Confidential Materials omitted and filed separately with the  
Securities and Exchange Commission. Double asterisks denote omissions.  
 Exhibit 10.15  
MANUFACTURING AGREEMENT  
This Manufacturing Agreement (this “Agreement”) is made this 18th day of March, 2014 (the “Effective Date”) by and between Spark Therapeutics, LLC, a Delaware limited liability company with a principal address at 0000 Xxxxx Xxxxxx Xxxxxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000, XXX (“Spark”), and Genable Technologies Limited, a limited liability company with a principal address at c/o Delta Partners, Xxxxx Xxxxx, Xxxxx Xxxxxx Xxxxxxxx Xxxx, Xxxxxxxxxxxx, Xxxxxx 00, Xxxxxxx (“Genable”). Spark and Genable may each be referred to herein as a “Party” and together as the “Parties”.  
WHEREAS, Genable is a company engaged in the discovery and development of biological products, including the Product (as defined below);  
WHEREAS, Spark has unique and valuable experience, skill and ability in, among other things, the research, development and manufacture of AAV-based therapeutic products; and  
WHEREAS, Genable desires, and Spark is willing to provide to Genable, certain manufacturing services in accordance with the terms and conditions of this Agreement.  
NOW, THEREFORE, in consideration of the promises, rights and obligations set out in this Agreement, the sufficiency of which is hereby acknowledged and intending to be legally bound, the Parties agree as follows:  
 1 Definitions.  
The following terms shall have the meanings ascribed to them below:  
 1.1 “AAV” shall mean adeno associated virus.  
 1.2 “Affiliate” shall mean, with respect to a Party, any Person that directly or indirectly controls, is controlled by, or is under common control with, such Party. For these purposes, “control” and its correlates means: (i) the ownership, directly or indirectly, of at least fifty percent (50%) of the issued voting shares or interests in an entity; or (ii) the possession, directly or indirectly, of the legal power to direct or cause the direction of the general management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise. Notwithstanding the foregoing, CHOP shall be deemed not to be an Affiliate of Spark.  
 1.3 “Agreement” shall have the meaning set forth in the Preamble.  
 1.4 “Batch” shall mean a specific quantity of a Product that is intended to be of uniform character and quality and is produced during the same cycle of manufacture and in accordance with the applicable manufacturing process.  
 1.5  
“cGMP” shall mean current good manufacturing practices pursuant to (a) the U.S. Federal Food, Drug, and Cosmetic Act as amended (21 USC 301 et seq.), (b) relevant U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations  
 1  
 (including but not limited to Parts 11, 210, 211, 600 and 610), (c) Commission Directive 0000/00/XX xx 00 Xxxxxxx 0000, (x) the EC Guide to Product Manufacturing Practice for Medicinal Drug Products, including respective guidance documents and (e) any comparable laws, rules or regulations of any agreed upon foreign jurisdiction, as each may be amended from time to time. cGMP also includes adherence to any applicable product license requirements, to the current requirements of the United States Pharmacopoeia/National Formulary, the current requirements of the European Pharmacopoeia and the relevant current International Conference on Harmonization (ICH) guidance documents.  
 1.6 “CHOP” shall mean The Children’s Hospital of Philadelphia.  
 1.7 “Claim” shall have the meaning set forth in Section 12.1.1.  
 1.8 “Commercially Reasonable Efforts” shall mean the carrying out of applicable obligations under this Agreement in a commercially reasonable manner in good faith using all such efforts and resources consistent with the practice of comparable contract manufacturers of a similar size and resources, both financial and otherwise, to Spark, that would be used by such companies were they developing a comparable biological product, and in any event Spark shall be required to perform all services under this Agreement to a standard comparable to that used in respect of the development of its own products and/or internal projects;  
 1.9 “Confidential Information” shall have the meaning set forth in Section 14.1.  
 1.10 “Delivery Failure” shall have the meaning set forth in Section 9.1.  
 1.11 “Development Agreement” shall mean the Development Consultancy Agreement of even date herewith, by and between the Parties.  
 1.12 “DMF” shall mean Device or Drug Master File, as defined in the CFR Section 314.420 or 814 and/or its equivalent in the other countries in which Regulatory Approval for the Product has been secured.  
 1.13 “EMA” shall mean the European Medicines Agency or any successor agency thereof having the authority to regulate the sale of medicinal or pharmaceutical products in the European Union through marketing approval, not including any governmental authority with responsibility solely for pricing or reimbursement approvals.  
 1.14 “Effective Date” shall have the meaning set forth in the Preamble.  
 1.15 “FDA” shall mean the United States Food and Drug Administration or any successor entity thereto.  
 1.16 “Genable” shall have the meaning set forth in the Preamble.  
 2  
 1.17 “Genable Assays” mean the proprietary assays of Genable relating to GT038 as more specifically set out in Exhibit C.  
 1.18 “Genable Intellectual Property” means any and all intellectual property rights owned, licensed or controlled by Genable relating to GT038 (other than pursuant to a license or sublicense from Spark).  
 1.19 “Genable Improvement” means improvements which predominately relate to the Genable Intellectual Property and which are developed (i) by Genable outside this Agreement, (ii) by Genable or Spark pursuant to this Agreement, and/or (iii) jointly by any combination of Genable or Spark or a third party (under contract to either party) pursuant to this Agreement.  
 1.20 “Genable Indemnitees” shall have the meaning set forth in Section 12.1.2.  
 1.21 “GT038” means a gene therapeutic comprising an AAV vector containing DNA encoding an RNAi targeting rhodopsin in combination with an AAV vector containing DNA encoding a rhodopsin gene for the treatment of rhodopsin-linked, autosomal dominant retinitis pigmentosa (RHO-adRP), which is in development by Genable as of the Effective Date, and as such gene therapeutic may be modified after the Effective Date.  
 1.22 “Indemnified Party” shall have the meaning set forth in Section 12.2.  
 1.23 “Indemnifying Party” shall have the meaning set forth in Section 12.2.  
 1.24 “Intellectual Property” shall mean all (a) patents, patent applications, patent disclosures and all related continuation, continuation-in-part, divisional, reissue, reexamination, utility model, certificate of invention and design patents, patent applications, registrations and applications for registrations; (b) trademarks, service marks, trade dress, Internet domain names, logos, trade names and corporate names and registrations and applications for registration thereof; (c) copyrights and registrations and applications for registration thereof; (d) mask works and registrations and applications for registration thereof; (e) computer software, data and documentation; (f) inventions, trade secrets and confidential business information, whether patentable or nonpatentable and whether or not reduced to practice, know-how, manufacturing and product processes and techniques, research and development information, copyrightable works, financial, marketing and business data, pricing and cost information, business and marketing plans and customer and supplier lists and information; and (g) copies and tangible embodiments thereof.  
 1.25 “Legal Requirements” shall mean (a) any present and future national, state, local or similar laws (whether under statute, rule, regulation or otherwise), (b) requirements under permits, orders, decrees, judgments or directives of any U.S. governmental entity and any governmental entity in the jurisdiction where the Manufacturing Services are performed, and (c) requirements of applicable Regulatory Authorities (including cGMP and GLP) and Regulatory Approvals.  
 3  
 1.26 “License Agreement” shall mean the License Agreement of even date herewith, by and between the Parties.  
 1.27 “Manufacturing Price” shall mean, with respect to a Product, the applicable price (depending on type of production) calculated pursuant to Exhibit A.  
 1.28 “Manufacturing Services” shall have the meaning set forth in Section 3.1.  
 1.29 “Manufacturing Standard” shall have the meaning set forth in Section 7.7.  
 1.30 “Non-Conforming Product” shall mean any Product that at the time delivered pursuant to Section 9.1, does not meet the applicable Manufacturing Standard.  
 1.31 “Party” and “Parties” shall have the meanings set forth in the Preamble.  
 1.32 “Person” shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.  
 1.33 “Product” shall mean a product incorporating GT038, as further described in the applicable Specifications.  
 1.34 “Records” shall have the meaning set forth in Section 4.1.  
 1.35 “Regulatory Approval” shall mean the final approval to market the Product in any country of the Territory.  
 1.36 “Regulatory Authority” shall mean with respect to the United States, the FDA, or, in the case of a country other than the United States, such other appropriate regulatory agency with similar responsibilities for granting Regulatory Approval for the Product, including but not limited to, the EMA.  
 1.37 “Retention Period” shall have the meaning set forth in Section 4.1.  
 1.38 “Senior Officers” shall have the meaning set forth in Section 15.2.  
 1.39 “Spark” shall have the meaning set forth in the Preamble.  
 1.40 “Spark Assays” mean the proprietary assays of Spark as more specifically set out in Exhibit D.  
 1.41 “Spark Indemnitees” shall have the meaning set forth in Section 12.1.1.  
 1.42 “Spark Intellectual Property” means any and all intellectual property rights owned, licensed or controlled by Spark relating to the research, development and manufacture of AAV-based therapeutic products.  
 1.43  
“Spark Improvement” means improvements which predominately relate to the Spark Intellectual Property and which are developed (i) by Spark outside this  
 4  
 Agreement, (ii) by Spark or Genable pursuant to this Agreement, and/or (iii) jointly by any combination of Spark or Genable or a third party (under contract to either party) pursuant to this Agreement.  
 1.44 “Specifications” shall mean the manufacturing, quality and testing specifications for the Product as set out in each applicable Work Order.  
 1.45 “Term” shall have the meaning set forth in Section 5.1.  
 1.46 “Third Party” shall mean any Person other than the Parties and their respective Affiliates.  
 1.47 “U.S.” or “United States” shall mean the United States of America.  
 1.48 “Work Order” shall have the meaning set forth in Section 3.1.  
 2 Technology Transfer  
 2.1 As soon as possible following the execution of this Agreement, Genable shall provide to Spark, unless it has already done so prior to the execution of this Agreement, data regarding GT038, as Genable determines may reasonably be required by Spark to successfully perform the Manufacturing Services. The foregoing data shall include, but shall not be limited to:-  
 (i) appropriate in-vitro and in-vivo analytical methods and procedures;  
 (ii) information as to handling and storage conditions; and  
 (iii) the desired Specifications for the Product.  
 2.2 It is acknowledged by the Parties that the Genable Assays shall be required by Spark in order to perform the Manufacturing Services. Genable and Spark shall use Commercially Reasonable Efforts to complete the transfer of the Genable Assays to Spark within [\*\*] months of the execution of this Agreement. The Genable Assays shall remain the sole property of Genable at all times. Spark covenants and undertakes to Genable to maintain the Genable Assays in confidence and not to use the Genable Assays for any other purpose other than the manufacture of the Product pursuant to this Agreement.  
 2.3 It is acknowledged by the Parties that the Spark Assays shall be required by Spark in order to perform the Manufacturing Services. Spark warrants to Genable that the Spark Assays are functioning and qualified/validated as appropriate to the stage of development for the purpose of manufacturing biological for human use. The Spark Assays shall remain the sole property of Spark at all times.  
 2.4 Spark shall only be entitled to outsource assay testing to a Third Party listed in Exhibit E or to a Third Party approved by Genable, such approval not to be unreasonably withheld or delayed.  
 5  
 2.5 Each of the Parties shall bear all of their own expenses in relation to the performance of the services set out in this Section 2.  
 2.6 Spark shall remain the sole owner of the Spark Intellectual Property. Genable shall remain the sole owner of the Genable Intellectual Property.  
 2.7 Spark shall remain the sole owner of the Spark Improvements. Any Spark Improvements which are made jointly by at least one employee/consultant of Spark and at least one employee/consultant of Genable shall be assigned to Spark by Genable at Spark’s request  
 2.8 Genable shall remain the sole owner of the Genable Improvements. Any Genable Improvements which are made jointly by at least one employee/consultant of Genable and at least one employee/consultant of Spark shall be assigned to Genable by Spark at Genable’s request.  
 2.9 Spark grants to Genable an [\*\*] to the Spark Improvements as are made jointly by at least one employee/consultant of Spark and at least one employee/consultant of Genable for use with GT038.  
 2.10 Genable grants to Spark an [\*\*] to the Genable Improvements as are made jointly by at least one employee/consultant of Genable and at least one employee/consultant of Spark for the manufacture of AAV-based therapeutic products; provided however, that any such use shall be subject to the provisions of Clause 3.4 of the Licence Agreement.  
 3 Manufacturing Services  
 3.1 Manufacturing Services; Work Orders. Genable may, from time to time during the term of this Agreement, request that Spark manufacture Batches of the Product (“Manufacturing Services”), and following each such request the Parties shall enter into written work orders (each such work order, a “Work Order”) substantially in the form set forth in Exhibit B.  
 3.2 Spark shall use Commercially Reasonable Efforts to perform such Manufacturing Services in accordance with this Agreement, as more specifically agreed in the applicable Work Order. Each Work Order shall be deemed incorporated into this Agreement. Notwithstanding the foregoing, if for any reason Product as delivered by Spark does not conform to the Specifications, such nonconformity shall be addressed in accordance with Section 9.1.  
 3.3 Each Work Order shall include (a) the Specifications applicable to the applicable Batch; (b) an allocation of responsibility for quality assurance for the Batch; (c) timelines related to the delivery of the Batch; (d) a detailed cost and pricing schedule, including the timing for the invoicing of costs; (e) a purchase order authorizing the initiation of work thereunder and (f) payment of [\*\*]% of the price for the Work Order.  
 6  
 3.4 The Parties from time to time may agree in writing on variations to the Specifications, depending on whether the Product supplied hereunder is intended to be cGMP, cGMP-comparable or research grade and depending on whether the Product supplied hereunder will be in bulk form or final finished form, and shall reference the Specifications applicable to each Work Order in the Work Order.  
 3.5 The Parties shall agree on each binding Work Order [\*\*] months before the delivery date specified therein for the applicable Batch, provided that the Parties will agree to Work Orders for the first GLP Batch and for the first GMP Batch less than [\*\*] months before the delivery date specified therein. In the event of any conflict between the terms of a Work Order and this Agreement, with the exception of the Specifications, the terms of this Agreement shall control. Without limiting the foregoing, Genable shall [\*\*] basis, provide Spark with a non-binding, good faith [\*\*] month forecast of Genable’s anticipated requirements for Product. Prior to the commencement of commercial scale manufacture and supply of Product by Spark to Genable, the Parties shall review forecasting, ordering and capacity commitments with respect to such manufacture and supply.  
 3.6 Performance Standard; Compliance with Law. Spark shall perform the Manufacturing Services (a) in a professional, competent and timely manner in conformance with the applicable Work Order and (b) in compliance with all applicable Legal Requirements, provided that, Spark’s failure to comply with the foregoing obligations of this Section 3.6(b) shall not constitute a breach of this Agreement unless and until Genable has notified Spark in writing of the noncompliance and Spark has failed to correct the noncompliance within [\*\*] days thereafter.  
 3.7 Equipment. As between the Parties, unless otherwise specified in an applicable Work Order, Spark shall be responsible for procuring all facilities, equipment and staff necessary to perform Manufacturing Services under each Work Order. Spark shall use Commercially Reasonable Efforts to make available all staff, facilities, equipment and other resources as may be necessary to support the provision of the Manufacturing Services pursuant to this Agreement.  
 3.8 Licenses and Permits. Spark shall have and maintain any and all licenses, permits and other authorizations, which are required for its performance of this Agreement, provided that Genable shall reimburse Spark for all reasonable costs and expenses of undergoing pre-approval inspections and other regulatory inspections solely related to the Product. Subject to the foregoing, Spark shall be solely responsible for all regulatory inspections relating to the approval of the Manufacturing Facility.  
 3.9  
Spark shall be responsible for filing and maintaining a DMF for the Product with the FDA as its owner. Spark grants Genable the right to reference the DMF in its regulatory filings for Products. Spark shall cooperate with Genable for purposes of creating a Common Technical Document and Genable will be permitted to reference and file EMA summary modules 2.3 and 3.0 of the Common Technical Document in such manner as may be necessary in ex-U.S. regulatory filings  
 7  
 relating to the sale and marketing of Products. Genable’s use of EMA summary modules 2.3 and 3.0 of the Common Technical Document shall be limited to such uses with respect to the Product. Genable shall solely bear all reasonable costs related to the development and maintenance of EMA summary modules 2.3 and 3.0 of the Common Technical Document.  
 3.10 Joint Manufacturing Committee. As soon as practicable after the Effective Date, the Parties will form a Joint Manufacturing Committee (the “Joint Manufacturing Committee”), a subcommittee of the Steering Group. The Joint Manufacturing Committee will meet regularly during the Term, as mutually agreed by the Parties. The meetings shall be by telephone conference or videoconference, or in person at mutually agreed locations. Each Party shall be responsible for its own costs in attending meetings. The Joint Manufacturing Committee will not have the power to amend or waive compliance with the terms of this Agreement or any Work Order. The Joint Manufacturing Committee shall have the responsibilities of monitoring the progress and results of the activities of the Parties pursuant to this Agreement and of facilitating coordination between the Parties with respect to such activities.  
 3.11 Process Modifications. Spark shall not be entitled to modify the process employed in the manufacture of the Product as set out in the DMF without first having consulted with Genable and then only with Genable’s prior written agreement and also in compliance with all applicable regulatory requirements in the United States and EU with respect to such modification.  
 3.12 Subcontractors. Spark shall not sub-contract the performance of the Manufacturing Services to any Third Party other than CHOP without the priorwritten consent of Genable, provided that nothing in this Agreement shall restrict Spark or CHOP from employing contractors to perform ancillary aspects of the Manufacturing Services under its supervision. Spark shall be responsible for any services it sub-contracts to a third party as if it had performed those services itself.  
 3.13 Exclusivity. During the Term, except as otherwise set forth in Section 9.1, Genable shall purchase Product exclusively from Spark, and Spark shall supply Product exclusively to Genable.  
 4 Records and Facility; Audits  
 4.1  
Facility and Records. Spark shall maintain its manufacturing facilities used in manufacturing the Products in accordance with cGMP and all other applicable Legal Requirements. Spark shall keep and maintain documents and records associated with the performance of Manufacturing Services as required by Legal Requirements. Spark will maintain all materials, data and documentation obtained or generated by Spark in the course of performing the Manufacturing Services, including all reference standards, retained samples of Product and key intermediates, and computerized records and files (the “Records”) in a secure area reasonably protected from fire, theft and destruction for the longer of (a) a period of  
 8  
 [\*\*] years following expiration or termination of this Agreement or (b) [\*\*] years past the last expiration date of Product supplied under this Agreement, or, in each case, such longer period as is required by applicable law (the “Retention Period”). At the end of the Retention Period, all Records will, at Genable’s option, either be (x) delivered to Genable or to its designee, at Genable’s cost, in such form as is then currently in the possession of Spark or (y) disposed of, at the cost, direction and written request of Genable. In no event will Spark dispose of or destroy all copies of a particular Record without first giving Genable at least [\*\*] days’ prior written notice of its intent to do so and an opportunity to have the Records transferred to Genable. While in the possession and control of Spark, Records will be available during audits or at other mutually agreed times for inspection, examination or review by Genable and its representatives as provided herein. Notwithstanding anything in this Section 4.1 to the contrary, Spark may retain copies of any Records as necessary to comply with Legal Requirements, subject to the obligations of confidentiality of Spark under this Agreement and as consistent with Spark policies and practices.  
 4.2 Audit by Genable. Spark will permit Genable representatives (which may include representatives of Genable’s Affiliates and any of their respective consultants or sublicensees), upon reasonable advance notice to Spark, to conduct, during normal business hours during the Term, audits and inspections of Spark’s records related to Manufacturing Services and Spark’s manufacturing facility. Genable shall be responsible for the costs incurred by Genable in performing such audits. Genable shall conduct audits and inspections under the preceding sentence no more than [\*\*] per facility (save where there has been a Delivery Failure, in which event Genable shall be entitled to conduct a further audit during such calendar year) provided that (a) any vendor selection audit and preparatory audits conducted in preparation for a pre-approval inspection by a Regulatory Authority may be conducted in addition to the foregoing [\*\*] audit; and (b) Genable may conduct additional audits in the event any audit conducted by Genable or an audit by a Regulatory Authority reveals a compliance deficiency. All information disclosed or ascertained by Genable, its Affiliates, consultants or sublicensees in connection with any audit or inspection will be deemed to constitute confidential information of Spark, subject to the terms of Article 14 and any Genable Affiliates, consultants or sublicensees acting hereunder shall be required to sign confidentiality agreements consistent with the terms of Article 14 prior to any audit or inspection in which they take part. Notwithstanding the foregoing or anything to the contrary set forth in this Agreement, Spark shall have the right to limit Genable’s access to confidential information relating to Spark’s manufacturing process to the extent not reasonably required to enable Genable to conduct such audits and inspections for quality assurance purposes.  
 4.3  
Regulatory Authority Inspections. Spark will be responsible for inspections of its facility by Regulatory Authorities, and will notify Genable within [\*\*] hours of receipt of notice from a Regulatory Authority of any such inspections that are specifically related to the Product or at least [\*\*] days in advance of the scheduled inspection date for other inspections of its facility. Such notifications may be given  
 9  
 by telephone, e-mail or other reasonable communications method. With respect to inspections specifically related to the manufacture of Product or if the results of a non-specifically related inspection could potentially impair the ability of Spark to perform the Manufacturing Services, Spark will (a) provide Genable with copies of all documents, reports or communications received from or given to any Regulatory Authority associated therewith; and (b) permit Genable’s representatives to be on site in an adjacent area to answer questions or requests specific to Genable or the Product and, to the extent practicable, keep Genable apprised of the progress of such inspections and consult with Genable regarding the same.  
 5 Term and Termination  
 5.1 Term. The term of this Agreement (“Term”) shall commence on the Effective Date and will expire ten (10) years after the first commercial sale of a Product.  
 5.2 Termination for Material Breach. This Agreement may be terminated by either Party if the other Party is in material breach of this Agreement and such material breach is not cured within [\*\*] days after receipt of written notice from the terminating Party with respect thereto.  
 5.3 Termination upon Termination of License Agreement. This Agreement shall terminate upon the expiration or termination of the License Agreement.  
 5.4 Effects of Termination; Survival. Upon termination or expiration of this Agreement, Genable shall pay Spark any undisputed monies due and owing Spark, up to the time of termination or expiration, including all authorized expenses and non-cancelable expenses which have been incurred by Spark prior to the notice of termination in accordance with the relevant Work Order (which costs shall not in any event exceed the amounts agreed herein or in the Work Order). Spark shall use its reasonable endeavors to cancel commitments prior to the termination. Termination of this Agreement for any reason is without prejudice to the Parties’ accrued rights and shall not be construed to release either Party from any obligation incurred prior to the effective date of such termination. The following provisions shall survive the expiration or termination of this Agreement: Articles 4, 10, 12, 13, 14, 15 and 16.  
 6 Prices/Payment  
 6.1 Fees. The supply price for Product shall be the Manufacturing Price for such Product, as such supply price may be modified by the Work Order.  
 6.2 Additional Manufacturing Services. In the event that Spark is requested to perform any additional manufacturing services for Genable other than as provided for in the Manufacturing Price for the Product, the cost of any such additional manufacturing services shall be agreed in advance in writing by the Parties and set forth in the Work Order.  
 10  
Invoices. Spark shall invoice Genable for all amounts due under a Work Order in accordance with the timing set forth in the Work Order. Invoices shall, except to the extent correctly disputed, be payable within [\*\*] days after Genable’s receipt thereof. Genable shall be responsible for the payment of all taxes arising from any Work Order or delivery or use of the Product (other than taxes on the income of Spark arising therefrom). For the avoidance of doubt, Genable shall pay to Spark within [\*\*] days of Spark receiving from Genable a properly executed work start order [\*\*]% of the total cost of the Work Order.  
The remaining [\*\*]% payment shall be made within [\*\*] days of Genable receiving the finished goods.  
 6.3  
If applicable laws of Ireland require that withholding taxes be withheld with respect to any payments by Genable to Spark under this Agreement, Genable will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to Spark on a timely basis following that tax payment. If Spark is a taxable entity in the United States and is therefore entitled to the benefits of the double taxation treaty between Ireland and the United States, and Spark provides Genable with a Form 6166 from the United States Internal Revenue Service with respect to such taxable status, at or prior to the time of any payment potentially subject to the Irish withholding tax is made hereunder, then payments made by Genable to Spark hereunder shall be made without withholding tax; provided that, if such double taxation treaty is modified after the Effective Date so that payments to Spark hereunder are subject to withholding taxes, Genable shall give notice to Spark of such change and shall pay to Spark such additional amount as may be necessary so that Spark shall receive, after deduction of such withholding tax, the amount which Spark would have received in the absence of such withholding tax less [\*\*] percent ([\*\*]%) of the withholding tax amount (i.e., the Parties [\*\*] percent ([\*\*]%) of the withholding tax amount). If Spark is not able to meet the above criteria for withholding tax treaty benefits (e.g., by ceasing to be, or by assigning its interest in this Agreement to an entity that is not, a taxable entity in the United States entitled to the benefits of the double taxation treaty between Ireland and the United States), then Genable shall make payments less any required withholding tax, and such withholding taxes required under Irish law shall be borne solely by Spark. If Genable or any successor or assign of Genable makes any payment to Spark hereunder in a manner that subjects such payment to a withholding tax obligation under the laws of any jurisdiction other than those of Ireland (i.e., either by such entity being or becoming domiciled in any jurisdiction other than Ireland or by such entity making any payment to Spark from a jurisdiction outside of Ireland), then Genable shall give notice to Spark of such requirement and shall pay to Spark such additional amount as may be necessary so that Spark shall receive, after deduction of such withholding tax, the amount which Spark would have received in the absence of such withholding tax. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in  
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 effect (e.g., Genable shall not withhold Irish withholding tax without first confirming with Spark that Spark is not able to provide the documentation of its taxable status as described above). The Parties shall discuss and cooperate regarding applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable law. In addition, the Parties shall cooperate in accordance with applicable law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement.  
 7 Spark’s Representations and Warranties  
 7.1 General Representations and Warranties. Spark hereby represents and warrants to Genable that it has the power to enter into this Agreement, and its performance hereunder will not violate any Legal Requirements and will not breach or in any way be inconsistent with the terms and conditions of any license, contract, understanding or agreement, whether express, implied, written or oral between Spark and any third party.  
 7.2 No Conflict. Spark hereby represents and warrants to Genable that it is not a party to any agreement that (a) would prevent Spark from performing its obligations under this Agreement; or (b) conflicts with Spark’s performance of its obligations under this Agreement.  
 7.3 Personnel; No Debarment. Spark represents and warrants that all of the personnel that Spark uses in the performance of the Manufacturing Services shall be appropriately qualified and experienced for the tasks that they are to perform. Spark warrants and covenants that all Spark employees and personnel that perform such Manufacturing Services are and will be subject to binding, written non-disclosure policies as are reasonably necessary for Spark to comply with the confidentiality obligations hereunder and the provisions of Article 14.  
 7.4 Spark represents that it has never been and to the best of its knowledge, none of its employees or contractors assigned to perform the Manufacturing Services has ever been, (a) debarred or threatened to be debarred under applicable law, or (b) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under 21 U.S.C. § 335a, as amended. Spark shall promptly disclose in writing to Genable (i) if Spark is debarred, is proposed to be debarred or if any action or investigation is pending relating to the debarment of Spark, or (ii) if an employee or agent of Spark assigned to perform Manufacturing Services is debarred, is proposed to be debarred, or if any action or investigation is pending relating to the debarment of an employee or agent of Spark assigned to perform Manufacturing Services.  
 7.5 Product Warranties; Disclaimers. Genable acknowledges, without limiting Spark’s responsibility for delivering Products that conform to the Manufacturing Standard, that the Product is experimental in nature and may have unknown characteristics, may carry infectious agents, or may be otherwise hazardous.  
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 7.6 EXCEPT AS EXPRESSLY SET FORTH BELOW IN SECTION 7.7, THE PRODUCT IS PROVIDED “AS IS” AND SPARK (INCLUDING THE SPARK INDEMNITEES) DISCLAIMS ANY WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE PRODUCT WILL NOT INFRINGE OR VIOLATE ANY INTELLECTUAL PROPERTY RIGHT OF ANY THIRD PARTY.  
 7.7 Spark represents and warrants to Genable that Product manufactured and supplied hereunder, including under any Work Order hereunder, (a) will conform to the applicable Specifications in each Work Order; (b) will be manufactured and supplied in compliance with applicable Legal Requirements (including cGMP, to the extent applicable) and Regulatory Approvals to the extent required under the applicable Work Order and Specifications; and (c) except as otherwise specifically set forth in writing in the applicable Work Order, will not be adulterated, contaminated or misbranded (“Manufacturing Standard”).  
 8 Genable’s Representations and Warranties; Obligations  
 8.1 General Representations and Warranties. Genable hereby represents and warrants to Spark that (a) it has the power to enter into this Agreement, and (b) its performance hereunder will not violate any Legal Requirements.  
 8.2 No Conflict. Genable hereby represents and warrants to Spark that it is not a party to any agreement that (a) would prevent Genable from performing its obligations under this Agreement; or (b) conflicts with Genable’s performance of its obligations under this Agreement.  
 8.3 Genable Supplied Materials. In case of material provided by Genable for use in the manufacturing of Products at Spark’s facilities, Genable is responsible for ensuring that such Genable supplied material is provided in time for the work to commence or continue as planned, in compliance with the applicable Specifications, is delivered with all necessary documentation and that Spark may use such material in accordance with the applicable Work Order without violating the Intellectual Property rights of any Third Party. Spark shall not use any Genable supplied materials for any purpose other than the performance of Manufacturing Services without the prior written consent of Genable. Upon completion of the relevant Manufacturing Services, any remaining quantities of Genable supplied materials will be, at Genable’s option, either destroyed by Spark or returned to Genable.  
 8.4 Genable Obligations. Genable shall provide Spark with any documentation or knowledge in its possession and control pertaining to known risks associated with GT038. This includes material safety data sheets for raw materials, intermediates and final product, chemical and operational hazard assessments and materials compatibilities.  
 13  
9 Delivery Requirements; Transfer of ownership and risk  
Spark shall use Commercially Reasonable Efforts to deliver Products in accordance with the terms of the relevant Work Order, including delivery dates and shipping instructions set forth therein. Spark shall promptly (within [\*\*] days) notify Genable if it becomes aware or believes that it will not be able to fully satisfy a particular delivery on time (in each case, a “Delivery Failure”), which notice shall include an explanation in reasonable detail of the reasons for such Delivery Failure, a detailed description of the action to be taken to remedy such failure, including an estimate of the time required to fulfill the obligations that were the subject of the Delivery Failure. The Parties shall promptly discuss the Delivery Failure.  
If (i) a Delivery Failure persists for more than [\*\*] consecutive days or (ii) there are delays in filling each of [\*\*] successive orders which delays cumulatively exceed [\*\*] days when each delay is measured beginning on the due date for delivery or (iii) there is a shortfall in [\*\*] successive orders delivered by Spark which on a cumulative basis, exceeds [\*\*] percent ([\*\*]%) of the total amount of said [\*\*] orders, then, at Genable’s request and at Spark’s sole cost and expense, and subject to the execution of a contract between Genable and the applicable Third Party protecting Spark’s intellectual property and trade secret rights therein (in the same manner to the extent set forth herein including restricting their use to the supply of Product to Genable), Spark shall provide all assistance and cooperation as are reasonably required by Genable to transfer Spark’s manufacturing process for the Product to Third Party contract manufacturer selected by Genable and reasonably acceptable to Spark, provided however that Spark shall only be entitled to object to such Third Party where Spark can show documentary evidence that such Third Party will not maintain the confidentiality of Spark’s intellectual property. To this end, Spark shall impart to the Third Party the documentation constituting the required material support, more particularly practical performance advice, shop practice, specifications as to materials to be used and control methods. For this purpose, Spark shall receive the Third Party’s scientific and manufacturing staff in its premises for periods the term of which shall be decided in good faith by common consent.  
 9.1 Applicable Incoterms. Unless otherwise agreed, all Products are supplied Ex Works Spark’s manufacturing facility in Philadelphia as defined in Incoterms 2010.  
 9.2 Certificates. An appropriate certificate of analysis shall precede the shipment of Products to Genable. Genable shall be entitled to rely upon such certificate of analysis without the requirement to perform additional testing.  
 10 Acceptance; Non-Conforming Products  
 10.1  
Testing by Spark. Unless otherwise specified in the applicable Work Order, after manufacture of Products, Spark shall perform quality testing in order to assure that the Products comply with the applicable Specifications, shall retain samples and records of the tests made on each such Batch and shall be responsible for release thereof, provided that, as to releases of Product for the EU, Genable may be  
 14  
 required perform a second release thereof. Unless otherwise specified in writing in the applicable Work Order, no Product shall be delivered until it has been tested. Spark shall maintain records with respect to the quality testing and shall deliver a certificate of analysis to Genable by facsimile or email and overnight courier prior to delivery of the Products. Spark’s records with respect to such testing shall also be available for inspection by Genable during normal business hours, upon prior written request, in accordance with Section 5.2. Spark shall promptly notify Genable of any Non-Conforming Products of which it becomes aware, which have been delivered to Genable.  
 10.2 Identification of Non-Conforming Product. At Genable’s election, Products may be subjected to testing by Genable in order to verify conformance to the applicable Specifications. Genable shall notify Spark of any Non-Conforming Product within the earlier of [\*\*] days after Genable becomes aware of the non-conformity or [\*\*] days after delivery of the Product. Spark shall have the right to examine and test any Products in Genable’s possession that Genable claims is Non-Conforming Product. The Parties shall cooperate to determine the point at which the non-conformance arose. Spark shall not be responsible for any naturally occurring degradation of Products after delivery thereof by Spark, provided that such degradation does not result from Products failing to conform to the applicable Specifications when delivered, or any damage to the Products making them Non-Conforming Products caused by Genable’s carrier or Genable. If the Parties fail to agree as to whether Product is Non-Conforming Product, then the Parties will promptly select a mutually acceptable, independent laboratory to evaluate if the Product is Non-Conforming Product. Such evaluation will be binding on the Parties, and if such evaluation certifies that the Product is Non-Conforming Product, Spark shall be liable for the costs of such evaluation. If such evaluation reveals that the Product in question complies with the Specifications, then Genable shall be liable for the costs of such evaluation.  
 10.3 Remedy. With respect to any Non-Conforming Product, at Genable’s option, Spark shall (a) without additional charge to Genable, replace such Non-Conforming Product with corresponding Product meeting the relevant Specifications or (b) refund any amounts paid by Genable with respect to such Non-Conforming Product. Spark shall also be responsible for delivery costs and expenses which may be incurred directly or indirectly by Genable, its Affiliates, licensees and/or sub-licensees with respect to the return to Spark of Non-Conforming Product or the shipment to Genable of replacement Product.  
 10.4 Complaints. Spark shall timely cooperate in investigating and completing investigations of complaints and deviations, including providing information applicable to each.  
 11 Force Majeure  
Neither Party shall be held liable for any delay or failure in the performance of any part of this Agreement or any breach of contract resulting from force majeure events, including  
 15  
but not limited to fire, flood, explosion, war, strike, embargo, act of God or similar causes. If either Party is affected by an event of force majeure, it will forthwith notify the other Party of the nature and extent of such force majeure event and the Parties will enter into bona fide discussions with a view to alleviating its effects and to agreeing to such alternative arrangements as may be fair, reasonable and practicable. The Party affected by a force majeure is under obligation to give full particulars thereof and to use its best efforts to minimize the effect of occurrence and to take the necessary remedial measures. If as a result of a force majeure event, Spark’s performance, in whole or material part, of the Manufacturing Services is suspended for more than [\*\*] days, Genable shall have the right to terminate the Agreement and/or any affected Work Order hereunder by giving written notice to that effect to Spark.  
 12 Indemnification; Insurance  
 12.1 Indemnification.  
 12.1.1 Genable shall indemnify, defend, and hold harmless Spark and its officers, directors, employees, members of its medical staff and agents (collectively “Spark Indemnitees”) from any claim, loss, judgment, liability, damage, settlement, fine or expense of any kind whatsoever (including reasonable attorneys’ fees, interest, penalties and costs) (a “Claim”) that may arise from or be asserted by any Third Party in connection with any of the following: (A) Genable’s conduct of research in any form utilizing the Product; (B) Genable’s distribution or other commercialization of the Product; (C) Genable’s use, handling, study, storage, return, or disposal of the Product; (D) Genable’s breach of this Agreement; or (E) Genable’s failure to conform to law or regulation applicable to (1) this Agreement or the subject matter hereof, (2) to the Product, or (3) to any research or activity conducted by Genable involving the Product provided, however, that to the extent that any such Claim results solely from the negligence or misconduct of, or breach of this Agreement by, a Spark Indemnitee, or from any matter for which Spark is obligated to indemnify Genable pursuant to Section 12.1.2, Genable shall have no such indemnity obligation to such extent with respect to any such Spark Indemnitee.  
 12.1.2 Spark shall indemnify, defend, and hold harmless Genable and its officers, directors, employees, members of its medical staff and agents (collectively “Genable Indemnitees”) from any Claim that may arise from or be asserted by any Third Party in connection with any of the following: (A) for death or personal injury arising from any failure by Spark to deliver Product conforming to the Manufacturing Standard, (B) Spark’s breach of this Agreement; or (C) Spark’s failure to conform to law or regulation applicable to the Manufacturing Services, provided, however, that to the extent that any such Claim results from the negligence or misconduct of, or breach of this Agreement by, a Genable Indemnitee, or from any matter for which Genable is obligated to indemnify Spark pursuant to Section 12.1.1, Spark shall have no such indemnity obligation to such extent with respect to any such Genable Indemnitee.  
 16  
 12.1.3 Procedure. To the extent reasonably feasible, the Party entitled to indemnification under Section 12.1.1 or 12.1.2 above (the “Indemnified Party”) shall notify the other Party (the “Indemnifying Party”) in writing of any Claim that, in Indemnified Party’s reasonable judgment, is likely to lead to a claim for indemnification. The Indemnifying Party shall promptly assume the entire defense of such Claim following the Indemnified Party’s written notice and reimburse the Indemnified Party for all expenses incurred prior to the Indemnifying Party’s assuming the defense of such Claim. The Indemnifying Party may settle a claim on terms which provide only for monetary relief, include a full release of the Indemnified Party and do not include any admission of liability, wrongdoing, infringement or invalidity or unenforceability of patent rights owned or controlled by the Indemnified Party. Save as aforesaid, neither the Indemnifying Party nor the Indemnified Party shall acknowledge the validity of, compromise or otherwise settle any claim without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. The Indemnified Party shall use cooperate with the Indemnifying Party in the defense of the Claim at the Indemnifying Party’s sole expense. The Indemnified Party may hire its own counsel, at its own expense, to monitor, but not control, the defense of any Claim. The Indemnified Party and the Indemnifying Party may execute such mutually acceptable confidentiality and joint defense agreements to protect privileged materials as shall be usual and customary in such proceedings and as shall be reasonably requested in writing by either the Indemnified Party or the Indemnifying Party.  
 12.1.4  
Insurance. Each Party shall obtain and maintain throughout the term of this Agreement and for a period of [\*\*] years after the termination of this Agreement insurance policies of such types (including professional liability, broad form comprehensive general liability and product liability) and in such amounts (but in no case less than $[\*\*] annual limits per policy or $[\*\*] annual aggregate) as shall be reasonably required to protect itself and the other Party from potential liabilities, risks and claims arising under this Agreement and/or from the performance of such Party’s acts or omissions arising in connection with or under this Agreement. The other Party shall be named prior to initiation of Manufacturing Services as an additional insured on all such policies of insurance throughout the term of this Agreement and for [\*\*] years thereafter. Prior to initiation of the Manufacturing Services, each Party shall provide the other Party with certificates from each of the insured Party’s insurers issuing insurance required under this Agreement evidencing the status of the other Party as an additional insured on each such policy. All policies of insurance required hereunder shall be placed with insurers with a current A.M. Best rating of A-VII or better except as otherwise approved in writing by the other Party.  
 17  
 Each policy of insurance obtained by a Party as required hereunder shall be endorsed to state that coverage shall not be suspended, voided, cancelled, reduced in coverage amounts or in limits or otherwise materially modified unless [\*\*] days advance written notice of such proposed change has been given to the other Party.  
 13 Limitation of Liability  
 13.1 Except with respect to the indemnification obligations of Article 12, neither Party’s overall liability with respect to any Work Order shall exceed three times the total amounts paid or payable to Spark under such Work Order.  
 13.2 In no event shall either Party be liable to the other Party, and each Party shall procure that none of its Affiliates shall make any claim against the other Party (or its Affiliates), for lost profits, loss of business, loss of contracts, diminished goodwill, diminished reputation, or consequential, indirect, incidental, punitive or special damages arising under or in connection with this Agreement.  
 14 Confidentiality  
 14.1 Each Party undertakes with the other that it shall keep, and that it shall procure that its respective directors and employees keep secret and confidential all know-how, technical, business and other information that has the quality of confidentiality and that is communicated to it by the other Party under or in respect of this Agreement or acquired from any other Party as a result of this Agreement (“Confidential Information”) and shall not disclose the same or any part of the same to any person whatsoever SAVE THAT either Party may disclose Confidential Information to its Affiliates and any of its directors, employees, consultants or subcontractors who are directly or indirectly legitimately involved with the Manufacturing Services and who require the said Confidential Information for the purposes of the said involvement.  
 14.2 The non-disclosure provision of Section 14.1 shall not apply to:  
 (a) Confidential Information in the public domain otherwise than by breach of this Agreement;  
 (b) Confidential Information in the lawful possession of a Party prior to disclosure by any other Party as evidenced by written records;  
 (c) Confidential Information that was created independent of disclosure as evidenced by written records; or  
 (d) Confidential Information obtained from a Third Party who is free to divulge the same.  
 14.3 The obligations of each Party under this Article 14 shall continue in force notwithstanding the termination of this Agreement.  
 18  
 14.4 Any Confidential Information disclosed by the disclosing Party shall be used by the receiving Party exclusively for the purposes of fulfilling the receiving Party’s rights and obligations under this Agreement and for no other purpose.  
 14.5 A Party will be entitled to make a disclosure or public statement concerning the existence, subject matter or any term of this Agreement, or to disclose Confidential Information that the such Party is required to disclose, pursuant to:  
 (a) a valid order of a court or governmental authority; or  
 (b) any other requirement of law or any securities or stock exchange; provided that, if such Party becomes legally required to make such announcement, public statement or disclosure hereunder, such Party shall (to the extent possible) give the other Party prompt notice of such fact to enable the other Party to seek a protective order or other appropriate remedy concerning any such announcement, public statement or disclosure, including confidential treatment and/or appropriate redactions.  
 14.6 The Party required to make a disclosure as described in Section 14.5 shall fully co-operate with the other Party in connection with that other Party’s efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude announcement, public statement or disclosure, the Party required to make the disclosure shall make such announcement, public statement or disclosure only to the extent that the same is legally required.  
 15 Disputes  
 15.1 If a dispute arises which cannot be resolved in the normal course of events, any Party to the dispute may give notice in writing to the others specifying the subject matter of the dispute and its proposal for its resolution. The Parties must procure that the dispute is considered by their respective authorized representatives and that such authorized representatives use all reasonable endeavors, in good faith, to resolve the dispute within 14 days of the date of the notice specifying the dispute. If the authorized representatives reach agreement on the matter in dispute in the period specified in this Section 15.1, the Parties shall procure that their respective representatives sign a joint memorandum to that effect recording the resolution and procure that such agreement is fully and promptly carried into effect.  
 15.2 If the authorized representatives fail to reach agreement, any Party may refer the matter to the Chief Executive Officers of the Parties (together, the “Senior Officers”). The Parties shall respectively procure that the Senior Officers attempt in good faith to resolve the dispute. If the Senior Officers reach agreement on the matter in dispute within [\*\*] days of the dispute being referred to them (or such other period as the Parties may mutually agree in writing) the Parties shall procure that their respective Senior Officers shall sign a joint memorandum to that effect recording the resolution and procure that such agreement is promptly and fully carried into effect.  
 19  
 15.3 The dispute resolution procedure shall have been exhausted if the matter in dispute:  
 (i) has not been resolved in accordance with Section 15.1 within the relevant period and is not referred to the Senior Officers within the relevant period; or  
 (ii) where it is so referred, has not been resolved in accordance with Section 15.2 within the relevant period.  
 15.4 For the avoidance of doubt, the fact that the dispute resolution procedure has been exhausted without resolution shall not prevent the Parties from agreeing that the dispute be referred to an independent alternative form of dispute resolution and/or to arbitration.  
 15.5 The foregoing provisions shall not prevent either Party from commencing legal proceedings or applying to the court for injunctive or other interim relief at any time.  
 15.6 Any controversy or claim related to or arising out of this Agreement (other than a patent dispute) shall be settled by arbitration conducted on a confidential basis under the Commercial Arbitration Rules of the International Centre for Dispute Resolution (“ICDR”) in effect at the time of the arbitration (“Rules”). Any arbitration shall be held in Manhattan, New York before one disinterested arbitrator selected by mutual agreement of the Parties; provided, however, that if the Parties are unable to agree on the arbitrator within [\*\*] days, the arbitrator shall be appointed in accordance with the Rules. Any Party desiring arbitration shall serve on the other Party pursuant to Section 16.6 and the regional case management center of the ICDR administering cases for such location in accordance with the aforesaid Rules, its notice of intent to arbitrate (“Arbitration Notice”). All arbitrations shall be administered by the ICDR.  
 15.7 The arbitrator shall have no authority to award damages expressly precluded under this Agreement. The award of the arbitrator shall be final and binding upon the Parties and judgment upon such award may be entered and enforced in any court of competent jurisdiction. Unless the arbitrator for good cause determines otherwise, the costs and expenses of the arbitrator shall be shared equally by the Parties and each Party will bear its own attorneys’ fees and other costs associated with the arbitration proceeding. If court proceedings to stay litigation or compel arbitration are necessary, the Party that unsuccessfully opposes such proceedings will pay all associated costs, expenses and attorneys’ fees that are reasonably incurred by the other Party. The Parties intend that each award rendered by an arbitrator hereunder shall comply with the United Nations Convention on the Recognition and Enforcement of Arbitral Awards and shall be enforceable in accordance therewith.  
 16 General Provisions  
 16.1  
Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist  
 20  
 upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by such Party or excuse a similar subsequent failure to perform any such term or condition by Genable.  
 16.2 This Agreement, together with the License Agreement and Development Consultancy Agreement of even date herewith between the Parties, constitutes the entire agreement between the Parties relating to the subject matter hereof and thereof, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by such agreements.  
 16.3 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law such determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.  
 16.4 If either Party desires a modification to this Agreement, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this Agreement or their designees.  
 16.5 The construction, validity, performance, and effect of this Agreement shall be governed by the Laws of the State of New York and, subject to Article 15, any and all actions or proceedings relating to this Agreement shall be brought and pursued exclusively in the federal or state courts sitting in United States District Court for the Southern District of the State of New York.  
 16.6 Any notice required to be given under this Agreement shall be in writing and shall be delivered personally, or sent by pre-paid post or recorded delivery or by commercial courier, to each Party required to receive the notice at its address as set out below:  
Spark:  
Spark Therapeutics, LLC  
0000 Xxxxx Xxxxxx Xxxx., 0xx Xxxxx  
Xxxxxxxxxxxx, XX 00000  
XXX  
Attention: Xxxxxxx Xxxxxxxx, CEO  
Genable:  
Genable Technologies Limited  
c/o Delta Partners  
Xxxxx Xxxxx, Xxxxx Xxxxxx Xxxxxxxx Xxxx  
Xxxxxxxxxxxx, Xxxxxx 00  
Ireland  
Attention: Xxxxx Xxxxxxxxx, CEO  
or as otherwise specified by the relevant Party by notice in writing to each other Party.  
 21  
Any notice shall be deemed to have been duly received:  
 (i) if delivered personally, when left at the address and for the contact referred to in this Section 16.6, or  
 (ii) if delivered by commercial courier, on the date and at the time that the courier’s delivery receipt is signed.  
A notice required to be given under this Agreement shall not be validly given if sent by e-mail. The provisions of this Section 16.6 shall not apply to the service of any proceedings or other documents in any legal action.  
 16.7 This Agreement, or any obligations of a party under this Agreement, may not be assigned except as expressly provided in this Agreement. This Agreement may be assigned by either Party as part of a sale or transfer of substantially the entire business of the assigning Party relating to operations which concern this Agreement, provided that the assigning Party notifies the other Party in writing within [\*\*] days of any assignment of this Agreement by the assigning Party.  
 16.8 Genable acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the relevant Agency of the U.S. Government or written assurances by Genable that it shall not export such items to certain foreign countries without prior approval of such agency. Spark neither represents that a license is not required or that, if required, it shall be issued.  
 16.9 Neither Party shall issue any press releases or public disclosure relating to this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Neither Party shall use the name or logo of the other Party, and Genable shall not use the name of past or present Spark employees, in any advertising, promotional or sales activities without prior written consent obtained from the other Party in each separate case, except as otherwise provided in this Agreement.  
In WITNESS OF THE FOREGOING, the Parties have caused their authorized representatives to sign this Agreement:  
 GENABLE TECHNOLOGIES LIMITED SPARK THERAPEUTICS, LLC  
BY:   
/s/ Xxxxx Xxxxxxxxx  
 BY:   
/s/ Xxxxxxx X. Xxxxxxxx  
NAME: Xxxxx Xxxxxxxxx NAME: Xxxxxxx X. Xxxxxxxx  
TITLE: CEO TITLE: President & CEO  
 22  
EXHIBIT A  
GMP, GLP, and Research Viral Vector Price Structure  
 GLP: $[\*\*]  
GMP $[\*\*]  
[\*\*]% payable within [\*\*] days of placing of a binding work start order  
[\*\*]% payable within [\*\*] days of receipt of Finished Goods  
 23  
EXHIBIT B  
WORK ORDER 001  
This Work Order 001 (the “Work Order”) is made this 18th day of March, 2014 (the “Effective Date”) by and between Spark Therapeutics, LLC, a Delaware limited liability company with a principal address at 0000 Xxxxx Xxxxxx Xxxxxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000, XXX (“Spark”), and Genable Technologies Limited, an Irish Limited Company with a principal address at c/o Delta Partners, Xxxxx Xxxxx, Xxxxx Xxxxxx Xxxxxxxx Xxxx, Xxxxxxxxxxxx, Xxxxxx 00, Xxxxxxx (“Genable”). Spark and Genable may each be referred to herein as a “Party” and together as the “Parties”.  
This Work Order is subject to the provisions of the Manufacturing Agreement between the Parties dated 18th March 2014.  
 A. SCOPE OF WORK  
The Work shall consist of the following:  
[\*\*]  
 1. GLP Work Order  
[\*\*]  
 2. Release Testing of AAV2/5-xxxxxx  
The Final Product AAV2/5-xxxxxx shall be subjected to Release Testing as defined below, consistent with Spark’s Policy for Specifications for new products:  
 TEST  
 STUDY  
NUMBER  
 SPECIFICATION  
 Final Product   
Appearance (by visual inspection) [\*\*] [\*\*]  
pH (potentiometry) [\*\*] [\*\*]  
Osmolality (osmometry) [\*\*] [\*\*]  
Potency: Vector genome titer by Q-PCR GT038-S [\*\*] [\*\*]  
Potency: Vector genome titer by Q-PCR GT038-R [\*\*] [\*\*]  
Purity: SDS-PAGE/ Silver Staining [\*\*] [\*\*]  
Purity: OD260/OD280 [\*\*] [\*\*]  
Purity: residual host cell DNA by Q-PCR [\*\*] [\*\*]  
Purity: Residual plasmid DNA by Q-PCR [\*\*] [\*\*]  
 24  
Purity: Residual BSA by ELISA [\*\*] [\*\*]  
Purity: Residual HEK293 proteins by ELISA [\*\*] [\*\*]  
Purity: Residual benzonase by ELISA [\*\*] [\*\*]  
Purity: Residual cesium by Mass Spec [\*\*] [\*\*]  
Safety: Bacterial endotoxin [\*\*] [\*\*]  
Safety: Sterility [\*\*] [\*\*]  
 3. Schedule for Work Order  
Spark shall commence the Work order no later than [\*\*] and shall deliver the Finished Goods to Genable on or before the [\*\*]. Finished Goods shall consist of:  
[\*\*]  
These total product amounts will be required for the Toxicology & Biodistribution Study, as Retained Samples, for Release Testing, Stability Assessments, Assay Development and Qualification of the Assays and as Reference Standards.  
 4. Stability testing  
Stability testing of the Final Product AAV2/5-xxxxxx as defined in the Schedule below shall be performed by Spark at its facilities and the results communicated to Genable in a detailed Report.  
 Assay SOP Volume Time Points (months)  
 0\*\* [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]  
Appearance Evaluation by Visual Inspection  
 QC047 NA [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]  
Safety: Bioburden  
 TBD one  
Container  
(600uL) [\*\*]  
Potency: Vector genome titer by Q-PCR  
 QC011 100uL [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]  
Purity: SDS-PAGE/Silver Staining  
 QC026 50uL [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]  
PH  
 TBD 500uL [\*\*] [\*\*] [\*\*] [\*\*]  
Light Scattering  
 XXX XXX [\*\*] [\*\*] [\*\*] [\*\*]  
Potency: In-vitro activity\*  
 XXX XXX [\*\*] [\*\*] [\*\*] [\*\*]  
\* lf available  
 [\*\*]  
Number of vials needed  
 [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]  
Number of reserve vials for re-test  
 [\*\*]   
Total number of vials for stability  
 [\*\*]   
 25  
5. Provided by Genable  
Genable shall provide:  
[\*\*]  
All other materials necessary to complete the Work Order shall be provided by Spark.  
 6. Delivery of Finished Goods  
Spark shall deliver to Genable or its nominee the Finished Goods.  
 B. PRICE & PAYMENT SCHEDULE FOR THE WORK  
The Total Cost of the Work shall be $[\*\*].  
Genable shall pay to Spark within [\*\*] days of Spark receiving from Genable a properly executed work start order [\*\*]% of the total cost of the Work Order.  
The remaining [\*\*]% payment shall be made within [\*\*] days of Genable receiving the Finished Goods.  
AGREEED BY THE PARTIES  
 ON BEHALF OF SPARK THERAPEUTICS ON BEHALF OF GENABLE TECHNOLOGIES  
/s/ Xxxxxxx X. Xxxxxxxx  
 /s/ Xxxxx Xxxxxxxxx  
NAME: Xxxxxxx X. Xxxxxxxx NAME: Xxxxx Xxxxxxxxx  
 26  
EXHIBIT C  
Genable Assays  
In vitro assay for suppression  
 27  
EXHIBIT D  
Spark Assays  
 TEST  
 STUDY NUMBER  
 SPECIFICATION  
Safety: Viral Contaminants  
In Vitro, including porcine circovirus  
 BioReliance [\*\*]  
Safety: Agar Cultivable and Non-cultivable Mycoplasmas 1993 PTC BioReliance [\*\*]  
Appearance  
(by visual inspection)  
 CCMT QC047 [\*\*]  
pH (potentiometry) CCMT QC028 [\*\*]  
Osmolality (osmometry) CCMT QC027 [\*\*]  
Potency: Vector genome titer by Q-PCR   
CCMT QC011  
QPR-07-022  
 [\*\*]  
Purity: SDS-PAGE/ Silver Staining CCMT QC026 [\*\*]  
Purity: OD260/OD280 CCMT QC121 [\*\*]  
Purity: residual host cell DNA by Q-PCR CCMT QC022 [\*\*]  
Purity: Residual plasmid DNA by Q-PCR CCMT QC023 [\*\*]  
Purity: Residual BSA by ELISA CCMT QC122 [\*\*]  
Purity: Residual HEK293 proteins by ELISA CCMT QC123 [\*\*]  
Purity: Residual benzonase by ELISA CCMT QC024 [\*\*]  
Purity: Residual cesium by Mass Spec   
Quantitative  
Technologies  
 [\*\*]  
Safety: Bacterial endotoxin BioReliance [\*\*]  
Safety: Bioburden by direct inoculation CCMT QC034 [\*\*]  
Safety: Replication competent AAV by ICA CCMT QC045 [\*\*]  
Appearance by Visual inspection CCMT QC047 [\*\*]  
pH (potentiometry) CCMT QC028 [\*\*]  
Osmolality (osmometry) CCMT QC027 [\*\*]  
Vector genome identity by PCR CCMT QC102 [\*\*]  
Potency: Vector genome titer by Q-PCR CCMT QC011 [\*\*]  
Purity: SDS-PAGE/ Silver Staining CCMT QC026 [\*\*]  
Safety: General Safety BioReliance [\*\*]  
Safety: Sterility <USP>, 21CFR BioReliance [\*\*]  
Safety: Bacterial Endotoxin   
BioReliance  
AB44MP.360012.BSV  
 [\*\*]  
Bacteriostatic/ Fungistatic activity   
BioReliance  
AB44MP.510021.BSV  
 [\*\*]  
 28  
EXHIBIT E  
Pre-Approved third parties  
 [\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
[\*\*] [\*\*]  
 29