall not use Company Information for any purpose other than the Manufacturing of Products for Company under this Agreement.  
10.2 Company will hold in strict confidence, and shall not disclose to any third party without AAIPharma’s prior written consent, all proprietary or confidential information and materials belonging to AAIPharma (“AAIPharma Information”).  
10.3 “Confidential Information” shall mean Company Information and AAIPharma Information. Each Party may disclose Confidential Information only to its directors, officers and employees who have need to know Confidential Information for the purposes of this Agreement, and each Party will be responsible for ensuring that all its directors, officers, and employees to whom Confidential Information is disclosed will also observe such obligations of confidentiality and non-use as provided herein.  
10.4 The above confidentiality obligation shall not apply or shall cease to apply to any information which the receiving party can demonstrate by documentary proof:  
(a) is already in the possession of the receiving party at the time it is disclosed by the disclosing party;  
(b) is in the public domain at the time it is disclosed by the disclosing party;  
(c) enters the public domain through sources independent of the receiving party and through no fault of the receiving party;  
(d) is lawfully obtained by the receiving party without any confidentiality restrictions from a third party who has a right to disclose such information to the receiving party;  
  
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(e) has been at any time developed by the receiving party independently of disclosure from the disclosing party.  
10.5 Neither Party (nor any of their respective Affiliates) shall issue any press release or make any public announcement with respect to this Agreement and the transactions contemplated hereby without obtaining the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), except as may be required by Applicable Law upon the advice of counsel and only if the disclosing Party provides the non-disclosing Party with a reasonable opportunity to first review the release or other public announcement, to the extent practicable.  
10.6 These confidentiality obligations shall survive termination or expiration of this Agreement for a period of [\*\*] years.  
ARTICLE 11  
INTELLECTUAL PROPERTY  
11.1 AAIPharma further agrees that all Company Information, know-how, data, discoveries and inventions relating to Product and API which result from the Manufacture of Products shall constitute the sole and exclusive property of Company. AAIPharma hereby assigns to Company all right, title and interest throughout the world in and to all inventions (whether or not patentable), processes, techniques, improvements, discoveries and developments discovered and reduced to practice by AAIPharma (collectively, “Project IP”) in the course of providing Services which are directly and solely related to the Manufacture of Product hereunder. AAIPharma will, at the expense and the written request of Company, do all reasonable acts and measures and execute all documents as Company may reasonably request to transfer to and vest in Company the ownership and registration of all intellectual property rights that may exist in such Project IP.  
11.2 Company acknowledges that AAIPharma possesses certain inventions, processes, techniques, improvements, know-how, trade secrets, discoveries and other intellectual property and other proprietary assets, including drug delivery technologies (hereinafter, “AAIPharma Proprietary Technology”) which have been independently developed by AAIPharma. In the event Company chooses to further develop and/or commercialize a technology comprising, in whole or in part, AAIPharma Proprietary Technology, Company will obtain a license from AAIPharma to use such AAIPharma Proprietary Technology. Such license agreement shall be memorialized in a separate agreement to be negotiated in good faith by the Parties.  
11.3 Company acknowledges that AAIPharma is in the business of providing services for a variety of organizations other than Company. Accordingly, nothing in this Agreement, with the exception of the exclusivity obligations set forth in Article 3.1 herein, shall preclude or limit AAIPharma from providing services or developing materials for itself or other clients, or from utilizing the general knowledge gained during the course of its performance hereunder to perform similar services for other clients, provided that such provision of services or development of materials do not constitute a breach of confidentiality under Article 10 or the exclusivity obligations set forth in Article 3.1 herein.  
  
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ARTICLE 12  
MISCELLANEOUS  
12.1 Successors and Assigns. Neither Party may assign its rights or obligations under this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement, in whole or in part, without such consent, to an Affiliate of such Party or to a Third Party that acquires substantially all of the assets of a Party to which this Agreement relates, upon written notice to the other Party of any such assignment and such Party hereby guarantees the performance of any such Affiliate, and, in the case of a Third Party assignment, such Third Party shall assume the obligations of the assigning Party under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any obligation, which such Party may have or incur hereunder. This Agreement shall be binding upon and inure to the benefit of each of the Parties and each such Party’s successors and permitted assigns.  
12.2 Notices. Any notice required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized overnight courier, confirmed facsimile transmission, or registered or certified mail service, postage prepaid, return receipt requested, to the following addresses or facsimile numbers of the Parties:  
Company:  
Marathon Pharmaceuticals, LLC  
0000 Xxxxxx Xxxx, Xxxxx 000  
Xxxxxx, XX 00000 XXX  
Attn: General Counsel  
Fax: [\*\*]  
AAIPharma:  
AAIPharma Services Corp.  
0000 Xxxxxxxxxx Xxxx Xxxxx  
Xxxxxxxxxx, XX 00000  
Attn: Legal Department  
Fax: [\*\*]  
All notices under this Agreement shall be deemed received (i) upon receipt when sent by hand, (ii) two (2) business days after deposit with a recognized overnight courier, (iii) upon confirmation of delivery when sent by facsimile, and (iv) five (5) business days after deposit in registered or certified mail service. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this Section.  
12.3 Waiver. No delay on the part of AAIPharma or Company in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of either Party of any right, power or privilege hereunder operate as a waiver of any other right, power or privilege hereunder, nor shall any single or partial exercise of any right, power or privilege  
  
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hereunder preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder. Any provision of this Agreement may be waived if, and only if, such waiver is in writing and signed by the Party against whom the waiver is to be effective.  
12.4 Entire Agreement. This Agreement and the Quality Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements, understanding and negotiations, both written and oral, between the Parties with respect to the subject matter of this Agreement.  
12.5 Amendment. This Agreement may be modified or amended only by written agreement of the Parties hereto.  
12.6 Counterparts. This Agreement may be executed by facsimile and in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute a single instrument. This Agreement may be executed on signature pages exchanged by facsimile, in which event each Party shall promptly deliver to the others such number of original executed copies as the others may reasonably request.  
12.7 Governing Law; Jurisdiction. This Agreement shall be governed and construed in accordance with the laws of the State of Delaware excluding any choice of law rules which may direct the application of the law of another state.  
12.8 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any Party hereto under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar to the terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.  
12.9 No Third Party Rights. Except as otherwise expressly set forth herein, no provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligations in any person not a Party to this Agreement.  
12.10 Exhibits. The Exhibits referenced in this Agreement are an integral part of this Agreement and are incorporated herein by reference.  
12.11 Force Majeure. If either Party is prevented from complying, either totally or in part, with any of the terms or provisions set forth herein by reason of force majeure, including, by way of example and not of limitation, fire, flood, explosion, storm, hurricane, strike, lockout or other labor dispute, riot, war, rebellion, accidents, acts of God, or acts of governmental agencies or instrumentalities, in each case to the extent beyond its control despite its commercially reasonable  
  
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efforts to avoid, minimize, and resolve such cause as promptly as possible, said Party shall (a) provide written notice of same to the other Party, and (b) subject to the obligations set forth above with respect to said Party’s efforts to remove the disability, its obligations that are prevented from compliance by such force majeure are suspended, without liability, during such period of force majeure. Said notice shall be provided within ten (10) business days of the occurrence of such event and shall identify the requirements of this Agreement or such of its obligations as may be affected. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the force majeure condition and the duration of the affected Party’s nonperformance.  
12.12 No Other Relationship. It is expressly agreed that AAIPharma, on the one hand, and Company, on the other hand, shall be independent contractors and that nothing contained herein shall be deemed to create any joint venture or partnership between the Parties hereto, and, except as is expressly set forth herein, neither Party shall have any right by virtue of this Agreement to bind the other Party in any manner whatsoever.  
12.13 Additional Product. The Parties covenant and agree that additional products may be added to this Agreement and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by an addendum hereto.  
12.14 Dispute Resolution.  
(a) Negotiated Settlement. In the event of a dispute regarding payment or the performance of Services pursuant to this Agreement (each, a “Dispute”), the Parties shall endeavor to negotiate in good faith an agreeable solution. If after [\*\*] business days following receipt of a Party’s written notification of a Dispute such Dispute has not been resolved, the Dispute shall be brought to the attention of the senior management of each Party and such senior manager or his/her designee will negotiate in good faith to define and implement a final resolution. The intent of this Section 12.14 is to encourage the Parties to work together to resolve any Dispute without having to rely on arbitration or any other legal proceeding. However, nothing in this Section 12.14 shall prevent or inhibit either Party to institute any other action to resolve such Dispute(s).  
(b) Binding Arbitration. If not resolved in accordance with the preceding paragraph (a) then any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof.  
[SIGNATURE PAGE FOLLOWS]  
  
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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.  
Marathon Pharmaceuticals, LLC  
By: /s/ Xxxxxxx X. Xxxxxx   
Printed Name: Xxxxxxx X. Xxxxxx   
Title: EVP of Legal Affairs and General Counsel   
Date: 10/9/15   
AAIPharma Services Corp.  
By: /s/ Xxxx X. Xxxxxx   
Printed Name: Xxxx X. Xxxxxx  
Title: Chief Commercial Officer  
Date: 10/7/15   
  
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Exhibit A  
Product(s), Batch Sizes, and Cost  
Deflazacort tablets in the following strengths to be marketed in the Territory.  
Dosage Strength  
Dosage  
Form  
Lot  
Size  
Bottle  
Count  
Price/ Bottle  
6-mg  
Tablet  
[\*\*]  
100  
$[\*\*]  
18-mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
30-mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
36-mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
  
  
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Exhibit B  
Specifications  
[Attached]  
  
  
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Bulk Product Specification  
SUBJECT: Deflazacort Tablets, 6 mg BP-3166-00  
CLIENT: Marathon Pharmaceuticals, LLC Page 2 of 2  
  
  
Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 12 pages were omitted. [\*\*]  
  
  
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Amendment #1  
THIS AMENDMENT #1 (“Amendment”) is entered into as of September 18, 2016 (the “Amendment Effective Date”) by and between Alcami Corporation, formerly known as AAIPharma Services Corp. (“Alcami”) and Marathon Pharmaceuticals, LLC (“Company”).  
WHEREAS, Company and Alcami entered into a Commercial Manufacturing Agreement with an effective date of September 18, 2015 (the “Agreement”);  
WHEREAS, the Parties have requested modifications to Exhibits A and B of the Agreement; and  
WHEREAS, the Parties wishes to implement the requested modifications upon the terms and conditions set forth herein.  
NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by each party hereto to the other, both parties mutually agree as follows:  
1.  
Capitalized terms not otherwise defined herein will have the meaning given to them in the Agreement.  
2.  
Where found in the Agreement, references to AAIPharma Services Corp. and AAIPharma shall be deleted and replaced with Alcami Corporation and Alcami, respectively.  
3.  
Exhibit A, Product(s), Batch Sizes, and Cost, shall be deleted in its entirety and replaced with the attached Exhibit A1.  
4.  
The specifications in Exhibit B shall be deleted in their entirety and replaced with the attached Exhibit B1.  
5.  
[\*\*].  
6.  
Notwithstanding, the Parties expressly agree that purchase orders #2348, #2349, #2350, #2351, #2365, and #2366 submitted by Company to Alcami prior to the Amendment Effective Date, shall be prepared and shipped according to the terms outlined in the previously agreed to Exhibit A and Exhibit B respectively.  
7.  
[\*\*].  
  
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Except as otherwise modified herein, the Agreement will remain in full force and effect.  
ACKNOWLEDGED, ACCEPTED, AND AGREED TO:  
Alcami Corporation  
  
  
By: /s/ Xxxx X. Xxxxxx   
  
Name: Xxxx X. Xxxxxx   
  
Title: Chief Commercial Officer   
  
Date: 11/30/2016   
  
Marathon Pharmaceuticals, LLC  
  
  
By: /s/ Xxxxxxx X. Xxxxxx   
  
Name: Xxxxxxx X. Xxxxxx   
  
Title: EVP of Legal Affairs and General Counsel   
  
Date: 11/11/16   
  
  
  
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Exhibit A1  
Product(s), Batch Sizes, and Cost  
Deflazacort tablets in the following strengths to be marketed in the Territory:  
Dosage  
Strength  
Dosage Form  
Lot Size (Bottles)  
Bottle Count  
Price/Bottle (USD)  
3 mg  
Tablet  
[\*\*]  
100  
$[\*\*]  
6 mg  
Tablet  
[\*\*]  
100  
$[\*\*]  
18 mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
30 mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
36 mg  
Tablet  
[\*\*]  
30  
$[\*\*]  
  
Secondary Packaging of Pre-Filled Deflazacort Oral Suspension Bottles  
(13ml fill, 22.75 mg/ml)  
  
Dosage  
Strength  
Dosage Form  
Lot Size (Bottles)  
Fill Volume  
Price/Bottle (USD)  
22.75 mg/mL  
Oral Suspension  
[\*\*]  
13mL  
$[\*\*]  
  
  
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Exhibit B1  
Specifications  
[Attached]  
[Note: not attached by the parties]  
  
  
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Amendment #2  
THIS AMENDMENT #2 (“Amendment”) is entered into as of January 6, 2017 (the “Amendment Effective Date”) by and between Alcami Corporation, formerly known as AAIPharma Services Corp. (“Alcami”) and Marathon Pharmaceuticals, LLC (“Company”).  
WHEREAS, Company and Alcami entered into a Commercial Manufacturing Agreement with an effective date of September 18, 2015 and as amended September 18, 2016 (the “Agreement”);  
WHEREAS, the Parties have requested modifications to the Agreement; and  
WHEREAS, the Parties wish to implement the requested modifications upon the terms and conditions set forth herein.  
NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is herby acknowledged by each party hereto to the other, both parties mutually agree as follows:  
1.  
Capitalized terms not otherwise defined herein will have the meaning given to them in the Agreement.  
2.  
Section 1.35, Territory, shall be deleted and replaced with the following:  
“1.35 “Territory” shall mean the United States, its territories and possessions[\*\*].”  
Except as otherwise modified herein, the Agreement will remain in full force and effect.  
IN WITNESS WHEREOF, the Parties hereto have executed this Amendment as of the Amendment Effective Date.  
Alcami Corporation  
  
  
By: /s/ Xxxx X. Xxxxxx   
  
Name: Xxxx X. Xxxxxx   
  
Title: Chief Commercial Officer   
  
Date: 1/11/2017   
  
Marathon Pharmaceuticals, LLC  
  
  
By: /s/ Xxxxxxx X. Xxxxxx   
  
Name: Xxxxxxx X. Xxxxxx   
  
Title: EVP of Legal Affairs and General Counsel   
  
Date: 1/6/17   
  
  
  
  
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