CONFIDENTIAL
EXECUTION VERSION

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Exhibit 10.2

FIRST AMENDED AND RESTATED

EVALUATION AGREEMENT

BY AND BETWEEN

FIBROGEN, INC.

AND

FORTIS THERAPEUTICS, INC.

JUNE 6, 2024

FIRST AMENDED AND RESTATED

EVALUATION AGREEMENT

This **First Amended and Restated Evaluation Agreement** (this "Agreement") is entered into as of June 6, 2024 (the "Restatement Effective Date") by and between **FIBROGEN, INC.,** a Delaware corporation, with its principal place of business at 000 Xxxxxxxx Xxxxxx, Xxx Xxxxxxxxx, Xxxxxxxxxx 00000 ("FibroGen"), and **FORTIS THERAPEUTICS, INC.**, having an address at 00000 Xxxxx Xxxxxx Xxxxx Xxxx, Xxxxx 000, Xx Xxxxx, XX 00000 ("Fortis"). FibroGen and Fortis may be referred to herein individually as a "Party", or collectively as the "Parties".

RECITALS

Whereas, FibroGen and Fortis are parties to an Option Agreement and Plan of Merger dated as of May 5, 2023, as amended and restated concurrently with the amendment and restatement of this Agreement (the "Option and Merger Agreement") pursuant to which Fortis granted to FibroGen an option to consummate the Merger (as defined below), pursuant to the terms of the Option and Merger Agreement;

Whereas, in order to evaluate whether FibroGen will exercise its Option (as defined below), FibroGen and Fortis entered into an evaluation agreement (the "Original Agreement") dated May 5, 2023 (the "Effective Date"), pursuant to which the Parties agreed to conduct certain activities for the development of certain drug candidates, including FOR46, and for the evaluation by FibroGen of existing Fortis assets including the Products, pursuant to the terms and conditions of this Agreement;

Whereas, as of the Effective Date, Fortis and UCSF (as defined below) have entered into the Fourth UCSF Amendment (as defined below) to amend certain terms of the UCSF License (as defined below) as they apply with respect to this Agreement; and

Whereas, the Parties desire to amend and restate the Original Agreement to clarify the Parties' understanding regarding certain data transfer and regulatory obligations of FibroGen by entering into this Agreement, which shall supersede and replace the Original Agreement in its entirety effective upon the Restatement Effective Date.

Now, therefore, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1DEFINITIONS

1.1"Affiliate" means, with respect to a particular Party, any Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party, wherein "control" means the power to direct or cause the direction of the management or policies of a Party or Person, whether through ownership of more than fifty percent (50%) voting securities of such Party or Person, by contract, by board of director membership or representation, or otherwise. Subject to the foregoing, a Person shall only be deemed an Affiliate of a Party under this Agreement solely for the period it qualifies as an Affiliate under this definition. For purposes hereof, with respect to any investor in Fortis that is an Affiliate of Fortis, the portfolio companies of that investor shall not be deemed to be an Affiliate of Fortis solely by virtue of the fact that Fortis and such other portfolio companies are deemed to be under the common control of such investor.

1.2"Agreement" is defined in the preamble hereto.

1.3"Alliance Manager" is defined in Section 3.1(a).

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1.4"Applicable Law" means any applicable federal, state, territorial, foreign or local law, common law, statute, ordinance, judicial decision, rule, regulation or code of any Governmental Authority, including, as applicable, the FFDCA, Public Health Service Act (42 U.S.C. § 262 et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

1.5"Assignable Subcontractor Agreement" means an agreement between FibroGen or any of its Affiliates and a Subcontractor that (a) relates solely to the performance of Development Activities under the Study Plan, (b) where the Subcontractor is [*], and (c) [*].

1.6"Bankruptcy Laws" is defined in Section 11.4(b).

1.7"BLA" means a Biologics License Application or supplement thereto submitted to FDA under 42 U.S.C. §262 and the regulations promulgated thereunder.

1.8"Breaching Party" is defined in Section 11.3(a).

1.9"Business Day" means a day other than Saturday, Sunday or any other day on which commercial banks located in San Francisco or San Diego, California, U.S.A. are authorized or obligated by Applicable Law to close.

1.10"Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.

1.11"Calendar Year" means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.

1.12"CD46 Agent" means any CD46-targeting agents or antibodies Controlled by Fortis [*], as further described in Schedule 1.12.

1.13"CDA" means that certain Mutual Confidential Disclosure Agreement [*] between the Parties.

1.14"CDR" means [*].

1.15"Claim" is defined in Section 13.1.

1.16"Clinical Study Report" means a report containing the results of a Clinical Trial of a pharmaceutical product that is consistent in content and format with Applicable Law and regulatory guidance and with the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) on Structure and Content of Clinical Study Reports.

1.17"Clinical Trial" means any human clinical study or trial of a pharmaceutical product.

1.18"COI" means COI Pharmaceuticals Inc.

1.19"COI STA Agreement" means that certain Master Services Agreement [*], between STA Pharmaceutical Hong Kong Limited and COI.

1.20"Collaboration Data" is defined in Section 8.3(a).

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1.21"Collaboration IP" means, collectively, the Collaboration Patent Rights and the Collaboration Know-How.

1.22"Collaboration Know-How" means any Know-How, other than FibroGen Other Collaboration Know-How, that is discovered, developed, invented, created or generated by or on behalf of either Party (including through its Affiliates or Subcontractors), either solely or jointly, in the course of conducting activities under this Agreement or otherwise in the course of the research and use of the Products during the Term.

1.23"Collaboration Patent Right" means any Patent Right that claims any invention included in Collaboration Know-How.

1.24"Commercialize" or "Commercialization" means, with respect to a product, all activities, whether initiated or conducted prior to or following Regulatory Approval for such product, undertaken in support of the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering product to customers) of such product, including: (a) sales force efforts, detailing, advertising, marketing and promotional materials, sales and distribution, pricing, contracting managed markets and medical affairs, including publications, medical education, medical information, clinical science liaison activities, investigator initiated sponsored research programs and health economics and outcomes research, (b) the preparation, filing, and maintenance of Regulatory Materials, including the filing of annual updates, but excluding any such activities relating to obtaining the first, and only the first, Regulatory Approval for such product, (c) post-approval Clinical Trials and (d) other similar activities directly relating to such product. "Commercialize" means to engage in Commercialization activities.

1.25"Commercially Reasonable Efforts" means, [*].

1.26"Complaining Party" is defined in Section 12.1(b).

1.27"Complete," "Completed," or "Completion" means, with respect to a Clinical Trial, the point in time at which database lock for such trial has occurred and, if such trial has a statistical analysis plan, the primary endpoint and key safety data (including tables, listings and figures generated based on that database lock) under the statistical analysis plan for such trial are available.

1.28"Confidential Information" means all non-public or proprietary information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority, data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds (including Materials), and the like, without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information includes all "Confidential Information" as defined under the CDA between the Parties and disclosed pursuant to the CDA prior to the Effective Date.

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1.29"Control" means, with respect to any Know-How, Patent Right or other intellectual property right, possession (through ownership, exclusive license/sublicense right or otherwise) by a Party, including its Controlled Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Know-How, Patent Right or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time as the Party would be first required under this Agreement to grant the other Party such access, license or sublicense.

1.30"Controlled Affiliate" means, with respect to a party to this Agreement, any other Person that is controlled (as such term is defined in Section 1.1) by such Party.

1.31"CREATE Act" means the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3).

1.32"Cure Period" is defined in Section 11.3(a).

1.33"Development" means, with respect to a product, all non-clinical and clinical drug development activities, including research, discovery, toxicology, pharmacology, and other non-clinical efforts, statistical analysis, formulation development, delivery system development, manufacturing development, statistical analysis, the performance of Clinical Trials, including the Manufacturing of such product for use in the Clinical Trials, or other activities reasonably necessary in order to obtain, but not maintain, Regulatory Approval of such product. "Development" will exclude all Commercialization activities. When used as a verb, "Develop" means to engage in Development activities.

1.34"Development Activities" is defined in Section 5.1.

1.35"Development Costs" is defined in Section 11.6(b).

1.36"Development Fee Schedule" is defined in Section 7.1.

1.37"Development Fees" is defined in Section 7.1.

1.38"Development Force Majeure Event" means a Force Majeure Event causing the failure or delay in the achievement of any Development Activities under the Study Plan or any related, Manufacturing activities that are reasonably necessary, based on the design of the then-current Study Plan, (i) [*], or (ii) [*].

1.39"Disclosing Party" is defined in Section 10.1.

1.40"Dispute Notice" is defined in Section 12.1(b).

1.41"Dispute(s)" is defined in Section 12.1(a).

1.42"Effective Date" is defined in the recitals hereto.

1.43"EMA" means the European Medicines Agency or any successor agency or authority having substantially the same function.

1.44"EOP1 Meeting" means a Type B meeting with the FDA [*], to review the data from such Phase 1 Clinical Trial and reach agreement on plans for Phase 2 Clinical Trials program.

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1.45"EOP2 Meeting" means a Type B meeting with the FDA [*], to evaluate the plans for the Phase 3 Clinical Trial program and protocols, and to identify any additional information necessary to support a marketing application for the uses under investigation.

1.46"EU" means all of the European Union member states as of the applicable time during the Term.

1.47"Evaluation Activities" is defined in Section 5.1.

1.48"Executive Officers" is defined in Section 12.1(b).

1.49"Existing Inventory" is defined in Section 5.10(a).

1.50"Exploit" or "Exploitation" means to research, make, have made, distribute, import, export, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured or otherwise dispose of.

1.51"FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.52"FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.53"FibroGen" is defined in the preamble hereto.

1.54"FibroGen Background IP" means, collectively, the FibroGen Background Patent Rights and the FibroGen Background Know-How.

1.55"FibroGen Background Know-How" means any Know-How, excluding all FibroGen Other Collaboration Know-How and Collaboration Know-How, that is Controlled by FibroGen on the Effective Date or that comes into the Control of FibroGen during the Term (other than through the grant of a license by Fortis under this Agreement) independent of its activities under this Agreement.

1.56"FibroGen Background Patent Right" means any Patent Right, excluding all FibroGen Other Collaboration Patent Rights and Collaboration Patent Rights, that is Controlled by FibroGen on the Effective Date or that comes into the Control of FibroGen during the Term (other than through the grant of a license by Fortis) independent of its activities under this Agreement.

1.57"FibroGen Clinical Studies" means (a) a Phase 2 Clinical Trial or any portion of the Phase 2/3 Clinical Trial of a Product that is a PET-driven mCRPC study investigating FOR46 and PET46, and (b) a Phase 1b Clinical Trial that is a tumor expansion study investigating FOR46.

1.58"FibroGen Indemnitee" is defined in Section 13.2.

1.59"FibroGen Other Collaboration Data" is defined in Section 8.3(b).

1.60"FibroGen Other Collaboration IP" means, collectively, the FibroGen Other Collaboration Patent Rights and the FibroGen Other Collaboration Know-How.

1.61"FibroGen Other Collaboration Know-How" means any Know-How that (a) is discovered, developed, invented, created or generated solely by or on behalf of FibroGen (including through its Affiliates or Subcontractors) in the course of conducting activities under this Agreement or otherwise in the course of the research and use of the Products during the Term, and (b) is not [*] related to any of the Products or Modified Products.

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1.62"FibroGen Other Collaboration Patent Right" means any Patent Right that claims any invention included in FibroGen Other Collaboration Know-How.

1.63"Field" means all fields.

1.64"FOR46" means a CD46-targeting antibody drug conjugate Controlled by Xxxxxx, as further described in Schedule 1.64.

1.65"Force Majeure Event" means act of God, plague, pandemic or any escalation or worsening or subsequent waves thereof, epidemic, hurricane, tornado, tsunami, flood, volcanic eruption, earthquake, nuclear incident, war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest, national or regional emergency or other natural or man-made disaster, or similar event or condition beyond the reasonable control, and not the result of the fault or negligence, of the affected Party or Person and such Party had been unable to overcome such act or event with the exercise of due diligence.

1.66"Fortis" is defined in the preamble hereto.

1.67"Fortis Additional Product Requirement" is defined in Section 5.10(a).

1.68"Fortis Background IP" means, collectively, the Fortis Background Patent Rights and the Fortis Background Know-How.

1.69"Fortis Background Know-How" means any Know-How, other than Collaboration Know-How, that is Controlled by Fortis on the Effective Date or that comes into the Control of Fortis during the Term (other than through the grant of a license by FibroGen under this Agreement) independent of its activities under this Agreement.

1.70"Fortis Background Patent Right" means any Patent Right, other than a Collaboration Patent Right, that (a) is Controlled by Fortis on the Effective Date or that comes into the Control of Fortis during the Term (other than through the grant of a license by FibroGen under this Agreement) independent of its activities under this Agreement.

1.71"Fortis Clinical Studies" means (a) NCT03575819, a Phase 1 Study of FOR46 in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) (also known as FOR46-001), (b) NCT05011188, FOR46 in Combination with Enzalutamide in Patients with Metastatic Castration Resistant Prostate Cancer, and (c) NCT05245006, PET Imaging Study of 89Zr-DFO-YS5 ("PET Technical Study") (each of (b) and (c), a "UCSF Study.").

1.72"Fortis Development Activities" is defined in Section 11.6(a).

1.73"Fortis Indemnitee" is defined in Section 13.1.

1.74"Fortis In-License" means each license agreement set forth in Schedule 1.74.

1.75"Fortis IP" means, collectively, the Fortis Know-How and the Fortis Patent Rights.

1.76"Fortis Know-How" means, collectively, the Fortis Background Know-How and the Collaboration Know-How.

1.77[*].

1.78"Fortis IP Infringement" is defined in Section 8.7(a).

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1.79"Fortis IP Infringement Action" is defined in Section 8.7(b)(i).

1.80"Fortis Patent Enforcing Party" is defined in Section 8.7(b)(ii).

1.81"Fortis Patent Non-Enforcing Party" is defined in Section 8.7(b)(ii).

1.82"Fortis Patent Rights" means, collectively, the Fortis Background Patent Rights and the Collaboration Patent Rights.

1.83"Fourth UCSF Amendment" is defined in Section 1.142.

1.84"FTE" means, with respect to a Party and the performance of an activity, the work carried out by one or more qualified employees, contractors or consultants of such Party or its Affiliates devoted to or in direct support of such activity, where the work of an FTE shall be considered full-time based on [*] and, in the case of work that is less than full-time, will be pro-rated based on the actual number of hours expended by such FTE.

1.85"FTE Cost" means, with respect to a Party and the performance of an activity, the amount calculated by multiplying the FTE Rate by the number of FTEs expended by such Party or its Affiliates over the course of such activity.

1.86"FTE Rate" means a rate of [*] per full-time FTE per Calendar Year; provided that such rate shall be increased or decreased [*], or an alternative methodology that is mutually agreed to by both Parties.

1.87"Good Clinical Practices," "GCP" or "cGCP" means, with respect to any applicable jurisdiction, the then-current standards, practices and procedures for clinical trials for pharmaceuticals promulgated or endorsed by the applicable Regulatory Authority in such jurisdiction as set forth in the Applicable Laws of such jurisdiction, including, with respect to the United States, 21 C.F.R. Parts 11, 50, 54, 56 and 312, the guidelines titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" and related regulatory requirements imposed by the FDA, and with respect to jurisdictions outside the United States, comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority, as applicable, including any applicable quality guidelines promulgated under the International Conference on Harmonization ("ICH"), in each case as they may be updated from time to time.

1.88"Good Laboratory Practices," "GLP" or "cGLP" means, with respect to any applicable jurisdiction, the then-current standards, practices and procedures for laboratory activities for pharmaceuticals promulgated or endorsed by the applicable Regulatory Authority in such jurisdiction as set forth in the Applicable Laws of such jurisdiction, including, with respect to the United States, 21 C.F.R. Part 58 and related regulatory requirements imposed by the FDA, and with respect to jurisdictions outside the United States, comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority, as applicable, including any applicable quality guidelines promulgated under the ICH, in each case as they may be updated from time to time.

1.89"Good Manufacturing Practices," "GMP" or "cGMP" means, with respect to any applicable jurisdiction, the then-current good manufacturing practices for the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, and holding pharmaceutical materials required by the applicable Regulatory Authority in such jurisdiction as set forth in the Applicable Laws of such jurisdiction, including, with respect to the United States, 21 C.F.R. Parts 210 and 211 and related regulatory requirements imposed by the FDA and with respect to applicable jurisdictions outside the United States, the guidelines promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.

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not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.90"Governmental Authority" means any instrumentality, subdivision, court, administrative agency, commission, official or other authority of any country, state, province, prefect, municipality, locality or other government or political subdivision thereof, or any multinational organization or authority, or any quasi-governmental, private body or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority.

1.91"ICH" is defined in Section 1.87.

1.92"IND" means an Investigational New Drug application as defined in the FFDCA, as amended, and applicable regulations promulgated hereunder by the FDA, or a clinical trial authorization application for a product filed with a Regulatory Authority in any other regulatory jurisdiction outside the United States, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.93"Indemnifying Party" is defined in Section 13.4(a).

1.94"Indemnitee" is defined in Section 13.4(a).

1.95"Indirect Tax" is defined in Section 7.4(f).

1.96"Joint Steering Committee" and "JSC" is defined in Section 3.2(a).

1.97"Judgment" means any writ, judgment, injunction, order, decree, stipulation determination or award entered by or with any Governmental Authority.

1.98"Know-How" means information (including confidential information), know-how, inventions, discoveries, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, correspondence and submissions, and information pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical, pre-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, specifications, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.99"Losses" is defined in Section 13.1.

1.100"Manufacture" means, with respect to a product, all activities related to the manufacturing of such product, or any ingredient or component thereof, including manufacturing of finished product for Development and Commercialization, labeling, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities to perform any of the foregoing activities.

1.101"Materials" means all biological materials or chemical compounds provided by a Party for use by the other Party to conduct activities pursuant to this Agreement, including Products, Clinical Trial samples, cell lines, compounds, lipids and assays so provided.

1.102"Merger" means the merger contemplated in the Option and Merger Agreement.

1.103"Modified Product" means [*].

1.104"Non-Breaching Party" is defined in Section 11.3(a).

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not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.105"Ongoing Clinical Study" is defined in Section 11.7(e).

1.106"Ongoing Clinical Study Payment" means, with respect to an Ongoing Clinical Study, an amount equal to (a) [*], including for clarity, all payments paid or accrued under Assignable Subcontractor Agreements and other agreements in connection with such Ongoing Clinical Study, *multiplied by* (b) [*].

1.107"Option" is defined in the Option and Merger Agreement.

1.108"Option and Merger Agreement" is defined in the recitals hereto.

1.109"Option Exercise Deadline" means the date that is [*] the Option Exercise Deadline may be extended to such date as is mutually agreed in writing by FibroGen and Fortis in each Party's sole discretion.

1.110"Original Agreement" is defined in the preamble hereto.

1.111"Outside Date" is defined in Section 1.109.

1.112"Party" and "Parties" is defined in the preamble hereto.

1.113"Patent Rights" means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, Patent Term Extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.

1.114"Patent Term Extension" means any term extensions, supplementary protection certificates and equivalents thereof offering patent protection beyond the initial term with respect to any issued patents.

1.115"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a Governmental Authority.

1.116"PET Technical Study" is defined in Section 1.71.

1.117"PET46" means a CD46-targeting PET agent Controlled by Fortis, as further described in Schedule 1.117.

1.118"Phase 1 Clinical Trial" means any Clinical Trial as described in 21 C.F.R. §312.21(a) (as amended or any successor regulation thereto), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial, that generally provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a).

1.119"Phase 1b Clinical Trial" means any Phase 1 Clinical Trial that includes criteria analyzing pharmacodynamics and clinical effect.

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1.120"Phase 2 Clinical Trial" means any Clinical Trial as described in 21 C.F.R. §312.21(b) (as amended or any successor regulation thereto), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product's efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), to permit the design of further Clinical Trials.

1.121"Phase 2 Data Submission Date" is defined in Section 1.109.

1.122"Phase 3 Clinical Trial" means any Clinical Trial as described in 21 C.F.R. §312.21(c) (as amended or any successor regulation thereto), or, with respect to a jurisdiction other than the United States, a similar Clinical Trial. For clarity, for purposes of this Agreement, where the data from Phase 2 Clinical Trials serves as the basis for obtaining Regulatory Approval for a Product, such Phase 2 Clinical Trials will not be deemed a Phase 3 Clinical Trial for purposes of this Agreement.

1.123"PMDA" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

1.124"Product" means any product containing, constituting or incorporating one or more of the following: (i) FOR46, (ii) CD46 Agent(s), or (iii) PET46.

1.125"Receiving Party" is defined in Section 10.1.

1.126"Regulatory Approval" means, with respect to a given product, all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of BLAs, supplements and amendments, pre- and post- approvals, and labeling approvals) of any Regulatory Authority in a particular jurisdiction that is necessary for the Commercialization of such product in such jurisdiction in accordance with Applicable Laws.

1.127"Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction, including, in the United States, the FDA and any other applicable Governmental Authority in the United States having jurisdiction over any product; in the EU, the EMA or any competent Governmental Authority in the EU; in Japan, the PMDA; and any other applicable Governmental Authority having jurisdiction over products.

1.128"Regulatory Materials" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals or other submissions, including any written correspondence or meeting minutes, made to, made with, or received from a Regulatory Authority relating to any Product in a particular country or jurisdiction. Regulatory Materials include INDs and drug approval applications for any product, and amendments and supplements for any of the foregoing.

1.129"Response" is defined in Section 12.1(b).

1.130"Responsible Party" is defined in Section 6.1.

1.131"Restatement Effective Date" is defined in the preamble hereto.

1.132"Safety Data Exchange Agreement" is defined in Section 6.3.

1.133"Study Plan" is defined in Section 5.1.

1.134"Subcontractor" is defined in Section 5.5.

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not material and (ii) would likely cause competitive harm to the company if publicly disclosed.