UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report:
(Date of earliest event reported)

November 18, 2024

GT Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction
of Incorporation)

1-40023	**94-1620407**
(Commission File Number)	(IRS Employer Identification No.)

N/A
(Address of Principal Executive Offices and zip code)

(415)-919-4040
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol(s)	Name of each Exchange on which registered
Common stock, $0.001 par value	GTBP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On November 18, 2024, the Registrant entered into an Investigator Initiated Clinical Trial Agreement (the "Agreement") with the Regents of the University of Minnesota (the "University"), pursuant to which, the University shall sponsor an Investigational New Drug ("IND") application for IND 165546 GTB-3650 (the "Research Program") and shall serve as a sponsor investigator for a phase 1 clinical trial entitled, "GTB-3650 (CD16/IL-15/CD33) Tri-Specific Killer Engager (TriKE) for the Treatment of High Risk Myelodysplastic Syndromes (MDS), Refractory/Relapsed Acute Myeloid Leukemia (AML), and Minimal Residual Disease in AML," designed by the University (the "Study"). The Research Program is being conducted for clinical research use. The budget for the Study, including without limitations, funding and resources, provides for up to approximately $2 million over the course of three years borne by the Company. The Study data will be owned by the University, however, the Company may use the Study data subject to any applicable signed informed consent documents and authorization forms, applicable law and terms of the Agreement. The University and the Company will each have the right to publish the Study results. The Agreement may be terminated by the Company or the University at any time upon thirty days' written notice to the other party, by the University immediately for health, welfare and safety reasons, or by either party if the other party materially breaches the Agreement, provided that the breaching party fails to cure such breach within thirty days.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement attached to this Current Report on Form 8-K as Exhibit 10.1 and incorporated by reference into this Item 1.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Investigator Initiated Clinical Trial Agreement, dated as of November 18, 2024, by and between GT Biopharma, Inc. and the Regents of the University of Minnesota.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

* Certain exhibits and schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GT BIOPHARMA, INC.

Date: November 21, 2024

By: */s/ Alan Urban*
Alan Urban
Chief Financial Officer

UNIVERSITY OF MINNESOTA

Investigator Initiated Clinical Trial Agreement

THIS INVESTIGATOR INITIATED CLINICAL TRIAL AGREEMENT (this "Agreement") is entered into effective as of the date of last signature (the "Effective Date") by and between Regents of the University of Minnesota (the "University"), a public educational institution and a Minnesota constitutional corporation, and GT Biopharma, Inc. (the "Company"), a Delaware corporation. This Agreement is entered into by the University through its Office of Sponsored Projects Administration. Company and University shall each be referred to herein, individually, as a "Party" and collectively as the "Parties."

WHEREAS, Mark Juckett, MD, is a University employee, and shall act on behalf of University as the sponsor of Investigational New Drug ("IND") application for IND 165546 GTB-3650 (the "Research Program") and in performance of the Study as Sponsor Investigator ("Sponsor-Investigator") for a phase 1 clinical trial entitled, "GTB-3650 (CD16/IL-15/CD33) Tri-Specific Killer Engager (TriKE) for the Treatment of High Risk Myelodysplastic Syndromes (MDS), Refractory/Relapsed Acute Myeloid Leukemia (AML), and Minimal Residual Disease in AML," designed by University (the "Study") shown as **Exhibit A** to this Agreement and incorporated herein as specified;

WHEREAS, the IND is designated as a research IND (non-commercial) involving GTB-3650 (CD16/IL-15/CD33) Tri-Specific Killer Engager (TriKE) (the "Study Drug") and the Study and Study Drug are strictly for clinical research purposes. Neither University nor Dr. Juckett intend to later commercialize the Study Drug;

WHEREAS, the Company is a biopharmaceutical company focused on developing immuno-oncology therapeutic products based on the TriKE protein biologic technology platform. University and the Company have entered a certain Amended and Restated Exclusive Patent License Agreement dated May 13, 2024, pursuant to which the Company has an exclusive worldwide license agreement with University to further develop and commercialize therapies TriKE product candidates;

WHEREAS, University has received funding from Company to maintain the Research Program and comply with obligations as the IND sponsor, and to conduct the Study for clinical research use;

WHEREAS, University has appropriate facilities and patient population to provide data for the Study; and

WHEREAS, the Research Program including the Study contemplated by this Agreement is of mutual interest and benefit to University and to the Company and will further the instructional and research objectives of University in a manner consistent with its status as nonprofit educational institution. University and the Company now wish to enter into this Agreement to establish the terms under which the Company will provide support including, but not limited to, the Study Drug, funding, and reasonable assurances for the Research Program and the Study, and for Dr. Juckett and University to comply with their Sponsor- Investigator responsibilities;

UNIVERSITY OF MINNESOTA

NOW, THEREFORE, the Parties agree as follows:

1. Sponsor-Investigator. Sponsor-Investigator shall be considered the sponsor of the Research Program and the Study. Sponsor-Investigator is responsible for the overall conduct of the Study at the University. Sponsor-Investigator both initiated and will conduct the Study in accordance with Applicable Laws (defined below), this Agreement and the Protocol (defined below). If Sponsor-Investigator is unable to continue to serve in that role and a successor acceptable to both University and Company is not available, this Agreement may be terminated in accordance with Section 5.

2. Compliance with Laws. Company and University, including their affiliates and contractors, and the Sponsor-Investigator shall comply with and conduct all aspects of the Research Program and the Study in compliance with all applicable federal, state, and local laws and regulations, including the Federal Food, Drug, and Cosmetic Act (FDCA) (21 USC 301 *et seq.*) and regulations issued by the U.S. Food and Drug Administration ("FDA") including, but not limited to, 21 CFR Part 312 (Investigational New Drug Application), 21 CFR 50 (Protection of Human Subjects), 21 CFR 54 (Financial Disclosure by Clinical Investigators), 21 CFR 56 (Institutional Review Boards), regulations pertaining to clinical trials registration and submission of results provided in 42 CFR 11, and all other generally accepted standards of good clinical practice as adopted by current FDA regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions (collectively, "Applicable Laws"). University and Sponsor-Investigator will only allow individuals who are appropriately trained and qualified to assist in the Research Program and the conduct and oversight of the Study.

3. Study. University agrees to conduct the Study in accordance with Applicable Laws, this Agreement and the study protocol ("Protocol") which has been written by Sponsor-Investigator and approved in writing by University and the Company. Sponsor-Investigator shall apply for approval to conduct the Study with University's Institutional Review Board ("IRB") or an independent Institutional Review Board approved by the University and the Company in writing. University shall not allow the Study to be initiated until such approval is obtained, and University and the Company are provided with a final written copy of the IRB approval letter for the Study. University's right to conduct the Study, including enrollment of the Study subjects, is expressly conditioned upon the approval of the reviewing IRB. University shall cooperate with Sponsor-Investigator in preparing and filing the Protocol, informed consent form, and other required information with the IRB. Changes to the Protocol require the prior written approval of the IRB. University shall be responsible for obtaining an informed consent which complies with all Applicable Laws signed by or on behalf of each human subject prior to the subject's participation in the Study.

4. Study Budget. The Parties agree that Study funding and resources provided by Company shall be allocated to the Study as outlined in the Budget attached hereto as **Exhibit B** and incorporated herein (the "Study Budget"). University acknowledges that the Study Budget represents fair market value for its services in connection with the Study, based on the research and services provided, and does not take into account in any manner whatsoever the volume or value of any prescriptions, referrals or business generated among the Parties. University and Sponsor-Investigator shall not incur additional costs beyond the Study Budget without first receiving the Company's prior written consent for such increase in expenditure. All changes to the Study Budget require the Company's prior written approval.

5. Term and Termination.

5.1 The term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under this Agreement, unless terminated early as further described in this Section 5.

5.2. Either Party has the right to terminate the Study upon thirty (30) days prior written notice to the other Party. The Study may be terminated immediately upon written notice at any time for any reason by the University or Company when, in its reasonable judgment or that of the Sponsor- Investigator, the IRB, the FDA or other applicable regulatory authority, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' health, welfare, and safety. If for any reason Sponsor-Investigator becomes unavailable to direct the performance of the Study under this Agreement, University shall promptly notify Company in writing. If the Parties are unable to identify a mutually acceptable successor within thirty (30) days following University's notice to the Company, this Agreement may be terminated by either Party upon thirty (30) days written notice.

5.3. Notwithstanding the above, either Party may, in addition to any other available remedies, terminate this Agreement immediately upon written notice to the other Party if the other Party materially breaches this Agreement, provided that the breaching Party fails to remedy such material breach within thirty (30) days after its receipt of written notice thereof; provided, however, that the cure period shall be suspended during any time that a Party seeks resolution of a dispute as to whether an alleged breach occurred pursuant to any dispute resolution mechanism under this Agreement.

5.4. In the event that this Agreement is terminated prior to completion of the Study, for any reason, University shall furnish to Company any required final report for the Study in a format mutually agreed upon by the Parties. Promptly following any such termination, University will provide to Company copies of Study Data collected pursuant to the Protocol.

5.5. If this Agreement is terminated early by either Party, University shall be reimbursed for all work completed, on a pro rata basis, and out-of-pocket, reasonable costs of bringing the Study to termination actually incurred by University through the date of termination, and for reasonable, non- cancelable commitments actually incurred by University in the performance of the Study through that date as set forth in the Study Budget. Upon receipt of notice of termination, University will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Company to provide for an orderly wind-down of the Study. Upon expiration or earlier termination of this Agreement, University shall return to the Company all unused Study Drug and Company Confidential Information. The following sections shall survive the expiration or earlier termination of this Agreement: Sections 2, 5.5, 6, 11, 13, 17, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 44, 45, and 46.

6. Study Drug. Company agrees to provide within a commercially reasonable time period, at no cost to University, sufficient quantities of the Study Drug to conduct the Study in accordance with the Protocol. University shall handle, store, and administer or dispense the Study Drug in accordance with the Protocol, this Agreement, Applicable Laws and the Company's written instructions for the conduct of the Study. Company and its contractors that perform drug manufacturing for the Study, are responsible for assuring that the Study Drug is manufactured in compliance with current good manufacturing practices (21 USC 351(a)(2)(B)) ("CGMP"). University shall maintain accurate and complete records of the shipment, delivery, receipt and disposition of the Study Drug in accordance with the Protocol, this Agreement, Applicable Laws and the Company's written instructions.

7. Batch Documentation. Company shall provide to University the following documents that Company receives from the supplier of the Study Drug (the "Supplier"): (a) records that document the Supplier's steps and processes utilized in the manufacture of the Study Drug; (b) the documents that are required under the applicable quality technical agreement; (c) the certificate of analysis for the Study Drug; and (d) the certificate of compliance for the Study Drug. Upon reasonable written request by University, Company shall request, and make reasonable efforts to obtain, additional records and documents from the Supplier to provide further assurance of conformance with CGMP; provided, however, Company shall not be obligated to provide additional records and documents unless such records and documents are received from the Supplier.

8. Acceptance Mechanism. University may reject any quantity of nonconforming Study Drug that has been delivered to University hereunder by delivering written notice to Company within thirty (30) days of delivery of such nonconforming Study Drug to Company. Any batch of Study Drug for which a notice of non-conformance is not delivered within such thirty (30) day period will be deemed to be accepted by University upon the expiration of such period, provided that University will have three (3) months from the date that a batch of Study Drug is accepted to reject the Study Drug by reason of a hidden or latent defect existing at the time of delivery that was not discoverable upon commercially reasonable physical inspection and testing of the Study Drug (a "Latent Defect"), and University must notify Company in writing of such Latent Defect within three (3) business days of such discovery. However, if the Study Drug expires prior to the three (3) month period in the foregoing sentence, University will have until one (1) week prior to the expiration of the Study Drug to reject the Study Drug because of a Latent Defect. The notice must detail the nature of the Latent Defect, and based on information reasonably available at the time, how the nonconformance could have resulted from the Supplier's manufacturing of the Study Drug.

9. Independent Testing. If the Supplier does not agree with University's rejection of any Study Drug as nonconforming Study Drug (as such is communicated to the Supplier by Company on behalf of University), then the Supplier, Company and University shall engage an independent person or persons of recognized standing in the industry with respect to the development and CGMP manufacture of biologic therapeutics, qualified to resolve a dispute between the Supplier, Company and University, and who is a recognized expert in the field of NK cell biology and the development of NK cell engagers (a "Third Party Expert") to resolve the dispute. If the dispute concerns the Study Drug's conformance to the specifications or the Supplier's adherence to the CGMP manufacturing process, the Supplier, Company and University will submit the master batch records, batch production records, specifications, applicable statement of work, and other information relevant to the dispute (including a representative sample of the Study Drug, if necessary) to an independent testing laboratory mutually agreed to by the Supplier, Company and University. If the dispute concerns the Supplier's adherence to CGMP, the Supplier, Company and University will submit the master batch records, batch production records, specifications, applicable statement of work, and other information relevant to the dispute to a CGMP consultant mutually agreed to by the Supplier, Company and University. The findings of the Third Party Expert shall be final and binding on the Supplier, Company and University, absent fraud or manifest error. In making its determination, the Third Party Expert shall consider the information supplied by the Supplier, Company and University, the Supplier's acts and omissions, the Company and University's acts and omissions, and any deficiencies in Company's technology, components, equipment, raw materials, and the CGMP manufacturing process. The Third Party Expert shall use the test and analysis methods contained in the CGMP manufacturing process and the applicable statement of work when conducting their analysis. If the Third Party Expert determines that the Study Drug was conforming, University shall pay the fees and expenses of the Third Party Expert. If the Third Party Expert makes any other determination, including, but not limited to, that the results are inconclusive or that the Study Drug was a non-conforming batch but not as a result of the Supplier's defective CGMP manufacturing, University shall pay the fees and expenses of the laboratory or consultant and will have no remedy against the Supplier or Company for the non-conforming Study Drug.

10. Facilities and Equipment. Company including its affiliates and contractors, shall at its sole cost and expense, maintain the manufacturing facility and all related quality documentation, processes and systems used in connection with the Study Drug in compliance with FDA and other CGMP quality standards and operate in compliance with all applicable environmental, occupational health and safety laws and regulations. Each Party shall secure and maintain, at its sole cost and expense, any registrations, approvals, permits, authorizations, and licenses as are required by Applicable Laws for such Party to perform its obligations under this Agreement.

11. Storage. University shall store and handle all materials and products in accordance with Applicable Laws, the specifications and quality standards for such Study Drug, including segregating Study Drug for which final release has not been provided or otherwise not accepted by University.

12. Packaging and Labeling. Company will package and label Study Drug in accordance with the University's IND, and will comply with all reasonable University instruction regarding the packaging and/or labeling of Study Drug, including timely updating any such packaging and/or labeling for the Study Drug. Company will use only University approved packaging and labeling for all Study Drug delivered hereunder and shall not modify any packaging or labeling for any such Study Drugs without University's prior written consent.

13. Qualified Personnel. University and Sponsor-Investigator shall only assign personnel who are trained, qualified, and experienced to perform the Study, and University and Sponsor-Investigator shall ensure that all personnel assisting with the performance of the Study comply with all provisions of this Agreement, including by requiring personnel to sign intellectual property assignment and confidentiality and nondisclosure agreements sufficient to enable University and Sponsor-Investigator to comply with their obligations under this Agreement.

UNIVERSITY OF MINNESOTA

14. Change Control. If either Party desires to implement a change to the manufacturing process, including any testing method with respect to any Study Drug or any specifications, or if University is required by FDA or any other governmental authority to implement any such change, the Parties will discuss in good faith the potential effect on the identity, strength, quality, purity, or potency of the Study Drug, and will agree in writing prior to the implementation of any such change to the manufacturing process. Unless agreed upon by the Parties in writing, Company has no obligation to provide new Study Drug incorporating any change of the manufacturing process.

15. Deviations and Nonconformances. Deviations and nonconformances including OOS results and unexplained discrepancies shall be investigated and documented and retained as part of the batch documentation for the batch of Study Drug affected according to the applicable written procedures. Company shall notify University in writing promptly of any deviation or nonconformance, where such finding is classified as serious or critical based on the risk of potential adverse impact on Study Drug quality and patient safety, but no longer than one (1) business day after Company's knowledge of the event, including insofar as the Company determines the Study Drug is subject to such deviations or nonconformances, including OOS results, after delivery to University.

    Company shall investigate all such deviations and nonconformances, and shall timely take corrective action to avoid future occurrences. Company shall use commercially reasonable efforts to complete its investigation of any deviations and nonconformances including confirmed OOS results within thirty (30) days of commencement, and will maintain a written justification where such investigation requires a longer period of time to complete.

16. Nonconforming Drug. Subject to Sections 8, 9, and 15 above, if either Party becomes aware that any batch or shipment of Study Drug does not conform to the approved specifications for Study Drug, such Party shall notify the other Party in writing as soon as reasonably practicable but in no event later than three (3) business days of becoming aware of such nonconformance. Any batch or shipment of nonconforming Study Drug shall be handled as follows: (a) any such Study Drugs held in inventory by Company shall not be shipped; and (b) any previously shipped nonconforming Study Drug held in stock by either Party or its affiliate shall be segregated and maintained in a "hold" or "quarantine" status, and in the case of each of clauses (a) and (b), such Study Drugs shall not be released or further distributed until the Parties have completed any investigations related to such nonconforming Study Drug.

17. Retention Samples. Company shall ensure adequate representative samples are retained for each batch or lot of Study Drug and of delivered materials used in manufacturing, packaging, and labeling the Study Drug to enable subsequent testing of such Study Drug, in accordance with the University's IND and University's instruction. Company shall accurately label such samples to identify the batch of Study Drug and shall store all such samples as appropriate in accordance with the applicable specifications. Company shall retain all samples of the Study Drug or materials and intermediates therein for the longer of (a) one (1) year following the indicated expiry date of such Study Drug and (b) such longer period of time as may be required by Applicable Laws.

18. Stability Testing. Company will maintain, retain, and store sufficient retention samples of Study Drug as necessary to perform applicable stability tests in conformance with CGMP and as required by FDA or any other governmental authority, in accordance with the specifications for such Study Drug and this Agreement. Retention samples shall be retained for the longer of (a) the expiry date of the applicable Study Drug plus one (1) year, or (b) such longer period of time as may be required by Applicable Laws.

19. Complaints and Adverse Events. As between the Parties, Company including its affiliates and contractors engaged in manufacturing the Study Drug, shall establish and maintain guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) around product quality complaints or adverse events and any other information concerning the quality or safety of the Study Drug. Each Party shall immediately notify the other Party of any product complaints or adverse events received by such Party concerning any Study Drug supplied hereunder. Company shall investigate all such complaints and adverse events and, where necessary and appropriate, shall take corrective action to avoid future occurrences. The Parties shall investigate any reports of nonconforming Study Drug or any other product complaint or adverse events in order to assess, as applicable, the potential risk of impact to the relevant Study Drugs and to determine the validity of such product complaint or adverse event. Company shall notify University immediately of any difficulty in manufacturing, packaging, labeling, or delivery any Study Drug in accordance with their applicable specifications, Applicable Laws, or the terms and conditions of this Agreement. University may, at its option, investigate the cause of any failure itself. Company will complete any quality investigation according to established written procedures, and shall provide University with a written report summarizing the results of Company's investigation. Company shall cooperate with University in handling such nonconforming products, complaints, or adverse events, and shall take reasonable actions and provide any additional assistance and information as University reasonably requests, including promptly investigating and conducting any follow-up with regard to such nonconforming products, product complaints, or adverse events, and providing any data, information, or other assistance that University may reasonably require in connection therewith.

20. Recovery or Withdrawal. Company shall keep University informed of any notification or other information, whether received directly or indirectly, which might affect the safety or effectiveness of any Study Drug or which might result in product recovery or withdrawal in connection with the Study Drug. If either Party in good faith determines that a product recovery or field action involving any Study Drug is warranted, such Party shall immediately notify the other Party and shall advise such other Party of the reasons underlying its determination that such product recovery or withdrawal if warranted; provided, however, that University shall retain full authority and responsibility for instituting any recovery or field action of any Study Drug and corresponding with the applicable governmental authorities. Company will cooperate with University in connection with any such recovery or withdrawal, and promptly provide to University, any data, information, or assistance as reasonably requested by University in connection therewith.

21. Safety Reporting and Monitoring.

21.1 Safety Reporting. University and Sponsor-Investigator shall be solely responsible for reporting all adverse events occurring in connection with the Study to FDA. University and Sponsor- Investigator shall contact Company immediately in writing, and in no event later than five (5) business days, to report any serious adverse drug experience or unexpected adverse drug experience, as defined at 21 CFR 312.32. University and Sponsor-Investigator shall respond promptly to all requests for follow- up information from Company. Company shall respond promptly to all requests for follow-up information from University and Sponsor-Investigator. University and Sponsor-Investigator shall inform the IRB of any adverse drug experiences, in accordance with the policies and procedures of the IRB.

UNIVERSITY OF MINNESOTA

21.2 Study Monitoring. University and Sponsor-Investigator shall be responsible for monitoring and quality assurance of all data and information set forth in Section 22 below in compliance with 21 CFR Part 312.

22. Study Data and Results.

22.1 University will provide progress reports to Company at least quarterly and updates following the completion of each Study subject's dose regimen in accordance with the Protocol. Within one (1) year of the conclusion or termination of the Study, University will submit a final Study report to the Company, which will include a clean limited data set in the format set forth in Exhibit C ("Limited Data Set"). Nothing herein shall authorize the Company to use or further disclose the Limited Data Set in a manner that would violate the requirements of University under 45 CFR 164.514. Company shall not use or further disclose the Limited Data Set other than as permitted by this Agreement or as otherwise required by law. Company shall report to the University any use or disclosure of the Limited Data Set not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure. Company will not use the Limited Data Set, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Limited Data Set without specific written approval from University and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Company inadvertently receive identifiable information or otherwise identify a Study subject, Company shall promptly notify University and follow University's reasonable written instructions, which may include return or destruction of the identifiable information.

22.2 All data and information generated in performance of the Study ("Study Data") shall be the sole property of University. University and Sponsor-Investigator each hereby grant to Company a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully sublicensable license to exploit the Study Data, progress reports and the final report prepared for Company for any purpose subject to any applicable signed informed consent documents and authorization forms, Applicable Laws and terms of this Agreement.

22.3 Notwithstanding anything to the contrary in this Agreement, upon reasonable request, University will provide Company with any information related to the Study that is necessary for Company to determine whether to pursue commercial development of GTB-3650 through a separate IND application for Company's Phase II trial.

23. HIPAA. The Parties understand and agree that any use of disclosure of Protected Healthcare Information, as defined in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA") shall be subject to the authorization provided by the Study subject in the informed consent or other authorization document. In addition, University shall collect, use, store and disclose data and materials, including any biological safety samples, collected from Study subjects only as allowed by the informed consents, or other authorizations, obtained from such Study subjects. University shall maintain Study records for the period of time and in a secure fashion as required by applicable Good Clinical Practices, federal, state, local laws, and regulations, including HIPAA.

24. Publications.

24.1 Company recognizes that under University policy the results of the Study must be publishable and agrees that researchers engaged in the Study shall be permitted to present at symposia, national or regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Study (each, a "Publication"). University shall have the final authority to determine the scope and content of any University Publication; provided, however, that University shall provide copies of any proposed Publication at least thirty (30) days in advance of the Publication to Company to review and object to such Publication because such draft either contains information deemed to be Confidential Information under the provisions of Section 27 of this Agreement, or reveals information that if published within thirty (30) days would have an adverse effect on a patent application in which Company owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. In the event that Company notifies the University in writing that the proposed Publication contains Company's Confidential Information, the University shall remove any Company Confidential Information from the draft prior to such Publication. In the event Company requests in writing a delay in Publication to file for patent protection, the University and the Sponsor- Investigator shall refrain from making such Publication for a maximum of ninety (90) days from the receipt of such objection, and Company shall indicate with specificity to what manner and degree University may disclose said information during the ninety (90) day period.

24.2 Company shall have the right to make Publications and issue press releases regarding the Study and the Study results (each, a "Company Publication"). Company shall have the final authority to determine the scope and content of any Company Publication; provided, however, that Company shall provide copies of any proposed Company Publication that includes the results of the Study at least thirty (30) days in advance of the Company Publication to University to review and object to such Company Publication because such draft either contains information deemed to be Confidential Information under the provisions of Section 27 of this Agreement, or reveals information that if published within thirty (30) days would have an adverse effect on a patent application in which University owns full or part interest. In the event that University notifies the Company in writing that the proposed Company Publication contains University's Confidential Information, the Company shall remove any University Confidential Information from the draft prior to such Company Publication. In the event University requests in writing a delay in the proposed Company Publication to file for patent protection, the Company shall refrain from making such Company Publication for a maximum of ninety (90) days from the receipt of such objection, and University shall indicate with specificity to what manner and degree Company may disclose said information during the ninety (90) day period.

24.3 Publication by either Party to this Agreement shall give proper credit to the other Party for the cooperative character of the Study; provided that, for any such Company Publication, Company shall obtain prior written approval pursuant to Section 35 below, to use the name, logos and other marks and trade names of University, or of any individual member of University staff, including Sponsor- Investigator and University personnel involved with the Research Program. For clarity, and notwithstanding the foregoing, Company may, without prior written approval of the University, state in a Publication in a factual, non-misleading manner that the Study is being conducted at the University.

UNIVERSITY OF MINNESOTA

25. Inspection. University shall notify Company in writing (including via electronic mail) of any proposed visit or inspection by any governmental authority if such visit or inspection has the potential to impact the Study. University shall in good faith cooperate with the governmental authority in the conduct of such inspection and provide such access to any locations, personnel or records as requested by such governmental authority. University shall provide Company with summaries of all reports, documents or correspondence with respect to any governmental authority requests or inspections of the facility related to the Study, as well as a copy of each such report, document or correspondence, which copies shall be provided promptly to Company. Company will be provided an opportunity to review and provide comments to any regulatory correspondence or other request, and University will provide Company with any proposed corrective actions, responses and other changes arising out of such review or inspection by such governmental authority. University shall cause Sponsor-Investigator and its permitted subcontractors to comply with this Section 25.

26. Documentation. University shall maintain complete, legible, and accurate Study records as required by Applicable Laws and Company's instruction. Upon and in accordance with Company's request, University shall provide Company with complete, legible, and accurate copies of any such requested Study records. Without limiting the foregoing, Study records shall be available at all reasonable times for review and inspection by Company for verification of compliance with this Agreement. Prior to destroying any such Study records, University shall provide Company with at least thirty (30) days written notice, and upon Company's request within such thirty (30) day period, shall cooperate with Company to transfer over any Study records to Company or its designee in accordance with Company's instructions and at Company's reasonable and documented expense.

27. Confidentiality.

27.1 For purposes of this Agreement, "Confidential Information" means written or tangible information disclosed by or on behalf of either Party (the "Disclosing Party") to the other Party (the "Receiving Party") or its Representatives (including Sponsor-Investigator), which at the time of disclosure is clearly and conspicuously labeled "Confidential" or "Proprietary". Confidential Information shall also include oral and visual disclosures which are identified as confidential at the time of such disclosures and which are confirmed and summarized within fifteen (15) days of the disclosure by the Disclosing Party in a writing that sets forth the substance of the Confidential Information disclosed. Notwithstanding the foregoing, information disclosed by the Disclosing Party pursuant to this Agreement that is not identified as "Confidential" or "Proprietary" will nevertheless be treated as Confidential Information by the Receiving Party if a reasonable person knowledgeable in the industry and field would, based upon the nature of the information or the circumstances surrounding its disclosure, consider such disclosure to be confidential and/or proprietary. The Protocol shall be considered University's Confidential Information regardless of being labeled as such. The Parties agree to maintain confidentiality of the Confidential Information during the term of this Agreement, including any renewal periods, and for a period of three (3) years from the effective termination or expiration date of this Agreement (except for trade secrets, which shall be held in confidence for so long as they are protected under applicable law). Neither Party shall use said Confidential Information for any purpose other than those purposes specified in this Agreement. The Parties may disclose Confidential Information to their officers, directors, employees, agents and representatives (collectively, "Representatives") requiring access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures each such Representative shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement and shall be bound in writing by obligations of confidentiality and non-use at least as stringent as the obligations set forth herein. Each Party shall be responsible for any breach of this Section 27 by its Representatives.

27.2 Nothing contained herein will in any way restrict or impair either Party's right to use, disclose, or otherwise deal with any Confidential Information which the Receiving Party can demonstrate through written documentation:

27.2.1 At the time of its receipt, is generally available in the public domain, or thereafter becomes available to the public through no act of the Receiving Party;

27.2.2 Was independently known prior to receipt thereof, or made available to such Receiving Party as a matter of lawful right by a third party;

27.2.3 Is received without obligation of confidentiality from a third party; or

27.2.4 Is developed independently by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party.

In the event that a Party is required by law (including the Minnesota Government Data Practices Act), and/or regulation or court order to disclose Confidential Information, the Party required to make such disclosure shall notify the other Party in writing to allow that Party to assert whatever exclusions or exemptions may be available to it under law. In the event that a protective order or other appropriate remedy is not obtained by the Disclosing Party, the Receiving Party shall only furnish that portion of the Confidential Information that is legally required to be disclosed.

28. Intellectual Property.

28.1 It is recognized and understood that certain existing inventions and technologies are the separate property of University or Company and are not affected by this Agreement, and neither Party shall have any claims or rights in such separate inventions. University agrees that any new patentable inventions, developments, or discoveries resulting from the Study ("Inventions") shall be promptly disclosed in writing to Company. Any Inventions developed in the course of the Study conducted hereunder shall be owned by the Party whose Representatives make or generate the Invention, in accordance with the Parties' respective intellectual property policies and procedures. Jointly made or generated Inventions shall be jointly owned by the Parties. In all cases, inventorship shall be determined in accordance with United States patent law.

UNIVERSITY OF MINNESOTA

28.2 Company is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to University for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty bearing license to any Invention owned by University ("University Inventions"), which option shall extend for no more than ninety (90) days after Company's receipt of an Invention disclosure from University in writing ("Option Period"). The Parties shall use their reasonable efforts to negotiate in good faith, for a period not to exceed ninety (90) days after Company's exercise of such option, a license agreement reasonably satisfactory to both Parties ("Negotiation Period"). In the event Company fails to exercise its option within the Option Period, or the Parties fail to reach agreement on the terms of such license within the Negotiation Period, University shall have no further obligation to Company under this Agreement with regard to such Invention.

28.3 Regardless of whether Company acquires a license to a University Invention, University retains an irrevocable, world-wide, royalty-free, non-exclusive right to use the University Inventions for non-commercial teaching, research and educational purposes. The University shall have the right to sublicense its rights under this section to one or more non-profit academic or research institutions for non-commercial purposes.

29. Insurance and Indemnification.

29.1 Each Party represents that it has and will continue to have at least the following levels of insurance or self-insurance during the term of this Agreement: (i) as to the University, Workers' Compensation in statutory compliance with Minnesota State Law; and (ii) as to both Parties, General Liability Insurance in an amount not less than one

million dollars ($1,000,000) each claim/three million dollars ($3,000,000) each occurrence. University represents that the University and Sponsor- Investigator have and will continue to have Professional Liability insurance in an amount not less than one million dollars ($1,000,000) each claim/three million dollars ($3,000,000) each occurrence. Company represents that it has and will continue to have Study Drug Liability insurance or self-insurance in an amount not less than one million dollars ($1,000,000) per claim/three million dollars ($3,000,000) per occurrence. Certificates of all insurance detailed above shall be furnished to the other Party upon request.

29.2 Each Party shall be responsible for its own acts and the results thereof and not for the acts of the other Party. Liability of the University is subject to the terms and limitations of the Minnesota Tort Claims Act, Minnesota Statutes Section 3.736.

29.3 Company shall indemnify, defend, and hold harmless University against any and all third party claims, costs, or liabilities, including attorneys' fees and court costs at both trial and appellate levels (collectively, "Claims"), to the extent arising from (a) a material breach of this Agreement by Company, (b) the gross negligence or willful misconduct of Company, or (c) a violation of law by Company in connection with Company's performance under this Agreement. Section 29.3 shall apply with the provision that (a) University promptly notifies Company in writing after University receives notice of any Claim and (b) University reasonably cooperates with Company in the defense of any such Claim. Notwithstanding the foregoing, Company shall not settle or dispose of any such Claim in any manner which would adversely affect the rights or interests of University without the prior written consent of University, or make any admission of guilt or negligence of University without University's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

29.4 Subject to the terms and limits of the Tort Claims Act, Minnesota Statutes Section 3.736, University shall indemnify, defend, and hold harmless Company against any and all Claims to the extent arising from (a) a material breach of this Agreement by University or Sponsor-Investigator, (b) the gross negligence or willful misconduct of University, Sponsor-Investigator or their Representatives, or (c) a violation of law by University, Sponsor-Investigator or their Representatives in connection with University and/or Sponsor-Investigator's performance under this Agreement. Section 29.4 shall apply with the provision that (a) Company promptly notifies University in writing after Company receives notice of any Claim and (b) Company reasonably cooperates with University in the defense of any such Claim. Notwithstanding the foregoing, University shall not settle or dispose of any such Claim in any manner which would adversely affect the rights or interests of Company without the prior written consent of Company, or make any admission of guilt or negligence of Company without Company's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

30. Reimbursement. If a Study subject suffers an adverse reaction, medical illness, or injury which was directly caused by a Study Drug that was properly administered in accordance with the Protocol and this Agreement, Company shall reimburse University for the reasonable and necessary expenses that are actually incurred in the diagnosis and treatment of any Study subject injury (not covered by 3rd party payers such as Medicare or privacy insurance), including hospitalization, but only to the extent such adverse reaction, medical illness or injury are not caused by (i) University's, Sponsor-Investigator's or the Study subjects' negligence or willful misconduct; (ii) the natural progression of an underlying or pre- existing condition or events, unless exacerbated by participating in the Study; or (iii) University's and/or Sponsor-Investigator's failure to adhere to and comply with the specifications of the Protocol and all reasonable written instructions furnished by Company for the use and administration of any Study Drug used in the Study, provided that deviations from the Protocol and written instructions resulting from an imminent threat to the health or safety of a Study subject that does not cause the injury to the Study subject will not disqualify University from reimbursement under this provision.

31. Disclaimer of Warranties. Except for Sections 1, 6, 10, and 12 above, neither Party makes any warranties, express or implied, as to any matter whatsoever, including without limitation, the condition, originality or accuracy of the research or any invention (s) or product(s), whether tangible or intangible, conceived, discovered, or developed under this Agreement; or the ownership, merchantability, or fitness for a particular purpose of the research or any such invention or product. COMPANY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE STUDY DRUG. THE STUDY DRUG IS PROVIDED "AS-IS".

32. LIMITATION OF LIABILITY. IN NO EVENT SHALL EITHER PARTY'S LIABILITY TO THE OTHER PARTY INCLUDE DAMAGES FOR WORK STOPPAGE, LOST DATA, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFIT) OF ANY KIND. EXCEPT FOR EACH PARTY'S OBLIGATIONS UNDER SECTIONS 29.3, 29.4, AND 30, NO PARTY'S LIABILITY TO THE OTHER PARTY UNDER THIS AGREEMENT SHALL EXCEED THE MONETARY CONSIDERATION DUE OR PAYABLE TO THE UNIVERSITY UNDER THIS AGREEMENT.

33. Debarment. Each Party represents and warrants that neither it nor any of its or its affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 USC 335a or by any regulatory authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 USC 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the term of this Agreement, it becomes aware that it or any of its or its affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this section, such Party will promptly notify the other Party in writing. Each Party further covenants that if, during the term of this Agreement, it becomes aware that it or any of its or its affiliates' employees or agents is the subject of any investigation or proceeding that could lead to that entity becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, in each case pursuant to subsections (a) through (d) of this section, such Party will promptly notify the other Party in writing.

34. Export Controls. The Parties acknowledge that their activities may be subject to export control laws and regulations, including, without limitation, the Export Administration Regulations (15 CFR Parts 730-774) ("EAR"), the International Traffic in Arms Regulations (22 CFR Parts 120-130) ("ITAR"), and the Foreign Assets Control Regulations (31 CFR Parts 501-598). Except as provided in the following paragraph, each Party will be solely responsible for its compliance with such export control laws and regulations. Before transferring any commodity, software, or technical data (collectively, "Items") subject to the EAR or ITAR to University, Company must first give notice to University that it intends to transfer the Items in question. Such notice shall identify the relevant classification on the Commerce Control List (for EAR Items) or category of the U.S. Munitions List (for ITAR Items). University shall have the right to decline receipt of Items subject to the EAR or ITAR. Company shall not transfer Items subject to the EAR or ITAR to University until University has furnished written confirmation that it (a) will accept the Items, and (b) either has implemented a technology control plan or has determined that one is not needed.

35. Publicity.

35.1 Company will not use the name, logos and other marks and trade names of University, nor of any individual member of University staff, including Sponsor-Investigator and University personnel involved with the Research Program, in any publicity, advertising, or news release without the prior written approval of an authorized representative of University, except where required by law. University will not use the name, logos and other marks and trade names of Company, nor any Representative of Company, in any publicity, advertising, or news release without the prior written approval of Company. For clarity, and notwithstanding the foregoing, Company may, without prior written approval of the University, state in a Publication in a factual, non-misleading manner that the Study is being conducted at the University.

35.2 Pursuant to the University's Openness in Research Policy (a copy of which may be found at http://www1.umn.edu/regents/policies/academic/Openness_in_Research.pdf) the University shall be allowed to disclose the following non-confidential information without the approval of the Company: (1) the existence of the contract or grant; (2) the identity of the Company or the grantor and, if a subcontract is involved, the identity of the prime contractor if the results of the research must be reported to the sponsor, grantor, or prime contractor; and (3) the purpose and the scope of the proposed research. The University may also disclose information as needed to comply with institutional reporting requirements, conflict of interest reviews, or in sponsored projects proposals or award documents (e.g., list of current and pending support.).

35.3 In accordance with the rules and regulations of the U.S. Securities Exchange Commission and other reporting requirements for publicly listed companies, Company may disclose the following non- confidential information in any such disclosures without the written approval of the University: (1) the existence of this Agreement; (2) the identity of the University and, if a subcontract is involved, the identity of the prime contractor; and (3) the purpose and the scope of the Research Program. For clarity, Company may also disclose any such information as needed to comply with U.S. Government reporting requirements or other such reporting requirements in accordance with Applicable Laws governing the Parties and research performed under the terms of this Agreement.

35.4 Each Party represents, warrants, and covenants that it will avoid deceptive, misleading or unethical practices and it will make no false or misleading statements regarding the Product or the Study (or the results thereof).

36. Modification. Any alteration, modification, or amendment to this Agreement must be in writing and signed by both Parties. No changes in the Protocol will be made unless agreed upon by University, the Sponsor-Investigator and the Company in writing and approved by the IRB, or if it is necessary to protect the safety, rights, or welfare of the Study subjects. Any such changes must be fully, accurately, and contemporaneously documented in accordance with established procedures. University shall, within one (1) business day from occurrence, or as otherwise specified in the Protocol, notify Company in writing of any change from the Protocol, including any change necessary to protect the safety, rights, or welfare of the Study subjects.

37. Survival of Regulatory Obligations. All regulatory obligations contained herein that are required of either Party or both Parties by an applicable governmental authority with respect to the Study shall survive termination of this Agreement and for the period of time required by Applicable Laws.

38. Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement without the other Party's written consent to an affiliate or in connection with a change of control, merger, acquisition, or sale of all or substantially all of its business or assets to which this Agreement relates. University may subcontract with subsites with the prior written consent of the Company and will execute a written agreement with subsites obligating them to comply with relevant terms and conditions of this Agreement.

39. Independent Contractor. University's relationship to Company under this Agreement shall be that of an independent contractor and not an agent, joint venturer, or partner of University.

40. Notice. Notices, requests, invoices, or communications, hereunder shall be deemed made upon submission to an overnight courier service or priority United States Mail, or three days after mailing by United States, first-class mail, certified or registered, postage prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other address as may hereafter be designated by notice in writing:

If to Company:

Name: GT Biopharma, Inc.
Address: 315 Montgomery Street
9th & 10th Floors
San Francisco, CA 94104

	Telephone:	(650) 808-7394
	E-Mail:	mb@gtbiopharma.com
If to University: (Insert Name)	Name:	Sponsored Projects Administration University of Minnesota 450 McNamara Alumni Center 200 Oak Street S.E. Minneapolis, MN 55455-2070 Telephone: (612) Fax : (612) E-Mail: @umn.edu
with a copy to Sponsor-Investigator (Insert Contact Information)	Name: Address:	Mark Juckett, M.D., Department of Medicine Hematology, Oncology, Transplantation 420 Delaware St SE Minneapolis, MN 55455
	E-Mail:	juck0001@umn.edu

41. Entire Agreement. This Agreement and its attached Exhibits represent the entire understanding between the Parties, and supersedes all other agreements, express or implied, between the Parties as to its subject matter. Any alteration, modification, or amendment to this Agreement must be in writing and signed by both Parties. In the event of conflict between the terms of the Protocol and this Agreement, the terms of the Protocol shall govern all medical and scientific matters, and the terms of this Agreement shall govern all other matters.

42. Force Majeure. If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party's reasonable control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather or other reason beyond the Party's reasonable control (a "Disability") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Study Budget shall be adjusted to account for cost increases or decreases resulting from the Disability as mutually agreed by the Parties in writing. The Party affected by the Disability shall promptly notify the other Party of such Disability in writing as provided for herein. Subject to Section 5 above, tn the event that a Disability shall occur and be continuing for a period in excess of sixty (60) days, either Party may terminate this Agreement upon written notice to the other Party.

43. Execution. This Agreement may be signed in counterpart by the Parties and the Sponsor-Investigator, and together shall serve as the final, agreed-upon representation of their respective assent to its terms. Each Party and the Sponsor-Investigator may execute this Agreement in portable document format, which shall constitute their assent to its terms.

44. Governing Law; Venue. This Agreement shall be governed and construed in accordance with the laws of the State of Minnesota, without regard to any conflicts of laws principles that would require interpretation under the laws of any other jurisdiction. Any action brought under this Agreement shall only be brought in the courts located of Hennepin County, Minnesota, USA.

45. Equitable Relief. Each Party agrees that any breach or threatened breach of Section 27 of this Agreement may result in significant and irreparable damage to a Party, and such Party shall be entitled, in addition to any other remedies available at law or in equity, to seek injunctive or other equitable relief by a court of appropriate jurisdiction.

46. Waiver; Severability. The failure to enforce any right or provision herein shall not constitute a waiver of that right or provision. No waiver of any breach, right, or obligation under this Agreement shall be effective unless in writing and signed by the Party to be charged. No consent to or waiver of a breach by either Party hereto, whether express or implied, shall constitute a consent to, waiver of, or excuse for any other, different, or subsequent breach by such Party. Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of the provisions of this Agreement in any other jurisdiction.

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UNIVERSITY OF MINNESOTA

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the Effective Date.

REGENTS OF THE UNIVERSITY OF MINNESOTA

Name:

Title:

Date:

GT BIOPHARMA, INC

Name:

Title:

Date:

I have read the above agreement and agree to perform my obligations as Sponsor-Investigator under this Agreement. I also understand and agree to the disposition of rights in inventions, discoveries, and other results as provided by this Agreement and to the provisions concerning confidentiality and Publications. I will inform students and other participants working on the Study of their rights and obligations under this Agreement.

Sponsor-Investigator

Name:

Title:

Date:

EXHIBIT A - PROTOCOL
EXHIBIT B – STUDY BUDGET
EXHIBIT C – DATA REPORT