Exhibit 10.1  
 MANUFACTURING AGREEMENT  
 THIS MANUFACTURING AGREEMENT (the “Agreement”) is made and entered into as of July 24, 2008 (the “Effective Date”), by and between Osiris Therapeutics, Inc. (“Osiris”), a Delaware corporation, and NuVasive, Inc. (“NuVasive”), a Delaware corporation.  
 RECITALS  
 WHEREAS, Osiris and NuVasive are parties to that certain Asset Purchase Agreement, dated May 8, 2008 (the “Asset Purchase Agreement”), pursuant to which Osiris sold, and NuVasive purchased, technology related to manufacturing the Osteocel product line (as more specifically set forth therein); and  
 WHEREAS, NuVasive and Osiris desire to herein set forth an arrangement whereby Osiris shall manufacture and deliver to NuVasive, and NuVasive shall purchase, the Product (as defined below).  
 NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:  
 ARTICLE 1  
DEFINED TERMS  
 As used herein, certain capitalized terms shall have the meanings ascribed to them as provided below:  
 1.1. “AATB” means the American Association of Tissue Banks.  
 1.2. “Action” shall have the meaning as such term is defined in Section 6.3 of this Agreement.  
 1.3. “Affiliate” means, with respect to a party, any person or entity which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such party.  
 1.4. “Certificate of Analysis” means, for each Lot produced, a document prepared by Osiris setting forth the measured and observable characteristics of Product from the Lot, confirming that such Lot meets the Specifications, certifying that such Lot was manufactured and released in accordance with applicable Laws and cGTP.  
 1.5. “cGTP” means current Good Tissue Practice as defined in FDA rules and regulations, including the United States regulations set forth at 21 CFR Parts 1270 and 1271, subparts C and D, as in effect and as may be amended or replaced by the FDA from time to time.  
 1.6. “Confidential Information” means information which is disclosed by a party (the “Disclosing Party”) to the other party (the “Receiving Party”) in whatever media, and is marked, identified or otherwise acknowledged to be confidential at the time of disclosure; provided that information shall not be deemed “Confidential Information” which is (a) publicly known, through no fault of the Receiving Party, (b) received by the Receiving Party from a source having the right to  
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 disclose such information, (c) known by the Receiving Party prior to disclosure of such information, or (d) independently developed by the Receiving Party without use of the Disclosing Party’s information. Notwithstanding the foregoing and for the avoidance of doubt, the Confidential Information of NuVasive includes all Licensed Technology, whether or not marked, identified or otherwise acknowledged to be confidential and whether or not known or developed by Osiris, and the use and disclosure of Licensed Technology by Osiris (as the Receiving Party hereunder) shall be subject to Section 8.3.  
 1.7. “CPI” shall mean the “Price Index for all Urban Consumers, U.S. city average, all items, for the then immediately preceding 12-month period” as published by the US Government.  
 1.8. “Damages” shall have the meaning as such term is defined in Section 6.1 of this Agreement.  
 1.9. “Deliver” or “Delivery” with respect to Product means, and shall take place upon, the transfer of possession of Product to a carrier, FCA the Facility (Incoterms 2000).  
 1.10. “Donor” means a human tissue donor.  
 1.11. “Donor Tissue” means human musculoskeletal tissue, including bone and connective tissue.  
 1.12. “Excess Quantities” shall have the meaning as such term is defined in Section 3.3 of this Agreement.  
 1.13. “Executives” shall have the meaning as such term is defined in Section 9.8 of this Agreement.  
 1.14. “Facility” means the facility at which Osiris or its subcontractors set forth on Schedule 3.11, or otherwise approved by NuVasive in accordance with Section 3.11, will Process Product under this Agreement.  
 1.15. “FDA” means the U.S. Food and Drug Administration, and any successor or replacement agency thereto.  
 1.16. “Inventions” shall have the meaning as such term is defined in Section 8.2 of this Agreement.  
 1.17. “Latent Defect” means any defect in any Lot or other shipment of Product that could not reasonably be found by the exercise of ordinary care in an initial physical inspection by NuVasive, such as, but not limited to, the presence of a contaminant or Osiris’ failure to Process Product in accordance with cGTP.  
 1.18. “Laws” means all laws, rules, regulations, ordinances, standards and guidelines that apply to the Processing of Product or the performance of either party’s obligations under this Agreement, as the context requires under this Agreement, including, without limitation, the Public Health Service Act, 42 U.S.C. §201 et seq .., the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Parts 1270 and 1271, Human Cells, Tissues, and Cellular and Tissue Based Products, other rules, regulations or standards promulgated by the FDA or any other applicable governmental agency, and of the AATB, as each may be amended from time to time.  
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 1.19. “Licensed Technology” means the intellectual property (including patents and patents pending of NuVasive), methods, technology, and know-how owned or licensed by NuVasive and used in, held for use in, intended for use in, related to or necessary for Processing the Product. Licensed Technology shall include all Transferred Technology as defined in and purchased by NuVasive under the Asset Purchase Agreement.  
 1.20. “Lot” means the Product, Processed in accordance with the Specifications, resulting from a single production run, traceable to a single source Donor.  
 1.21. “Lot Records” means manufacturing, packaging and test records, donor suitability determination documentation, cleaning, labeling and “sterilization” processes documentation and documentation relating to Processing and release of each Lot, including exception documentation, deviations/discrepancies, raw data or data worksheets and additional documentation generated and/or processed as part of the production record of the related Lot.  
 1.22. “Minimum Performance Level” shall have the meaning as such term is defined in Section 3.3 of this Agreement.  
 1.23. “NuVasive Indemnitee” shall have the meaning as such term is defined in Section 6.1 of this Agreement.  
 1.24. “NuVasive Responsible Party” shall have the meaning as such term is defined in Section 6.2 of this Agreement.  
 1.25. “Order” shall have the meaning as such term is defined in Section 3.2 of this Agreement.  
 1.26. “Osiris Indemnitee” shall have the meaning as such term is defined in Section 6.2 of this Agreement.  
 1.27. “Osiris Product Warranty” shall have the meaning as such term is defined in Section 3.7 of this Agreement.  
 1.28. “Osiris Responsible Party” shall have the meaning as such term is defined in Section 6.1 of this Agreement.  
 1.29. “Parties” shall mean Osiris and NuVasive; “Party” shall mean Osiris or NuVasive,  
 1.30. “Process” or “Processing” shall mean any or all of the acts of manufacturing (including procuring materials, Donor Tissue and Donors suitability for determination, for manufacturing), handling, storing, analyzing, testing, packaging, labeling and preparing for shipment Product by Osiris pursuant to this Agreement.  
 1.31. “Product” means osteobiologic allograft material containing cancellous bone (which contains viable mesenchymal stem cells) Processed by Osiris using the Licensed Technology and meeting the Specifications attached hereto as Exhibit A, and which has passed all required inspections and testing and has been released for distribution for human implantation.  
 1.32. “Product Fees” shall have the meaning as such term is defined in Section 4.1.  
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 1.33. “Product-Related Inspection” shall have the meaning as such term is defined in Section 5.1 of this Agreement.  
 1.34. “Product Withdrawal” shall have the meaning as such term is defined in Section 5.7 of this Agreement.  
 1.35. “Publication” shall have the meaning as such term is defined in Section 8.4 of this Agreement.  
 1.36. “Specifications” means the Product specifications set forth in Exhibit A attached hereto, as the same may be amended in accordance with this Agreement.  
 1.37. “Term” shall have the meaning as such term is defined in Section 7.1 of this Agreement.  
 ARTICLE 2  
PROCUREMENT AND SUPPLY OF DONORS  
 Donor Procurement Obligations. Osiris shall use its commercially reasonable best efforts to procure Donor Tissue as necessary to meet the Minimum Performance Levels and to Process Product in accordance with the terms of this Agreement.  
 ARTICLE 3  
MANUFACTURING OF PRODUCT; TECHNOLOGY LICENSE  
 3.1. Manufacturing Obligations. Osiris shall Process for and supply to NuVasive Product in accordance with the terms of this Agreement. Osiris shall Process and supply the Product to NuVasive hereunder in conformity with the Specifications and in compliance with cGTP and all applicable Laws. If either party seeks a change to the Specifications or there is a change in applicable Laws that would necessitate a change in the Specifications, the parties will meet and confer in good faith to determine whether and what changes (if any) should be made thereto. Any and all amendments or modifications in the Specifications must be agreed upon in writing by both parties.  
 3.2. Forecasting and Orders. On or before sixty (60) days prior to each calendar quarter, NuVasive shall provide to Osiris a binding order (“Order”) for the quantity and size of Product to be delivered by Osiris to NuVasive in the following calendar quarter. Each Order shall be in writing, and shall specify the quantity of units of Product by size, the brand name of each unit of Product ordered, the requested Delivery date(s), the destination shipping address(es), and the Product Fees therefor. Osiris shall be required to supply to NuVasive all such quantities of Product as NuVasive orders pursuant to such Orders in accordance with the Product unit sizes and brand names specified in such Orders and shall use its commercially reasonable best efforts to conform to the requested Delivery date(s) set forth in such Orders, provided in each case such Orders do not exceed the Minimum Performance Levels during the applicable periods set forth in Section 3.3 below. Osiris shall deliver the Product to NuVasive pursuant to the Orders, subject to available Product being released for transplantation; provided, that the Parties understand and agree the final Delivery dates for Orders may vary from the requested dates based upon Donor Tissue procurement.  
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 3.3. Performance Levels.  
 3.3.1. Minimum Performance Levels. Osiris shall use its commercially reasonable best efforts to Deliver Product to NuVasive at least in the quantities set forth below during the applicable periods (“Minimum Performance Levels”) and shall Deliver any such Product according to Product unit size and brand name specifications established by NuVasive and set forth in each Order. NuVasive shall provide Orders to purchase from Osiris Product in quantities of at least the Minimum Performance Level for the applicable period.  
 Minimum Performance  
 Applicable Period  
 Level Delivered (cc)  
 Effective Date to April 15, 2009  
 125,000  
 April 16, 2009 to eighteen (18) months following the Technology Closing Date (as defined in the Asset Purchase Agreement)  
 125,000  
 3.3.2. Additional Product. Osiris shall have the right, in its discretion, to Process and Deliver Product hereunder in quantities that exceed NuVasive’s Orders (the “Excess Quantities”), provided that Osiris gives advance written notice to NuVasive of its intent to Process and Deliver the Excess Quantities. Following receipt of such written notice, the Parties shall discuss and attempt in good faith to reach agreement on the unit sizes of the Excess Quantities. If the parties are unable to reach agreement on the unit sizes of any Excess Quantities within ten (10) days from the notice, Osiris shall Process and Deliver to NuVasive unit sizes of such Excess Quantities in the same proportion as the unit sizes of Product set forth in NuVasive’s most recent Order. Subject to the notice and sizing provisions immediately above, in addition to NuVasive’s requirement to purchase from Osiris Product in quantities of at least the Minimum Performance Level (provided that Osiris and/or its subcontractors Processes at least such quantities) for the applicable period, NuVasive shall purchase from Osiris the Excess Quantities that Osiris Processes in accordance with this Agreement during the Term; provided, however, that NuVasive shall have no obligation hereunder to purchase Product in quantities greater than \*\*\* cubic centimeters, and the Delivery and purchase of such greater quantities of Product, if any, shall be by mutual written agreement of both parties. For all Product Processed hereunder, Osiris shall provide NuVasive with a monthly forecast of projected Product manufacturing quantities for such month.  
 3.4. Shipment and Delivery. All Product shall be shipped to NuVasive or NuVasive’s customers as directed by NuVasive using a shipping company designated by NuVasive. Osiris shall tender Product for Delivery, FCA the Facility, in accordance with the Specifications and addressed to the shipping address specified by NuVasive in the Orders or to such other address as NuVasive may provide to Osiris in writing in advance of any Delivery. NuVasive shall provide Osiris with standard shipping instructions prior to the first requested shipping date hereunder; thereafter, such shipping instructions may be changed upon written notice given to Osiris by NuVasive. Osiris shall not Deliver any Product prior to completion of quality control and release testing by Osiris. NuVasive shall be responsible for all shipping and insurance charges and risk of loss associated with the shipment of Product hereunder (from and after Delivery), provided that Osiris has complied with  
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 Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.  
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 the shipping instructions of NuVasive and that the Product is tendered for Delivery in accordance with the Specifications. Title to Product shall pass to NuVasive upon Delivery of Product to the carrier selected by NuVasive.  
 3.5. Quality Control; Release Testing; Documentation. Osiris shall be responsible for quality control tests to ensure that each Lot conforms to the Specifications and is produced in accordance with applicable Laws and cGTP, and Osiris shall be responsible for all release testing. All quality control test results and release testing and other documents related to quality control and quality assurance and copies thereof shall be made available to NuVasive at Osiris’s offices upon written request of NuVasive. Such information is considered NuVasive’s Confidential Information in accordance with this Agreement and shall be transferred to NuVasive upon the termination of this Agreement. Any testing performed by or on behalf of Osiris (including tests to confirm that each Lot meets the Specifications) shall be performed at Osiris’s sole cost and expense and may be used by NuVasive for final release of each Lot without additional testing by NuVasive; provided, however, that NuVasive may conduct its own release testing of each Lot in its discretion. NuVasive (in its sole discretion) shall determine the form and substance of any release testing information that is submitted to any regulatory authority. At the time of Delivery of each Lot, Osiris shall send to NuVasive a signed Certificate of Analysis with respect to such Lot. Within thirty (30) days following the Delivery of each Lot, Osiris shall provide NuVasive with properly completed copies of Lot Records for such Lot prepared in accordance with the Specifications and applicable Laws.  
 3.6. Rejection and Cure. Upon receipt of each shipment of Product, NuVasive or its customers shall perform an initial physical inspection of such Product and review any related documentation. If any Product (including without limitation any documentation related thereto) fails, in whole or in part, to conform to the applicable Specifications and the terms hereof, or if any Product is not Processed in accordance with cGTP or applicable Laws, then NuVasive shall have the right to reject such nonconforming Product. NuVasive shall give written notice to Osiris of its rejection hereunder as soon as possible, but no more than thirty (30) days after NuVasive’s or its customer’s receipt of such shipment, specifying the grounds for such rejection. If at any time thereafter NuVasive discovers a Latent Defect, NuVasive shall give written notice to Osiris of its rejection hereunder as soon as possible, but no more than ninety (90) days after NuVasive’s receipt of the Product, specifying the grounds for such rejection. The nonconforming Product shall be held for Osiris’s disposition, or shall be returned to Osiris, in each case at Osiris’s expense, as directed by Osiris. Osiris shall use commercially reasonable best efforts to correct the root cause of the nonconformance in order to comply with the requirements of the applicable Specification. In addition, Osiris shall, at its expense, promptly replace each nonconforming Product with conforming Product.  
 3.7. Warranty. With respect to Product supplied hereunder, Osiris warrants (“Osiris Product Warranty”) that the (a) Product shall conform with the applicable Specifications therefor, shall be free from defects in materials or workmanship, and shall not be adulterated, misbranded, contaminated, tampered with or otherwise altered or mishandled while in the custody and control of Osiris; and (b) Product shall be Processed in accordance with the applicable Specifications, and in compliance with cGTP and all applicable Laws. Osiris hereby represents, warrants and covenants that it will not, and has not, employed or otherwise used in any capacity the services of any person debarred under Section 21 U.S.C. 335a in performing any portion of the Processing of Product. EXCEPT AS PROVIDED HEREIN, OSIRIS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, WITHOUT LIMITATION, ANY  
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 WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.  
 3.8. Packaging; Labeling; Marketing. Osiris shall package and label the Product according to the Specifications and in compliance with cGTP and all applicable Laws, rules, regulations, and/or standards. Product supplied to NuVasive shall be labeled as determined by NuVasive, provided that NuVasive shall provide Osiris with at least thirty (30) days prior written notice of any labeling changes (including, but not limited to, brand names), and Osiris shall be entitled to recover, and NuVasive shall be responsible to pay to Osiris, all reasonable out of pocket costs that Osiris incurs associated with such labeling change. Each unit of Product shall have a unique identification number.  
 3.9. Regulatory Approvals. Product is currently regulated under 21 CFR parts 1270 and 1271 as a human cellular and tissue based tissue product. NuVasive shall obtain at its expense all regulatory approval by the FDA or other regulatory authority necessary or required for the distribution, sale and marketing of Product under current Laws as of the Effective Date. At NuVasive’s request during the Term, Osiris will assist NuVasive in preparing the portions of NuVasive’s regulatory filings that pertain to Processing and will make appropriate Osiris personnel reasonably available for meetings with regulatory authorities relating to Processing, provided that all such regulatory filings shall be the sole and exclusive property of NuVasive and NuVasive shall have sole authority and responsibility with respect to contacts and communications with regulatory authorities relating to the Product. In the event of changes in applicable Laws, or significant regulatory differences in foreign countries where NuVasive distributes Product, the Parties shall cooperate to determine what actions, if any, are required to meet any new or foreign regulations and shall negotiate in good faith changes to this Agreement including but not limited to, changes to Orders, Product Fees and Minimum Performance Levels to reflect any change in Product manufacturing costs. No change in Product-specific manufacturing processes, test methods, or other procedures or documentation relating to Processing shall be implemented by Osiris unless and until the parties have agreed in writing to such change.  
 3.10. Technology License. NuVasive hereby grants to Osiris during the Term, for the sole purpose of performing its duties and fulfilling its obligations under this Article 3, a non-exclusive and non-transferable license, without a right to sublicense, to use the Licensed Technology solely to the extent necessary to Process the Product under the terms and conditions of this Agreement. Notwithstanding the foregoing, NuVasive hereby consents to the sublicense by Osiris of the Licensed Technology to the Persons listed on Schedule 3.11 solely to the extent necessary for such subcontractor to provide processing services to Osiris, provided that the terms of any such sublicense arrangement shall either be pursuant to (i) the terms of those Contracts between Seller and such Persons which are identified on Schedule 3.11 hereto as such Contracts are in effect on the date hereof or (ii) require the prior written consent of NuVasive, which consent shall not be unreasonably withheld.  
 3.11. Subcontracting. Except as provided on Schedule 3.11, Osiris shall not assign, subcontract, or delegate any of its responsibilities under this Agreement without the prior written consent of NuVasive, which consent may be granted or withheld in NuVasive’s sole discretion. Such subcontractors shall be subject to confidentiality obligations at least as stringent, when taken as a whole, as provided in this Agreement. No subcontractor may further subcontract any responsibilities under this Agreement without the prior written consent of NuVasive, which consent may be granted or withheld in NuVasive’s sole discretion. Any approved subcontractor shall be  
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 subject to all of the terms and conditions applicable to Osiris under this Agreement. Osiris shall be responsible, and shall remain liable, for the performance of all of its obligations under this Agreement and for any breach by any subcontractor thereof. NuVasive shall have the right to audit and inspect all subcontractors with whom Osiris may enter into agreements in the performance of its responsibilities under this Agreement. Such audit and inspection rights shall be substantially similar to the rights of NuVasive to audit and inspect Osiris under this Agreement.  
 ARTICLE 4  
FEES  
 4.1. Product Fees. NuVasive shall pay to Osiris $ \*\*\* per cubic centimeter of Product (“Product Fees”) Delivered to NuVasive and that is not timely rejected by NuVasive pursuant to Section 3.6 above. All payments due hereunder shall be made in U.S. dollars, without set-off or counterclaim. For the avoidance of doubt, NuVasive shall be responsible for paying to Osiris the Product Fee for all conforming Product that is Delivered to NuVasive as a replacement of Product rejected in accordance with Section 3.6 to the extent that payment for such Product was not previously made.  
 4.2. Adjustments to Product Fees. The Product Fees shall be escalated on January 1, 2009 by the then current increase in CPI. Adjustments to Product Fees shall be effective January 1st and shall apply to all shipments of Product made on or after January 1st.  
 4.3. Billing. NuVasive shall pay to Osiris the Product Fees within thirty (30) days of Delivery of the conforming Product. In the event NuVasive fails to pay in accordance with this Section 4.3, Osiris may, in addition to any other remedies available to it, assess interest at a rate of one and one-half percent (1.5%) per month on all unpaid amounts.  
 4.4. Taxes. All payments required under this Agreement are exclusive of any applicable federal, state and local taxes. Each of the Parties shall be responsible for the payment of taxes and other assessments for which it is liable under Laws.  
 ARTICLE 5  
ADDITIONAL OBLIGATIONS  
 5.1. Inspections. Upon reasonable prior written notice, NuVasive may, at its expense, audit Osiris during normal business hours for quality control and assurance, compliance with Laws, cGTP, and other applicable regulations or standards, and the terms hereof, and otherwise inspect facilities and records, each as related to the Processing of Product hereunder; provided, however, that such audits and inspections may be conducted no more than twice during the Term hereof, other than “for cause” audits, which NuVasive shall be entitled to conduct as necessary to address specific quality problems relating to Product, as well as in preparation for regulatory filings and in response to regulatory authority requirements. Any corrective action mutually agreed upon by the parties in response to NuVasive’s audit or inspection shall be implemented by Osiris, at Osiris’ expense, prior to filling new or outstanding Orders. Osiris hereby agrees to advise NuVasive promptly (and, in any event, within thirty-six (36) hours) of any proposed or unannounced visit or inspection by any agent of a regulatory authority to the Facility where such visit or inspection is specifically related to the Product or its Processing (a “Product-Related Inspection”). Osiris agrees to permit, to the extent reasonably practical, one or more qualified representative(s) of NuVasive to be present during a  
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 Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.  
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 Product-Related Inspection if requested by NuVasive. If NuVasive is not present during a Product-Related Inspection, Osiris shall promptly provide a summary report of the results of the Product-Related inspection to NuVasive. Osiris shall promptly notify NuVasive of the results of any inspection, comments, responses or notices received from the FDA, AATB, or other applicable regulatory authorities, which relate to the Processing of Product hereunder. With respect to the forgoing, each Party shall provide the other Party at such other Party’s request with copies of any notices or correspondence from or to such regulatory authorities that directly relate to Product. Such notices and correspondence are considered Confidential Information in accordance with this Agreement. The Parties will cooperate in the development and review of responses that are required to be submitted to any regulatory authority relating to the Processing of Product prior to submission to the regulatory authority.  
 5.2. Records; Safety. Osiris shall maintain accurate and complete records of its procurement, Processing and supply of Product hereunder for the longer of five (5) years after shipment of any such Product, or the period of time required by applicable Laws, regulations and/or standards, whichever is greater. No records required by this Agreement shall be discarded by Osiris without specific prior written notification of Osiris’ intent to discard to NuVasive. Those records (or copies of those records) that Osiris is unwilling to retain will be transferred to NuVasive for storage. Osiris shall promptly (and, in any event, within twenty four (24) hours) notify NuVasive of any information of which it becomes aware concerning Product supplied to NuVasive. Any such notification will include all related information in reasonable detail. Upon such notification, the parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either party to make a timely report of such matter to any regulatory authority or take other action that it deems to be appropriate or required by applicable Laws.  
 5.3. Regulatory Compliance. With respect to each Party’s performance under this Agreement, Osiris and NuVasive shall each comply with all applicable Laws, regulations, and standards.  
 5.4. AATB Accreditation. The Parties agree that Osiris is actively pursuing AATB accreditation, and that NuVasive shall continue to perform its obligations under this Agreement despite the pendency of such AATB accreditation for so long as Osiris is using reasonable commercial efforts to obtain such accreditation. Once obtained, Osiris agrees to maintain its accreditation with the AATB and should Osiris’ accreditation lapse at any time or for any reason, it shall promptly communicate to the NuVasive the reasons for such lapse and the actions taken to cure the loss of AATB accreditation. In the event that Osiris fails to cure such loss within six months, notwithstanding any provision to the contrary contained in this Agreement, NuVasive shall be immediately and forever relieved of any obligation to order Product or to pay any fees with respect thereto and shall have the right to cancel or amend, without liability, any Orders then pending; provided, however, NuVasive shall pay the Product Fees for all Orders shipped as long as such Orders are filled with Product Processed while Osiris was accredited.  
 5.5. Complaints. Osiris hereby agrees to advise NuVasive promptly (and, in any event, within thirty-six (36) hours) of any complaint information (including adverse event information) Osiris receives relating to Product. Osiris will assist NuVasive in investigating and resolving all complaints and adverse events related to the Processing of Product. NuVasive will be responsible for evaluating and investigating complaints and the Parties will cooperate in preparing communications to any regulatory authorities regarding Product complaints or adverse events.  
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 Osiris will take any corrective actions agreed to by the parties to avoid future occurrences of Product complaints or adverse events related to the Processing of the Product.  
 5.6. Product Tracking. NuVasive shall be responsible for maintaining trackability for all Products provided by Osiris. Tracking records shall be maintained by NuVasive in accordance with all applicable Laws.  
 5.7. Product Withdrawal. In the event Osiris or NuVasive believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to Product (a “Product Withdrawal”), NuVasive shall make all decisions as to such Product Withdrawal and Osiris shall cooperate with NuVasive in any Product Withdrawal. NuVasive shall bear all costs in connection with any such Product Withdrawal and NuVasive shall reimburse Osiris for all reasonable out-of-pocket expenses incurred by Osiris in connection with any such Product Withdrawal; provided, however, that if such Product Withdrawal is attributable to any breach, misrepresentation or non-fulfillment of any covenant, agreement, representation or warranty made or to be performed by Osiris under the Asset Purchase Agreement or this Agreement (including, without limitation, the failure of any Product supplied hereunder to meet the Osiris Product Warranty) or to the negligent act or omission or willful misconduct of Osiris, Osiris shall reimburse NuVasive for all costs reasonably incurred by NuVasive in connection with any such Product Withdrawal.  
 ARTICLE 6  
INDEMNIFICATION AND INSURANCE  
 6.1. Osiris’s Indemnity Obligations. Osiris shall defend, indemnify and hold harmless NuVasive, its Affiliates and their respective successors and permitted assigns (the “NuVasive Indemnitees”) from and against any and all losses, liabilities, claims, actions, proceedings, damages and expenses (including without limitation reasonable attorneys’ fees and expenses) (herein “Damages”) relating to or resulting from a claim that arises out of (a) any breach by Osiris or its Affiliates, sublicensees, contractors or subcontractors, or any of their respective officers, directors, employees, or agents (the “Osiris Responsible Parties”) of this Agreement, including without limitation, the failure of any Product supplied hereunder to meet or comply with the Specifications or Osiris Product Warranty, (b) the negligence or willful misconduct of any of the Osiris Responsible Parties, (c) any violation of Law by any of the Osiris Responsible Parties; or (d) the unauthorized use of Licensed Technology by any of the Osiris Responsible Parties; provided, however, this Section 6.1 shall not impose any obligation on Osiris to indemnify the NuVasive Indemnitees to the extent of any Damages for which NuVasive is obligated to indemnify the Osiris Indemnitees pursuant to Section 6.2.  
 6.2. NuVasive’ Indemnity Obligations. NuVasive shall defend, indemnify and hold harmless Osiris and its Affiliates, and their respective successors and permitted assigns (the “Osiris Indemnitees”) from and against any and all Damages relating to or resulting from a claim that arises out of (a) any breach by NuVasive or its Affiliates, sublicensees, contractors or subcontractors, or any of their respective officers, directors, employees, or agents (the “NuVasive Responsible Parties”) of this Agreement, (b) the negligence or willful misconduct of any of the NuVasive Responsible Parties, (c) any changes to the Specifications requested by NuVasive in writing, or (d) any violation of Law by any of the NuVasive Responsible Parties; provided, however, this Section 6.2 shall not impose any obligation on NuVasive to indemnify the Osiris Indemnitees to the extent of any Damages for which Osiris is obligated to indemnify the NuVasive Indemnitees pursuant to Section 6.1.  
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 6.3. Notice of Claim. The indemnification obligations of the parties pursuant to this Agreement shall be proportional to the relative responsibility or fault of each party for the Damages incurred as a result of the actions or inactions of such party. Promptly after receipt by a NuVasive Indemnitee or Osiris Indemnitee of the commencement of any such claim, demand, action, suit or proceeding (collectively, “Action”) which is the subject of the other party’s indemnification obligations hereunder, such Indemnitee shall notify the other party of the commencement of the Action. Any failure to provide such notice shall only relieve the other party of its indemnification obligations hereunder to the extent the indemnifying party has been materially prejudiced by such failure. The indemnifying party shall have sole right to select and retain attorneys (reasonably acceptable to the Indemnitee) to assert or negotiate, and sole right to control, the defense and any settlement of the Action, to the extent of the indemnifying party’s corresponding indemnification and defense obligations, except that under no circumstances shall the indemnifying party enter into any settlement that involves an admission of liability, negligence or other culpability by the Indemnitee, or requires the Indemnitee to contribute to the settlement, without the Indemnitee’s prior written consent. Without limiting the indemnifying party’s foregoing right to select and retain attorneys and to sole control of the defense and settlement of such Action, the Indemnitee may, at its own expense, participate in the defense of, or otherwise consult with counsel of its own choice in connection with, an Action that is the subject of the other party’s indemnification obligations.  
 6.4. Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE, WHETHER AS A RESULT OF CONTRACTUAL BREACH, TORT OR OTHERWISE, TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL, OR INCIDENTAL DAMAGES INCURRED BY SUCH OTHER PARTY, INCLUDING BUT NOT LIMITED TO INJURY TO GOODWILL, OR DIRECT, INDIRECT OR SPECULATIVE LOST PROFITS. The foregoing Limitation of Liability shall not apply to a party’s liability for breach of its confidentiality obligations hereunder or to the extent such damages are paid to a third party in connection with a third party claim that is indemnified hereunder.  
 6.5. Insurance. Each party agrees to procure and maintain in full force and effect during the term of this Agreement, at its sole cost and expense, general liability and product liability insurance in amounts of not less than $2,000,000 per incident and $7,000,000 annual aggregate, which insurance shall be written on an “occurrence” basis policy form, or, in the alternative, shall continue for a period of ten (10) years following the termination or expiration of this Agreement, with a reputable insurance carrier and name the other party as an additional insured. Each party shall, on request, provide to the other party a copy of a certificate of coverage or other written evidence reasonably satisfactory to such requesting party of such insurance coverage.  
 ARTICLE 7  
TERM AND TERMINATION  
 7.1. Term. Unless terminated earlier pursuant to the terms of this Agreement, this Agreement shall commence on the Effective Date and remain in effect for eighteen (18) months therefrom (the “Term”).  
 7.2. Termination.  
 7.2.1. This Agreement may be terminated, prior to the expiration of its Term, by either party immediately upon written notice to the other party after the material breach of any  
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 provision of this Agreement by the other party if the other party has not cured such breach within thirty (30) days after receipt of written notice thereof from the non-breaching party.  
 7.2.2. This Agreement may be terminated, prior to the expiration of its Term, immediately upon written notice by either party if the other party shall have become insolvent or bankrupt, or shall have made a general assignment for the benefit of its creditors, or any case or proceeding shall have been commenced by or against the other party in bankruptcy or seeking reorganization, liquidation, dissolution, or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law, and any such event shall have continued for sixty (60) days undismissed or undischarged.  
 7.2.3. This Agreement may be terminated, prior to the expiration of its Term, by NuVasive at any time and for any reason, immediately upon written notice to Osiris, after Osiris has Delivered to NuVasive an aggregate of \*\*\* cubic centimeters of Product hereunder.  
 7.3. Effect of Termination or Expiration. After either party provides notice of termination under Section 7.2.1 or 7.2.2 and pending termination of this Agreement under such Sections, the Parties shall continue to perform their respective obligations hereunder. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 3.7, 5.2, 6.1, 6.2, 6.3, 6.4, 6.5, 8.1, 8.2, and 8.3 and the applicable provisions of Article 9 shall survive any expiration or termination of this Agreement. Each party agrees to return upon the expiration or termination of this Agreement all Confidential Information acquired from the other party, except as to such information it may be required to retain under applicable Laws, and except for one copy of such information may be retained by such party’s legal department; provided , that if Osiris elects not to retain a copy of any such Confidential Information provided to NuVasive pursuant to Section 3.5 hereof, then NuVasive shall, upon reasonable notice to NuVasive and during NuVasive’s normal business hours, provide Osiris with access to such Confidential Information as is reasonably necessary for purposes of Osris’ compliance with applicable Laws or in connection with Osiris’ defense of any third party claims related thereto.  
 ARTICLE 8  
INTELLECTUAL PROPERTY AND CONFIDENTIALITY  
 8.1. Intellectual Property. Subject to the license expressly granted by this Agreement, NuVasive is the sole and exclusive owner of all right, title and interest in and to the methods of Processing Product and all of NuVasive’s patents, trademarks, inventions, copyrights, know-how, and trade secrets.  
 8.2. Other Inventions. The parties do not contemplate that any inventions, discoveries, improvements, modifications, derivations, information, know-how and the like that arise out of the performance of this Agreement (collectively, the “Inventions”), including those related to processes, compositions of matter and methods of use, whether protectable by patent or as a trade secret, shall by Osiris. Accordingly, any and all Inventions made by either party individually or jointly hereunder, including any Inventions hereunder pertaining to Processing of Product, shall be owned solely by NuVasive, and Osiris hereby assigns to NuVasive all right, title and interest in and to all Inventions. Osiris shall, upon NuVasive’s request, execute such documents, including any and all applications, assignments or other instruments, give any testimony and take such other actions as  
 \*\*\*  
 Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.  
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 NuVasive deems necessary for NuVasive to obtain such ownership and to apply for, secure, and maintain patent or other proprietary protection in the United States or any other country with respect to Product or Inventions, provided that NuVasive shall compensate Osiris for its reasonable out of pocket costs and expenses associated with such actions. All Inventions and any information with respect thereto shall be the Confidential Information of NuVasive.  
 8.3. Confidentiality. The Receiving Party shall ensure the confidentiality of the Disclosing Party’s Confidential Information it receives by taking substantially the same precautions as the Receiving Party does with its own Confidential Information, but not less than a reasonable standard of care. The Receiving Party shall not use the Disclosing Party’s Confidential Information for any purpose other than to carry out the Receiving Party’s obligations hereunder. The obligations of confidentiality shall not apply to information that the Receiving Party is required by applicable Laws to disclose; provided, however, that the Receiving Party shall so notify the Disclosing Party of the Receiving Party’s intent to disclose and shall cooperate with the Disclosing Party at the Disclosing Party’s expense on reasonable measures to protect the confidentiality of the Disclosing Party’s Confidential Information. The Receiving Party may not disclose the Disclosing Party’s Confidential Information received pursuant to this Agreement except to the Receiving Party’s directors, officers, employees, consultants, attorneys and accountants who reasonably require disclosure of such Confidential Information for the Receiving Party to exercise its rights or perform its obligations under this Agreement, provided that such persons and entities are obligated to hold the Confidential Information in confidence in accordance with restrictions and procedures no less stringent than provided for herein and such persons enter into a written confidentiality agreement whereunder they agree not to disclose such information. The fact that general information may be in or become part of the public domain, in and of itself, does not exclude any specific Confidential Information from the obligations of this Agreement. The Parties hereto understand and agree that this Section 8.3 is reasonable and necessary to protect NuVasive’s and Osiris’ respective business interests. The Parties further agree that the other may suffer irreparable harm from a breach of this Section 8.3. Thus, in addition to any other rights or remedies, all of which shall be deemed cumulative, a party shall be entitled to pursue injunctive relief to enforce the terms of this Section 8.3.  
 8.4. Publications. No announcement, news release, public statement, publication, or presentation relating to this Agreement or either party’s performance hereunder (collectively, a “Publication”) shall be made without the other party’s prior written approval, except as required by Law. Each party agrees to submit each Publication it proposes to make to the other party for purposes of such other party’s review, comment and approval. Each party further agrees to respond as promptly as reasonably possible.  
 ARTICLE 9  
MISCELLANEOUS  
 9.1. No Assignment. Except as otherwise set forth herein, neither Party shall transfer, assign or cede any rights or delegate any obligations hereunder, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of the other Party, which consent may be withheld at the other Party’s reasonable business discretion, provided, that (a) Osiris may transfer this Agreement without prior written consent of NuVasive to an Affiliate or in connection with a merger or sale of all or substantially all of the stock or assets of Osiris to any party that NuVasive does not reasonably deem to be a competitor, and (b) NuVasive may transfer this  
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 Agreement without prior written consent of Osiris to an Affiliate of NuVasive or in connection with a merger or sale of all or substantially all of the assets of NuVasive.  
 9.2. Notices. All notices or other communications given pursuant hereto shall be in writing and deemed given (a) when delivered by messenger, (b) when sent by facsimile, (with receipt confirmed), (c) when received by the addressee, if sent by Federal Express or other express delivery service (receipt requested), or (d) five days after being mailed in the U.S., first-class postage prepaid, registered or certified, in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate as to itself by notice to the other party):  
 If to Osiris:  
 If to NuVasive  
 Osiris Therapeutics, Inc.  
 NuVasive, Inc.  
0000 Xxxxxx Xxxxxxxx Xxxxx  
 0000 Xxxx Xxxxxxxxx  
Xxxxxxxx, XX 00000  
 Xxx Xxxxx, XX 00000  
Attention: Chief Executive Officer  
 Attention: General Counsel  
Fax No.: 000-000-0000  
 Fax No.: 000-000-0000  
 With a copy to:  
With a copy (which shall not constitute notice) to:  
 XxXxxxx Long & Xxxxxxxx LLP  
 DLA Piper US LLP  
000 Xxxxxxxxx Xx., XX, Xxxxx 0000  
 0000 Xxxxxxxxx Xxxxx  
Xxxxxxx, XX 00000  
 Suite 1100  
Attention: Xxxxxxx Xxxxxxx, Esq.  
 Xxx Xxxxx, XX 00000  
Fax No.: 000-000-0000  
 Attention: Xxxxxxx Xxxxxxx  
 Fax No.: 000-000-0000  
 9.3. Force Majeure. Nonperformance by either party hereto shall be excused to the extent that performance is rendered impossible by strike, fire, explosion, flood, acts of God, terrorism, war or civil commotion, governmental acts or orders or restrictions, failure of suppliers, public utilities or common carriers, or any other reason where failure to perform is beyond the reasonable control of and is not caused by the negligence of the non-performing party. Such non-performing party shall exercise best efforts to eliminate the force majeure event and to resume performance of its affected obligations as soon as practicable. In the event that, as a result of such force majeure event, a party does not perform all of its obligations hereunder for any period of ninety (90) consecutive days, in addition to any other rights hereunder, the other party may terminate this Agreement on thirty (30) days’ prior written notice to the non-performing party.  
 9.4. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.  
 9.5. Partial Invalidity. If any provision of this Agreement is held to be invalid, the remaining provisions shall nevertheless remain in full force and effect. In addition, the Parties shall  
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 renegotiate in good faith any term held to be invalid, and be bound by the mutually agreed upon substitute provision.  
 9.6. Entire Agreement; Inconsistent Terms; Waiver. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and may not be amended, modified, waived or cancelled except by a writing signed by each of the Parties or, in case of a waiver, by the party effecting such waiver. If any terms or conditions of any standard form (e.g., purchase order, order acknowledgment, etc.) of Osiris or NuVasive conflict or are inconsistent with any terms or conditions of this Agreement, the terms and conditions of this Agreement shall govern. Failure to require performance of any provision hereof shall in no manner affect the right of such party at a later time to enforce the same, and no waiver in any one instance shall be deemed to be a further or continuing waiver of the same or any other provision.  
 9.7. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by the laws of the State of Delaware, without regard to conflicts of laws principles.  
 9.8. Dispute Resolution. In the event of a dispute arising under this Agreement, each party agrees to notify the other party of the specific complaints or points of disagreement, and to use its good faith efforts to resolve such dispute, without legal action, by referring such dispute to Xxxxx Xxxxx, the Chief Executive Officer of Osiris, and the General Counsel of NuVasive (collectively, “Executives”) for resolution. The Executives shall meet promptly after such referral to attempt to resolve such dispute through good faith discussions. In the event the Executives cannot resolve such dispute within fifteen (15) days of such initial meeting, either party may request that such dispute be resolved by binding arbitration before one (1) neutral arbitrator in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association, applying the substantive law specified in Section 9.7. The parties shall jointly select the arbitrator. Within three (3) months of the conclusion of an arbitration proceeding, the arbitration decision shall be rendered in writing and shall specify the basis on which the decision was made. Any award rendered by the arbitrator shall be final and binding upon the parties, and judgment upon any such award may be entered in any court having jurisdiction thereof. Arbitration shall be conducted in Chicago, Illinois. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against either party. The costs of the arbitration, including administration fees, shall be shared by the parties in proportion to their fault, as determined by the arbitrator. Notwithstanding the foregoing, the parties agree that if any breach or threatened breach of this Agreement would necessarily result in immediate, irreparable injury to a party, that party, in addition to any other remedies available under this Agreement, shall have the right to seek injunctive relief in any court of competent jurisdiction. Notwithstanding anything to the contrary in this Agreement, this Section 9.8 shall not apply to any disputes arising under Section 8.3 (Confidentiality) or to any disputes relating to a party’s intellectual property (including, without limitation, disputes relating to ownership or inventorship of inventions, validity or infringement of patents, or scope of patent claims).  
 9.9. Independent Contractor. The relationship between NuVasive and Osiris established by this Agreement is that of independent contractors. Neither party shall have authority to conclude contracts or otherwise to act for or bind the other party in any manner, whatsoever, as agent or otherwise.  
 9.10. Further Actions. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purpose and intent of this Agreement.  
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 9.11. Representations and Warranties. Each of the Parties represents and warrants that (i) it is fully authorized to enter into this Agreement; (ii) its entering into and performance under this Agreement does not violate or breach it Certificate of Incorporation or corporate bylaws or any agreement or contract to which it is a party; (iii) there is no claim, demand, action, suit or proceeding or investigation pending or currently threatened against it or any of its Affiliates involving or relating to the subject matter hereof, or which, if adversely determined, would restrict it from entering into this Agreement and carrying out its obligations under this Agreement; and (iv) it has no legal obligations which would prevent this Agreement from being fully implemented in accordance with its terms.  
 [THE REMAINDER OF THIS PAGE IS INTENTIONALLY BLANK]  
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 IN WITNESS WHEREOF, the undersigned caused this Agreement to be executed as of the Effective Date.  
 OSIRIS THERAPEUTICS, INC.  
NUVASIVE, INC.  
 By:  
/s/ C. Xxxxxx Xxxxx  
 By:  
/s/ Xxxxxx Xxxxxxxx  
 Name:  
C. Xxxxxx Xxxxx  
Name:  
Xxxxxx Xxxxxxxx  
 Its:  
President & CEO  
Its:  
Chief Executive Officer  
 SIGNATURE PAGE TO  
MANUFACTURING AGREEMENT  
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 Exhibit A Product Specifications  
 Osiris Materials Specifications numbers 90055, 90067, 90080, 90081, 90103, 90128, 90129, 90149, and 90188, as may be amended by mutual written agreement of the parties.  
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