Exhibit 10.2  
 MANUFACTURING AND SUPPLY AGREEMENT  
  
BETWEEN  
  
EDGE THERAPEUTICS, INC.  
  
AND  
  
OAKWOOD LABORATORIES, L.L.C.  
  
June 30, 2017  
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MANUFACTURING AND SUPPLY AGREEMENT  
  
This MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”), dated as of June 30, 2017 (the “Effective Date”), is made by and between Edge Therapeutics, Inc., having a place of business at 000 Xxxxxxx Xxxxx, Xxxxx 0000, Xxxxxxxx Xxxxxxx, XX 00000 (“Edge”) and Oakwood Laboratories, L.L.C., a limited liability company organized and existing under the laws of Delaware having an address of 0000 Xxxxx Xxxxx, Xxxxx X, Xxxxxxx Xxxxxxx, XX 00000 (“Oakwood”). Edge and Oakwood are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.  
  
RECITALS  
  
WHEREAS, subject to the terms and conditions set forth in this Agreement, Edge wishes to have Oakwood manufacture and supply the Product (as defined herein) for Edge, and Oakwood wishes to manufacture and supply the Product for Edge; and  
  
WHEREAS, the Parties are entering into an amended and restated formulation and development agreement dated as of the date hereof (such agreement, as may be further amended, the “Development Agreement”), pursuant to which Oakwood has and will continue to perform certain formulation development services in connection with the Product on the terms and conditions set forth therein.  
  
NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:  
  
ARTICLE I.  
  
DEFINITIONS  
  
As used herein, the following terms shall have the following meanings:  
  
1.1 “Accepted Excess Product” has the meaning set forth in Section 3.2.  
  
1.2 “Accountant” has the meaning set forth in Section 5.5(c).  
  
1.3 “Actual Yield” means, with respect to the API for a particular period, the percentage of the applicable Quantity Dispensed of API during such period that was Manufactured by Oakwood into Product that conforms to the Product Specifications for Edge during such period.  
  
1.4 “Affiliate” means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such other Person controls, is controlled by or is under common control with such first Person. “Control” and, with correlative meanings, the terms “controlled by” and “under common control with” mean to possess the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract or otherwise.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
 1.5 “Agreement” has the meaning set forth in the preamble hereto.  
  
1.6 “API” means nimodipine in bulk form.  
  
1.7 “API Specifications” means the specifications for the API as provided by Edge to Oakwood in writing, as the same may be amended from time to time in accordance with the Quality Agreement.  
  
1.8 “Applicable Law” means (a) all applicable laws, rules and regulations that may be in effect from time to time, including all rules regulations, guidelines or other requirements of all Regulatory Authorities and (b) all applicable laws, rules and regulations that may be in effect in any jurisdiction in which Oakwood Manufactures the Product, including any rules, regulations or other requirements of the Regulatory Authorities in any such jurisdiction.  
  
1.9 “Batch” means a specific quantity of the Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single Manufacturing order during the same cycle of the Manufacturing Process for the Product.  
  
1.10 “Batch Minimum Order Commitment” has the meaning set forth in the definition of Minimum Order Commitment.  
  
1.11 “Batch Price” means during (a) the period from [\*\*] until [\*\*], [\*\*] per Batch produced by Oakwood hereunder and (b) [\*\*], an amount equal to [\*\*].  
  
1.12 “Business Day” means a day other than a Saturday, Sunday or a day on which banking institutions in New York, New York are obligated by law to remain closed.  
  
1.13 “Calendar Quarter” means each successive period of three (3) consecutive calendar months commencing on January 1, April 1, July 1 and October 1; provided, however, that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the first to occur of March 31, June 30, September 30 and December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term.  
  
1.14 “Calendar Year” means each successive period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.  
 1.15 “Certificate of Analysis” means a document certifying that the Product conforms to the Product Specifications and was Manufactured in accordance with cGMPs.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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1.16 “cGMPs” means (a) current good manufacturing practice in accordance with guidance issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); (b) United States Current Good Manufacturing Practices, including as specified in the FFDCA (21 U.S.C. § 501(a)(2)), FDA regulations (21 C.F.R. parts 210 and 211) as established under the FFDCA (21 C.F.R. parts 210 and 211); (c) FDA’s guidance documents, and all successor regulations and guidance thereto; (d) good manufacturing practice in accordance with Commission Directive 2004/27/EC (2001/83/EC as amended) and any guidance issued pursuant to such Directive and any successor legislation or guidance with respect thereto; and (e) any comparable practices of a Regulatory Authority in the United States, Australia, Canada, China, Hong Kong, Iceland, Israel, Japan, Liechtenstein, Mexico, New Zealand, Norway, Singapore, South Korea, Switzerland, Thailand, the European Union (including, for clarity, the United Kingdom and any other country that is a member of the European Union on the Effective Date even if such country ceases to be a member of the European Union during the Term), or any other jurisdiction of which Edge provides Oakwood with not less than three (3) months’ prior written notice and Oakwood agrees in writing to be subject thereto, such agreement not to be unreasonably withheld, conditioned or delayed, and in which Edge obtains Regulatory Approval for the Product, in each case, together with any rules and regulations promulgated thereunder governing the Manufacturing of the Product, in each case as may be amended from time to time.  
  
1.17 “CMC Data” means the chemistry, manufacturing and controls data required by Applicable Law to be included or referenced in an application for Regulatory Approval.  
  
1.18 “Commercial Year” means each twelve (12)-consecutive-month period beginning on the first (1st) day of the Calendar Quarter following the Calendar Quarter in which Launch occurs; provided, however, that the first Commercial Year shall begin on the date of Launch and end on the last day of the Calendar Quarter in which the first (1st) anniversary of Launch occurs. For example, if Launch occurs on January 15, 2018, the first Commercial Year will end on March 31, 2019, with subsequent Commercial Years beginning on April 1 and ending on March 31.  
  
1.19 “Commercially Usable Unit” means a Unit that is either (a) retained by Oakwood as a stability or reference standard or other sample in accordance with the Quality Agreement or as otherwise instructed by Edge in writing or (b) delivered to Edge in accordance with the terms and conditions of this Agreement, in each case ((a) and (b)) as evidenced by the applicable Batch record with respect to such Unit.  
  
1.20 “Commitment Period” means Commercial Year 3 (i.e., Launch + 25-36 months), Commercial Year 4 (i.e., Launch + 37-48 months) and Commercial Year 5 (i.e., Launch + 49-60 months).  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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1.21 “Confidential Information” means any and all information or material that, at any time before, on or after the Effective Date, has been or is provided or communicated to a Party by or on behalf of the other Party pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto (including any Confidential Information provided pursuant to the Original Agreement (as defined in the Development Agreement) or that certain Mutual Confidentiality Agreement dated October 10, 2014 by and between Edge and Oakwood), including any data, ideas, concepts or techniques contained therein. Confidential Information may be disclosed orally, visually, in writing, by delivery of materials containing Confidential Information or in any other form now known or hereafter invented. For purposes of this Agreement, notwithstanding the Party that disclosed such information or material, the Product Specifications, the Edge Materials Specifications, the Manufacturing Process for the Product, the Edge Project IP and any other information or materials relating exclusively or primarily to the Product or the Manufacturing thereof, including Batch records (collectively, “Product Confidential Information”), shall be Confidential Information of Edge, and Edge shall be deemed to be the Disclosing Party, and Oakwood shall be deemed to be the Receiving Party, with respect thereto and Oakwood Background IP (as defined in the Development Agreement) shall be the Confidential Information of Oakwood, and Oakwood shall be deemed to be the Disclosing Party, and Edge shall be deemed to be the Receiving Party, with respect thereto.  
  
1.22 “Destruction Notice” has the meaning set forth in Section 4.3.  
  
1.23 “Development Agreement” has the meaning set forth in the preamble hereto.  
  
1.24 “Disclosing Party” means, subject to the last sentence of the definition of Confidential Information, the Party disclosing Confidential Information.  
  
1.25 “Dollars” or “$” means United States Dollars.  
  
1.26 “Edge” has the meaning set forth in the preamble hereto.  
  
1.27 “Edge Indemnitees” has the meaning set forth in Section 9.1.  
  
1.28 “Edge Materials” means (a) the API and (b) the Polymer.  
  
1.29 “Edge Materials Specifications” means (a) the API Specifications and (b) the Polymer Specifications.  
  
1.30 “Effective Date” has the meaning set forth in the preamble hereto.  
  
1.31 “Excess Product” has the meaning set forth in Section 3.2.  
  
1.32 “Excess Replacement Cost” has the meaning set forth in Section 3.5(b)(i).  
  
1.33 “Excluded Lists” means the United States Department of Health and Human Service’s List of Excluded Individuals/Entities and the United States General Services Administration’s Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs, and any analogous lists pursuant to Applicable Law outside the United States.  
  
1.34 “Expected Commercially Usable Units per Batch” has the meaning set forth in Section 2.3(g).  
  
1.35 “Expert” has the meaning set forth in Section 10.3(b).  
 1.36 “Exploit” or “Exploitation” means to make, have made, import, use, sell, offer for sale or otherwise dispose of the Product, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, export, transport, distribution, promotion or marketing of the Product.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
 4  
1.37 “Facility” means the Manufacturing facility of Oakwood located at 27070 Miles Road, Solon, Ohio, or such other Manufacturing facility as is designated by Oakwood and agreed to in writing by an executive officer of Edge.  
  
1.38 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
  
1.39 “FFDCA” means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et. seq., as it may be amended from time to time, and the rules, regulations, guidances, guidelines, and requirements promulgated or issued thereunder.  
  
1.40 “Force Majeure Event” has the meaning set forth in Section 10.2.  
  
1.41 “Forecast” has the meaning set forth in Section 3.1.  
  
1.42 “GAAP” means United States generally accepted accounting principles consistently applied.  
  
1.43 “Indemnification Claim Notice” has the meaning set forth in Section 9.3(a).  
  
1.44 “Indemnified Party” has the meaning set forth in Section 9.3(a).  
  
1.45 “Indemnifying Party” has the meaning set forth in Section 9.3(a).  
  
1.46 “Initial Forecast” has the meaning set forth in Section 3.1.  
  
1.47 “Launch” means the date of the first commercial sale of the Product by or on behalf of Edge for monetary value to a Third Party in a country after Regulatory Approval of the Product in such country. Sales prior to receipt of Regulatory Approval for the Product in such country, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” shall not be construed as Launch in such country.  
  
1.48 “Losses” has the meaning set forth in Section 9.1.  
  
1.49 “Manufacture” or “Manufacturing” means the manufacturing, processing, formulation, bulk packaging, bulk labeling, holding and quality control, stability and other manufacturing-related testing of the Product.  
  
1.50 “Manufacturing Process for the Product” means the specific process for Manufacture of the Product (as distinct from the manufacture of other products or compounds), including any portions of such process developed under the Original Agreement (as defined in the Development Agreement), and as such process may be amended pursuant to the Development Agreement or this Agreement, or otherwise with the written agreement of both Parties.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
 5  
1.51 “Maximum Supply Obligation” means, with respect to any period, the number of Batches set forth in the column titled “Maximum Supply Obligation for applicable period” on Schedule 1.51 for such period.  
  
1.52 “Minimum Order Catch-Up Price” has the meaning set forth on Schedule 1.52.  
  
1.53 “Minimum Order Commitment” means, with respect to a Commercial Year during the Commitment Period, the greater of (a) five (5) Batches (the “Batch Minimum Order Commitment”) and (b) fifty percent (50%) of the aggregate Units purchased by Edge from Oakwood and any Third Party in such Commercial Year (the “Percentage Minimum Order Commitment”).  
  
1.54 “Oakwood” has the meaning set forth in the preamble hereto.  
  
1.55 “Oakwood Indemnitees” has the meaning set forth in Section 9.2.  
  
1.56 “Oakwood Materials” means all ingredients, materials, packaging and labeling components, and all other supplies of any kind used in connection with Manufacturing the Product, other than the Edge Materials.  
  
1.57 “On-Site Edge Representative” has the meaning set forth in Section 2.2(b).  
  
1.58 “Owed Party” has the meaning set forth in Section 5.4.  
  
1.59 “Owing Party” has the meaning set forth in Section 5.4.  
  
1.60 “Party” and “Parties” has the meaning set forth in the preamble hereto.  
  
1.61 “Percentage Minimum Order Commitment” has the meaning set forth in the definition of Minimum Order Commitment.  
  
1.62 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.  
  
1.63 “Polymer” means a [\*\*].  
  
1.64 “Polymer Specifications” means the specifications for the Polymer as provided by Edge to Oakwood in writing, as the same may be amended from time to time in accordance with the Quality Agreement.  
  
1.65 “Product” means the pharmaceutical product that Edge refers to as EG-1962 as of the Effective Date.  
 1.66 “Product Confidential Information” has the meaning set forth in the definition of “Confidential Information”.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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1.67 “Product Specifications” means the specifications for the Product to be provided to Oakwood by Edge following optimization of the Manufacturing Process for the Product, as such Product Specifications may be amended from time to time in accordance with the terms of the Quality Agreement.  
  
1.68 “Product Warranty” has the meaning set forth in Section 3.4.  
  
1.69 “Project Manager” has the meaning set forth in Section 2.2(a).  
  
1.70 “Purchase Order” has the meaning set forth in Section 3.2.  
  
1.71 “Purchase Price” has the meaning set forth in Section 5.2.  
  
1.72 “Purchase Price per Unit” means the Batch Price divided by the then current Expected Commercially Usable Units per Batch.  
  
1.73 “Quality Agreement” has the meaning set forth in Section 3.6(a).  
  
1.74 “Quantity Dispensed” means, with respect to the API during a particular period, (a) the total quantity of API that complies with the API Specifications supplied by Edge to Oakwood during such period, plus (b) the inventory of API that complies with the API Specifications held at the Facility at the beginning of such period, less (c) the inventory of API that complies with the API Specifications held at the Facility at the end of such period; provided, that the Quantity Dispensed shall not include any: (i) API that must be retained by Oakwood as samples; (ii) API used in testing or pursuant to any Project Plan (as defined in the Development Agreement), other than any validation batches covered thereby that become commercially salable; or (iii) API received or dispensed in Manufacturing Process Transfer (as defined in the Development Agreement) activities during the applicable period, including any engineering, regulatory, stability or test batches Manufactured in connection therewith, other than any validation batches that become commercially salable, in each case ((i)-(iii)) during such period. For clarity, the Quantity Dispensed will include API that (x) expire due to Oakwood’s failure to manage inventory levels of API or a breach of Oakwood’s supply obligations hereunder, (y) are destroyed, spoiled or lost due to damage, theft or deterioration while in Oakwood’s possession or due to Manufacturing failures, unless and to the extent Oakwood can demonstrate that any such Manufacturing failure is attributable to any action or omission of Edge or (z) become obsolete due to an amendment to the Product Specifications requested by Oakwood.  
  
1.75 “Recall” means a “recall,” “market withdrawal” or “stock recovery” of a product as such terms are defined under Applicable Law.  
  
1.76 “Receiving Party” means, subject to the last sentence of the definition of Confidential Information, the Party receiving Confidential Information.  
  
1.77 “Recipients” has the meaning set forth in Section 7.1.  
  
1.78 “Regulatory Approval” means any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation of the Product in a country.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
 7  
1.79 “Regulatory Authority” means the FDA and any other applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Product or the Manufacture of the Product anywhere in the world.  
  
1.80 “Reimbursement Invoice” has the meaning set forth in Section 5.4.  
  
1.81 “Rejection Date” has the meaning set forth in Section 3.6(c).  
  
1.82 “Replacement Cost” means, with respect to each type of Edge Materials, Edge’s actual, fully burdened cost to obtain such quantity of such Edge Material, including transportation costs, taxes and testing and release costs with respect to such quantity of such Edge Material.  
  
1.83 “Senior Executives” means (a) with respect to Edge, its Chief Operating Officer, and (b) with respect to Oakwood, its Chief Financial Officer.  
  
1.84 “Shortfall” has the meaning set forth in Section 2.3(e).  
  
1.85 “Supply Security Plan” has the meaning set forth in Section 3.5(c).  
  
1.86 “Target Yield” has the meaning set forth in Section 2.3(d).  
  
1.87 “Technical Dispute” has the meaning set forth in Section 10.3(b).  
  
1.88 “Term” has the meaning set forth in Section 8.1.  
  
1.89 “Third Party” means any Person other than Oakwood, Edge or their respective Affiliates.  
  
1.90 “Third Party Claim” has the meaning set forth in Section 9.1.  
  
1.91 “Unit” means one (1) vial of the Product.  
 1.92 “Waste” means all refuse, garbage, or rejected, discarded or waste materials, whether or not hazardous or radioactive, resulting from or related to performance of any Project Plan (as defined in the Development Agreement) or the Manufacturing activities performed by Oakwood hereunder, including excess or unused Product, Edge Materials and Oakwood Materials, air emissions, wastewater effluents, waste materials resulting from any release, spill, emission, leaking, pumping, deposit, disposal, discharge, dispersal, injection, leaching or migration of any Product, Edge Materials, Oakwood Materials or other materials or from any response thereto or other remedial or corrective action, and protective clothing.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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ARTICLE II.  
  
RELATIONSHIP OVERVIEW  
  
Section 2.1 Supply Obligations.  
  
(a) Subject to the terms and conditions hereof, Oakwood shall Manufacture and supply to Edge, and Edge shall purchase from Oakwood, such quantities of the Product as are set forth on Edge’s Purchase Orders therefor in accordance with the terms hereof from time to time during the Term; provided, that, (i) if as of the end of any Commercial Year during the Commitment Period, Edge does not order at least the Minimum Order Commitment for such Commercial Year from Oakwood hereunder, subject to Section 3.2 of this Agreement and Section 10.7(c) of the Development Agreement, Edge shall pay to Oakwood within [\*\*] following the end of such Commercial Year the applicable Minimum Order Catch-Up Price and (ii) subject to Section 3.2, notwithstanding anything to the contrary contained in this Agreement, the Development Agreement or the Quality Agreement, Oakwood shall have no obligation to Manufacture or supply to Edge more than the Maximum Supply Obligation for any applicable period. Schedule 1.52 sets forth certain examples illustrating the calculation of the Minimum Order Catch-Up Price, which examples are for illustrative purposes only.  
  
(b) Except as set forth in Schedule 2.1(b), which represents a list of Oakwood subcontractors pre-approved by Edge, Oakwood shall not utilize a Third Party to perform any activities with respect to the Product without first obtaining Edge’s written consent, which consent shall not be unreasonably withheld, conditioned or delayed. No such permitted subcontracting shall relieve Oakwood of any obligation hereunder (except to the extent satisfactorily performed by such subcontractor) or any liability hereunder and the agreement pursuant to which Oakwood engages any permitted Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property and all other relevant provisions of this Agreement and (iii) contain terms obligating such subcontractor to permit Edge rights of inspection, access and audit substantially similar to those provided to Edge in this Agreement. Oakwood hereby unconditionally guarantees the performance of its Affiliates and permitted Third Party subcontractors.  
  
Section 2.2 Personnel.  
  
(a) Each Party shall designate an individual to serve as the main point of contact for such Party to exchange information, facilitate communication and coordinate the Parties’ activities under this Agreement (each such individual, a “Project Manager”). Each Party may change its designated Project Manager from time to time upon written or electronic notice to the other Party.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(b) During the Term, upon reasonable prior written notice, during Oakwood’s regular business hours or at such other times as Oakwood is Manufacturing the Product, and in a manner that does not unreasonably disrupt Oakwood’s business or the Manufacture of Product, Oakwood shall allow Edge to place in the Facility, on an on-going basis at no additional cost (other than any internal costs and expenses of Edge with respect to the hiring, employment, compensation or reimbursement of the On-Site Edge Representatives), up to three (3) employees, representatives or contractors of Edge or its Affiliates, including, if elected by Edge, representatives from Edge’s supply chain, quality, technical or development groups, as Edge reasonably deems appropriate from time to time (each, an “On-Site Edge Representative”) for the purpose of observing, and providing input regarding the conduct of, the Project Plans (as defined in the Development Agreement) and observing, reporting on and consulting with respect to Manufacture of the Product. Oakwood shall provide reasonable access to Manufacturing Batch records and other documentation as deemed necessary by Edge in connection with the foregoing. Oakwood shall provide each On-Site Edge Representative with reasonable working space at the Facility free of charge and in a location within the Facility that is appropriate in light of the responsibilities of the On-Site Edge Representative. Edge shall cause each On-Site Edge Representative to comply with all of Oakwood’s internal policies applicable to visitors at the Facility that are provided by Oakwood to Edge in advance in writing.  
  
Section 2.3 Edge Materials; Yield; Expected Commercially Usable Units Per Batch.  
  
(a) Edge, at its sole cost and expense, shall provide and deliver (or cause to be provided and delivered) to the Facility from time to time quantities of Edge Materials as reasonably requested by Oakwood in order to maintain appropriate inventory levels of the Edge Materials as necessary to comply with Oakwood’s obligations hereunder; provided, that Edge shall have no obligation to replace any Edge Materials that are lost, spoiled or are destroyed while in Oakwood’s possession or control as a result of Oakwood’s acts or omissions. Each request by Oakwood for Edge Materials shall be made sufficiently in advance of the date on which Oakwood anticipates using any such Edge Materials, such that Edge has a reasonable period of time to provide and deliver (or to cause to be provided and delivered) such Edge Materials prior to such usage date, and Oakwood shall maintain sufficient inventory to accommodate a reasonable period for fulfillment by Edge (or its suppliers) of such request for Edge Materials. In addition, Edge may deliver (or cause to be delivered), an additional amount of Edge Materials as reasonably determined by Edge to be held by Oakwood as safety stock therefor. All shipments of Edge Materials shall be accompanied by certificate(s) of analysis from the Edge Materials manufacturer confirming the identity of the Edge Materials and their compliance with the applicable Edge Material Specifications and this Agreement. Oakwood, at its expense, shall perform all testing and other requirements required under this Agreement for such Edge Materials, including identification testing and quality release of the Edge Materials. If any Edge Materials do not conform with the applicable Edge Material Specifications with respect thereto, then Oakwood shall not use such Edge Materials in the Manufacture of Product hereunder and shall timely notify Edge of such nonconforming Edge Materials, whereupon Edge shall replace such Edge Materials with substitute Edge Materials that conform to the applicable Edge Material Specifications. Oakwood shall not be held liable for failure to deliver any quantity of Product hereunder to the extent that such failure is due to Edge failing to supply Oakwood with Edge Materials as required under this Agreement. Oakwood shall separate any such nonconforming Edge Materials and place them in quarantine. Oakwood shall dispose of any nonconforming shipment of Edge Materials in accordance with Edge’s reasonable written instructions. Edge shall notify Oakwood promptly if it expects a shortage of Edge Materials and the Parties promptly shall meet to discuss how to address such situation; provided, that, in all events, Edge shall retain responsibility for the supply of all Edge Materials to Oakwood hereunder.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(b) Oakwood shall use the Edge Materials solely for Manufacturing the Product for Edge and performing its other obligations under and in accordance with the terms of this Agreement and for no other purposes. Oakwood at all times shall store all Edge Materials exclusively at the Facility in a physically secure area in a manner that prevents, to the extent reasonably possible, degradation or contamination and in accordance with the storage instructions therefor provided by Edge or the Third Party supplier of the Edge Materials and Applicable Law. Oakwood shall use commercially reasonable efforts to protect the Edge Materials in Oakwood’s possession or under its control following delivery thereof to Oakwood by Edge or its designee from damage, contamination, adulteration and theft. Oakwood shall store all Edge Materials by lot number and all Edge Materials shall be clearly marked as being the property of Edge and shall be segregated from other goods and materials stored in the Facility. Oakwood shall use all Edge Materials on a first-expired, first-out basis, and Oakwood shall not use any Edge Materials after the applicable retest date for such Edge Materials.  
 (c) Oakwood shall use its commercially reasonable efforts to minimize waste and losses of the Edge Materials. Within five (5) Business Days after the end of each Calendar Quarter of the Term, Oakwood shall provide Edge with a Calendar Quarterly inventory report of each type of Edge Materials held by and used by Oakwood using an inventory reporting form reasonably acceptable to Edge, which form shall contain, at a minimum, the following information for the preceding Calendar Quarter: (i) the total quantity of such type of Edge Materials received by Oakwood during the applicable period that complies with the applicable Edge Materials Specifications when received by Oakwood, (ii) the total quantity of such type of Edge Materials received by Oakwood during the applicable period that does not comply with the applicable Edge Materials Specifications when received and the disposition of such Edge Materials, (iii) the total quantity of such type of Edge Materials held by Oakwood that ceased to comply with the applicable Edge Material Specifications after receipt, the reasons for such noncompliance and the disposition of such Edge Materials, (iv) the total Quantity Dispensed of such type of Edge Materials during the applicable period (including the calculation therefor), and (v) the total amount of such type of Edge Materials contained in Product Manufactured and actually delivered by Oakwood to Edge during the applicable period (excluding the total amount of such type of Edge Materials contained in any Product that is rejected, recalled or returned in accordance with this Agreement during the applicable period).  
 (d) The initial target yield for conversion of API into Product (the “Target Yield”) shall be equal to [\*\*]. The Target Yield for API shall be reviewed by the Project Managers (i) following completion of the Project Plan attached as Exhibit A-7 to the Development Agreement and (ii) upon the request of either Party to reflect actual Manufacturing experience, and the Parties shall discuss in good faith whether the Target Yield for API should be adjusted to reflect such actual Manufacturing experience. If the Parties are unable to agree as to the initial Target Yield or whether the Target Yield for API should be adjusted, either Party may submit such dispute for resolution in accordance with Section 10.3; provided, that, if such dispute is with respect to whether the initial Target Yield for API should be adjusted, Oakwood shall not be obligated to achieve any proposed adjusted Target Yield for any API unless and until such dispute is fully and finally resolved.  
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(e) Within thirty (30) days after the end of each Calendar Year, Oakwood shall prepare an annual reconciliation report with respect to the API in a form reasonably acceptable to Edge, including the calculation of the Actual Yield for the API for such Calendar Year. If the Actual Yield for the API is less than the applicable Target Yield for the API for such Calendar Year (a “Shortfall”), and such Shortfall is caused by the actions or omissions of Oakwood, and not caused by Edge, its Affiliates, or its or their respective employees, agents, or contractors, then Oakwood will credit Edge’s account for the Replacement Cost of the API comprising such Shortfall. With respect to Product that is lost, expires, is destroyed or becomes obsolete or spoiled as a result of the actions or omissions of Oakwood and while in Oakwood’s possession or control, and not a result of the actions or omissions of Edge, its Affiliates, or its or their respective employees, agents, or contractors, Oakwood will credit Edge’s account for the Replacement Cost of the Edge Materials incorporated into such Product, except to the extent such Product became obsolete due to an amendment to the Product Specifications requested by Edge or is otherwise not the result of the actions or omission of Oakwood. Any credit provided under this Section 2.3(e) shall be summarized on the reconciliation report provided to Edge under this Section 2.3(e).  
 (f) Edge shall have the right once per Calendar Year (and more frequently if Edge reasonably believes that Oakwood has breached or is reasonably likely to breach any of its obligations under this Agreement) to conduct a physical inventory of Edge Materials and Product held at the Facility during normal business hours with at least five (5) Business Days’ advance notice, during Oakwood’s regular business hours, in a manner that does not unreasonably disrupt Oakwood’s business, and at Edge’s sole cost and expense, and Oakwood shall be entitled to have an Oakwood representative attend and supervise any such audit.  
 (g) The initial per-Batch yield (expressed as Units) shall be equal to [\*\*] (the “Expected Commercially Usable Units per Batch”). For example, if [\*\*]. The Expected Commercially Usable Units per Batch shall be reviewed by the Project Managers upon the request of either Party in the event that the actual Commercially Usable Units produced with respect to each of any three (3) consecutive Batches Manufactured by Oakwood is [\*\*] or [\*\*] of the then-current Expected Commercially Usable Units per Batch, in which case the Expected Commercially Usable Units per Batch shall be adjusted to equal [\*\*]. Oakwood shall use commercially reasonable efforts to maximize the number of Commercially Usable Units produced with respect to each Batch Manufactured hereunder.  
  
Section 2.4 Oakwood Materials and Equipment.  
 (a) Except as otherwise agreed in writing by the Parties, Oakwood, at its sole cost and expense, shall obtain all Oakwood Materials necessary to Manufacture the Product in accordance with the terms hereof from such Third Party suppliers as Edge shall have approved in writing from time to time; provided, that such approval shall not be unreasonably withheld, conditioned or delayed. Oakwood shall maintain appropriate inventory levels of Oakwood Materials at the Facility as necessary to comply with its obligations hereunder. Oakwood shall promptly notify Edge of any supply shortage of any Oakwood Material or any quality issues with respect to any Oakwood Material, and the Parties promptly shall consult in good faith to resolve any such issue. [\*\*].  
 (b) Oakwood, at its sole cost and expense, shall obtain and maintain all equipment necessary to Manufacture the Product in accordance with the terms hereof, including such equipment as may be set forth in any Project Plan (as defined in the Development Agreement)  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(c) The Parties agree that any Oakwood Materials or equipment obtained by Oakwood shipped to the United States from a foreign jurisdiction in conjunction with Oakwood’s performance of its obligations under this Agreement will be imported by Oakwood and delivered to the Facility. Unless otherwise directed by Edge, Oakwood shall be the “importer of record” and shall comply in all material respects with its obligations as defined in 19 U.S.C. § 1484, including, to the extent applicable: (i) payment of all import related fees or expenses, customs duties and fees, and fees for custom house brokerage; (ii) arrangement of all logistics for importation, including selection of customhouse brokers, carriers and freight forwarders; (iii) obtaining and filing all necessary import documentation, authorizations, and declarations; and (iv) compliance with all Applicable Laws related to the exportation of such Oakwood Materials or equipment from the country(ies) of origin.  
  
Section 2.5 Title to Materials.  
 (a) All right, title and interest in and to all Edge Materials at the Facility or otherwise in the possession of Oakwood shall at all times remain the sole property of Edge. All right, title and interest in and to all Oakwood Materials at the Facility or otherwise in the possession of Oakwood or any Third Party shall at all times remain the sole property of Oakwood except for specific items of Oakwood Materials that are incorporated into specific Units of Product during Manufacturing, at which time those specific items of Oakwood Material incorporated into Product shall become the property of Edge as part of the specific Units of Product in which they are incorporated for the purpose of permitting Edge to exercise its rights in and to such Product.  
 (b) All right, title and interest in and to the specific Units of Product and work in process at the Facility incorporating Edge Materials or otherwise in the possession or control of Oakwood shall be the sole property of Edge or its Affiliates. At no time and under no circumstance shall Oakwood have title to, or any right or interest in or to, any Edge Materials, or such Product or work in process at the Facility or otherwise in Oakwood’s possession or control; provided, that if any such Edge Materials, Product, work in process or other materials are rejected, discarded, spilled, released or otherwise become Waste for any reason, then Oakwood shall, at its sole cost and expense, handle and dispose of all Waste as required by Applicable Law. Oakwood hereby expressly waives and releases any and all liens and claims in respect of any Edge Materials, or such Product, or work in process arising under any statute, common law or otherwise. Oakwood shall, at Edge’s request, promptly execute such forms, documents and instruments evidencing Edge’s ownership of the Edge Materials, and such Product and work in process as Edge reasonably shall request, including financing statements under the Uniform Commercial Code and bailment agreements in a form acceptable to Edge and its lenders. Neither Party shall take any action that is inconsistent with the right, title and interest of the other Party in and to the Edge Materials, Oakwood Materials, Product or work in process and any attempt by a Party to sell, or to grant or create a lien on or security interest in, any Edge Materials, Oakwood Materials, Product or work in process shall be void ab initio.  
  
Section 2.6 Packaging. Oakwood shall package the Product as set out in the Product Specifications. Edge shall specify the information to be included on the bulk labels and bulk packaging of the Product in the applicable Purchase Order or in a manner otherwise agreed by the Parties. Oakwood shall determine and imprint the batch numbers and expiration dates for the Product shipped as outlined in the Product Specifications and as required by Applicable Law. Any decisions regarding changes to the packaging or labeling for the Product shall be made by Edge in its sole discretion and at its sole cost and expense; provided, however, that Oakwood shall bear the cost associated with any changes to the packaging or labeling for the Product requested by Oakwood and approved by Edge (other than any change required by Applicable Law, the cost of which shall be borne by Edge). Edge shall notify Oakwood sufficiently in advance of all changes to the bulk packaging and bulk labeling for the Product to permit Oakwood to satisfy its obligations hereunder. Edge shall be responsible for communicating with the Regulatory Authorities regarding packaging and labeling matters in respect of the Product. Except to the extent arising from Oakwood’s acts or omissions (including the failure by Oakwood to implement any changes to the packaging or labeling for the Product in accordance with Edge’s instructions, other than changes that are in violation of Applicable Law), Edge shall be solely responsible for any and all defects or deficiencies in, or the failure to comply with Applicable Laws, with respect to Product labeling and packaging.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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ARTICLE III.  
  
SUPPLY  
  
Section 3.1 Forecasts. On or before the date on which a New Drug Application (as defined in the FFDCA) for the Product is accepted for filing by the FDA, Edge shall provide to Oakwood an initial [\*\*] Calendar Quarter nonbinding forecast for the period commencing on the date such Forecast is provided and ending [\*\*] thereafter (the “Initial Forecast”). Thereafter, Edge shall provide Oakwood with written rolling [\*\*] Calendar Quarter nonbinding forecasts of the Product (each, including the Initial Forecast, a “Forecast”) by the fifth (5th) Business Day of the last month of each Calendar Quarter that sets forth the amount of Product that Edge expects to order from Oakwood for each Calendar Quarter during the [\*\*] period that begins with the immediately following Calendar Quarter (e.g., the Forecast provided by Edge by March 5, 2021 would cover April 2021 through [\*\*]). All Forecasts provided hereunder shall be nonbinding estimates of future Product orders.  
  
Section 3.2 Form of Orders. Edge shall order Product to be delivered in any Calendar Quarter pursuant to written purchase orders (each, a “Purchase Order”) that specify the quantity of Product (expressed as both a number of Batches and a total number of Units based on the Expected Commercially Usable Units per Batch), delivery location and delivery dates in accordance with the terms of this Agreement; provided, that the delivery date specified for any quantity of Product in any Purchase Order shall be at least [\*\*] after the date of the applicable Purchase Order. Oakwood shall accept and fulfill such Purchase Orders from Edge with respect to quantities of Product subject to the foregoing sentence and the Maximum Supply Obligation and shall use commercially reasonable efforts to accept and fulfill, but shall not be liable, if despite such use of commercially reasonable efforts, Oakwood cannot accept and fulfill Purchase Orders with respect to quantities of Product in excess of the Maximum Supply Obligation (“Excess Product”), in each case subject to the terms and conditions of this Agreement. Oakwood shall promptly notify Edge in writing of its acceptance or rejection of Purchase Orders to the extent of any Excess Product. Any Purchase Order shall be deemed accepted by Oakwood to the extent the quantity of Product ordered does not exceed the Maximum Supply Obligation. Any Purchase Order stating a quantity of Product ordered in excess of the Maximum Supply Obligation shall be deemed rejected by Oakwood unless Oakwood delivers to Edge written notice of acceptance of such Purchase Order within seven (7) days of Oakwood’s receipt thereof (such accepted excess, “Accepted Excess Product”). For clarity, (a) any Accepted Excess Product shall be deemed to have been ordered by Edge hereunder for purposes of determining whether Edge has ordered the Minimum Order Commitment for the applicable Commercial Year pursuant to Section 2.1(a) and (b) with respect to any portion of any Purchase Order for Excess Product rejected by Oakwood pursuant to the foregoing sentence, notwithstanding such rejection by Oakwood, such rejected portion shall be deemed to have been ordered by Edge hereunder solely for purposes of determining whether Edge has ordered the Percentage Minimum Order Commitment for the applicable Commercial Year pursuant to Section 2.1(a). ANY ADDITIONAL TERMS OR CONDITIONS OF ANY PURCHASE ORDER, ACKNOWLEDGMENT, OR SIMILAR STANDARDIZED FORM GIVEN OR RECEIVED BY A PARTY SHALL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY REJECTED. If Edge requests changes to any Purchase Order (as documented by a change order in a form reasonably acceptable to both Parties) after receipt thereof by Oakwood, Oakwood shall use commercially reasonable efforts to comply with such changes. If Oakwood is unable to comply with such changes notwithstanding its use of commercially reasonable efforts to do so, it shall not be liable for such inability.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 3.3 Delivery. Oakwood shall, on the required delivery date set forth in each Purchase Order, deliver the quantities of Product set forth in such Purchase Order FCA (as defined in Incoterms 2010) Oakwood’s Facility, whereupon Edge shall be solely responsible for the carriage of such Product to Edge’s destination set forth on the applicable Purchase Order including, all shipping costs and the costs of insurance. All quantities of Product shall be labeled in accordance with this Agreement and Applicable Law and packed for shipping in accordance with the Product Specifications and the packing instructions provided by Edge. Title to and risk of loss of Product shall pass to Edge at the time of delivery to Edge’s carrier at Oakwood’s Facility. Each delivery of Product shall be accompanied by a Certificate of Analysis and such other documents as may be required pursuant to the Quality Agreement or Applicable Law. Each quantity of Product shall be delivered to Edge no later than [\*\*] after the commencement of Manufacturing of such quantity of Product as set forth in the applicable Batch record for such quantity of Product; provided, that notwithstanding the first sentence of this Section 3.3, in each Commercial Year, Oakwood shall be permitted to deliver one (1) Batch that is subject to a Purchase Order prior to the delivery date therefor set forth in the applicable Purchase Order.  
  
Section 3.4 Product Warranty. Oakwood warrants that, at the time of delivery of any Product to Edge hereunder: (a) such Product shall conform with the Product Specifications and the Certificate of Analysis therefor provided pursuant to Section 3.3; (b) such Product shall have been Manufactured in conformance with cGMPs, all other Applicable Law, this Agreement, the Quality Agreement and the Manufacturing Process for the Product; (c) such Product shall not be adulterated or misbranded under the FFDCA or any foreign equivalent thereof under Applicable Law; (d) such Product will have been Manufactured in facilities that are in compliance with all Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities); and (e) such Product may be introduced into interstate commerce pursuant to the FFDCA or any foreign equivalent thereof under Applicable Law (collectively ((a)-(e)), the “Product Warranty”).  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 3.5 Failure or Inability to Supply Product.  
 (a) If Oakwood, at any time during the Term, has reason to believe that it will be unable to supply Edge with the full quantity of Product forecasted to be ordered or actually ordered by Edge in a timely manner and in conformity with the Product Warranty (whether by reason of a Force Majeure Event or otherwise), Oakwood promptly shall notify Edge thereof. Promptly thereafter, the Parties shall meet to discuss how Edge shall obtain such full quantity of conforming Product.  
 (b) Except as otherwise set forth in this Agreement, if Oakwood fails to deliver the full quantity of Product specified in a Purchase Order within [\*\*] after the required delivery date specified therein and in conformity with the Product Warranty, Edge, at its option, may:  
 (i) cancel the portion that Oakwood failed to fulfill under this Agreement, in which event Edge shall have no liability with respect to the portion of such Purchase Order so cancelled. With respect to any portion of a Purchase Order that Oakwood failed to fulfill and that was canceled by Edge hereunder, if Edge purchases such quantity from a Third Party, Oakwood shall be liable to Edge for all costs and expenses incurred in connection therewith that exceed the Purchase Price that Edge would have otherwise paid to Oakwood for such Product pursuant to this Agreement, for which Oakwood shall provide to Edge a credit against amounts due and payable by Edge to Oakwood under this Agreement, in an amount equal to the amount paid by Edge to a Third Party to cover such quantities not fulfilled by Oakwood in such Purchase Order that exceed the Purchase Price that Edge would have otherwise paid to Oakwood for such Product pursuant to this Agreement (the “Excess Replacement Cost”); provided that, [\*\*]. To the extent that such amount paid by Edge to a Third Party is greater than amounts then due and payable to Oakwood by Edge, Oakwood shall refund to Edge any such amount paid by Edge to a Third Party; or  
 (ii) accept late delivery of all or any portion of such Product specified in such Purchase Order, in which event the Purchase Price otherwise payable by Edge with respect to that portion of Product accepted late by Edge under such Purchase Order shall be reduced by [\*\*] per day for each day after the date that is [\*\*] after such required delivery date (i.e., commencing on the [\*\*] day after such required delivery date) and continuing until the date on which Oakwood has delivered to Edge one hundred percent (100%) of the quantity of Product required to be delivered under such Purchase Order.  
 (c) At all times during the Term, Oakwood shall maintain and implement a plan to prevent a shortfall of Product that is within Oakwood’s control, which shall include the reasonable use of duplicative systems and the availability of recovery or back-up systems (such plan, the “Supply Security Plan”). Promptly after the Effective Date (if not previously provided to Edge) and promptly after any modification or supplement to the Supply Security Plan, Oakwood shall provide to Edge a copy of its then-current Supply Security Plan. Edge shall have the right to discuss its comments on the Supply Security Plan with Oakwood, which comments Oakwood shall consider in good faith.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 3.6 Nonconforming Product.  
  
(a) Quality Agreement. As soon as practicable after the execution hereof, Edge and Oakwood will enter into a quality agreement with respect to the Product to be supplied to Edge by Oakwood hereunder (the “Quality Agreement”).  
 (b) Quality Assurance. All Product supplied by Oakwood shall conform to the Product Warranty. Prior to each delivery of Product, Oakwood shall perform all quality responsibilities necessary to ensure that the Product to be delivered conforms to the Product Warranty. Each delivery of Product shall be accompanied by a Certificate of Analysis and certificate of conformance (identifying the Product, the expiry date therefor and component lot numbers and describing all current requirements of the Product Specifications and results of tests performed certifying that the quantities of each Product delivered have been Manufactured, controlled and released according to the Product Specifications and cGMPs) and such additional documents as may be required under the Quality Agreement or reasonably requested by Edge from time to time. If after delivery of any Product to Edge, Oakwood discovers that any lot of such Product or any portion thereof is defective or otherwise does not conform to the Product Warranty, Oakwood shall promptly notify Edge in writing and shall provide replacement Product therefor as soon as reasonably practicable.  
 (c) Rejection. Edge shall have forty-five (45) days following its receipt of a delivery of Product (or thirty (30) days after discovery of any nonconformity that could not reasonably have been detected by a customary inspection on delivery) to reject in good faith such Product on the grounds that all or part of the delivery fails to conform to the Product Warranty (provided that Edge may reject such Product prior to the forty-fifth (45th) day of such forty-five (45)-day period or prior to the thirtieth (30th) day of such thirty (30)-day period, as applicable), which rejection shall be accomplished by (i) giving written notice to Oakwood specifying in detail the manner in which such Product fails to meet the foregoing requirements and (ii) returning such Product to Oakwood (the date of the latter of which, the “Rejection Date”).  
 (d) Resolution of Disputes. Oakwood shall respond in writing to Edge accepting or refusing a rejection notice from Edge within fifteen (15) days after the Rejection Date. If Oakwood does not agree with Edge’s determination that the Product fails to conform to the Product Warranty, then Edge and Oakwood shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, Edge and Oakwood shall discuss in good faith mutually acceptable testing procedures pursuant to which both Edge and Oakwood will re-test a sample of the disputed Product. Notwithstanding the foregoing, if Edge and Oakwood are unable to resolve such disagreement within thirty (30) days of the Rejection Date, then such disagreement shall be submitted to dispute resolution pursuant to Section 10.3.  
  
Section 3.7 Returns and Settlement of Claims. If the Expert or Oakwood confirms that any Product does not conform to the Product Warranty, except to the extent such Product’s failure to conform to the Product Warranty is due to (a) the failure of Edge Materials supplied by Edge to conform with the applicable Edge Materials Specifications and such nonconformity of such Edge Materials was not detected by Oakwood or (b) the acts or omissions of Edge, Oakwood, at Edge’s option, promptly shall (i) supply Edge with a conforming quantity of Product at Oakwood’s expense or (ii) reimburse Edge for the Purchase Price paid by Edge with respect to such nonconforming Product if already paid. In addition, Oakwood promptly shall reimburse Edge for all amounts paid by Edge to Oakwood with respect to the nonconforming Product and the Replacement Cost of Edge Materials incorporated into such nonconforming Product, and returns, destruction and, subject to Section 3.8, any Recall of the nonconforming Product, which costs Edge shall have the right to offset against any payments otherwise owed by Edge to Oakwood under this Agreement.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 3.8 Recalls. If Oakwood reasonably believes a Recall may be necessary with respect to any Product provided under this Agreement, Oakwood shall promptly notify Edge in writing. As between the Parties, Edge or its designee shall make all decisions regarding, and in all events shall have sole authority for, conducting any Recalls with respect to the Product. Oakwood shall provide reasonable assistance to Edge (or its designee), as reasonably requested, in conducting such Recall, including providing all pertinent records that may assist Edge in effecting such Recall. Edge shall bear the cost of all Recalls of Product and shall reimburse Oakwood for any reasonable, documented out-of-pocket expenses incurred by Oakwood (including reasonable attorneys’ fees) related to any such Recall, except to the extent a Recall results from (a) the gross negligence or willful misconduct of Oakwood; or (b) a breach by Oakwood of this Agreement (including a breach of any of the representations or warranties in Article VI or the Product Warranty), in either case ((a) or (b)), Oakwood shall reimburse Edge for its reasonable costs and expenses (including reasonable attorneys’ fees) incurred by or on behalf of Edge with respect to such Recall.  
  
ARTICLE IV.  
  
QUALITY/REGULATORY  
  
Section 4.1 Ownership of Regulatory Approvals. Edge shall own and control all Regulatory Approvals (including the CMC Data contained therein) with respect to the Product. Oakwood shall not file any drug master file for the Product with the FDA or other Regulatory Authority without the prior written consent of Edge, which Edge may withhold in its sole discretion.  
  
Section 4.2 Regulatory Cooperation of Oakwood. Oakwood shall cooperate with any reasonable requests by Edge for assistance with respect to obtaining and maintaining any and all Regulatory Approvals, including by:  
  
(a) making its employees, consultants and other staff reasonably available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning the Manufacture of the Product; and  
 (b) disclosing and making available to Edge, in whatever form Edge may reasonably request, all Manufacturing and quality control data, CMC Data and other information related to the Product as is reasonably necessary or useful to prepare, file, obtain or maintain any Regulatory Approval.  
  
Section 4.3 Manufacturing Records. Oakwood shall maintain, or cause to be maintained, complete and accurate records of its activities under this Agreement, including (a) all records necessary to comply with cGMPs and all other Applicable Law and (b) batch records, validation data, stability testing data and quality control data, in each case ((a) and (b)) for the greater of [\*\*] and such longer period as required by Applicable Law. Oakwood shall notify Edge at least sixty (60) days before the date on which Oakwood intends to destroy any such records (such notification, a “Destruction Notice”). Edge shall have the right to require that Oakwood deliver such records to Edge by so notifying Oakwood within sixty (60) days after receipt of the applicable Destruction Notice. Edge shall reimburse Oakwood for its reasonable and documented out-of-pocket shipping costs incurred pursuant to this Section 4.3 within forty-five (45) days after receipt of documentation reasonably acceptable to Edge with respect thereto.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 4.4 Compliance with Applicable Laws; Product Specifications. Oakwood and Edge each shall comply, and shall cause each Third Party that it utilizes in connection with this Agreement to comply with the Product Specifications, cGMPs and all other Applicable Law in carrying out its duties and obligations under this Agreement.  
  
ARTICLE V.  
  
PAYMENTS  
  
Section 5.1 Milestone Payments. As additional consideration for Oakwood’s performance of certain activities hereunder, and on the terms and subject to the conditions set forth herein, Edge shall pay to Oakwood a milestone payment within [\*\*] days after the achievement of each of the following milestones, as follows:  
  
(a) [\*\*] in accordance with the Project Plan attached as Exhibit A-7 to the Development Agreement, [\*\*] Dollars ($[\*\*])];  
 (b) after [\*\*], [\*\*] Dollars ($[\*\*])]; and  
 (c) after [\*\*], [[\*\*] Dollars ($[\*\*])].  
  
Each milestone payment in this Section 5.1 shall be payable only upon the first achievement of such milestone event and no amounts shall be due for subsequent or repeated achievements of such milestone event. For clarity, the maximum aggregate amount of milestones payable by Edge pursuant to this Section 5.1 is Two Million, Two Hundred Fifty Thousand Dollars ($2,250,000).  
  
Section 5.2 Purchase Price. The price payable by Edge (the “Purchase Price”) for each Commercially Usable Unit of Product shall be equal to the Purchase Price per Unit (as may be adjusted from time to time to take account of any adjustments to the Expected Commercially Usable Units per Batch in accordance with Section 2.3(g)). For example, [\*\*]. For clarity, the Purchase Price applicable to any quantity of Product ordered by Edge hereunder shall be the Purchase Price in effect as of the date that Edge places a Purchase Order for such quantity of Product.  
  
Section 5.3 Invoice, Payment and Taxes. Within three (3) days after the end of each month, Oakwood shall provide to Edge via e-mail to xxxxxxxx@xxxxxxxxxxxxxxxx.xxx nonbinding estimate of amounts incurred or paid by Oakwood in connection with this Agreement during such month. Within five (5) days after the end of each month, Oakwood shall invoice Edge via e-mail to xxxxxxxx@xxxxxxxxxxxxxxxx.xxx for all quantities of Product produced in accordance herewith. Payment with respect to delivered Product shall be due within thirty (30) days after receipt by Edge of the invoice with respect thereto; provided that if Edge rejects any Product pursuant to Section 3.6, then payment shall be due within thirty (30) days after receipt by Edge of a notice from the Expert that such Product conforms to the Product Warranty or receipt by Edge of replacement Product, as the case may be; provided, further, that if Edge in good faith disputes any portion of an invoice, it shall pay the undisputed portion and shall provide Oakwood with written notice of the disputed portion and its reasons therefor, and Edge shall not be obligated to pay such disputed portion unless and until such dispute is resolved in favor of Oakwood. The Parties shall use good faith efforts to resolve any such disputes promptly. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control. Payment of invoices shall be made by wire transfer to an account designated in writing by Oakwood in Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales (as defined in the Development Agreement) expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate’s or its or their licensee’s or sublicensee’s standard conversion methodology consistent with such Party’s accounting standards.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 5.4 Payment of Reimbursable Costs; Invoices. For all costs for which a Party (the “Owing Party”) is obligated to reimburse the other Party (the “Owed Party”) pursuant to this Agreement for which no specific provision is made hereunder for such payment, the Owed Party shall send to the Owing Party an invoice (in the case that Edge is the Owing Party, via e-mail to xxxxxxxx@xxxxxxxxxxxxxxxx.xxx) for such amount within forty-five (45) days of the Owed Party’s determination that such amount is payable by the Owing Party, which invoice shall include a reference to the section of this Agreement under which the Owed Party is requesting reimbursement or payment and be accompanied by reasonable documentation of the incurrence or accrual of the costs to be reimbursed (such invoice as described, a “Reimbursement Invoice”). Payment with respect to each Reimbursement Invoice shall be due within sixty (60) days after receipt by the Owing Party thereof; provided, however, that if the Owing Party in good faith disputes any portion of a Reimbursement Invoice, it shall pay the undisputed portion and shall provide the Owed Party with written notice of the disputed portion and its reasons therefor, and the Owing Party shall not be obligated to pay such disputed portion unless and until such dispute is resolved in favor of the Owed Party. The Parties shall use good faith efforts to resolve any such disputes promptly. In the event of any inconsistency between a Reimbursement Invoice and this Agreement, the terms of this Agreement shall control. Payment of Reimbursement Invoices shall be made by wire transfer to an account designated in writing by the Owed Party in Dollars.  
  
Section 5.5 Records and Audit Rights.  
  
(a) Each Owed Party shall keep and maintain complete and accurate books and records of its costs incurred with respect to any activities for which it is entitled to reimbursement or payment under this Agreement in sufficient detail to allow confirmation of the amounts owed under this Article V for at least five (5) Calendar Years after issuance of an invoice with respect thereto.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(b) At the request of the other Party, each Party shall permit an independent certified public accountant retained by the other Party, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 5.5(a). Except as provided in Section 5.5(c), the cost of any audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [\*\*] percent ([\*\*]%) from the invoiced amounts in favor of the audited Party, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 5.5(c), if such audit concludes that additional payments were owed or that excess payments were made during such period, the Party owing such additional payments shall pay such additional amounts, or the Party that received such excess payment shall reimburse such excess payments, as applicable, in either case, within thirty (30) days after the date on which such audit is completed and the conclusions thereof are notified to the Parties.  
  
(c) If either Party disputes the results of any audit conducted pursuant to Section 5.5(b), Edge and Oakwood shall work in good faith to resolve such dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for arbitration to a certified public accounting firm selected by each Party’s certified public accountants or to such other Person as the Parties shall mutually agree (the “Accountant”) or failing such agreement, as the Chairman of the International Chamber of Commerce (or such other body as the Parties may mutually agree), may nominate. The decision of the Accountant shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in a manner proportional to the Accountant’s determination of the Parties’ respective liability. If the Accountant determines that additional payments were owed by a Party or that excess payments were made by a Party for the applicable period, no later than thirty (30) days after such decision and in accordance with such decision, the Party owing such additional payments shall pay such additional amounts or the Party that received such excess payments shall reimburse such excess payments, as applicable. Any arbitration award against a Party may be entered in and enforced by any court having jurisdiction over such Party’s assets.  
  
Section 5.6 Costs and Expenses. Except as set forth in this Agreement, each Party shall bear its own costs and expenses with respect to this Agreement.  
  
ARTICLE VI.  
  
REPRESENTATIONS AND WARRANTIES  
  
Section 6.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as follows:  
 (a) Such Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or in equity.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(b) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.  
 (c) The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Law or any provision of the organizational documents of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party or any of its Affiliates is bound.  
  
Section 6.2 Additional Representations, Warranties and Covenants of Oakwood.  
 (a) Oakwood represents, warrants and covenants to Edge that (i) neither Oakwood nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States or listed on any Excluded List, and (ii) neither Oakwood nor any of its Affiliates will use in any capacity, in connection with the activities to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States, or who is the subject of a conviction described in such Section or analogous provisions of Applicable Law outside the United States, or listed on any Excluded List. Oakwood shall inform Edge in writing immediately if it or any Person who is performing activities hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States or listed on any Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Oakwood’s knowledge, is threatened, relating to the debarment or conviction Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States, or listing on any Excluded List, of Oakwood or any Person performing activities hereunder or under the Development Agreement.  
  
Section 6.3 Disclaimer of Other Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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ARTICLE VII.  
  
CONFIDENTIALITY  
  
Section 7.1 Confidential Information. Subject to the provisions of Section 7.2 and Section 7.3, at all times during the Term and thereafter the Receiving Party (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information of the Disclosing Party, except to those of the Receiving Party’s Affiliates and its or their respective directors, officers, employees, consultants, financial advisors, attorneys, accountants, agents or other representatives who have a need to know such information (collectively, “Recipients”) to perform such Party’s obligations or exercise such Party’s rights hereunder (and who shall be advised of the Receiving Party’s obligations hereunder and who are bound by confidentiality obligations with respect to such Confidential Information substantially similar those set forth in this Article VII) and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. Subject to Section 7.3(c), notwithstanding anything in this Agreement to the contrary, in no event shall (i) Oakwood use or disclose any Product Confidential Information or any of Edge’s other Confidential Information in connection with the Manufacture of the Product for itself or any of its Affiliates or any Third Party, or (ii) Edge use or disclose any of Oakwood’s Confidential Information for itself or any of its Affiliates or any Third Party. The Receiving Party shall be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement. Without limiting anything in this Article VII, neither Party shall disclose the terms of this Agreement without the prior written consent of the other Party, except as may be permitted by Section 7.3, and the terms of this Agreement shall be deemed the Confidential Information of each of the Parties. Each Party shall, and shall ensure that its Recipients: (x) not copy or otherwise duplicate any embodiments of the Confidential Information of the other Party, except as necessary for the Receiving Party’s Recipients to perform such Party’s obligations or exercise such Party’s rights under this Agreement (provided that any such copies or duplications of such Confidential Information shall be identified as belonging to the Disclosing Party and shall be marked “confidential,” “proprietary,” or the like); (y) at the request of the other Party, provide the other Party with a list of all Persons to whom any such Confidential Information has been disclosed; and (z) notify the other Party immediately, and cooperate with the other Party as the other Party Edge may reasonably request, upon any discovery of any loss or compromise of the other Party’s Confidential Information.  
  
Section 7.2 Exceptions to Confidentiality. The Receiving Party’s obligations set forth in this Article VII shall not extend to any Confidential Information of the Disclosing Party:  
  
(a) that is or hereafter becomes part of the public domain through no breach of this Agreement by the Receiving Party or its Recipients;  
 (b) that is received from a Third Party without restriction and without breach of any obligation of confidentiality between such Third Party and the Disclosing Party;  
 (c) that the Receiving Party can demonstrate by competent evidence was already in its possession without obligation of confidentiality to the Disclosing Party prior to its receipt from the Disclosing Party; provided, that the foregoing exception shall not apply to Product Confidential Information;  
 (d) that is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(e) that the Receiving Party can demonstrate by competent evidence was independently developed by or on behalf of the Receiving Party or its Affiliates; provided, that the foregoing exception shall not apply to Product Confidential Information.  
  
Section 7.3 Disclosure.  
 (a) The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is required to be made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction, is required by the rules of any stock exchange upon which the Receiving Party’s securities are listed or to which application for listing has been submitted or is otherwise required by law or regulation, in the opinion of counsel to the Receiving Party; provided, however, that the Receiving Party shall (to the extent permitted by Applicable Law) first have notified to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information of the Disclosing Party or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information of the Disclosing Party disclosed in response to such court or governmental order or as otherwise required by law or regulation shall be limited to that information that is legally required to be disclosed in such response to such court or governmental order or otherwise required by law or regulation.  
 (b) Edge may disclose Confidential Information of Oakwood to the extent that such disclosure is made to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval or the maintenance of any Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.  
 (c) (i) Either Party may disclose Confidential Information of the other Party to its Affiliates or its or their attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees or acquirers, or other Third Parties (A) as is necessary or useful in connection with the performance of such Party’s obligations or the exercise of such Party’s rights under this Agreement, or (B) as is necessary or useful to permit the evaluation by any such Person of any potential or actual merger, acquisition, asset sale, licensing, collaboration or similar transaction with such Party; provided, however, that, except in the cases of disclosure to Persons subject to professional duties of nondisclosure, such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use as are set forth in this Article VII; provided, further, that, in the case of clause (B), such Party shall limit such disclosure to only that Confidential Information of the other Party that is specifically applicable to the transaction being evaluated.  
 (ii) Edge may disclose Confidential Information of Oakwood to Edge’s Affiliates or its or their attorneys, auditors, advisors, consultants, contractors, existing collaboration partners, licensees or acquirers, or other Third Parties with which Edge has a contractual relationship with respect to the Manufacture of the Product to the extent necessary or useful in connection with the performance of any actual transaction with respect to the Product; provided, however, that, except in the cases of disclosure to Persons subject to professional duties of nondisclosure, such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use as are set forth in this Article VII; and provided, further, that Edge shall limit such disclosure to only that Confidential Information of Oakwood necessary or useful to enable such Person to Manufacture the Product and shall not, for clarity, disclose Confidential Information of Oakwood that is applicable solely to the Manufacture of products other than the Product.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(iii) Each Party shall be responsible for any violation of the confidentiality and non-use obligations applicable to the Confidential Information of the other Party by any Person to which such first Party discloses Confidential Information of the other Party.  
  
Section 7.4 Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party’s discovery of any loss or compromise of the Disclosing Party’s Confidential Information by the Receiving Party or any Person to whom it has disclosed such Confidential Information.  
  
Section 7.5 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 7.5 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law or requested by any Regulatory Authority or prevent Edge from identifying Oakwood as the Manufacturer of Product supplied hereunder.  
  
Section 7.6 Press Releases and Other Public Announcements. Except as expressly provided in Section 7.3, neither Party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other Party, except for any such press release or other public announcement that is required by Applicable Law or the rules of a stock exchange on which the securities of the Party making such press release or announcement are listed (or to which an application for listing has been submitted), in which case such Party shall provide the other Party with the proposed text of any such press release or public announcement for review and approval (which approval shall not be unreasonably withheld, conditioned or delayed) as early as possible, but in no event less than three (3) Business Days in advance of the publication, communication or dissemination thereof; provided, however, that such other Party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing Party in writing of any objections to such press release or public announcement within two (2) Business Days of receipt by such other Party of the text of such press release or public announcement.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 7.7 Return or Destruction of Confidential Information. Within ninety (90) days after the earliest of (a) the expiration of the Term, (b) the termination of this Agreement, and (c) the earlier written request of the Disclosing Party, the Receiving Party shall, at the Disclosing Party’s discretion, promptly destroy or return to the Disclosing Party all documentary, electronic or other tangible embodiments of the Confidential Information of the Disclosing Party to which the Receiving Party does not retain rights hereunder and any and all copies thereof, and destroy those portions of any documents that incorporate or are derived from the Confidential Information of the Disclosing Party to which the Receiving Party does not retain rights hereunder, and provide a written certification of such destruction, except that the Receiving Party may retain one (1) copy thereof, to the extent that the Receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this Agreement that may survive such expiration or termination, for archival purposes, in connection with any filing, application or request for Regulatory Approval or the maintenance of any Regulatory Approval or as otherwise required by Applicable Law; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information. Notwithstanding the foregoing, the Receiving Party also shall be permitted to retain such additional copies of, or any computer records or files containing, the Confidential Information of the Disclosing Party that have been created solely by the Receiving Party’s automatic electronic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party’s standard archiving and back-up procedures, but not for any other use or purpose.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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ARTICLE VIII.  
  
TERM AND TERMINATION  
  
Section 8.1 Term. The term of this Agreement (the “Term”) shall commence on the Effective Date and, unless terminated earlier in accordance with this Article VIII, continue in full force until the date that is three (3) years after Launch. Thereafter, this Agreement shall automatically renew for additional two (2)-year periods unless terminated sooner in accordance with this Agreement or unless Edge provides notice of non-renewal at least twelve (12) months prior to the end of the then-current Term. Upon termination of the Development Agreement for any reason, this Agreement shall automatically terminate and be of no further force or effect.  
  
Section 8.2 Breach. This Agreement may be terminated by either Party if the other Party materially breaches this Agreement and fails to remedy the material breach within [\*\*] after being given written notice thereof; provided, that subject to the last sentence of this Section 8.2, (a) if a breach cannot reasonably be remedied within such [\*\*] period, but the breaching Party establishes that it has commenced actions necessary to remedy such breach within such period and is employing ongoing, good-faith efforts to remedy such alleged breach, then such period shall be extended by a further period of [\*\*] to enable the breaching Party to complete the remedy thereof and (b) if either Party initiates a dispute resolution procedure under Section 10.3 as permitted under this Agreement before the end of such [\*\*] period to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, the cure period set forth in this Section 8.2 shall be tolled and the termination shall become effective only if such breach remains uncured for [\*\*] after the final resolution of the dispute through such dispute resolution procedure. Without limitation of the foregoing, this Agreement may be terminated by Edge upon written notice to Oakwood, which notice shall specify an effective date for such termination, if Oakwood fails two (2) or more times within any [\*\*] to deliver at least [\*\*] of the quantity of Product specified in a Purchase Order by the date that is [\*\*] after] the required delivery date specified therein and in conformity with the Product Warranty and such failure is not caused by the acts or omissions of Edge, its Affiliates, or its or their employees, agents or subcontractors.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 8.3 Convenience.  
  
(a) Either Party may terminate this Agreement upon two (2) years’ prior written notice to the other Party; provided that neither Party shall provide such notice prior to the first (1st) anniversary of Launch.  
 (b) In the case of such a termination, the Parties’ obligations, including Oakwood’s obligation to supply Product ordered by Edge and Edge’s obligation to purchase and pay for Product (to the extent actually delivered in accordance herewith) included in any Purchase Order issued prior to the effective date of such termination shall survive. With respect to any Product that Oakwood produces after a Party has provided notice of termination pursuant to this Section 8.3, (i) promptly after the receipt of such notice, Oakwood shall provide Edge an accounting of the quantities of Oakwood Materials for the Manufacture of the Product that Oakwood has in inventory, (ii) the Parties shall agree in good faith on the quantity of additional Oakwood Materials, if any, that Oakwood will need to purchase to fulfill its supply obligations under this Section 8.3 and (iii) if any such agreed additional Oakwood Materials that are of a quality suitable for use in the Manufacturing of the Product in accordance with the Quality Agreement are not used in Product supplied by Oakwood to Edge under this Section 8.3, then Oakwood shall promptly deliver such Oakwood Materials to Edge and Edge shall reimburse Oakwood for the costs of any such Oakwood Materials within thirty (30) days after receipt of an invoice with respect thereto.  
  
Section 8.4 Product Failure. Edge may terminate this Agreement immediately upon notice to Oakwood in the event that (a) any Regulatory Authority requires or causes the withdrawal of the Product or (b) Edge ceases to develop or commercialize the Product; provided, that in the case of a termination under clause (b) prior to completion of the Project Plan (as defined in the Development Agreement) attached to the Development Agreement as Exhibit A-7, Edge will pay to Oakwood the Termination Fee (as defined in the Development Agreement).  
 Section 8.5 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation, including the obligation to pay outstanding invoices and amounts accruing prior to such expiration or termination. Those provisions that by their terms or intent are required to survive the expiration or earlier termination of this Agreement in order to give effect to the intent of the Parties shall so survive. Without limiting the foregoing, Section 2.5, Section 3.4, Section 3.7, Section 3.8, Section 4.3, Sections 5.2-5.4 (for final accounting), Section 5.5 (for the period set forth therein), Section 6.3, Section 8.3(b), Section 8.4(b) (proviso only), this Section 8.5 and Section 9.4 (for the period specified therein), Section 9.5, and Article VII, Article IX and Article X will survive expiration or termination of this Agreement.  
 ARTICLE IX.  
  
INDEMNIFICATION  
  
Section 9.1 Oakwood Indemnification. Oakwood shall indemnify Edge, its Affiliates and its and their respective directors, officers, employees, consultants and agents (the “Edge Indemnitees”), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys’ fees and disbursements) (collectively, “Losses”) incurred by any of them in connection with any and all claims, actions, suits or proceedings brought by a Third Party (each, a “Third Party Claim”) arising from or occurring as a result of or in connection with (a) [\*\*], (b) the gross negligence, recklessness or willful misconduct of any Oakwood Indemnitee, (c) any infringement of any intellectual property rights of a Third Party by the Manufacture of the Product in accordance with any change to or deviation from the Manufacturing Process for the Product made by Oakwood and not approved in writing by Edge or to the extent arising from any Oakwood Background IP (as defined in the Development Agreement) (but for clarity, to the extent that Oakwood has not made any changes to the Manufacturing Process for the Product that have not been approved in writing by Edge, Oakwood will not be required to indemnify Edge with respect to infringement arising from the Manufacturing Process for the Product) or (d) the failure of Oakwood or any of the Oakwood Indemnitees to comply with Applicable Laws, except, in each case, for any such Losses for which Edge has an obligation to indemnify the Oakwood Indemnitees pursuant to Section 9.2, as to which Losses each Party shall indemnify the Edge Indemnitees or Oakwood Indemnitees, as applicable, for the applicable Losses to the extent of its responsibility, relative to the other Party, under this Article IX, for the facts underlying such Losses.  
  
Section 9.2 Edge Indemnification. Edge shall indemnify Oakwood, its Affiliates and its and their respective directors, officers, employees, consultants and agents (the “Oakwood Indemnitees”), and defend and hold each of them harmless, from and against any and all Losses incurred by any of them in connection with any and all Third Party Claims arising from or occurring as a result of (a) [\*\*], (b) the gross negligence, recklessness or willful misconduct of any Edge Indemnitee, (c) any infringement of any intellectual property rights of a Third Party by the Manufacture of the Product pursuant to the Manufacturing Process for the Product, except to the extent arising from Oakwood Background IP (as defined in the Development Agreement), any Oakwood Project IP or any change to or deviation from the Manufacturing Process for the Product made by Oakwood and not approved in writing by Edge, (d) the failure of Edge or any of the Edge Indemnitees to comply with Applicable Laws, or (e) the Exploitation of Product by or on behalf of Edge, except, in each case, for any such Losses for which Oakwood has an obligation to indemnify the Edge Indemnitees pursuant to Section 9.1, as to which Losses each Party shall indemnify the Edge Indemnitees or Oakwood Indemnitees, as applicable, for the applicable Losses to the extent of its responsibility, relative to the other Party, under this Article IX, for the facts underlying such Losses.  
  
Section 9.3 Indemnification Procedure.  
  
(a) Notice of Claim. All indemnification claims in respect of an Edge Indemnitee or a Oakwood Indemnitee shall be made solely by Edge or Oakwood, as applicable (each of Edge or Oakwood in such capacity, the “Indemnified Party”). The Indemnified Party shall give the Party from whom indemnity is being sought (the “Indemnifying Party”) prompt written notice (an “Indemnification Claim Notice”) of any claim of Loss or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 9.1 or Section 9.2, as applicable. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses; provided that the Indemnified Party shall not be required to disclose legally privileged information unless and until procedures reasonably acceptable to the Indemnified Party are in place to protect such privilege. A failure by the Indemnified Party to give an Indemnification Claim Notice as required by this Section 9.3(a) shall not limit the obligation of the Indemnifying Party under this Article IX, except to the extent such Indemnifying Party is actually prejudiced thereby.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(b) Procedures. The obligations of an Indemnifying Party under this Article IX shall be governed by and be contingent upon the following additional terms and conditions:  
 (i) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party’s receipt of an Indemnification Claim Notice with respect thereto; provided that the Indemnifying Party acknowledges in writing that the Losses resulting from such Third Party Claim are within the scope of indemnified Losses subject to Section 9.1, in the case of Oakwood as the Indemnifying Party, or Section 9.2, in the case of Edge as the Indemnifying Party; provided, further, that the Indemnifying Party shall not be entitled to (A) assume the defense, appeal or settlement of any Third Party Claim that (1) relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation; or (2) seeks any injunction or equitable relief against any Edge Indemnitee or Oakwood Indemnitee, as applicable; or (B) maintain control of the defense, appeal or settlement of any Third Party Claim if the Indemnifying Party has failed or is failing to defend in good faith the Third Party Claim. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party that is reasonably acceptable to the Indemnified Party. If the Indemnifying Party assumes the defense of a Third Party Claim, to the extent legally permissible the Indemnified Party shall promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Edge Indemnitee or Oakwood Indemnitee, as applicable, in connection with such Third Party Claim. Subject to Section 9.3(b)(ii), if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or Edge Indemnitee or Oakwood Indemnitee, as applicable, in connection with the analysis, defense or settlement of the Third Party Claim.  
  
(ii) Right to Participate in Defense. If, with respect to a Third Party Claim, the Indemnifying Party has assumed the defense and employed counsel in accordance with Section 9.3(b)(i), the Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose at its sole cost and expense; provided, however, that the Indemnifying Party shall pay the fees and expenses of such separate counsel (A) incurred by the Indemnified Party prior to the date the Indemnifying Party assumed control of the defense of such Third Party Claim, (B) if the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (C) (1) if the Indemnifying Party is not entitled to or does not assume or maintain control of the defense pursuant to Section 9.3(b)(i) or (2) if the interests of the Indemnified Party and Edge Indemnitee or Oakwood Indemnitee, as applicable, on the one hand, and the Indemnifying Party, on the other hand, with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles, in which case ((1) and (2)), the Indemnified Party shall have the right to control its own defense.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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(iii) Settlement. If the Indemnifying Party has assumed the defense of a Third Party Claim in accordance with Section 9.3(b)(i), with respect to any Losses relating solely to the payment of money damages in connection with such Third Party Claim that will not result in the Indemnified Party’s or any Edge Indemnitee’s or Oakwood Indemnitee’s, as applicable, becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party or any Edge Indemnitee or Oakwood Indemnitee, as applicable, in any manner, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with such Third Party Claim, the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Regardless of whether the Indemnifying Party chooses to defend any Third Party Claim, no Indemnified Party nor any Edge Indemnitee or Oakwood Indemnitee, as applicable, shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party or any Edge Indemnitee or Oakwood Indemnitee, as applicable, that is reached without the prior written consent of the Indemnifying Party.  
  
(iv) Cooperation. Each Party and each Edge Indemnitee or Oakwood Indemnitee, as applicable, shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to each Party to, and reasonable retention by the Edge Indemnitee or Oakwood Indemnitee, as applicable, of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder; provided, that neither Party nor any Edge Indemnitee or Oakwood Indemnitee, as applicable, shall be required to disclose legally privileged information unless and until procedures reasonably acceptable to such Party are in place to protect such privilege.  
  
(v) Expenses. Subject to the other provisions of this Section 9.3, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim for which indemnification is available shall be reimbursed on a monthly basis in arrears by the Indemnifying Party.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 9.4 Insurance. Each Party shall have and maintain, at its sole cost and expense, procure and maintain in full force during the entire Term and for [\*\*] thereafter the following types of insurance in the minimum amounts set forth below with insurance carriers having a rating A as to financial strength by the latest edition of A. M. Best & Co:  
  
[\*\*].  
  
Upon request by a Party following execution of this Agreement, the other Party shall furnish the requesting Party a copy of the certificate of insurance evidencing such coverages referred herein on an Accord form. No policy provided hereunder shall be cancelled nor materially changed without thirty (30) days’ written notice to the other Party.  
  
Section 9.5 Limitation on Damages. EXCEPT (A) IN THE EVENT OF (I) THE GROSS NEGLIGENCE, INTENTIONAL OR WILLFUL BREACH OR MISCONDUCT OR FRAUD OF A PARTY, OR (II) A PARTY’S BREACH OF ITS OBLIGATIONS UNDER ARTICLE VII, OR (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER SECTION 9.1 OR SECTION 9.2, AS APPLICABLE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES UNDER THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR (X) ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS OR LOST REVENUES, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR (Y) ANY LIABILITY, DAMAGE, LOSS OR EXPENSE UNDER THIS AGREEMENT IN EXCESS OF [\*\*].  
  
ARTICLE X.  
  
MISCELLANEOUS  
  
Section 10.1 Notices. All notices, requests and other communications hereunder must be in writing and delivered personally, by email transmission with answer back confirmation or by overnight courier, to the Parties at the following addresses or facsimile numbers:  
  
If to Edge to:  
  
Edge Therapeutics, Inc.  
000 Xxxxxxx Xxxxx, Xxxxx 0000  
Xxxxxxxx Xxxxxxx, Xxx Xxxxxx 00000  
Attention: Chief Executive Officer  
Email: xxxxxxxxxx@xxxxxxxxxxxxxxxx.xxx  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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With a copy to:  
  
Edge Therapeutics, Inc.  
000 Xxxxxxx Xxxxx, Xxxxx 0000  
Xxxxxxxx Xxxxxxx, Xxx Xxxxxx 00000  
Attention: General Counsel  
Email: xxxxxxxxxxxx@xxxxxxxxxxxxxxxx.xxx  
  
If to Oakwood to:  
  
Oakwood Laboratories, LLC  
0000 Xxxxx Xxxxx, Xxxxx X  
Xxxxxxx Xxxxxxx, Xxxx 00000  
Attention: Xxxxxxx X. Xxxx  
Email: xxxxx@xxxxxxxxxxx.xxx  
  
With a copy to:  
  
Benesch, Friedlander, Xxxxxx & Aronoff LLP  
000 Xxxxxx Xxxxxx, Xxxxx 0000  
Xxxxxxxxx, Xxxx 00000-0000  
Attention: Xxxxxxx X. Xxxxxxx  
Email: xxxxxxxx@xxxxxxxxxx.xxx  
  
All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section 10.1, be deemed given upon receipt, (b) if delivered by facsimile to the facsimile number as provided in this Section 10.1, be deemed given upon receipt by sender of the answer back confirmation and (c) if delivered by overnight courier to the address as provided in this Section 10.1, be deemed given one (1) Business Day after acceptance by the overnight courier service (in each case regardless of whether such notice, request or other communication is received by any other Person to whom a copy of such notice, request or other communication is to be delivered pursuant to this Section 10.1). Either Party from time to time may change its address, facsimile number or other information for the purpose of notices to that Party by giving notice as provided herein to the other Party specifying such change. This Section 10.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement (including as set forth in the last sentence of Section 2.2(a)).  
  
Section 10.2 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 10.2, where delivery or performance has been affected by a condition beyond such Party’s reasonable control, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, acts of god or acts or omissions or delays in acting by any governmental authority (each, a “Force Majeure Event”); provided, however, that the Party affected by such a Force Majeure Event shall, within ten (10) days of its occurrence, give notice to the other Party stating the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that if the suspension of performance continues for sixty (60) days after the date of the occurrence or it is clear from the circumstances that the suspension of performance shall continue for more than sixty (60) days after the date of the occurrence, the non-affected Party may terminate this Agreement by written notice to the other Party.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 10.3 Dispute Resolution.  
  
(a) If any dispute arises out of this Agreement, the Parties will first try to resolve the dispute amicably. Either Party may send a notice of dispute to the other, in which case such dispute will be referred to the Project Managers within ten (10) Business Days from receipt of the notice of dispute. If the Project Managers fail to resolve the matter within ten (10) Business Days after such referral, the dispute shall be referred to the Senior Executives. Except as set forth in Section 5.5(c) or Section 10.3(b), if the Senior Executives fail to resolve the matter within ten (10) Business Days after referral, either Party may initiate litigation in accordance with Section 10.7.  
 (b) If the Senior Executives fail to resolve a dispute under Section 2.3(d) or Section 3.6(d) of this Agreement (a “Technical Dispute”) within ten (10) Business Days after referral to the Senior Executives, then either Party may refer such Technical Dispute to an independent testing organization, or to a consultant of recognized repute within the United States pharmaceutical industry, in either case mutually agreed upon by the Parties (the “Expert”) for resolution, the appointment of which shall not be unreasonably withheld, conditioned or delayed by either Party. The determination of the Expert shall be final and binding upon the Parties, absent manifest error (in which event the dispute may be submitted to the courts for resolution or to such other alternative dispute resolution procedure upon which the Parties mutually agree in writing). The fees and expenses of the Expert making such determination shall be borne by Oakwood if the Expert resolves the Technical Dispute in favor of Edge and by Edge if such Technical Dispute is resolved in favor of Oakwood. If the Parties cannot agree that a dispute is a Technical Dispute, Section 10.3(a) shall apply.  
 (c) Nothing in this Section 10.3 shall prevent either Party from obtaining interim relief from a court of competent jurisdiction in order to preserve its rights pending resolution of any dispute hereunder.  
  
Section 10.4 Entire Agreement; Amendment; Conflicts. This Agreement, together with the Schedules attached hereto, the Development Agreement and the Quality Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. To the extent there is any conflict between the terms and conditions of this Agreement, the Development Agreement and the Quality Agreement, the Quality Agreement shall govern with respect to matters of Product quality, the Development Agreement shall govern with respect to matters pertaining to Product development, the payment of fees by Edge to Oakwood therefor, and this Agreement shall govern with respect to all other matters. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 10.5 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.  
  
Section 10.6 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Edge, Oakwood and their respective successors and permitted assigns.  
  
Section 10.7 Governing Law. This Agreement shall be governed and interpreted in accordance with the law of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Subject to Section 10.3, each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of Delaware for any action, suit or proceeding arising out of or relating to this Agreement, and neither Party shall commence any action, suit or proceeding related thereto except in such courts. Each Party further hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement in the courts of the State of Delaware, and hereby further irrevocably and unconditionally waives and shall not plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.  
  
Section 10.8 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Neither Party shall export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.  
  
Section 10.9 Assignment. Except as expressly provided herein, neither Party may, without the prior written consent of the other Party, sell, transfer, assign, delegate, pledge, subcontract or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that (a) Edge may, without such consent, assign this Agreement and its rights and obligations hereunder to a licensee of Edge’s right and interest in the Product and (b) either Party may, without such consent (i) assign this Agreement and its rights and obligations hereunder to an Affiliate or to the transferee of all or substantially all of such Party’s assets to which this Agreement relates, or to any successor entity or acquirer in the event of a merger, consolidation or change in control of such Party or (ii) pledge this Agreement and its rights hereunder in connection with any financing transaction. Any attempt to assign, transfer, subcontract or delegate any portion of this Agreement in violation of this Section 10.9 shall be null and void. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Edge or Oakwood, as the case may be. If either Party assigns or delegates its rights or obligations to another Person in accordance with the terms hereof, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement and the assignor or transferor shall cease to be a Party to this Agreement and shall cease to have any rights or obligations under this Agreement from and after the effective date of such assignment. If the Development Agreement is assigned to any Affiliate of the assigning Party or to any Third Party pursuant to the terms thereof, the assigning Party also shall assign this Agreement to such Affiliate or Third Party unless such assigning Party obtains the prior written consent of the other Party; provided, however, that if the assigning Party seeks to assign this Agreement to an Affiliate other than the Affiliate to which the Development Agreement is assigned, such other Party shall not unreasonably withhold, condition or delay such consent.  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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Section 10.10 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.  
  
Section 10.11 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 either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall 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 shall remain in full force and effect and shall 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 shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.  
  
Section 10.12 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer, employee, or joint venture relationship between the Parties. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.  
  
Section 10.13 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (d) the terms “Article,” “Section,” “Exhibit” or “clause” refer to the specified Article, Section, Exhibit or clause of this Agreement; (e) the term “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or”; (f) the term “including” or “includes” means “including without limitation” or “includes without limitation”; (g) the term “will” means “shall” and (h) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.  
  
Section 10.14 Remedies. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.  
  
Section 10.15 Counterparts; Facsimile Execution. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement (and each amendment, modification and waiver in respect of it) by facsimile or other electronic transmission shall be as effective as delivery of a manually executed original counterpart of each such instrument.  
  
Section 10.16 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.  
 (The remainder of this page is left blank intentionally.)  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
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IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first above written.  
  
Edge Therapeutics, Inc.  
 Oakwood Laboratories, L.L.C.  
 By:  
/s/ Xxxxx Xxxxxxxx  
 By:  
/s/ Xxxxxxx X. Xxxx  
 Name:  
Xxxxx Xxxxxxxx  
 Name:  
Xxxxxxx X. Xxxx  
 Title:  
President and Chief Executive Officer  
 Title:  
Executive Vice President  
 Signature Page to Manufacturing and Supply Agreement  
 Schedule 1.51  
  
Maximum Supply Obligation  
  
 Maximum Supply Obligation  
 Maximum Supply  
 Obligation per  
 Calendar Quarter  
during applicable period  
 (number of Batches)  
Maximum Supply  
Obligation during  
 applicable period  
 (number of Batches)  
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 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.  
 Schedule 1.52  
  
Minimum Order Catch-Up Price  
  
“Minimum Order Catch-Up Price” means, with respect to a Commercial Year during the Commitment Period, an amount equal to:  
  
[\*\*]  
 [\*\*] Material omitted and separately filed with the Commission under a request for confidential treatment.