Exhibit 10.9  
  
EXECUTION VERSION  
  
AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT  
  
  
This Amended and Restated Manufacturing and Supply Agreement (this “Agreement”) is entered into as of January 10, 2018 (the “Amendment Effective Date”), by and between Silk Road Medical, Inc., a corporation duly organized and existing under the laws of the State of Delaware and having its principal office at 000 Xxxxx Xxxxxxxx Xxxxxx, Xxxxxxxxx, XX 00000 (“Silk Road Medical”), and Galt Medical Corporation, a Texas corporation having a place of business at 0000 Xxxxxxx Xxxxx, Xxxxxxx, Xxxxx 00000 (“Supplier”), and amends and restates in its entirety that certain Manufacturing and Supply Agreement, effective as of September 18, 2014 (the “Effective Date”), by and between the Parties (the “Original Agreement”). Each of Silk Road Medical and Supplier is referred to herein by name or as a “Party,” and, collectively, as the “Parties.”  
RECITALS  
  
WHEREAS, Supplier manufactures medical devices and products; and  
  
WHEREAS, Silk Road Medical desires to have manufactured certain micro-puncture kit products (as further described below, the “Products”) with certain specifications (as further described below, the “Specifications”), as generally set forth in Attachment A;  
  
WHEREAS, the Parties hereto wish to set forth in this Agreement the terms and conditions under which Silk Road Medical shall purchase Products from Supplier and Supplier shall manufacture, sell and deliver Products to Silk Road Medical for commercial distribution; and  
  
WHEREAS, the Parties further wish to amend certain terms of the Original Agreement, and to restate the Original Agreement, as so amended, in its entirety in this Agreement, all on the terms and conditions set forth in this Agreement.  
  
NOW, THEREFORE, in consideration of the mutual promises, and of the representations, warranties, covenants and agreements contained herein, the Parties agree as follows:  
  
1. Definitions.  
For purposes of this Agreement, the following capitalized terms shall have the following meanings:  
1.1“Adverse Event” means any adverse health event to which a Product has or may have contributed. The term is generally limited to those events that would be reportable to Competent Authorities.  
(a) For the European Union, adverse events are defined as “incidents”. Incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for us which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.  
(b) For the United States, adverse events are defined as Medical Device Reports (MDRs). MDRs are events that manufacturers become aware of that reasonably suggest that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction where to recur.  
  
[\*\*\*] Information has been omitted and submitted separately to the Securities and Exchange Commission. Confidential  
treatment has been requested with respect to the omitted portions.  
  
  
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1.2“Affiliate” means, with respect to a Party, each and every corporation or other business entity controlled by, controlling or under common control with such Party. For the purposes of this definition, “control” shall, in the context of a corporation, mean direct or indirect beneficial ownership of at least fifty percent (50%) of the shares entitled to vote for members of the Board of Directors of such corporation, and, in the context of any other business entity, shall mean the right to exercise similar management and control of such entity.  
1.3“Applicable Laws” means all applicable laws, rules, regulations and guidelines that may apply to the development, manufacturing, marketing and/or sale of the Products or the performance of either Party’s obligations under this Agreement including laws, regulations and guidelines governing the import, export, development, manufacturing, marketing, distribution and sale of the Products and including all current good manufacturing practices standards (“cGMP”) or guidelines promulgated by Competent Authorities including the Federal Food, Drug and Cosmetic Act and trade association guidelines.  
1.4“Competent Authorities” means the entities responsible for the regulation of medical devices intended for use in treating humans, and shall include the United States Food and Drug Administration (“FDA”).  
1.5“Intellectual Property Rights” means any and all drawings, specifications, samples, models, processes, procedures, instructions, technology, applied development engineering data, reports, and all other technical or commercial information, data, and documents of any kind whatsoever and all forms of protection afforded by law to inventions, models, designs or technical information, and applications therefore or which otherwise arises or is enforceable under the laws of the United States or other jurisdiction including, but not limited to, any and all patents (including reissues, divisions, continuations and extensions thereof), patent registrations, utility models, trademarks, trade secrets, registered and unregistered designs including mask works, copyrights, and moral rights.  
1.6“Notified Body” means an entity licensed, authorized or approved by an applicable Competent Authority to assess and certify the conformity of a medical device or product with Applicable Laws.  
1.7“Products” means Supplier’s micro-puncture kit products listed in Attachment A, as manufactured and supplied by Supplier from time to time in accordance with the Specifications.  
1.8“Purchase Order” means any written or electronic purchase order issued by Silk Road Medical to Supplier for a Product, each of which shall be governed by the terms of this Agreement. All Purchase Orders, acceptances and other writings or electronic communications between the Parties shall be governed by this Agreement and the terms and conditions noted in any Quotation provided by Supplier. In case of conflict, the following order of precedence will prevail: a) this Supply Agreement; b) this Supply Agreement’s Attachments; c) any Quotation(s) provided by Supplier; d) individual Purchase Orders; and e) the Specifications and related documents specifically incorporated herein by reference.  
1.9 “Quotation” means, with respect to a Purchase Order, any written quotation provided in advance by Supplier to Silk Road Medical specific to such Purchase Order.  
1.10“Specifications” means Supplier’s functional specifications, descriptions, drawings and other requirements as generally specified in Attachment A, including any mutually agreed amendments thereof.  
  
2. Manufacture and Purchase.  
2.1 Agreement to Manufacture and Purchase. Supplier hereby agrees to manufacture and sell the Products to Silk Road Medical, and Silk Road Medical agrees to purchase the Products from Supplier, all in accordance with the terms and conditions of this Agreement. Supplier will manufacture the Products in accordance with the Specifications set forth in Attachment A. Supplier shall notify Silk  
  
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Road Medical, in writing, of any proposed changes in raw materials, components, design or processes at least one hundred twenty (120) days prior to any such actions.  
2.2 Quality Control and Assurance. Supplier shall manufacture the Products in accordance with the Specifications, Applicable Laws and with proper standards of quality control and quality assurance. Supplier shall permit Silk Road Medical or its designated representative to perform such reasonable audits and inspections as may be requested by Silk Road Medical of the facilities, procedures and records that are relevant to Supplier’s manufacturing of the Products, and to the extent reasonably obtainable by Supplier, of facilities, procedures and records that are relevant to such reasonable audits or inspections of unaffiliated parties with responsibility for testing, analyzing, labeling or packaging the Products. Supplier shall maintain such records for a period of no less than seven (7) years following the manufacture of any particular Product. Supplier shall notify Silk Road Medical immediately upon receipt of all warning letters, 483s and other correspondence with the Competent Authority, Notified Body or other governmental authority related to the Product.  
2.3 Product Recall. Silk Road Medical and Supplier shall each notify the other Party promptly if any Products are the subject of a recall, market withdrawal or other correction, and the Parties shall cooperate in the handling and disposition of such recall, market withdrawal, advisory notice or correction. Supplier shall bear the cost of all recalls, market withdrawals, advisory notices or corrections of the Products, up to a maximum cost not to exceed the unit price(s) Silk Road Medical has paid for the Products multiplied by the number of units subject to the product recall, as well as all shipping costs therefor.  
2.4 Adverse Event Reporting. Each Party shall advise the other Party, by telephone, e-mail or as otherwise provided in Section 12.4 within such time as is required to comply with Applicable Laws, after it becomes aware of any Adverse Event involving the Products. Such advising Party shall provide the other Party with a written report, delivered as provided in Section 12.4, stating the full facts known to it regarding the Adverse Event, including but not limited to customer name, address, telephone number, batch, lot and serial numbers, as required by Applicable Laws. Except as otherwise required by Applicable Laws, as between the Parties, Supplier shall be responsible for investigating all Adverse Events and reporting to Competent Authorities and other governmental authorities.  
2.5 Customer Complaints. As between the Parties, Supplier shall be responsible for handling all customer complaints relating to the Products that relate to the manufacturing or design of the product. Notwithstanding the foregoing, each Party shall advise the other Party, by telephone or e-mail within such time as is required to comply with Applicable Laws, after it becomes aware of any customer complaint involving the Products. Supplier agrees to cooperate and assist Silk Road Medical in investigating such complaints and in providing an appropriate response.  
  
3. Prices.  
3.1 Prices. The prices for the Products shall be as set forth on Attachment B and shall apply to all Purchase Orders for Products sold to Silk Road Medical during the term, unless otherwise agreed. In the event of a change in Specifications resulting from a request by Silk Road Medical, which request is agreed to by Supplier, the Parties shall negotiate in good faith to reach agreement on the new price for any Product that embodies such changes. Further, after the first twenty-four (24) months of this Agreement and after each twelve (12) month period thereafter, the Parties shall reasonably and in good faith negotiate prices for each new twelve (12) month period of this Agreement taking the applicable changes in labor, production and material costs into account, provided that Supplier may not propose any increase by an amount greater than the percentage change in the CPI for Medical Care Commodities during the immediately preceding twelve (12) month period. Any adjusted prices under this Section 3.1 shall be valid for the succeeding twelve (12) month period. No price adjustment  
  
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shall affect any order due to be shipped within three (3) months of the price adjustment or shipped prior to the effective date of the price adjustment.  
  
4. Forecasts, Purchase Orders and Inventory.  
4.1 Forecasts. During the term, Silk Road Medical will furnish to Supplier written, non-binding annual demand forecasts of its expected orders of the Products. For the first year following the Amendment Effective Date Silk Road Medical will furnish to Supplier monthly revisions, and for each year thereafter quarterly revisions, of such forecasts as reasonably necessary to reflect its expected orders of the Products as may be required to meet market conditions and customer requirements. Supplier acknowledges that Silk Road Medical’s ordering of Products is subject to market demands. Silk Road Medical shall in no way be liable for Supplier’s commitments or production arrangements.  
4.2  
Purchase Orders. From time to time during the term of this Agreement, Silk Road Medical will submit Purchase Orders for the Products to Supplier in writing, and each Purchase Order will set forth (a) a reference to this Agreement; (b) an identification of the Product ordered by part number; (c) the quantity requested; (d) the requested delivery date in accordance with established lead times; and (e) the term of the Purchase Order. Silk Road Medical’s obligation to purchase Products and Supplier’s obligation to supply Products under this Agreement is limited to the quantity specified in each individual Purchase Order.  
4.3 Acceptance of Orders. Each Purchase Order delivered to Supplier in accordance with the terms of this Agreement will give rise to a contract for the purchase of Products under the terms set forth in this Agreement to the exclusion of any additional or contrary terms set forth in Supplier’s confirmation of acceptance, invoice or other document not signed by an executive officer of Silk Road Medical. If a Purchase Order is not acceptable to Supplier, Supplier shall inform Silk Road Medical in writing within two (2) business days after receipt of such Purchase Order; provided that Supplier shall be required to accept any Purchase Order submitted in accordance with Section 4.2 for any quantity that does not exceed the lesser of one hundred twenty five percent (125%) of the quantity in the most recent forecast or one hundred twenty five percent (125%) of the monthly average order quantity for the three (3) months preceding delivery of the Purchase Order. Notwithstanding the foregoing, Supplier shall use its commercially reasonable efforts to accept any quantity in excess of such percentage.  
  
5. Delivery, Acceptance and Change Orders.  
5.1 Delivery Conditions. All deliveries of Products pursuant to this Agreement shall be FOB Supplier’s port of shipment, as defined in Incoterms 2010. Risk and title to the Products shall pass to Silk Road Medical as defined by such Incoterm. Transport of all Products shall be performed by a service provider selected and contracted by Silk Road Medical. Alternative transport is permitted only after written approval of Silk Road Medical. Silk Road Medical may request that Supplier ship Products by premium freight. In the event Supplier pays any related freight charges, such charges shall be invoiced to Silk Road Medical and Silk Road Medical shall reimburse Supplier for such charges.  
5.2 Packing. Products shall be boxed, crated, carted and stored without charge and in a manner that ensures undamaged and safe arrival at their ultimate destination. As between the Parties, Supplier shall be responsible for any loss or damage due to its failure to properly preserve, package and handle the Products.  
  
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5.3 Acceptance. All Products are subject to final inspection and acceptance by Silk Road Medical at destination notwithstanding any payment or prior inspection at source. Final inspection will be made within thirty (30) days after receipt of Products. Supplier agrees to permit Silk Road Medical’s inspectors to have access to Supplier’s plant at all reasonable times for the purposes of inspecting the items set forth in this Purchase Order and of work in process for production of such items.  
  
5.4 Change Orders.  
(a)  
General. All change orders and acceptance or rejection of such change orders shall be in writing and made pursuant to the change order procedure set forth below. All changes are subject to mutual agreement of the Parties. Pending agreement on a change order or in the event agreement regarding the change order is not reached, Supplier will continue to perform and be paid as if such change order had not been requested or recommended, provided that in the event of any recall or field action Supplier will cease performing hereunder until such recall or field action has been satisfactorily resolved. Satisfactory resolution of a recall or field action shall be deemed to have occurred as of the date that:  
(i)  
An action plan has been negotiated and agreed upon with the relevant Competent Authorities and other governmental authorities; and  
(ii)  
A written confirmation has been issued by Supplier that all affected products have been redesigned or reworked per the agreed action plan.  
(b)  
Pricing Changes. When the change affects pricing, the written approval must be in the form of a Purchase Order issued by Silk Road Medical. Supplier shall provide Silk Road Medical with a quote for all costs associated with any requested changes. Upon Supplier’s receipt of a Purchase Order for any changes issued by Silk Road Medical, Supplier will initiate and complete the specified changes.  
(c)  
Silk Road Medical Request. Upon Silk Road Medical’s submission of a change order, Supplier will, within seven (7) business days, advise Silk Road Medical of the resultant impact and will provide such information as Silk Road Medical may reasonably request to determine the reasonableness of the impact. Silk Road Medical and Supplier will negotiate the change order request in good faith. After reaching agreement Supplier will proceed with the change order. Supplier will assess the regulatory impact of any changes and acquire regulatory clearance/approval with Notified Body and FDA as needed. Supplier shall provide Silk Road Medical with a quote for all costs associated with regulatory clearance/approval change requests. Upon Supplier’s receipt of a Purchase Order for any changes issued by Silk Road Medical, Supplier will initiate and complete the applicable services. Supplier will communicate regulatory issues/approvals to Silk Road Medical within ten (10) days of receipt.  
(d)  
Supplier Request. Supplier may request a change order, provided the request is properly detailed with such information that will permit Silk Road Medical to determine the reasonableness thereof. Silk Road Medical and Supplier will negotiate the change order request in good faith. After reaching agreement, Supplier will proceed with the change order. Supplier will assess the regulatory impact of any changes and acquire regulatory clearance/approval with Notified Body and FDA as needed. Supplier will provide evidence of any such regulatory approvals to Silk Road Medical within ten (10) days of receipt.  
  
  
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6.  
Invoicing and Payment. Unless otherwise specified by Silk Road Medical, a separate invoice shall be issued by Supplier for each shipment and payment in U.S. dollars is due within thirty (30) days of Silk Road Medical’s receipt of each invoice (except to the extent disputed in good faith by Silk Road Medical).  
  
7. Representations and Warranties.  
7.1 Supplier Representations and Warranties. Supplier represents and warrants to Silk Road Medical that all Products delivered under this Agreement:  
(i)strictly comply with the Specifications;  
(ii)are new (do not contain any used or reconditioned parts or materials) and fit for the purposes for which they are intended;  
(iii)are of sound workmanship, good quality and free from defects in design, construction, manufacture and material;  
(iv)do not violate or infringe any third party domestic or foreign patent, copyright, trade secret, trademark or other intellectual property right;  
(v)satisfy all Applicable Laws, regulations, certification requirements and agreed standards, including applicable regulatory requirements for the design, manufacture and shipment of the Products, including FDA and any other appropriate international standards;  
(vi)are free and clear of all liens, encumbrances, and other claims against title; and  
(vii)strictly comply with the terms of this Agreement and the applicable Purchase Orders.  
If any of the Products are found to be defective or otherwise not in conformity with the warranties in this Section 7.1, then Silk Road Medical and Supplier will mutually agree upon one (or more) of the following courses of action: a) Supplier will take commercially reasonable effort to inspect, remove, reinstall, ship and repair or replace/re-perform nonconforming Products with Products that conform to all requirements of this Purchase Order; b) Supplier will make commercially reasonable effort to take such actions as may be required to cure all defects and/or bring the Products into conformity with all requirements of this Purchase Order, in which event all related costs and expenses (including, but not limited to, material, labor and handling costs or other service) and other reasonable charges shall be for Supplier’s account; and/or c) Silk Road Medical will reject and return all or any portion of such Products. These actions will be at Supplier’s expense and will be undertaken in addition to any other rights, remedies and choices Silk Road Medical may have by law, contract or at equity, and in addition to seeking recovery of any and all damages and costs emanating therefrom. Any repaired or replaced Product, or part thereof, shall carry warranties on the same terms as set forth above.  
7.2 Survival. The foregoing warranties shall survive any inspection, delivery, acceptance, or payment by Silk Road Medical and shall be enforceable by Silk Road Medical and its Affiliates, distributors, dealers, agents and customers.  
  
  
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8.  
Confidentiality. Confidential Information means all documents, designs, drawings, procedures, engineering and manufacturing know-how, data and other information, provided by or on behalf of a Party or any of its Affiliates directly or indirectly, before or after the Effective Date, in whatever form (including on paper, electronically, on magnetic media, orally or otherwise), relating to this Agreement, provided that any information shall not be Confidential Information to the extent that the information:  
(a)  
is or becomes generally lawfully available to the public without violation of this Agreement or any other obligation of confidentiality;  
(b)  
is lawfully known by the recipient prior to disclosure by the provider, as demonstrated by contemporaneous written records;  
(c)  
is lawfully obtained by the recipient from a third party without any breach or obligation of confidentiality or violation of law; or  
(d)  
is independently developed by the recipient without use or reference to the Confidential Information of the provider, as demonstrated by contemporaneous written records.  
  
The terms of this Agreement, its execution, as well as any Confidential Information shall be maintained in confidence by the receiving Party, and shall not be reproduced, disclosed, duplicated, or used, except to the extent required in connection with this Agreement or by law or to potential acquirers, lenders, and investors in connection with due diligence in connection with a merger, acquisition, financing or other strategic corporate transaction, without the prior written consent of the disclosing Party.  
  
Each Party shall protect the other Party’s Confidential Information against disclosure in the same manner and with the same degree of care, but not less than a reasonable degree of care, with which the receiving Party protects confidential information of its own; and shall limit use of and circulation of the Confidential Information disclosed by the other to such employees of the Parties and of their Affiliates as have a need to know in connection with the requirements of this Agreement. The receiving Party shall return to the disclosing Party or destroy all Confidential Information promptly upon request, except for one (1) archival copy in the receiving Party’s secure archives.  
  
These confidentiality obligations shall be in effect for a period of five (5) years from the expiration or termination of this Agreement.  
  
9. Intellectual Property.  
9.1 Supplier Indemnity. Supplier shall defend, indemnify and hold harmless Silk Road Medical and its Affiliates, distributors, dealers, agents and customers from and against all liability and expenses, including reasonable attorneys’ fees, arising from or related to any claim made or any suit or proceeding brought against Silk Road Medical based on an allegation that Products infringe upon any third party’s Intellectual Property Rights.  
  
9.2 License to Silk Road Medical. Supplier hereby grants to Silk Road Medical and its Affiliates, and their subcontractors, distributors, agents and customers, an irrevocable, world-wide, royalty-free, non-exclusive, non-transferable license under all Intellectual Property Rights and regulatory clearance rights Supplier owns or controls to use, build-in, market, sell, lease, distribute or otherwise dispose of the Products.  
  
  
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10. Indemnity, Insurance and Limitation of Liability.  
10.1 General Indemnification.  
  
(a)Supplier Indemnity. Supplier agrees to indemnify and hold each of Silk Road Medical and its Affiliates, distributors, dealers, agents and customers harmless from and against any loss, claim, damage, liability or expense (including reasonable fees and expenses of counsel) which may be payable by reason of or on account of injury (including death resulting from such injury) to any person caused by, arising from, incident to, connecting with or growing out of the possession or use by any person of any Product manufactured by Supplier and sold by Silk Road Medical.  
  
(b) Defense. If any action or proceeding is brought or asserted against an indemnified Party, in respect of which indemnity may be sought from an indemnifying Party pursuant to Sections 9.1or 10.1(a) hereof, the indemnified Party will promptly notify the indemnifying Party in writing, and the indemnifying Party will assume the defense thereof, including the employment of counsel reasonably satisfactory to the indemnified Party and the payment of all expenses. The indemnified Party will have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel will be at the expense of the indemnified Party. The indemnifying Party will not be liable for any settlement of any action or proceeding effected without its written consent, but if settled with its written consent, or if there be as final judgment for the plaintiff in any such action or proceeding, the indemnifying Party will indemnify and hold harmless the indemnified Party from and against any loss or liability by reason of such settlement or judgment.  
  
10.2 Insurance. Supplier will, throughout the term of this Agreement, carry product liability insurance, in an amount acceptable to Silk Road Medical, covering any loss, damage, expense or liability incurred or suffered by any Party other than Silk Road Medical or Supplier arising out of any use of the Product. Such policy or policies will have aggregate limits of liability of not less than two million dollars ($2,000,000) with respect to any incident or occurrence and of not less than two million dollars ($2,000,000) in the aggregate. The Parties will consult and cooperate with respect to the obtaining of all product liability insurance requirements hereunder in the event changes in the cost or availability of such insurance occur during the term of this agreement.  
  
10.3 Limitation of Liability.  
  
EXCEPT WITH RESPECT TO CONFIDENTIALITY, INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, AND THE TERMINATION OF THIS AGREEMENT BY SILK ROAD MEDICAL CAUSED BY A MATERIAL BREACH BY SUPPLIER, SUPPLIER SHALL NOT BE LIABLE TO SILK ROAD MEDICAL FOR ANY SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF BUSINESS, GOODWILL, REVENUE OR PROFITS, BY REASON OF ANY ACT OR OMISSION OR ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.  
  
10.4 Responsibility for Subcontractors. Supplier shall be fully responsible for all of its participating Affiliates, subcontractors and vendors. Supplier shall ensure that each subcontract contains all applicable Specifications and obligations needed to fully comply with this Agreement. Supplier shall indemnify, defend and hold harmless each of Silk Road Medical and its Affiliates, distributors, dealers, agents and customers from and against any and all claims and liabilities, including all costs and expenses, arising out of or in any way connected with any actual or alleged action or failure to act by Supplier’s Affiliates, subcontractors or vendors.  
  
  
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11. Term and Termination.  
  
11.1 Term. This Agreement will take effect as of the Effective Date and, unless terminated earlier in accordance with Section 11.2, will continue in force until the fifth (5th) year anniversary of the Amendment Effective Date. After the initial term, this Agreement shall automatically renew for successive one (1) year periods. In the event that Silk Road Medical fails to purchase Products under this Agreement for twenty four (24) continuous months, this Agreement will automatically terminate at the end of the existing term.  
11.2 Termination. Notwithstanding the provisions of Section 11.1 above, this Agreement may be terminated in accordance with the following provisions:  
(a)Termination for Breach. Either Party may terminate this Agreement by giving written notice to the other Party in the event the other Party is in material breach of this Agreement and will have failed to cure such material breach within thirty (30) days of receipt of written notice thereof, provided the non-breaching Party, at its discretion, may extend such period;  
(b) Termination for Insolvency. Either Party may terminate this Agreement at any time by giving written notice to the other Party, which notice will be effective upon dispatch, should the other Party file a petition of any type as to its bankruptcy, be declared bankrupt, become insolvent, make an assignment for the benefit of creditors, or go into liquidation or receivership; or  
(a)  
Termination without Cause. Either Party may terminate this Agreement at any time by giving twelve (12) months’ prior written notice to the other Party.  
  
11.3 Rights and Obligations Upon Termination. In the event of the expiration or termination of this Agreement for any reason, the Parties will have the following rights and obligations:  
(a)Silk Road Medical will remain responsible for payment of all Products for which delivery has been made prior to the effective date of expiration or termination or for which delivery will be made after the effective date of expiration or termination pursuant to Section 11.3(b); provided, however, Silk Road Medical will continue to have the right to reject any Product that does not conform to the Specifications.  
(b)All Purchase Orders that are outstanding on the date this Agreement expires or terminates, for any reason, shall be deemed automatically terminated as of the date the Agreement is expired or terminated, provided that Silk Road Medical shall remain responsible for any raw material, in-process Products, or Finished Goods Inventory costs incurred directly as a result of Purchase Orders accepted prior to and fulfilled after the effective date of expiration or termination.  
(c)Supplier shall return in the same condition as originally received by Supplier, except for reasonable wear and tear, all tools, equipment, or material and other items purchased, furnished or charged to or paid for by Silk Road Medical, and any replacement of these items, used by Supplier in connection with manufacturing and assembling Products pursuant to this Agreement.  
(d)Expiration or termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.  
  
  
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12. Miscellaneous.  
12.1 Entire Agreement. This Agreement, including Attachments A through B, all of which are attached to and incorporated into this Agreement, constitutes the entire agreement of the Parties with respect to the subject matter of this Agreement, and supersedes all previous proposals, negotiations, conversations or discussions, oral or written, between the Parties related to this Agreement, except for the Purchase Orders and related Quotations issued under the terms of this Agreement. Each Party acknowledges that it has not been induced to enter into this Agreement by any representations or statements, oral or written, not expressly contained in this Agreement. For clarity, it is understood that this Agreement supersedes and replaces the Original Agreement in its entirety as of the Amendment Effective Date.  
12.2 Amendment. This Agreement will not be deemed or construed to be modified, amended, rescinded, cancelled or waived, in whole or in part, other than by written amendment signed by the Parties to this Agreement.  
12.3 Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the United States of America and the State of New York without reference to or application of their choice of laws or conflict of laws provisions.  
12.4 Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered personally (including delivery by courier service), transmitted by electronic mail, return receipt requested, or mailed by registered or certified mail, postage prepaid, return receipt requested, or sent by a nationally recognized overnight courier service, as follows:  
(i)  
If to Silk Road Medical, to:  
Silk Road Medical, Inc.  
000 Xxxxx Xxxxxxxx Xxxxxx,  
Xxxxxxxxx, XX 00000  
Attention: Xxxxx Xxxxxxxx, Chief Financial Officer  
Email: xxxxxxxxx@xxxxxxxxxxxxxxx.xxx  
(ii)  
If to Supplier, to:  
GaltMedical Corporation  
0000 Xxxxxxx Xxxxx  
Xxxxxxx Xxxxx  
Attention: Xxxx Xxxxxx, Executive Vice President of Sales & Marketing  
Email: xxxxxxx@xxxxxxxxxxxxxx.xxx  
or to such other address as the Party to whom notice is to be given may have previously furnished to the other Party in writing in accordance herewith. Notice shall be deemed given on the date received (or, if receipt thereof is refused, on the date of such refusal).  
12.5 Dispute Resolution. The Parties shall make good faith efforts to settle all disputes or differences which may arise under this Agreement, or in connection herewith, amicably and to the benefit of all Parties by means of informal negotiations.  
In the event that the Parties are unable to resolve their differences amicably, disputes which may arise out of this Agreement or in connection with its breach, termination or invalidity shall be finally settled by binding arbitration conducted in accordance with the Rules of Commercial Arbitration of the American Arbitration Association, by one or more arbitrators appointed in accordance with  
  
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such Rules. The applicable law shall be that set forth in Section 12.3 of this Agreement. The arbitration shall be held in Wilmington, DE. The award of the arbitrator(s) shall be final and binding on the Parties and may be entered in any court having jurisdiction over the Parties or their assets. No waiver by any Party of any non-compliance, default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent non-compliance, default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrator’s and any administrative fees of arbitration, unless the arbitrator determine that a Party has incurred unreasonable expenses due to vexatious or bad faith position taken by the other Party, in which event, the arbitrator may make an award of all or any portion of such expense so incurred.  
12.6 Severability. If any term or provision of this Agreement shall, to any extent, be held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of this Agreement or the application of such term or provision to persons or circumstances other than those as to which it has been held invalid or unenforceable, shall not be affected thereby and this Agreement shall be deemed severable and shall be enforced otherwise to the fullest extent permitted by law.  
12.7 Rights Cumulative. Except as expressly provided herein, the rights and remedies provided in this Agreement shall be cumulative and not exclusive of any other rights and remedies provided by law or otherwise.  
12.8 Independent Contractors. This Agreement does not make either Party the employee, agent or legal representative of the other for any purpose whatsoever. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party. In fulfilling its obligations pursuant to this Agreement, each Party will be acting as an independent contractor.  
12.9 Headings/Interpretation. The headings preceding the text of sections and sub-sections included in this Agreement and the headings to the Exhibits attached to this Agreement are for convenience only and shall not be deemed part of this Agreement or be given any effect in interpreting this Agreement. The use of the masculine, feminine or neuter gender herein shall not limit any provision of this Agreement. The use of the terms “including” or “include” shall in all cases herein mean “including, without limitation” or “include, without limitation,” respectively.  
12.10 No Assignment. Neither Party may assign or delegate this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party, which shall not be unreasonably withheld; provided that Silk Road Medical may assign this Agreement without Supplier’s consent to an Affiliate or to a third party that acquires all or substantially all of the business or assets to which this Agreement pertains, whether by merger, consolidation, change of control or otherwise. Any attempted assignment in violation of this Section 12.10 shall be null and void. Subject to the foregoing, this Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors, heirs, legatees, distributees and assigns.  
12.11 Further Assurances. At any time from and after the Effective Date, each Party shall, without additional consideration, upon the request of the other Party, execute, acknowledge, and deliver such documents, and will take such other action consistent with the terms of this Agreement, as may be reasonably required to consummate the transactions contemplated by this Agreement and to permit each Party to enjoy their prospective rights and benefits hereunder.  
12.12 Certain Costs and Expenses. Supplier, on one hand, and Silk Road Medical, on the other hand, will bear their own respective expenses and legal fees incurred with respect to this Agreement and the transactions contemplated hereby.  
  
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EXECUTION VERSION  
  
12.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to constitute an original and shall become effective when one or more counterparts have been signed by each Party hereto and delivered to the other Party. Counterparts delivered in “pdf” form shall be as effective as manually signed counterparts; provided, however, that any Party supplying a pdf counterpart shall promptly forward an originally executed counterpart.  
12.14 Survival. Sections 1, 2.2 (solely for seven (7) years), 2.3, 2.4, 2.5, 8 (solely for five (5) years), 9, 10, 11.3 and 12 shall survive termination of this Agreement.  
12.15 Compliance with Laws. Supplier will at all times comply with all applicable standards, provisions and stipulations of all United States federal, state and local laws, rules, regulations and ordinances relevant to performance under this Agreement and each Purchase Order, including but not limited to all fair labor, equal opportunity and environmental compliance laws, rules, regulations and ordinances. Supplier shall furnish to Silk Road Medical any information required to enable Silk Road Medical to comply with such laws, rules, and regulations in its use of the Products.  
12.16 HIPAA Compliance. Silk Road Medical and Supplier agree that Supplier shall not use or further disclose individually identifiable health information (“PHI”) as defined in and subject to protection under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated pursuant thereto (“HIPAA”) other than as permitted by this Agreement or required by law. Supplier shall use appropriate safeguards to prevent the use or disclosure of the PHI other than as permitted by this Agreement, and shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information (“ePHI”) (“Safeguards”). Supplier shall report to Silk Road Medical: (a) any use or disclosure of the PHI not permitted by this Agreement or by law of which Supplier becomes aware; and (b) any Security Incident of which Supplier becomes aware. To the extent that Supplier uses one or more subcontractors or agents to provide services under this Agreement, and such subcontractors or agents receive or have access to the PHI, each such subcontractor or agent shall: (i) enter into a written agreement with Supplier containing the same restrictions and conditions set forth in the business associate provisions of HIPAA that apply through Supplier; and (ii) implement reasonable and appropriate Safeguards to protect ePHI. Supplier agrees to make (A) its internal practices, books and records relating to the use and disclosure of PHI and (B) its policies, procedures and documentation required by the Security Rule relating to the Safeguards, available to the Secretary of the U.S. Department of Health and Human Services or his designee to the extent necessary to determine Supplier’s customer’s compliance with HIPAA. Supplier agrees to make available to Silk Road Medical the information in its possession required to provide an accounting of Supplier’s disclosures of PHI as required by HIPAA. Supplier shall use reasonable commercial efforts to mitigate any harmful effect that is known to Supplier of a use or disclosure of PHI by Supplier in violation of this Agreement. Upon the termination of this Agreement for any reason, Supplier shall remain bound by the provisions of this Section 12.16 with respect to any PHI that remains in its possession.  
12.17 Excluded Provider. Supplier represents and warrants that it, and, to the best of its knowledge, its employees and subcontractors providing the Products are not debarred, excluded, suspended or otherwise ineligible to participate in a federal health care program, nor have they been convicted of any health care related crime (an “Excluded Provider”). Supplier shall promptly notify Silk Road Medical in writing in the event that it becomes aware that any of its employees or subcontractors providing the Products has become an Excluded Provider. Silk Road Medical may terminate this Agreement upon written notice to Supplier if Supplier, or any of its employees or subcontractors providing the Products becomes an Excluded Provider.  
  
  
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EXECUTION VERSION  
  
12.18 Force Majeure. Neither Party will be in default under this Agreement, because of any failure to perform any of its obligations under this Agreement if such failure arises from causes beyond the control of such Party and without the fault or negligence of such Party, including, but not limited to, Acts of God, acts of the public enemy, terrorism, acts of the government, fires, floods, earthquakes, epidemics, quarantine restrictions, strikes, freight embargoes, failure of carriers, and inability to obtain materials. If it appears that either Party’s performance under this Agreement may be delayed by an event of force majeure, such Party will notify the other Party as soon as practicable, and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. During the period that the performance by one of the Parties of its obligations under this Agreement has been suspended by reason of an event of force majeure, the other Party may likewise suspend the performance of all or part of its obligations hereunder (other than the obligation to pay any amounts due and owing) to the extent that such suspension is commercially reasonable.  
  
  
  
[SIGNATURE PAGE FOLLOWS]  
  
  
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EXECUTION VERSION  
  
IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed on the Amendment Effective Date.  
  
  
SILK ROAD MEDICAL, INC.  
 By  
/s/ Xxxxx Xxxxxxxx  
 Name: Xxxxx Xxxxxxxx  
 Title: Chief Financial Officer  
 GALT MEDICAL CORPORATION  
 By  
/s/ Xxxx Xxxxxx  
 Name: Xxxx Xxxxxx  
 Title: Executive Vice President of Sales & Marketing  
   
  
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EXECUTION VERSION  
  
Attachment A – Specifications  
  
Silk Road Medical’s  
Part #  
Description  
Supplier’s Part #  
11789-05  
Sterile Micro Introducer Kit with 4cm 21Gauge needle with depth indicator, 0.018” nitinol wire with depth indicator, 4F sheath with non-stiffened and stiffened dilators  
KIT-075-00  
11789-06  
Sterile Micro Introducer Kit with 7cm 21Gauge needle with depth indicator, 0.018” nitinol wire with depth indicator, 4F sheath with non-stiffened and stiffened dilators  
KIT-075-01  
11789-07  
Sterile Micro Introducer Kit with 4cm 21Gauge needle with depth indicator, 0.018”x50cm nitinol wire with depth indicator, 4Fx15cm sheath with depth indicators, non-stiffened and stiffened dilators, 20cm extension tube with stopcock.  
KIT-075-02  
11789-08  
Sterile Micro Introducer Kit with 7cm 21Gauge needle with depth indicator, 0.018”x50cm nitinol wire with depth indicator, 4Fx15cm sheath with depth indicators, non-stiffened and stiffened dilators, 20cm extension tube with stopcock.  
KIT-075-03  
  
  
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EXECUTION VERSION  
  
Attachment B – Prices, Estimated Order Quantity  
  
Silk Road Medical P/N  
Supplier P/N  
Quantity\*  
Unit Price  
11789-05, -06  
KIT-075-00, -01  
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[\*\*\*\*\*\*]  
11789-07, -08  
KIT-075-02, -03  
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\* Quantity represents the combined number of units ordered:  
•  
11789-05 and 11789-06, or  
•  
11789-07 and 11789-08  
  
  
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