Exhibit 10.25  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
MANUFACTURING AND SUPPLY AGREEMENT  
This Agreement (the “Agreement”) is entered into as of the 8 day of December, 2015 (the “Effective Date”), by and between Vention Medical Design and Development, Inc. with its principal place of business at 000 Xxxxx Xxxx Xxxxxx, Xxxxxxxxxxx, Xxxxxxxxxxxxx (“Supplier”), and Nevro Corp. having its principal place of business at 0000 Xxxxxx Xxxxxxx, Xxxxxxx Xxxx, Xxxxxxxxxx 00000 (“Customer”).  
WHEREAS, Supplier has agreed to manufacture and supply to Customer those products listed in Appendix A, attached and made a part hereof (“Products”), and Appendix A may be amended and/or supplemented from time to time in writing upon mutual agreement of the Parties; and  
WHEREAS, Customer desires that Supplier manufacture and supply the Products to Customer;  
NOW, THEREFORE, in consideration of the terms and provisions of this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Supplier and Customer (each a “party” and collectively the “parties”), agree as follows:  
 1. DEFINITIONS  
1.1 “Applicable Laws” means all applicable statutes, ordinances, codes, executive or governmental orders, laws (including common law), rules, and regulations, including without limitation any rules, regulations, guidelines or other requirements of Regulatory Authorities, that may be in effect from time to time.  
1.2 “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the commencement of such period to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.  
1.3 “cGMP” means the regulations set forth in (a) 21 C.F.R. Parts 210–211, 820 and 21 C.F.R. Subchapter C (Drugs), Quality System Regulations and requirements thereunder imposed by the FDA, (b) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use and requirements thereunder imposed by the EMA, and (c) any similar or equivalent regulations and requirements in jurisdictions where services are provided pursuant to this Agreement.  
1.4 “Components” shall mean any raw materials, work-in-process inventory and supplies included in or required for the manufacture of Products in accordance with the Specifications, including without limitation those parts, materials and supplies list set forth on Appendix D.  
 Manufacture and Supply Agreement – VENTION Medical, Inc.  
1.5 “Confidential Information” means any and all technical and non-technical information provided by either party to the other, either directly or indirectly, whether in graphic, written, electronic or oral form, whether or not marked or identified at the time of disclosure as confidential, so long as by its context the information would reasonably be deemed to be confidential, including without limitation unpublished patent applications and other filings, trade secrets, and other proprietary information, including (i) information regarding ideas, technology and processes (such as, but not limited to, assays, techniques, sketches, schematics, drawings, models, designs, inventions, know-how, technical documentation, equipment, algorithms, software programs, software source documents, formulae); (ii) information concerning or resulting from research and development projects and other projects (such as, but not limited to design details and specifications, engineering information, and works in process); (iii) business and financial information (such as, but not limited to, current, future, and proposed products and services, financial information and models, information relating to procurement requirements, purchasing, manufacturing, customer lists, product plans, product ideas, business strategies, marketing or business plans and information regarding third parties, suppliers, customers, employees, investors or facilities); and (iv) any information created using the foregoing Confidential Information; in each case of the party disclosing the Confidential Information. The Confidential Information may also include information the disclosing party provides regarding third parties, or previously disclosed to the disclosing party by a third party.  
1.6 “GMP” shall mean compliance with ISO13485:2003 and the Quality System Regulations set forth in 21 CFR Part 820, and all additional standards, documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.  
1.7 “Intellectual Property Rights” shall mean all rights held by a party in its technology, products and business information, some or all of which may constitute Confidential Information, and including but not limited to patent rights, copyrights, trademark rights, goodwill, inventions, improvements, discoveries, designs, modifications, data, rights in business information (including without limitation financial information, clinical information and regulatory information), trade secrets, mask works, know-how and all other intellectual property and proprietary rights known now or in the future in any jurisdiction, including the right to apply for any of the foregoing, and the right to xxx with respect to any of the foregoing.  
1.8 “Minimum Quarterly Volume” shall mean the aggregate number of Products required to be ordered by Customer in a given Calendar Quarter, as set forth in Appendix E.  
1.9 “Product Inventions” shall mean all designs, data, information, inventions, improvements, discoveries (whether patentable or not), processes, software, and devices developed by either party in connection with performing services under this Agreement.  
1.10 “Product Specifications” shall mean Customer’s written specifications for the manufacture and testing of the Products, the current form of which is set forth at Appendix G, as such specifications may be amended from time to time by Customer by written notification to Supplier.  
1.11 “Purchase Order” shall mean an order in the form attached as Appendix H placed by Customer for the purchase of a specified quantity of (a) Products, or (b) Components, during the Term of this Agreement.  
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1.12 “Safety Stock” shall mean the quantity of Components to be purchased by Supplier, upon written request by Customer (including by way of a Purchase Order) and at Customer’s sole expense, in excess of the amount required by Supplier to meet Customer’s Binding Forecasts or Component lead times.  
1.13 “Shipment Date” shall mean the requested shipment date for Products from the Supplier manufacturing facility as specified in a Purchase Order, or as otherwise mutually agreed by the parties in writing.  
1.14 “Test System” shall mean shall mean a production system for conducting software and/or hardware testing at various stages of Product assembly to verify the functionality and ensure the quality of the Product.  
 2. MANUFACTURE AND SUPPLY OF PRODUCTS  
2.1 Supplier’s Obligations Supplier shall use its best efforts to manufacture and supply Customer with its requirements for Products, and to manufacture all Products in accordance with the Product Specifications.  
2.2 Change Orders. If Customer wishes to make any change or modification to the Product and/or the Product Specifications, including without limitation any change to the Components included therein (a “Change”), Customer shall notify Supplier in writing of the details of such Change. Supplier shall agree to promptly implement any reasonable and lawful Change requested by Customer, including without limitation any Change that is required by applicable laws or regulations or any regulatory authority. The parties shall discuss in good faith the steps required to implement such Change, including any adjustment to pricing for Products at the time of such Change, which may be required so as to allow Supplier to maintain its profit margins at the level immediately prior to such Change. Supplier shall (i) have a reasonable period of time (not less than thirty (30) days) to implement any such Change and (ii) be entitled to full reimbursement by Customer for any reasonable out-of-pocket costs incurred by implementing such Change, in addition to any agreed modification to the Product pricing mutually agreed by the parties in accordance with the foregoing sentence Supplier shall not implement any Change, or make any other changes to equipment, Components, manufacturing and quality assurance procedures, or methods and techniques used to manufacture a Product without Customer’s prior written consent, which may be withheld in Customer’s sole reasonable discretion.  
2.3 Subcontracting. Supplier shall have the right to subcontract services provided under this Agreement to third parties solely with the prior written consent of Customer, such approval not to be unreasonably withheld. Supplier shall provide to Customer any reasonable information requested by Customer in relation to such third party, including the identity of such third party and the nature and extent of the services intended to be subcontracted. Upon Customer granting consent to the use of a specified third party subcontractor, such third party shall be an approved “Sub-Tier Supplier” (as defined in the Quality Agreement). Supplier shall enter into a binding written agreement with any approved Sub-Tier Supplier, which shall be consistent with the terms of this Agreement, and shall contain, at a minimum, terms relating to the ownership of Intellectual Property Rights and Confidential Information consistent with those set forth herein. Supplier shall remain liable for all acts and omissions of any approved Sub-Tier Supplier, and for  
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any breach of this Agreement by such Sub-Tier Supplier. Notwithstanding the foregoing, Supplier is responsible for communicating all requirements to Sub-Tier Suppliers that are engaged and managed by Supplier. This includes Sub-Tier Suppliers that have been identified as third party suppliers for any part of the Services hereunder by Customer. In the event that Customer needs to communicate directly with a Sub-Tier Supplier, Customer will make all reasonable efforts to coordinate any such communications with Supplier.  
2.4 Customer’s Purchase Obligations Within five (5) days following the Effective Date, Customer shall provide Supplier with a twelve (12) month forecast of Customer’s expected purchase of Products (the “Initial Forecast”), with the earliest Shipment Date for the Products covered by such forecast mutually agreed upon by both parties. The first six (6) months of such Initial Forecast shall be binding, and the second six (6) months of the Initial Forecast shall be non-binding. Following the Effective Date, Customer shall issue quarterly rolling forecasts by the last day of each Calendar Quarter for the twelve (12) months immediately following the date of such forecast, with the first six (6) months of each such rolling forecast being binding upon the parties (such six (6) month forecast the “Binding Forecast”).  
2.5 Cooperation. Supplier and Customer agree to cooperate with each other and work jointly to establish and maintain a smooth and efficient timetable for the manufacture and supply of Products to Customer hereunder. Supplier shall use its best efforts to supply Customer with all of its Product requirements in accordance with Section 2.1, provided that Supplier shall not be in breach of this Agreement or otherwise liable for any failure to supply quantities of Products (a) in excess of Customer’s most recent Binding Forecast to the extent provided in Section 3.2 or (b) at volumes materially in excess of Supplier’s expected production capacity set forth on Appendix B. Unless otherwise agreed to between the parties, the parties will use their best efforts to allocate the manufacture and supply of Products relatively evenly over the course of time under the expected production schedule set forth on Appendix B.  
2.6 Component Supply  
(a) Component Supply. Supplier shall purchase a quantity of Components required for the manufacture of Products for the first [\*\*\*] ([\*\*\*]) months of the Initial Forecast. Upon Customer’s request, Supplier and Customer will also discuss any amendments that should be made to the list of Components to be purchased by Supplier, including by reason of more favorable pricing terms that may be available to Customer, and at Customer’s discretion, Customer may request that certain Components become Consigned Components (in which case Section 2.6(d) shall apply to such components), or that Consigned Components should be purchased by Supplier. Supplier shall be responsible for acquiring all Components, including associated costs of shipping, freight, taxes and duties, and for managing inventory of Components and ensuring that Supplier has sufficient quantities (not to be less than [\*\*\*] ([\*\*\*]) months’ supply) of Components in stock to meet Customer’s Binding Forecasts. Supplier shall keep Customer regularly informed of the status of the Component inventory, and shall immediately notify Customer in the event of any potential material delays or shortages that may impact the ability to manufacture Products in accordance with Binding Forecasts, or to meet Shipment Dates.  
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(b) Additional Components In addition to the inventory of Components to be held by Supplier against Customer’s future Purchase Orders based on the Binding Forecasts pursuant to Section 2.6(a), upon the reasonable written request of Customer, which may include to address anticipated long third party vendor lead times, and at Customer’s expense, Supplier shall purchase Safety Stock of Components in quantities specified by the Customer, up to an additional [\*\*\*] ([\*\*\*]) month supply of such Components, provided that Customer shall be fully liable for the cost of any Safety Stock that remains unused at the date of termination or expiration of this Agreement, provided that Supplier shall use reasonable efforts to utilize such Safety Stock for other customers or in other activities, and Customer shall not be liable for the cost of any Safety Stock so utilized.  
(c) Specification Changes. In the event that as a result of a Change, Components purchased by Supplier prior to such Change (as defined in Section 2.2) become obsolete or are no longer able to be utilized in the manufacture of Products, Customer shall reimburse Supplier for Supplier’s out-of-pocket costs incurred in relation to the purchase of such Components, within thirty (30) days following the presentation by Supplier of a valid invoice for such costs, unless Customer requests in writing that Supplier to use such Components to manufacture Products under the Specifications in existence prior to such Change, rather than reimburse Supplier for the costs of such Components, and provided that Supplier shall use commercially reasonable efforts to return such Components to the applicable third party vendor.  
(d) Consigned Components. During the Term, in lieu of Supplier purchasing certain Components pursuant to Sections 2.6(a) and 2.6(b) Customer may notify Supplier in writing that Customer wishes to supply certain materials, parts and supplies directly to Supplier for incorporation into Products manufacture by Supplier (such directly supplied materials, parts and supplies, the “Consigned Components”). Customer shall be solely responsible for determining the required quantities of Consigned Components, and for all orders, payments and timing of delivery of such Consigned Components. Customer shall use commercially reasonable efforts to ensure that sufficient quantities of Consigned Components are delivered to Supplier in sufficient time to enable Supplier to meet its manufacturing and delivery obligations with respect to Products based on Purchase Orders and Binding Forecasts, provided that Supplier shall have no liability for any failure to deliver Products to Customer where such failure arises as a result of Customer’s failure to deliver Consigned Components to Supplier in a timely fashion or at all, or to provide Supplier with adequate quantities of Consigned Components. Customer assumes all liability for the quality of all Consigned Components, and Supplier shall not be responsible for any defects discovered therein, provided that Supplier shall carry out a reasonable inspection of such Consigned Components in accordance with Supplier’s standard operating procedures promptly upon delivery to Supplier. Supplier shall, within ten (10) days following receipt of any Consigned Components, notify Customer of any defects identified in such Consigned Components or any discrepancy in quantity  
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delivered. Without limiting the foregoing, Supplier shall promptly inform Customer of any additional defects in the Consigned Components discovered or revealed by further inspection by or through the manufacturing process for Products that could not have been discovered at the time of delivery of such Consigned Components. Supplier will provide Customer with a written statement of Consigned Components used by Supplier at the end of each month.  
 3. ORDERS; DELIVERY; INVOICING AND PAYMENT  
3.1 Orders. During the term of this Agreement, and subject to Section 3.2, Customer shall issue quarterly Purchase Orders on or before the first day of each quarter for quantities for Shipment Dates in the Calendar Quarter commencing no less than six (6) months from the date of placement of such Purchase Orders, unless the parties mutually agree upon a shorter lead time for manufacture of such Products based on the production schedule established jointly between the parties and set forth in Appendix E. By way of example, on or before December 31st, Purchase Orders will be issued for Shipment Dates in the third Calendar Quarter commencing July 1st. Each Purchase Order shall specify the type and quantity of the Product to be delivered, as well as requested Shipment Date, provided that the aggregate quantity of Products ordered on Purchase Orders for Shipment dates in a given Calendar Quarter shall not be less than the Minimum Order Quantity for such Calendar Quarter. Each Purchase Order, or any acknowledgment thereof, invoice, xxxx of lading or acceptance by Customer, shall be governed by the terms of this Agreement, which shall supersede any printed terms on any Purchase Order, quotation, acknowledgement, confirmation or invoice.  
3.2 Increases in Order Quantity. Customer may place Purchase Orders for quantities of Products in excess of the quantities specified in Customer’s most recent Binding Forecast, and Supplier shall use its best efforts to meet such increased demand, provided that (i) Supplier shall have no obligation to supply quantities of Products in excess of [\*\*\*] percent ([\*\*\*]%) in excess of Customer’s most recent Binding Forecast and (ii) Supplier shall not be liable for any failure to supply any quantity of Products in excess of Customer’s most recent Binding Forecast, to the extent that such failure results from a failure by Customer to place an order for sufficient quantities of Components to meet the quantity specified in such Purchase Order, or a failure by Customer to supply the necessary quantities of Consigned Components required to fulfil such increased Customer demand for Products. Where Customer places a Purchase Order for a quantity of Products in excess of its most recent Binding Forecast, the Parties shall discuss any expedite fees, overtime and/or freight charges required to support such increased orders and any such costs shall be borne by Customer and subject to Customer’s prior written approval, not to be unreasonably withheld. Supplier shall have no obligation to manufacture any increased quantities of Products unless and until Customer has approved any associated excess charges associated with such increase. Customer shall reimburse Supplier for all such costs within thirty (30) days following the presentation of a valid invoice for such costs by Supplier.  
3.3 Cancellation and Rescheduling of Purchase Orders. Supplier shall use commercially reasonable efforts to accommodate requests by Customer to reschedule, decrease or cancel the  
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manufacture of quantities of Product in a given Purchase Order. Customer shall be liable for any reasonable costs incurred by Supplier as a direct result of such decrease, rescheduling or cancellation, provided that Supplier shall use commercially reasonable efforts to minimize any such costs, and provided further that Customer shall not be liable for the costs of any Components that are able to be used or reused in the manufacture of Products under any subsequent Purchase Order.  
3.4 Delivery. Unless otherwise agreed to in writing by the parties, all Products manufactured for Customer shall be sold to Customer F.O.B. (INCOTERMS 2010) Supplier’s dock. Customer may specify the carrier and mode of transportation for each Purchase Order, or may provide a standing instruction for all Purchase Orders, provided that if no carrier or mode of transportation is specified by Customer, Supplier may select the carrier and mode of transportation that Supplier reasonably believes is most appropriate to meet Customer’s delivery requirements.  
3.5 Acceptance Testing; Defects.  
(a) Customer will be entitled to conduct acceptance testing on all Product deliveries. Within thirty (30) calendar days of Customer’s receipt of the Product (the “Product Acceptance Period”), If the product fails the acceptance testing the Customer will provide Supplier with a written notice detailing the Product Specifications that such Product has failed to meet. If the Product delivered hereunder fails to conform to the Product Specifications or to such other testing and acceptance criteria as may be mutually agreed upon by the parties, Customer shall notify Supplier in writing of such failure, detailing the nature of the alleged failure, and the parties will promptly discuss means to resolve any such failure. Assuming that Supplier agrees that the Product is non-conforming, all costs associated with remedying such failure shall be borne by Supplier. The parties will work in good faith to mutually resolve any disputes in accordance with section 3.5(c) below. Supplier shall then deliver to Customer, pursuant to an agreed-upon schedule, but in no event in greater than thirty (30) days, Products that meet the applicable Product Specifications. Upon re-delivery, Customer shall have an additional fifteen (15) business day period to acceptance test the applicable Product and provide either written acceptance of the Product or a written statement detailing the Product Specifications such Product failed to meet. If after two (2) such cycles, Customer reasonably rejects such Product again, Customer may elect to continue the process of modification and acceptance testing or terminate the applicable Purchase Order or the Agreement, provided that Supplier shall be required to refund to Customer all amounts paid by Customer with respect to such non-conforming Product, and any amounts prepaid under such Purchase Order for Products not yet manufactured and delivered to Customer.  
(b) Notwithstanding the foregoing, if Customer does not submit a written notice of rejection within the Product Acceptance Period, such shipment will be deemed accepted by Customer, except with respect to any defect in the Product that results in the Product not conforming to the Product Specifications that was not discoverable with commercially reasonable inspection (“Latent Defect”). Customer shall notify Supplier within twenty (20) days after discovery of any Latent Defect not discoverable upon reasonable physical inspection, and in any event no later than twelve (12) months after the date the Product was delivered to Customer, otherwise such shipment will be deemed accepted by Customer.  
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(c) If there is any dispute regarding the conformity of a shipment of Product with the Product Specifications, following delivery by Customer of a notice of non-conformity within the Product Acceptance Period, then the Parties agree that Customer will submit a sample of the relevant nonconforming Product to an independent testing laboratory of recognized repute selected by Customer and reasonably acceptable to both parties for analysis, subject to terms of confidentiality no less restrictive than those set forth in this Agreement, and under procedures approved by the Parties’ quality assurance personnel, of the conformity of such Product with the Product Specifications. The costs associated with such analysis by such independent testing laboratory will be paid by the party whose assessment of the conformity of the Product with the Product Specifications was mistaken. The determination by the independent testing laboratory, unless clearly erroneous, will be final and binding.  
3.6 Recurrent Product Non-Conformity In the event that (a) a material number of Products in a single delivery do not conform with the Product Specifications, or (b) the same or similar reason for non-conformity with Product Specifications occurs multiple times within a single shipment of Products, or occurs repeatedly within multiple or consecutive shipments of Products (such non-conformity a “Recurrent Defect”), then the Parties shall discuss in good faith the nature of such Recurrent Defect and a mutually acceptable plan for addressing such Recurrent Defects, and Supplier shall promptly carry out an investigation of the possible causes of such Recurrent Defect, including without limitation a review of Supplier’s manufacturing processes and quality control and quality assurance activities with respect to Products, and shall notify Customer in writing of its findings and its proposal for steps to remedy such Recurrent Defect. All costs associated with the conduct of such investigation, preparation of a remedial plan, and implementation of such remedial plan to eliminate the occurrence of such Recurrent Defects shall be borne solely by Supplier, unless such Recurrent Defect is the result of Customer’s breach of this Agreement, gross negligence or willful misconduct, in which case the costs shall be borne by Customer.  
 4. PRICE  
4.1 Purchase Price. The initial prices for Products purchased hereunder are set forth in Appendix B, attached hereto. Without limiting any other provision hereunder, including Section 4.2, at the end of the first quarter of the Term, and each quarter thereafter that this Agreement remains in effect, Supplier shall notify Customer of any proposed Product price increase or decrease for the next succeeding quarter, and the basis on which such price is to be increased or decreased. No price increase shall be take effect until Customer has provided its written consent, not to be unreasonably withheld or delayed. Any increase or decrease in Product unit price shall be applicable only to those product lots of Product for which the production process is completed after the parties have agreed upon the change in Product price and shall remain in effect until another price change occurs.  
4.2 Price Adjustment. Upon written notice to Customer, the purchase price for Products may be adjusted by Supplier, to appropriately reflect material changes in Supplier’s direct manufacturing costs, including, but not limited to documented increases in the costs of raw material, packaging and other materials, that adjust completed device cost by greater than [\*\*\*] dollars. Upon request from Customer, Supplier will provide documentation evidencing increases  
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in such costs, and in the event of a disagreement as to a Product pricing adjustment, the parties will, in good faith, negotiate such adjustment. Additionally, the parties understand and agree that the prices reflected in the Initial Pricing List, attached as Appendix B and referenced above, are based upon certain assumptions and information provided by Customer, including, but not limited to, information regarding the type, size and condition of tooling, testing and packaging requirements. To the extent that such information and assumptions are inaccurate, thereby effecting manufacturing costs, Supplier may adjust, accordingly, Product pricing, as reflected in the Initial Pricing List.  
4.3 Invoicing; Payment. Supplier shall send invoices by email to Customer for delivered Product on the Shipment Date. Customer shall pay all undisputed amounts in each invoice within thirty (30) days from the date of receipt of the invoice, provided that any dispute over an invoiced amount is in good faith. All payments and communications regarding the Product shall be delivered to Supplier at the address designated above. Failure to make payment of all undisputed amounts by the due date shall result in interest accruing on any unpaid balance, from the due date until payment is made, at the rate of [\*\*\*] percent ([\*\*\*]%) per month or the highest interest rate allowable by law, whichever is less. Failure to pay may also result in delay of further shipments until all unpaid undisputed balances are paid in full.  
4.4 Cost Reduction Efforts. Both parties agree to cooperate in good faith to work towards reducing costs to manufacture Nevro Products. Yield improvements and cost reductions will be reviewed by Supplier and Customer quarterly (or more frequently) for potential inclusion into product pricing. For Cost Reduction Projects that have been funded by Supplier and approved by Customer, after full cost recovery, Customer will receive [\*\*\*]% of the demonstrated cost reduction upon implementation. If due to any circumstance Customer is unable to release Supplier initiated and funded cost reduction changes (i.e. due to regulatory or product management restrictions) then Customer will reimburse Supplier for [\*\*\*]. For Cost Reduction Projects that have been initiated by Customer and funded by Customer, Customer will receive [\*\*\*]% of the demonstrated cost reduction upon implementation.  
4.5 Taxes. Any federal, state, county or municipal sales or use tax, excise or other tax (except for income taxes imposed upon Supplier), or other similar charge levied or assessed or charged on or for the sale, production or transportation of Products sold hereunder (“Taxes”), shall be paid by Customer. If Supplier is required to pay any such Taxes, Customer agrees to reimburse Supplier for any amounts so paid upon demand.  
 5. QUALITY CONTROL AND REGULATORY COMPLIANCE  
5.1 Quality Agreement. Supplier shall perform all manufacturing, testing and supply of Products, and all other obligations under this Agreement, in accordance with (a) the terms of the quality agreement entered into by and between the parties dated November 6, 2013 and attached hereto as Appendix F (the “Quality Agreement”), and (b) all Applicable Laws, including cGMP. The Quality Agreement includes, without limitation, Customer’s rights, and Supplier’s obligations with respect to (i) any audit or inspection, including without limitation any audit or inspection required or required to be conducted by a regulatory authority in any jurisdiction, and (ii) any person in plant visits or inspections required by Customer.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
5.2 Regulatory Inspection. Without limiting the audit and inspection rights set forth in the Quality Agreement, Supplier shall reasonably cooperate in relation to Customer’s efforts to obtain regulatory approval of Products. Without limiting the foregoing, if a regulatory authority makes an inquiry or otherwise requests information or assistance relating to Products, whether to Supplier or Customer, Supplier shall provide access to, and coordinate and make available, applicable personnel, facilities, materials, and documents as necessary to respond to such inquiries. In the event of any such inquiry, request, or other communication relating to Product, Supplier will promptly notify and provide information regarding such inquiry, request, or communication to Customer. Supplier will promptly forward to Customer copies of any findings that Supplier receives from a government authority or regulatory authority in connection with services performed hereunder or Products. Supplier shall also provide Customer with an opportunity to comment prospectively on any Supplier responses to a government authority regarding Products.  
5.3 Certificate of Compliance. Supplier shall provide to Customer, with each delivery of Products manufactured hereunder, a written certificate of compliance certifying that the Product and all Components meet the Product Specifications and have been manufactured in accordance with, and comply with Section 5.1. Supplier shall provide such certificate of compliance to Customer electronically (via scanned and emailed copies) within one (1) business day following each shipment of Product and in hard copy for Shipment Dates during the preceding month within five (5) business days after such month’s end. Supplier shall also provide Customer in connection with any shipments of Products, copies of any certificates of compliance Supplier has been provided by third party suppliers of any Components incorporated within such Products. For clarity, the certificate of compliance shall not certify that the Components comply with the specifications for such Components, provided that Supplier shall carry out a reasonable inspection of all Components prior to use of such Components in relation to the manufacture of any Product and shall use commercially reasonable efforts to discover any defects in such Components prior to use in manufacture of Products.  
5.4 Records. Supplier shall maintain true and accurate books, records, test and laboratory data, reports and all other information (“Records”) relating to services provided hereunder, and manufacture or supply of Products under this Agreement, including, without limitation, all information required to be maintained by Applicable Laws and any regulatory authority. Supplier shall provide Customer with a copy of all Records and any documents related to the services performed under this Agreement or the supply or manufacture of Product at Customer’s request or upon expiration or termination of this Agreement. The Records shall be Confidential Information of Customer. Supplier shall retain copies of all Records for a period of at least seven (7) years after date of final payment under this Agreement. Prior to destruction, Supplier shall obtain Customer’s consent to destroy records or return the records to Customer at Customer’s expense.  
5.5 Regulatory Compliance. Supplier shall be solely responsible for all permits and licenses required by any regulatory authority or Applicable Laws to enable Supplier to perform services and manufacture and supply of Products under this Agreement. Supplier will maintain  
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ISO13485 certification at all times during the Term of this Agreement. For clarity, Customer shall be responsible for all other permits and licenses required in order to use, sell, import or export Products.  
5.6 Ownership of Regulatory Filings. As between the parties, Customer will own all regulatory filings for Products. Upon Customer’s request, Supplier shall cooperate reasonably with Customer to draft and file applications and other materials with any regulatory authority relevant to Products, and to seek approval of Products by such regulatory authorities.  
 6. CAPITAL EQUIPMENT; DESIGNS/SPECIFICATIONS  
6.1 Capital Equipment. Supplier shall provide for such capital equipment as Supplier deems reasonably necessary for the manufacture of Product at Supplier’s facility (excluding any equipment to be provided or funded by Customer, under Section 6.1(b) below), at Supplier’s sole expense. All such capital equipment provided by Supplier shall remain the sole property of Supplier, and all processes and specifications that relate to such capital equipment shall constitute Supplier’s proprietary Confidential Information, as defined in Section 8 herein, and shall belong exclusively to Supplier.  
(b) As part of, and for the entire duration of this Agreement, Customer shall, at its sole expense, provide Supplier with the equipment specified in Appendix C, which is specific to the design or manufacture of the Products in accordance with the Product Specifications (the “Customer Equipment”). Customer shall at all times retain exclusive ownership of the Customer Equipment, and all specifications that relate to the Customer Equipment shall constitute Customer’s Confidential Information, as defined in Section 8, and shall belong exclusively to Customer.  
(c) Supplier shall not use any Customer Equipment, except in connection with the manufacture of Products for Customer, without Customer’s prior written consent.  
(d) Customer shall compensate Supplier for all reasonable out-of-pocket costs and expenses incurred in connection with the sampling, validation and performance of capability studies for all assembly steps, packaging equipment, sterility validation and testing protocols, in each case solely to the extent specifically applicable to Products. Supplier will provide Customer with cost estimates of each activity prior to its performance, for Customer’s written approval. Customer shall not be liable for any costs incurred in relation to any of the foregoing activities until it has provided its consent in writing to such costs, such consent not to be unreasonably withheld. Payment terms shall be the same as provided in Section 4.3.  
(e) Supplier shall be responsible for maintaining the Customer Equipment in good operating condition (normal wear and tear expected), and Supplier shall have the right to make such repairs and alterations as may be appropriate for such equipment’s intended use and good working order with the exception of the Test System, which shall be subject to Section 6.1(f). Supplier shall seek the approval of Customer in advance of any required repairs maintenance on the Customer Equipment for any costs associated with such repair and maintenance, and subject to Customer’s approval (not to be unreasonably withheld), Supplier shall invoice customer for any such repairs and/or alterations that are necessary and required in order to use the Customer Equipment to  
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perform services in accordance with the terms of this Agreement. Notwithstanding Supplier’s routine care responsibilities, Customer shall be solely responsible for all non-routine care, repair, maintenance, upgrades and refurbishments of all Customer Equipment (including maintaining a spare parts inventory, where appropriate, for the Customer Equipment), provided that Supplier shall provide reasonable assistance, at Customer’s request and Customer’s expense, in arranging any such non-routine maintenance, upgrades and refurbishments.  
(f) Customer shall be responsible for maintaining the Test System provided to Supplier to ensure the equipment is properly calibrated and functioning properly. All updates to software, hardware, and any fixtures relating to the Test System shall be the sole responsibility of the Customer. Supplier shall notify the Customer of any and all issues that arise with the Test System and Customer shall be solely responsible for determining the cause of any problems with the equipment to avoid delays in manufacturing delivery dates, provided that Supplier shall provide reasonable assistance, upon Customer’s request and at Customer’s expense, in determining the cause of, and resolving, such issues with the Test System.  
 7. INTELLECTUAL PROPERTY  
7.1 Background IP. Each party shall solely own all Intellectual Property Rights owned or controlled by such party prior to the Effective Date, or developed, created, or reduced to practice outside of the services provided under this Agreement (“Background IP”). Except as expressly set forth herein, nothing in this Agreement shall be construed to grant, transfer or convey to either party any right, title or interest in the other party’s Background IP. Each party’s Background IP shall include all Intellectual Property Rights in such party’s capital equipment (including, in the case of Customer, the Customer Equipment).  
7.2 Product Inventions The parties acknowledge and agree that all Product Inventions and all Intellectual Property Rights therein, excluding the Supplier Background IP shall be solely owned by Customer. Supplier shall promptly disclose any such items to Customer. Upon payment in full for services rendered, Supplier assigns, and shall cause all of its employees, agents, affiliates, subcontractors and other authorized representatives to execute assignment documents, to Customer any interest it or they may have in any such Product Inventions and all Intellectual Property Rights therein. Supplier agrees to cooperate with Customer, at Customer’s expense, for the purpose of filing and prosecuting patent applications, and enforcing Intellectual Property Rights, including the execution of any and all legal papers which are necessary or desirable to affect the intent of this Section 7.2, consultations with Customer’s attorneys, and any necessary testimony to appropriate tribunals.  
7.3 License to Customer. Supplier hereby grants to Customer, its successors and assigns, a perpetual, fully paid, world-wide, sublicensable, nonexclusive license under all Supplier Background IP and any improvements, variations, modifications or derivatives thereto, that is (a) incorporated within any Product, (b) necessary for the manufacture, use or sale of any Products, (c) necessary to use or practice the Product Inventions, or (d) necessary for the use, distribution, copying or transmission of any data, information or materials provided in connection with Products (such Supplier Background IP, the “Incorporated Supplier IP”), to make, use, sell, offer for sale and import Products, and to use and practice the Product Inventions, including the right to make improvements, derivatives or successor works of any of the foregoing. The license  
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granted to Customer under this Section 7.3 includes rights in all future improvements or derivatives of such Incorporated Supplier IP, solely to the extent that such improvements or derivatives are necessary to make, use, sell, offer for sale and import Products, and to use and practice the Product Inventions. Nothing in the foregoing license shall be construed to grant to Customer the right to market, sub-license or otherwise use the Supplier Background IP or Incorporated Supplier IP other than in connection with one or more Products or Product Inventions, or any improvements, derivatives or successor works of any of the foregoing.  
7.4 License to Supplier. Customer hereby grants to Supplier a limited, royalty-free, non-exclusive, non-transferable, non-sublicenseable license, solely for the term of this Agreement, under all Customer Background IP, solely to the extent required for Supplier to perform services and manufacture Products pursuant to the terms of this Agreement.  
 8. CONFIDENTIALITY  
8.1 Confidentiality. Each party acknowledges and agrees that from time to time during the Term, each party (the “Disclosing Party”) may disclose Confidential Information to the other party (the “Receiving Party”) for the purposes of exercising rights and carrying out obligations under this Agreement. Each party acknowledges and agrees that all the other party’s Confidential Information is confidential and proprietary to the disclosing party. Neither party shall use or disclose to any third party or Affiliate the other party’s Confidential Information without the other party’s prior written consent for any purpose other than as permitted or required hereunder.  
8.2 Permitted Disclosures. The Receiving Party may disclose Confidential Information to its directors, officers, employees, authorized agents and professional advisers to the extent such persons have a need to know such information for the purpose of performing each party’s duties and obligations hereunder, provided that the Receiving Party advises each such individual of the terms of this Agreement and ensures that each such individual receives and hold such information as if that individual were a party to this Agreement. A party may, from time to time, designate in writing individuals as authorized representatives of that party to whom Confidential Information may be provided directly by the disclosing party, and any Confidential Information so provided will be deemed to have been provided to the other party and be subject to this Agreement. Each party shall take the same reasonable measures necessary to prevent any disclosure by its employees, agents, contractors, sub-licensees, or consultants of the Disclosing Party’s Confidential Information as it applies to the protection of its own Confidential Information.  
8.3 Exclusions. Information shall not be considered Confidential Information hereunder if it:  
(a) was already in the possession of the Receiving Party prior to its receipt from the Disclosing Party, as shown by the Receiving Party’s books and records;  
(b) is, or becomes, part of the public knowledge or literature through no fault, act or omission of the Receiving Party, provided, Confidential Information relating to the Product shall not be deemed to have entered the public domain by reason of its having been filed with any regulatory agency;  
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(c) is, or becomes, available to the Receiving Party from a source other than the Disclosing Party, which source has rightfully obtained the same information and has no obligation of confidentiality to the Disclosing Party with respect to it; or  
(d) is required to be revealed pursuant to law, provided, however, the Receiving Party which is under any such requirement of law shall give reasonable notice to the Disclosing Party of such requirement and shall cooperate with the Disclosing Party in reasonable legal efforts to limit or mitigate any such revelation so as to preserve the proprietary nature of any Confidential Information contained therein.  
8.4 Duration; Surviving Obligation. Each party’s obligations of non-use and non-disclosure of the other party’s Confidential Information shall apply during the term of this Agreement and shall also survive for a period of five (5) years after its termination for any reason. All Confidential Information disclosed under the Mutual Confidentiality and Non-disclosure Agreement by and between the parties dated March 6 2012 shall be deemed to have been disclosed under this Agreement, and shall be subject to the non-disclosure and non-use provisions set forth in this Article 8. Upon any termination or expiration of this Agreement, or upon the written request of a party, each party shall promptly return to the other party all of such other party’s Confidential Information, provided that each party shall be permitted to retain a single copy of such Confidential Information for the purpose of performing any obligations that survive such termination or expiration, or for evidencing compliance with the terms of this Agreement.  
 9. WARRANTIES; LIMITATION OF LIABILITY  
9.1 General Warranties Each party hereby represents and warrants to the other party that:  
(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has taken all necessary action, including without limitation obtaining any necessary approval of its board of directors, to execute and deliver this Agreement and to consummate the transactions contemplated herein;  
(b) it has full power and authority to enter into and perform this Agreement and does not require the consent, approval or authorization of any person, shareholder, public or governmental authority or other entity, and that this Agreement and the provisions hereof constitutes and when executed will constitute, its valid and legally binding obligations, enforceable in accordance with its terms, except as may be limited by bankruptcy and equitable principles limiting specific performance  
(c) the execution and delivery of this Agreement by each party, and the performance of each party’s obligations hereunder, (a) are not in violation of, breach of, and will not conflict with or constitute a default under, the Articles of Incorporation or Bylaws of either party, or any material agreement, contract, commitment or obligation to which Customer or Supplier is a party or by which either party is bound; and (b) will not conflict with or violate any applicable law, rule, regulation, judgment, order or decree of any governmental agency or court having jurisdiction over either party or its assets or properties.  
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9.2 Supplier Warranties Supplier hereby represents and warrants to Customer that:  
(a) it has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted;  
(b) it shall manufacture and supply Products in accordance with the terms of this Agreement and the Quality Agreement, and shall comply with all Applicable Laws, including without limitation cGMP, in performing services under this Agreement;  
(c) all waste, including but not limited to all hazardous waste, generated at the time of manufacture of Products shall be disposed of in accordance with all Applicable Laws and regulations governing such matters in the country of manufacture; and  
(d) all Products manufactured, sold and shipped pursuant to this Agreement shall be manufactured in accordance with all applicable national and local environmental, health and safety laws and regulations in effect at the time and place of manufacture of the Products.  
9.3 Product Warranties  
(a) Subject to the provisions set forth in Section 9.3(b), Supplier warrants: (i) that all Products delivered hereunder shall conform to Product Specifications at the time of shipment; (ii) that all Products shall be manufactured in accordance with the terms of this Agreement and the Quality Agreement, and shall comply with all Applicable Laws, including without limitation cGMP and the Federal Food, Drug and Cosmetic Act, as amended (the “Act”) and, relevant to their manufacture and sale; and (iii) that no Product delivered hereunder shall at time of shipment be adulterated or misbranded within the meaning of the Act, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, provided such laws are constituted and effective at the time of such delivery (collectively the “Product Warranties”). The Product Warranties as to any Product supplied hereunder shall expire [\*\*\*] ([\*\*\*]) [\*\*\*] after date of delivery of such Product or the Product’s stated shelf-life, which ever shall come first. These Product Warranties shall be null and void and shall not apply to any Product which is in any way altered, modified, damaged or replaced by any person other than Supplier, or which is abused or misused whether intentionally or accidentally. SUPPLIER’S SOLE LIABILITY, AND CUSTOMER’S EXCLUSIVE REMEDY, FOR BREACH OF THESE PRODUCT WARRANTIES SHALL BE, AT SUPPLIER’S SOLE DISCRETION, CREDIT OR REPLACEMENT OF THE NONCONFORMING PRODUCT.  
(b) Supplier represents, warrants and covenants that insofar as components received from suppliers selected by Customer, the warranty provisions relating to those specific components shall be in accordance with existing agreements between Customer and that supplier. Supplier shall have no obligation to offer any warranty greater than what Customer has already negotiated.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
9.4 Limitation of Liability  
EXCEPT FOR THE WARRANTIES SET FORTH IN THIS AGREEMENT, SUPPLIER HEREBY DISCLAIMS ALL OTHER WARRANTIES AND REPRESENTATIONS, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND/OR PARTICULAR PURPOSES. EXCEPT WITH RESPECT TO CLAIMS FOR BREACH OF CONFIDENTIALITY OR WITH RESPECT TO A PARTY’S INDEMNIFICATION OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES OF ANY NATURE WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY LOST REVENUES OR PROFITS OF THE OTHER PARTY AND/OR SUCH PARTY’S CUSTOMERS, AGENTS AND  
DISTRIBUTORS, RESULTING FROM OR ARISING OUT OF OR IN CONNECTION WITH ANY SALE, MANUFACTURE, DISTRIBUTION OR ANY USE OF ANY PRODUCT, WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF DAMAGES. THE FOREGOING LIMITATION OF LIABILITY APPLIES BROADLY, AND TO ANY AND ALL PRODUCTS MANUFACTURED AND SUPPLIED HEREUNDER, AND SHALL NOT BE CONSTRUED TO APPLY ONLY TO DAMAGES OCCURRING AS A RESULT OF BREACH OF ANY PRODUCT WARRANTIES, BUT SHALL ALSO APPLY TO ANY DAMAGES TO CUSTOMER OCCURRING AS A CONSEQUENCE OF THIS AGREEMENT OR ANY BREACH THEREOF. ALL LIMITATIONS OF LIABILITY, PURSUANT TO THE TERMS HEREIN, SHALL SURVIVE ANY TERMINATION OR EXPIRATION OF THIS AGREEMENT.  
 10. INDEMNIFICATION  
10.1 Supplier Indemnification. Supplier hereby indemnifies and holds harmless and agrees to defend Customer, its Affiliates and their respective officers, directors, employees and agents from and against all liabilities, damages, losses, costs and expenses (including reasonable attorneys’ fees) (“Losses”) arising out of actions, claims, suits or proceedings brought by a third party (“Claims”) as a result of (a) any negligent, malfeasant, willful or unlawful conduct by Supplier, (b) any Supplier breach of any representation, warranty or obligation under this Agreement, or (c) any claim or allegation that the manufacture of any Product by Supplier hereunder constitutes an infringement or misappropriation of any Intellectual Property Right of any third party in the United States or any other jurisdiction.  
10.2 Customer Indemnification. Customer agrees to and shall indemnify and defend Supplier, and hold Supplier harmless, from and against any and all claims, alleged claims, losses, xxxxx, damages, liabilities, penalties, lawsuits, threats of lawsuits, recalls or other governmental action, costs and expenses, including, without limitation, reasonable attorneys’ fees, suffered or incurred by Supplier, arising from or as a result of (i) any actual or alleged defects in the design of any Product and/or the Product Specifications; (ii) any Customer breach of this Agreement; (iii) death of or bodily injury to any person, or property damage, arising as a result of the use or sale of any Product; (iv) any negligent, malfeasant, willful or unlawful conduct by Customer or its employees, customers and/or agents, in connection with Customer’s sale, marketing or distribution of Product; and/or (v) any claims or allegations that the design, use or sale of any Product manufactured by Supplier hereunder constitutes an infringement or misappropriation of any Intellectual Property Right of any third party in the United States or any other jurisdiction.  
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10.3 Indemnification Process. Whenever an indemnified party becomes aware of a claim, suit or proceeding as to which it believes it is entitled to indemnification under this Article, it shall promptly give notice in writing to the indemnifying party, shall permit indemnifying party to assume exclusive control of the defense or settlement of the matter, and shall provide, at the expense of indemnifying party, all authority, information and assistance which indemnifying party may reasonably request for purposes of such defense. An indemnified party may engage its own counsel, at its own expense, to monitor the defense of any such matter. In no event shall the indemnifying party be entitled to settle any of the above-mentioned claims that could materially adversely affect the indemnified party without the indemnified party’s consent, such consent not to be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, the indemnities set forth in Sections 10.1 and 10.2 shall not apply to the extent that (a) the party seeking indemnification fails to give notice to the other party of such claim or threatened claim, and such failure materially prejudices the indemnifying party or such party’s ability to defend or settle such claim, (b) the indemnifying party is not given the opportunity to assume control of the defense and settlement of any such claim, and (c) the indemnified party does not provide reasonable assistance to the indemnifying party, at the indemnifying party’s expense, in relation to such claim.  
10.4 The obligations of indemnification, cooperation and subrogation under this Article 10 shall survive the termination of this Agreement for any reason.  
 11. TERM  
The term of this Agreement shall be five (5) years from the Effective Date (the “Initial Term”). At the end of the Initial Term, this Agreement shall automatically renew for one (1) year periods (each a “Renewal Term”, and the Initial Term and all Renewal Terms, the “Term”), until and unless either party notifies the other, in writing, no less than twelve (12) months prior to the end of the Initial Term or any Renewal Term of its intent to not renew this Agreement.  
 12. TERMINATION  
12.1 The parties may, at any time, mutually agree, in writing, to terminate this Agreement. Customer may terminate this Agreement for any reason by providing Supplier with one hundred eighty (180) days prior written notice  
12.2 Either party may immediately terminate this Agreement by written notice upon the occurrence of any of the following events: (i) the other party is or becomes insolvent or unable to pay its debts as they become due within the meaning of the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute; or (ii) the other party appoints or has appointed a receiver for all or substantially all of its assets, or makes an assignment for the benefit of its creditors; or (iii) the other party files a voluntary petition under the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute; or (iv) the other party has filed against it an involuntary petition under the United States Bankruptcy Code (or any successor statute) or any analogous foreign statute, and such petition is not dismissed within ninety (90) days.  
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12.3 Either party may terminate this Agreement, in writing, in the event of a material breach by the other, provided, however, that the party asserting such breach must first serve written notice of the alleged breach on the offending party, and must allow the offending party thirty (30) days, from the date of delivery of such notice, within which to cure the alleged breach.  
12.4 Notwithstanding anything to the contrary, termination of this Agreement may only be effected in writing, and according to the terms of this Agreement. Termination of this Agreement, for whatever reason, shall not affect any rights or obligations that may have accrued to either party prior to the effective date of termination.  
12.5 Effects of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. Upon expiration or termination without cause or by mutual agreement, Supplier shall continue to fulfill, subject to the terms of this Agreement, all Purchase Orders placed by Customer and accepted by Supplier in accordance with this Agreement prior to the effective date of termination. Upon expiration or termination of this Agreement for any reason, Supplier shall promptly deliver to Customer, at Customer’s cost, all Products and related documentation, whether or not completed, and each party shall promptly return to the other party all Confidential Information provided by the other party for the purposes of this Agreement. All Components (including any Safety Stock) remaining at the conclusion of Purchase Order fulfillment will be invoiced to Customer and returned to Customer with any remaining Consigned Components. Any remaining balance of Customer deposits with Supplier will be offset against amounts owing to Supplier. The parties shall use commercially reasonable efforts to complete all payments, and the final transfer of all Confidential Information, Products, Components (including any Safety Stock), Consigned Components and all related documentation and information, within forty-five (45) days following the effective date of such termination or expiration. Each party’s obligations under Sections 5.4, 7.1, 7.2, 7.3, 8, 9.3 (for the period specified in the applicable Product Warranty), 9.4, 10, 12.5, 13 and 14 shall survive the termination or expiration of this Agreement.  
Last Time Buy. Supplier shall upon Customer’s request manufacture another [\*\*\*] continuous supply of Product, based on the [\*\*\*], at the prices in effect at termination (“Last Time Buy”). Customer shall purchase all Product manufactured by Supplier under this Last Time Buy and such Products will be invoiced and delivered during such [\*\*\*] period as requested by Customer.  
 13. BINDING EFFECT/ASSIGNMENT  
This Agreement and the performance of any obligations hereunder shall be binding upon, shall inure to the benefit of, and be enforceable by the parties hereto and any and all permitted assignees, successors and legal representatives of the parties hereto. Neither party may assign rights nor delegate duties, including to a subcontractor, under this Agreement without the prior  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
written consent of the other party. Any assignee or delegate must agree to be bound by the terms of this Agreement. Notwithstanding the foregoing, Customer may assign this Agreement without consent of Supplier to any Affiliate, or to a successor in interest in the context of a merger, acquisition or sale of Customer, or a sale of all or substantially all of Customer’s business or assets to which this Agreement relates.  
 14. MISCELLANEOUS  
14.1 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, which shall not be unreasonably withheld, provided, however, that either party may, without the other party’s consent, assign this Agreement to an Affiliate or to an acquirer or successor of substantially all of the business or assets of the assigning company to which this Agreement relates. Any assignment in violation of this Section 14.1 shall be null and void.  
14.2 Further Assurances. Each party hereto agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.  
14.3 Force Majeure. Each of the parties hereto shall be excused from performance of its obligations hereunder to the extent such performance is prevented by a cause beyond the reasonable control of such party, including, without limitation, acts of God; laws or governmental regulations that become effective subsequent to the effective date of this Agreement war; insurrection; embargo; civil commotion; destruction of product facilities or materials by fire, earthquake or storm; labor disturbance; severe economic dislocation rendering the prices hereunder uneconomic or otherwise insufficient; judicial action; and failure of public utilities or common carriers.  
14.4 Relationship. The parties are independent contractors and shall not be deemed to have formed any partnership, joint venture or other relationship. Neither party shall make, or represent to any other person that it has the power or authority to make, any financial or other commitment on behalf of the other party  
14.5 Notice. All notices, requests or communications contemplated or required by this Agreement shall be in writing and, in order to be valid, shall be delivered by personal delivery or sent by certified or registered mail or equivalent, return receipt requested, by facsimile or telex, promptly confirmed by a writing sent by registered or certified mail, or by recognized overnight courier, addressed to the parties at the addresses set forth on the first page of this Agreement, or such other addresses as may be designated, in writing, by the respective parties. Any notice shall be deemed given when received by the other party.  
14.6 Legal Construction/Severability. If any part of this Agreement shall be held invalid or unenforceable, the remainder of the Agreement shall nevertheless remain in full force and effect.  
14.7 Section Headings/Construction. The captions and headings appearing in this Agreement are for reference purposes only and shall not be considered part of this Agreement. Such captions and headings shall not modify, amend or affect the provision hereof. This Agreement has been jointly prepared and shall not be strictly construed against either party hereto.  
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14.8 Entire Agreement; Modifications; Consents; Waivers. This Agreement, together with the Quality Agreement and all Appendices attached hereto, contains the entire Agreement of and between Supplier and Customer, with respect to the subject matter hereof. Neither this Agreement nor the Quality Agreement may be modified or amended except by an instrument or instruments in writing, signed by both parties. Each party hereto may, by an instrument in writing, waive compliance by the other party with any term or provision of this Agreement on the part of such other party to be performed or complied with. The waiver by either party hereto of a breach of any term or provision of this Agreement shall not be construed as a waiver of any subsequent breach.  
14.9 Dispute Resolution. Any dispute that arises between the parties arising out of or in connection with this Agreement or any breach thereof shall first be presented to the senior executives of the parties for consideration and resolution. If such executives cannot reach a resolution of the dispute within a reasonable time, then such dispute shall be resolved by submission to a court of applicable jurisdiction in the State of Delaware, and each party hereby consents to the jurisdiction and venue of such court.  
14.10 Governing Law. The provisions of this Agreement shall be construed and governed, in all respects, by the laws of the State of Delaware without regard to its conflicts of laws provisions that would seek to apply the laws of any other jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.  
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IN WITNESS HEREOF, the parties hereto have executed this Agreement as of the date first written above.  
 Vention Medical Design and Development, Inc.   
 Nevro Corp.  
By:   
/s/ Xxxxxx Xxxxxx  
 By:   
/s/ Xxxxxx Xxxxxxxx  
Title:   
VP, Design and Development  
 Title:   
Chief Financial Officer  
Printed Name:   
Xxxxxx Xxxxxx  
 Printed Name:   
Xxxxxx Xxxxxxxx  
Date:   
12/16/2015  
 Date:   
12/18/2015  
 21  
APPENDIX A  
PRODUCTS  
List of products to be manufactured by Supplier in accordance with this Agreement. Part numbers listed are Customer’s internal reference numbers unless otherwise specified.  
 1.1 Nevro Part Specification [\*\*\*]: Implantable Pulse Generator (IPG) Model IPG 1500  
 1.2 Nevro Part Specification [\*\*\*]: Implantable Pulse Generator (IPG) Model IPG 2000  
 1.2.1 Model 2000 incorporation pending completion of Development Plan.  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
APPENDIX B  
Model Unit Costing – Current, Potential, & Estimated  
Model 1500 Unit Costing - Current & Potential  
 Current [\*\*\*]% Potential [\*\*\*]% Potential   
Yield  
 [\*\*\*] % [\*\*\*] % [\*\*\*] %   
Yielded Material Cost / Unit  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Time (Hours)  
 [\*\*\*] [\*\*\*] [\*\*\*]   
Direct & Indirect Labor Cost (Yield Adjusted)  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Nevro Unit Price  
 $ [\*\*\*] \*\*\* $ [\*\*\*] \*\*\* $ [\*\*\*] \*\*\*   
 \* Does not include consigned material  
Model 2000 Unit Costing - Estimated  
 Current [\*\*\*]% Potential [\*\*\*]% Potential   
Yield\*  
 [\*\*\*] % [\*\*\*] % [\*\*\*] %   
Yielded Material Cost / Unit\*  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Time (Hours)\*  
 [\*\*\*] [\*\*\*] [\*\*\*]   
Direct & Indirect Labor Cost (Yield Adjusted)  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Nevro Unit Price  
 $ [\*\*\*] \*\*\* $ [\*\*\*] \*\*\* $ [\*\*\*] \*\*\*   
 \* Yielded Material cost includes [\*\*\*]% materials acquisition cost.  
\*\* Yielded Material cost include [\*\*\*]% materials acquisition cost.  
\*\*\* Based on Model 1500 baseline. Actual Model 2000 pricing will be confirmed and adjusted at conclusion of DVT or sooner.  
 23  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
APPENDIX C  
EQUIPMENT  
Equipment currently owned by Nevro that is maintained at Vention, including the Test System components.  
 Vention Part Number  
 Description  
 Manufacturer  
 Model  
 Serial Number  
 Nevro ID  
 Location  
[\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*]  
 24  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
APPENDIX D  
MODEL 1500 MATERIALS  
 Nevro IPG Cost Model 1500 / 2000 - Fixed Pricing  
 [\*\*\*] -Quote   
 Model 1500   
Estimated Material Cost - Vention Only  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Materials Margin  
 [\*\*\*] % [\*\*\*] % [\*\*\*] %   
Materials Cost with Margin  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Consigned Materials - Inspection  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
Yield  
 [\*\*\*] % [\*\*\*] % [\*\*\*] %   
Yielded Material Cost / Unit  
 $ [\*\*\*] $ [\*\*\*] $ [\*\*\*]   
 Nevro Supplied Materials  
 #  
 Description  
 UM  
 Qty  
Per  
Device  
 Vention P/N  
[\*\*\*]-xxxx-xx  
 Nevro  
P/N  
 Current  
Source  
1  
 [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*]  
 25  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
Vention Supplied Materials and Costing  
 Total Cost: $[\*\*\*] (noted that [\*\*\*])  
#  
 Description  
 UM  
 Qty  
Per  
Device  
 Vention P/N  
[\*\*\*]-xxxx-xx  
 Nevro  
P/N  
 Current  
Source  
 Cost  
[\*\*\*]  
 [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*]  
 26  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
APPENDIX E  
Vention will provide the following fulltime resources to support Nevro production based on minimum [\*\*\*] per month / [\*\*\*] year.  
 • Dedicated Vention Technical Team  
([\*\*\*])  
 • [\*\*\*]  
 • Line support: [\*\*\*]  
 • [\*\*\*]  
 • Line support: [\*\*\*]  
 • [\*\*\*]  
 • Line support: [\*\*\*]  
 27  
[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 APPENDIX F  
Quality Agreement  
Supplier Quality Agreement  
This Quality Agreement is made and entered into as of November 6, 2013 (“Effective Date”) by Vention Medical Design and Development (“Vention”), 000 Xxxxxxx Xxx Xxxxxxxxx, XX 00000 and Nevro Corp (“Nevro”), with its headquarters at 0000 Xxxxxxxx Xxxxxx, Xxxxx Xxxx, XX 00000.  
This Quality Agreement defines the duties of Vention and Nevro in the Quality System for the contract manufacture of the Product(s) set forth below:  
Vention will manufacture and perform assembly and test operations of the Implantable Pulse generator (IPG) for Nevro.  
SCOPE:  
This Quality Agreement applies to all Products and their associated Specifications and requirements supplied on or after its Effective Date.  
Responsibility for each activity is assigned to either “Vention” or “Nevro” in the appropriate box.  
This Quality Agreement is intended to define the responsibilities as set forth minimally by ISO13485 and FDA Quality System Regulations (QSR) 21 CFR Part 820.  
DEFINITIONS:  
For purposes of this Quality Agreement, the following definitions shall apply:  
 A. “Adverse Event Report” means the written report to the appropriate Regulatory Authority from a device manufacturer required whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.  
 B. “Applicable Laws” means the laws within a political entity that govern any aspect of the development, manufacture, market, approval, sale, distribution, packaging or use of the Product.  
 C. “Regulatory Authority” means any government regulatory authority, in the United States or other countries, where Vention manufactures Products, or mutually agreed upon additional countries in which Vention has responsibility to ensure compliance with applicable requirements, responsible for granting approvals for the performance of services under this Quality Agreement or for the Manufacturing, use, marketing, sale, pricing and/or other disposition of Nevro product(s) in which the Product(s) are used.  
 D. “CAPA” means a corrective action and preventive action system for identifying and preventing or eliminating the cause of an existing or potential nonconformity, defect, or other undesirable situation in order to prevent occurrence or recurrence.  
 E. “Certificate of Conformance”, “Certification of Compliance” or “Certification of Analysis” means a document, signed by an authorized representative of Vention, attesting that a particular Product is Manufactured or serviced in accordance with applicable Quality Management System requirements, the Specifications and this Quality Agreement.  
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 F. “Component” means any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the Product(s) or consumed during the Manufacture of the Product(s).  
 G. “Correction(s)” means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.  
 H. “Device Master Record” means the compilation of Records containing the procedures and specifications for the Product.  
 I. “Device History Record” or “DHR” means a compilation of Records containing the production history of the Product(s).  
 J. “Field Action”means an activity outlining the steps for management of and/or communication regarding the performance of distributed clinical, custom, and/or market released Product currently in use by the customer. These activities may include educational briefs, health safety alerts, and notifications, Corrections or Recall of Product(s) in any Nevro product.  
 K. “Finished Device” means any Product that constitutes a device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled or sterilized.  
 L. “Good Manufacturing Practice” or “GMP”means FDA regulations and guidelines regarding manufacturing practices and quality systems.  
 M. “ISO13485” means the “ISO Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes” standard.  
 N. “Lot” means one or more Products Manufactured under essentially the same conditions that are intended to have uniform characteristics and quality within specified limits.  
 O. “Lot History Record” or “LHR” means the document that authorizes and controls the production of a single lot of components or finished devices. When completed, the LHRs required to manufacture a finished device comprise the DHR.  
 P. “Manufacture(d)”or “Manufacturing”means all steps, processes and activities necessary to produce Product(s), including without limitation, the design, to the extent that Vention is responsible for the design, manufacturing, processing, quality control testing, release and storage of Product(s) by Vention in accordance with the terms and conditions of this Agreement.  
 Q. “Nonconforming Product” means product that does not meet Specifications. Examples include, but are not limited to:  
 • Product built to an incorrect configuration,  
 • Product built not in conformance with the validated process, or  
 • Product built with unapproved Components, counterfeit Components, or Components not meeting Specification.  
 R. “Notified Body” means a government agency in a member state of the European Union that carries out conformity assessment procedures for some classes of medical devices.  
 S. “Qualification” or “Qualify” means activity and analysis performed to demonstrate adherence to predetermined criteria. Qualification for a Product means Product testing or inspection conducted according to an approved and controlled protocol to ensure the Product meets Specifications.  
 T. “Quality System”, “Quality Management System” or “QSR” means the regulatory requirements under the Applicable Laws of an Regulatory Authority for the methods used in, and the facilities and controls used for, the design, Manufacture, packing, labeling, storage, installation and servicing of Product.  
 U. “Recall”means a firm’s removal or correction of a marketed product that Regulatory Authorities considers to be in violation of the laws it administers, and against which the agency would initiate legal action (e.g., seizure).  
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 V. “Records” means written or electronic accounts, notes, data, record of, and information and results obtained from performance of Services of all work done under this Quality Agreement.  
 W. “Specification(s)” means all applicable specifications, protocols and other documents relevant to the design, physical characteristics, function, performance, Manufacture, packaging, labeling and quality of the Product(s) communicated in writing by Nevro or mutually agreed upon in writing by the parties.  
 X. “Standard Operating Procedure” means the standard operating procedures in effect at Vention which have been approved by Vention’s quality department and which are applicable to the processing of the product.  
 Y. “Sub-tier Supplier” means any supplier that either directly or indirectly provides product or Services to Vention in connection with any Product.  
 Z. “Validation” (or “Validate”) means confirmation by examination and provision of objective evidence that the applicable requirements can consistently be fulfilled.  
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 Responsibilities Table  
Table Key: N/A = Not Applicable  
 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
1.0 Regulatory Compliance   
1.1 Maintain all licenses, registrations and other authorizations as are required under the Applicable Laws. ¨ x x  
1.2 Maintain and operate the facility in compliance with this Quality Agreement. ¨ x ¨  
1.3 Manufacture the Product in accordance with this Quality Agreement. ¨ x ¨  
1.4 Product Clearances and Approvals. Vention shall provide reasonably necessary assistance to Nevro in obtaining all necessary regulatory approvals for the Manufacturing, marketing, sale and distribution of the Product(s). ¨ x ¨  
1.5 Regulatory Approval of Product Modifications. Nevro shall be responsible for making the final determination as to whether proposed Product/Process modifications require regulatory approval prior to implementation and shall be responsible for filing and obtaining any required approvals, clearances and/or supplements. ¨ ¨ x  
1.6 Compliance History. Vention shall provide Nevro with a review of Vention’s regulatory compliance history related to the Products or related to the manufacturing processes used to manufacture the Products. ¨ x ¨  
2.0 Management Responsibility   
2.1 Vention shall have personnel with executive responsibility to oversee its Quality System. Vention also shall maintain an organizational structure which ensures the Product(s) are designed, developed and/or Manufactured in accordance with this Quality Agreement. ¨ x ¨  
2.2 Vention shall assign a person or person(s) with executive responsibility, or who report(s) directly to a person with executive responsibility, to serve as a contact for Nevro under this Quality Agreement, and to oversee compliance with this Quality Agreement. ¨ x ¨  
2.3 Quality Plan. Vention shall have a quality plan and/or quality system manual that defines the elements of the Quality System relevant to the design, development and/or Manufacture of the Product(s), and shall establish how the quality requirements shall be met. ¨ x ¨  
2.4 Identification. Vention shall ensure that Product(s) and Components are identified during all stages of receipt, production and distribution. ¨ x ¨  
2.5   
Traceability. Vention shall be responsible for setting up and maintaining controlled documentation of Product and Component traceability during all stages of receipt, production and distribution.  
 • It is expected that the results of a full product traceability will be provided to Nevro upon request, and the results will be available within 24 hours of the request.  
 ¨ x ¨  
3.0 Corrective and Preventive Actions/Performance   
3.1 Standard Operating Procedures. Vention shall establish and maintain procedures for implementing a CAPA system in compliance with the industry standards and Quality Management System requirements. ¨ x ¨  
3.2 Resolution. Vention shall implement the CAPA system with regard to any quality, Manufacturing or performance issue raised by Vention or Nevro related to Product(s). ¨ x ¨  
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 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
3.3 Field Actions. Nevro has the sole authority for decisions related to any Product(s) in the field, including any Field Action. Suppler shall support Nevro by providing access to necessary Product information and quality records. ¨ x x  
4.0 Nonconforming Product   
4.1 Vention shall establish and maintain procedures to control Product that does not conform to specified requirements in compliance with the Quality Management System requirements or this agreement. ¨ x ¨  
4.2 Control of Nonconforming Product. Vention shall have Standard Operating Procedures to control Product that does not conform to Nevro Specifications. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including a determination of a need for an investigation, which shall be documented. ¨ x x  
4.3 Nevro shall have thirty days from the delivery of the Product to notify Vention that it has delivered non-conforming Product. In the event that Nevro does not notify Vention of non-conformity or non-compliance within such thirty (30) day period, then the Product(s) shall be deemed accepted. In the event that Nevro shall reject any Product(s), Nevro shall provide written notice to Vention within forty-five (45) days after receipt of the shipment, together with a reasonably detailed written statement of its reason for rejection and, where appropriate, Product samples demonstrating the proposed nonconformance. If no such written notice is received by Vention, then Nevro shall be deemed to have accepted the shipment of Product. In the event of proper rejection by Nevro, Vention shall, within a reasonable period of time notify Nevro of whether it accepts the notice of nonconformity. If Vention disagrees with any proposed nonconformity by the Nevro, then both parties agree to cooperate and make every reasonable effort to resolve the disagreement. If Vention confirms Nevro’s rejection, Vention shall, in a reasonably prompt manner, either replace (if it has not already done so) the nonconforming Product with conforming Product within thirty (30) days; or (ii) credit to Nevro the purchase price therefor. Replacement shipments shall also be subject to the terms and conditions of this Quality Agreement. ¨ x x  
4.4 Product Performance. Nonconforming Products may be returned to Vention for investigation and analysis. ¨ x ¨  
4.5 Disposition of Nonconforming Product. Vention shall have Standard Operating Procedures covering disposition of Nonconforming Product, including review and documentation of decisions. The parties shall jointly determine the procedures for rework, retest and reevaluation of Nonconforming Product to ensure the Product(s) meet Specifications. Vention shall document rework activities in the DHR, and provide report of rework activities to Nevro upon request. ¨ x x  
5.0 Document Control   
5.1 The Vention shall establish a process for document control and document changes related to Product(s). ¨ x ¨  
5.2 Vention shall not modify Product Specifications or process specifications without Nevro written approval. Vention shall maintain records of changes to documents related to the Product(s), which shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and the effective date. ¨ x x  
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 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
6.0 Purchasing Controls   
6.1 For Components not supplied by Nevro, Vention shall establish and maintain controls on the purchase of Components to ensure conformance to specified requirements, including visual inspection of packaging, labeling, or shipping containers, and dimensional inspection or analytical testing. Vention shall maintain documentation that clearly describes the quality requirements for Components, and shall require Component sources to notify Vention of any proposed changes in the Manufacturing of the Components prior to making any change. ¨ x ¨  
6.2 For Components not supplied by Nevro, Vention shall establish and maintain acceptance procedures with respect to the Manufacture of the Products. ¨ x ¨  
7.0 Design Controls   
7.1 Nevro shall collaborate with Vention to ensure that the design requirements for the Product(s) are appropriate and address the intended use of the Product(s) including the needs of the user and patient, in compliance with the Quality Management System requirements. ¨ x x  
7.2 Nevro has the sole authority to make design changes. Vention shall not implement design change(s) unless it receives updated Specifications from Nevro. ¨ ¨ x  
8.0 Preventive Maintenance and Calibration   
8.1 Maintain calibration and preventive maintenance procedures and schedules for selected equipment/instruments used in the manufacture, packaging, testing and Validation/qualification of the Product. Include calibration tagging where appropriate. ¨ x ¨  
8.2 Document and review preventive maintenance and calibration performed for equipment and make available to Nevro designee for onsite review upon request. ¨ x ¨  
9.0 Packaging and Labeling   
9.1 Compliance with Specifications. All Products shall be packaged and labeled in accordance with any applicable Specifications. ¨ x ¨  
9.2 Procedures. Vention shall establish and maintain Standard Operating Procedures to control labeling activities in compliance with the Quality Management System requirements. ¨ x ¨  
9.3 Labeling Mix-Ups. Vention shall store labels and labeling in a way that prevents an incorrect label from being used with a Product. Vention shall control labeling and packaging operations to prevent labeling mistakes, and shall document the label and labeling used for each production unit, Lot or batch in the DHR. ¨ x ¨  
10.0 Audits   
10.1 Nevro retains the right to audit Vention Manufacturing and Quality Systems upon advanced written notice, at a date and time mutually agreed to between the parties. ¨ ¨ x  
10.2 Nevro or an approved designee has the right to audit Vention’s facilities and systems for a time period not to exceed three working days, as they relate to the manufacture and testing of Product, at mutually agreed upon time and date. Nevro or an approved designee retains the right to conduct “for cause” audits as necessary upon agreement with Vention. ¨ ¨ x  
10.3 Issue responses to all observations in writing to Nevro or approved designee within thirty (30) days of receipt. Responses are to include timelines and plans for closure of all commitments. ¨ x ¨  
10.4 Management of Sub-tier Suppliers. Vention is responsible for management of Vention’s Sub-tier suppliers based upon risk as determined per Vention’s own internal procedures. ¨ x ¨  
 33  
 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
10.5 Vention is responsible for communicating all requirements to third party suppliers that are managed by Vention. This includes third party suppliers that have been identified as third party suppliers by Nevro. Any communication with a third party supplier by Nevro must be coordinated with Vention. If said communication is not shared with Vention, Vention shall be under no obligation to follow any directives received by third party supplier through Nevro until Vention is made aware of the communication/requirements. Further, Vention shall not be deemed to be in default of this Agreement if Nevro communicates directly with a third party supplier without coordinating through Vention and Nevro shall indemnify and hold Vention harmless for any issues that may arise as a result of any communication with a third party supplier that has not been coordinated through Vention. ¨ x x  
10.6 Vention is responsible for qualifying, monitoring and maintaining the list of Sub-Tier suppliers used for this Product in accordance with Vention’s internal procedures. ¨ x ¨  
10.7 Regulatory Audits and Inspections. Vention agrees that Regulatory Authorities shall have access to and the right to inspect or audit any pertinent Product(s) design, Manufacturing, or quality processes, and associated documentation or Records. ¨ x ¨  
10.8 Third Party Audits. Vention shall promptly notify Nevro when an Authority inspection of its facilities (or an inspection by third parties in accordance with FDA regulations or inspection by another governmental authority such as a Notified Body) relating to any Product(s) is expected and/or underway. ¨ x ¨  
10.9 Regulatory Correspondence. Vention shall promptly provide Nevro with copies of all regulatory correspondence, including without limitation Form FDA 483s and FDA warning letters and any correspondence with the FDA or any other Authority related to processes, Components or equipment which are the same or similar to those used in the Manufacture of the Product(s). ¨ x ¨  
10.10 Regulatory Commitments. Vention shall secure Nevro’s written agreement prior to making any commitment to a regulatory agency regarding the Product. Nevro shall be provided with draft responses to regulatory observations that involve the Product and its Manufacture prior to submission to any Regulatory Authority and Vention shall permit Nevro’s input into responses and corrective actions. Vention shall retain the final authority and responsibility for the content of the responses to the Regulatory Authority related to a Finished Device. ¨ x x  
11.0 Personnel Training   
11.1 Personnel and Training. Vention shall have sufficient personnel with the necessary education, background, training and experience to perform under this Quality Agreement. ¨ x ¨  
11.2 Provide adequate number of personnel qualified by appropriate training and experience to perform and supervise the manufacture, testing, packaging and disposition of the Product. ¨ x ¨  
11.3 Assure training is regularly conducted, assessed and documented by qualified individuals in accordance with Vention’s documented procedures. ¨ x ¨  
11.4 Have written job descriptions for positions responsible for performing GMP related activities. ¨ x ¨  
11.5 Assure that non-employees, including consultants, advising on the manufacture and control of the Product have sufficient education, training, and experience to advise on the subject for which they are retained. ¨ x ¨  
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 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
12.0 Complaints/Adverse Events   
12.1 Each party shall cooperate fully with the other party in dealing with customer and third party complaints concerning the Product(s) and shall take such action to promptly resolve such complaints as may be reasonably requested by the other party. ¨ x x  
12.2 Nevro shall have the sole authority to correspond with all applicable regulatory authorities with respect to complaints about the Product(s). ¨ ¨ x  
12.3 Nevro is responsible for complying with all applicable Regulatory Authorities regulatory requirements pertaining to Adverse Event reporting. Vention shall reasonably cooperate with Nevro to enable Nevro to fulfill such requirements. If Vention becomes aware of a potentially reportable event, notice of such event shall be given to Nevro within two (2) business days. ¨ x x  
13.0 Field Alerts and Recalls   
13.1 If Vention becomes aware of any defect or problem with respect to any Nevro Product, they shall notify Nevro no later than two (2) business days after becoming aware of the issue. ¨ x ¨  
13.2 Notification. If either party in good faith determines that a Recall or other action involving a Product(s) should be considered, such party shall immediately notify the other party and shall advise such other party of the reasons underlying its determination. ¨ x x  
13.3 Nevro Determination. Nevro has the sole authority to determine whether any action such as a Recall or other action should be undertaken. ¨ ¨ x  
13.4 Analysis. Product returned related to Recall shall be analyzed by Nevro or by Vention at Nevro’s request. If Vention is required to perform this analysis, Vention will quote the additional costs for the analysis. Work will commence once agreement is made between parties in writing. ¨ x x  
14.0 Handling, Storage, Distribution and Installation   
14.1 Vention shall establish and maintain procedures for the handling, storage, distribution and installation of the Product(s). ¨ x ¨  
14.2 Handling. Vention shall have systems in place to ensure that mix-ups, damage, deterioration, contamination or other adverse effects do not occur during handling of the Product(s). ¨ x ¨  
14.3 Storage. Vention shall control storage areas to prevent mix-ups, damage, deterioration, contamination or other adverse effects pending distribution of the Product(s). ¨ x ¨  
14.4 Distribution. Vention shall have systems in place to control distribution of Product(s) so that only Product(s) approved for release are distributed. Vention shall ensure that no obsolete, rejected, expired or deteriorated Product(s) are distributed, unless they are distributed to Nevro at its written request. ¨ x ¨  
15.0 Production   
15.1 Process Control-Generally. Vention shall have systems in place to define and maintain the Manufacturing process and associated controls so that all Product(s) conform to their Specifications (ie. Device Master Records). ¨ x ¨  
15.2 Process Monitoring. Vention shall monitor and control the Manufacturing process using the industry standard tools such as in-process inspection, Validation and statistical process control. ¨ x ¨  
15.3 Certificate of Conformance. If requested by Nevro, Vention shall provide to Nevro a Certificate of Conformance consistent with the Specifications for each Lot/batch of Product shipped. ¨ x ¨  
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 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
15.4 Inspection, Measurement, and Test Equipment. Vention shall notify Nevro in writing of any out-of-tolerance equipment that may affect the testing or Manufacturing of any Product(s) or Component. The written notification shall include identification of the affected Product(s) or Component. ¨ x ¨  
15.5 Nevro has the sole authority to make/approve process changes. Vention shall not implement process change(s) unless it receives written approval from Nevro.   
16.0 Change and Change Notification   
16.1 Changes by Nevro. The Specifications may be revised by Nevro, to be agreed upon by Vention. Such revisions may require additional Qualification. If additional Qualification is required, Supplier will quote the additional qualification costs. Nevro shall notify Vention of all relevant Specification revisions, which shall be agreed to by Vention. Vention shall implement all revisions by dates specified by Nevro when possible and if such date cannot be met, then the parties shall mutually agree to a date that is achievable. ¨ ¨ x  
16.2 Changes by Supplier. Upon approval by Nevro of the initial design, Component or process changes, design changes or deviations considered by Vention must be submitted to Nevro in writing for review and approval prior to making any changes. Said approval shall be provided in a timely manner. ¨ x ¨  
16.3 Change/Approval. Nevro personnel shall review and approve changes that may affect the Product(s). ¨ ¨ x  
17.0 Record Retention   
17.1 Creation and Maintenance Quality System Record. Each party shall create and maintain Records for the activities for which they are responsible under this Quality Agreement in compliance with the Quality Management System requirements. ¨ x x  
17.2 Copies. Upon Nevro’s request, Supplier shall promptly provide Nevro with copies of non-proprietary portions of Records and other documents required to be maintained pursuant to this Quality Agreement. ¨ x ¨  
17.3 Retention. Vention shall keep Records for 7 years minimally from date of Record creation; thereafter, Vention shall notify Nevro prior to disposing of such Records and upon Nevro’s request, either (i) transfer custody of the Records to Nevro or (ii) Nevro may elect to have such Records retained in Vention’s archives for an additional period of time at a reasonable charge to Nevro. At any time upon written request, or termination of this Quality Agreement, Vention shall return all Records to Nevro. ¨ x ¨  
18.0 Resolution of Quality Issues   
18.1 Quality related disagreements between Vention and Nevro that are not resolved in the normal course of business shall be brought to the attention of the appropriate contact person for notices (as set forth below) at Vention and Nevro, in writing. If both parties agree that a resolution of the disagreement is reasonably possible, then both Vention and Nevro shall agree to work jointly to develop a strategy for such resolution. Vention and Nevro further agree to record such resolution in writing. If a resolution cannot be reached, then the parties agree to resolve the same through non-binding arbitration. ¨ x x  
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 Section  
 Responsibilities  
 N/A  
 Vention  
 Nevro  
19.0 Quality Reporting   
 Vention shall report the following quality information to Nevro on a quarterly basis:  
 • Nonconforming Material Reports (NCMR’s) for Nevro product, including trend analysis of defect types.  
 • Supplier performance of Suppliers that provide Nevro parts or services, including trend analysis for supplier issues.  
 • Supplier Corrective Actions for Suppliers that provide Nevro parts and services.  
 • Environmental Monitoring (at minimum Cleanroom particle, viables)  
 • Production Yields, including trend analysis of defect types  
 • Number of devices manufactured  
 • Number of devices shipped  
 ¨ x ¨  
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 XII. ATTACHMENTS  
 x ISO 13485 Certificate  
 ¨ Organizational Chart  
 ¨ Quality Manual  
 ¨   
 ¨   
Approval:  
 SUPPLIER NEVRO CORPORATION  
REPRESENTATIVE  
 QUALITY REPRESENTATIVE  
Xxxxxxx Xxxxxx, V.P., Quality & Regulatory  
 Xxx Xxxx, Director, Quality Assurance  
Print (Name and Title) Print (Name and Title)  
/s/ Xxxxxxx Xxxxxx  
 /s/ Xxx Xxxx  
Signature Signature  
11/07/2013  
 08 Nov 2013  
Date Date  
Xxx Xxxxxxxxxxx, Director, Quality & Regulatory  
 Print (Name and Title)   
/s/ Xxx Xxxxxxxxxxx  
 Signature   
11/7/2013  
 Date   
Xxxxxx Xxxxxxxx, Product Development Engineer  
 Print (Name and Title)   
 Signature   
 Date   
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APPENDIX G  
Form of Purchase Order  
Sample Below: PA12131  
[\*\*\*]  
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.