

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): October 5, 2020

GT Biopharma, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other Jurisdiction of
Incorporation or organization)

000-08092
(Commission File Number)

94-1620407
(IRS Employer I.D. No.)

9350 Wilshire Blvd. Suite 203
Beverly Hills, CA 90212
Phone: (800) 304-9888
(Address, including zip code, and telephone number, including area code, of
registrant's principal executive offices)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- 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
None	N/A	N/A

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.

Effective October 5, 2020, the Registrant, GT Biopharma, Inc. (the "Company"), entered into a Master Services Agreement (the "Agreement"), with Cytovance Biologics, Inc., ("Cytovance"), a subsidiary of Shenzhen Hepalink Pharmaceutical Group Co., Ltd. Cytovance is headquartered in Oklahoma City, Oklahoma.

Under the Agreement, the Company will engage Cytovance as the exclusive manufacturer for three of the Company's TriKE™ therapeutic product candidates. Cytovance will manufacture TriKE™ using Cytovance's proprietary Keystone® bacterial or mammalian expression systems. Subject to the completion of certain milestones by Cytovance, GT Biopharma has the option to pay Cytovance up to \$6 million for its manufacturing services in either cash or in shares of the Company's common stock valued at the time Cytovance achieves each of several milestones over the next 12 months.

Item 9.01 Exhibits.

(d) Exhibits

No. Description

[10.1](#) Master Services Agreement

[99.1](#) Press Release

SIGNATURE PAGE

Pursuant to the requirement of the Securities and 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.

Dated: October 6, 2020

By: /s/ Steven Weldon
Steven Weldon
Chief Financial Officer

Master Services Agreement

This Master Services Agreement (this "Agreement"), effective October 5, 2020 (the "Effective Date"), is between GT Biopharma, Inc. ("Client"), a Delaware corporation having a place of business at 9350 Wilshire Blvd., Suite 203, Beverly Hills, CA 90212, and Cytovance Biologics, Inc. ("Cytovance"), a Delaware corporation having a place of business at 800 Research Parkway, Suite 200, Oklahoma City, OK 73104. Client and Cytovance are each referred to as a "Party" and collectively referred to as the "Parties".

Recitals

WHEREAS, Client desires Cytovance to perform various biologic development and manufacturing services from time to time in accordance with the terms of this Agreement;

WHEREAS, Cytovance desires to perform the development and manufacturing services requested by Client in accordance with the terms of this Agreement;

NOW THEREFORE, for and in consideration of the mutual promises, covenants, and conditions, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged and which form part of this Agreement, the Parties agree as follows:

Agreement

1. Definitions. The following terms, whether used in the singular or plural, have the respective meanings set forth below:

1.1 "Affiliate" means, with respect to a Party, any person or Entity that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" means: (i) direct or indirect ownership of more than 50% of the shares of stock entitled to vote for the election of directors (in the case of a corporation), (ii) more than 50% of the equity interest in the case of any other type of Entity, (iii) status as a general partner in any partnership, or (iv) any other structure or arrangement that includes the right to control the board of directors or equivalent governing body of the Entity or the ability to cause the direction of the management and policies of the Entity.

1.2 "Authorized Agent" means, with respect to a Party, the Party, its Affiliates, and their respective officers, directors, employees, consultants, advisors, agents, representatives, and subcontractors.

1.3 "Batch" means Client Product that is produced during the same cycle of manufacture and is intended to be of uniform character and quality as defined in the applicable Manufacturing Process.

1.4 "Batch Production Records" means the records completed by Cytovance that document Cytovance's steps and processes utilized in the manufacture of a CGMP Batch.

1.5 “CGMP” means “current Good Manufacturing Practices” or “CGMP” as promulgated under U.S. Food, Drug & Cosmetics Act (21 U.S.C. §301*et seq.*) and the regulations thereunder including 21 Code of Regulations chapters 210 and 211, as amended from time to time. If Cytovance agrees to manufacture Client Product in accordance with EMA regulations, then “CGMP” also includes “Good Manufacturing Practices” or “EU GMP” as specified in the EU Guidelines to Good Manufacturing Practices: Medicinal Products for Human or Veterinary Use, as amended from time to time.

1.6 “CGMP Batch” means a Batch required to be manufactured in accordance with CGMP.

1.7 “CGMP Batch Documentation” means a complete and accurate copy of the Batch Production Records and other documents required by the Quality Technical Agreement, a certificate of analysis, and a certificate of compliance for a Conforming CGMP Batch, which are completed and approved by Cytovance.

1.8 “CGMP Manufacturing Process” means the process and procedures that Cytovance agrees to follow when manufacturing a CGMP Batch, as evidenced by the Master Batch Records and the Quality Technical Agreement.

1.9 “Change Order” means an agreed-upon amendment, change, or revision to an applicable SOW.

1.10 “Client Components” means all materials provided by Client, its Affiliates, or their respective designees to Cytovance, such as cell lines, cell banks, and plasmids.

1.11 “Client Equipment” means all equipment and tools provided by Client, its Affiliates, or their respective designees to Cytovance.

1.12 “Client Indemnitees” means Client and its Affiliates and their respective officers, directors, employees, consultants, advisors, agents, and representatives.

1.13 “Client Inventions” means all Inventions except for Cytovance Inventions.

1.14 “Client Product” means the RCB, MCB, Drug Substance, Drug Product or other TriKE Product produced for Client by Cytovance during performance of Services.

1.15 “Client Technology” means all Know-How, Patents, and other technology, methods, and processes transferred or otherwise shared with Cytovance by Client or its Affiliates or their respective designees.

1.16 “Confidential Information” means any confidential or proprietary Know-How or other data or information, in any form or medium.

1.17 “Conforming CGMP Batch” means a CGMP Batch that was manufactured in accordance with the CGMP Manufacturing Process and meets the applicable Specifications.

1.18 “Conforming CGMP Product” means the Client Product resulting from a Conforming CGMP Batch that has been accepted in writing by Client.

- 1.19** “Cytovance Indemnitees” means Cytovance and its Affiliates and their respective officers, directors, employees, consultants, advisors, agents, and representatives.
- 1.20** “Cytovance Inventions” means any: (a) Invention that does not use or incorporate Client Technology, Client Product, or Client Components; and (b) improvements or modifications to Cytovance Technology.
- 1.21** “Cytovance Technology” means any and all Know-How, Patents, and other technology controlled by Cytovance or its Affiliates as of the Effective Date or at any time during the term of this Agreement.
- 1.22** “Discloser” means a Party that discloses its Confidential Information to the other Party.
- 1.23** “Deliverables” means all materials, reports, information, data, findings, results, conclusions, items, and recommendations, including Client Product, that Cytovance is required to produce for Client during the Services, as described in the applicable SOW.
- 1.24** “Defective CGMP Manufacturing” means Cytovance’s failure to follow the CGMP Manufacturing Process when manufacturing a CGMP Batch, which results in a Non-Conforming CGMP Batch.
- 1.25** “Drug Substance” means the unformulated TriKE Product.
- 1.26** “Drug Product” means the final marketed dosage form of the Drug Substance.
- 1.27** “EMA” means the European Medicines Agency or its successor Entity.
- 1.28** “Engineering Batch” means a test Batch manufactured in a CGMP-qualified manufacturing suite at the same scale and with a Manufacturing Process similar to the intended CGMP Manufacturing Process of an intended CGMP Batch, but not subject to CGMP and without any obligation to meet any Specifications.
- 1.29** “Entity” means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, trust, joint stock company, joint venture, association, organization, governmental body, or any other entity, association, or organization.
- 1.30** “Facility” means Cytovance’s laboratory and manufacturing facilities located in Oklahoma City.
- 1.31** “FDA” means the United States Food and Drug Administration or its successor Entity.
- 1.32** “Invention” means any invention, discovery, innovation, or improvement, whether or not patentable, that is discovered, first conceived, made, developed, or reduced to practice during the Services.

1.33 “Know-How” means any and all tangible and intangible information, know-how, data, results, and materials, including SOPs, discoveries, improvements, compositions of matter, cell lines, assays, sequences, processes, methods, knowledge, protocols, formulas, utility, formulations, data, inventions, strategy, and trade secrets, whether patentable or otherwise, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, and commercial information or data, in each case treated as confidential or proprietary information and that is not generally known by the public, but excluding any of the foregoing to the extent described or claimed in any Patents.

1.34 “Latent Defect” means a defect or other non-conformance in Conforming CGMP Product that: (i) was not discoverable upon commercially reasonable physical inspection and testing of the Conforming CGMP Product; and (ii) causes the Conforming CGMP Product to be a Non-Conforming CGMP Batch.

1.35 “Law” means any federal, state, or local law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, or similar order by any Regulatory Authority or government authority with competent jurisdiction.

1.36 “Manufacturing Audit” means Client’s planned, independent, documented, objective assessment of Cytovance and the portions of the Facility used for production of Client Product to verify that Cytovance’s systems and processes used to manufacture Client Product are in accordance with the agreed-upon quality expectations and applicable requirements from Regulatory Authorities. A Manufacturing Audit is not all inclusive and only includes review of systems, processes, procedures, and documentation related to Client Product.

1.37 “Manufacturing Process” means the process and procedures that Cytovance agrees to follow when manufacturing a Batch.

1.38 “Master Batch Records” means the Client-approved, step-by-step description of the entire Manufacturing Process and all necessary production tasks and activities for the manufacture of a CGMP Batch and the MCB.

1.39 “Master Cell Bank” or “MCB” shall mean a single pool of E. coli cells or CHO cells expressing the TriKE Product that has been derived from the RCB using a single E. coli cell clone or CHO cell clone expressing the TriKE Product. The MCB will be prepared under CGMP conditions in accordance with the applicable Manufacturing Process, and subsequently dispensed into multiple containers, and stored under defined conditions. The MCB is used to derive all working cell banks used to manufacture an Engineering Batch or CGMP Batch.

1.40 “Non-Conforming CGMP Batch” means a CGMP Batch that does not meet the applicable Specifications.

1.41 “Patents” means all patents, patent applications, and any patents issuing therefrom, including all certificates of invention, applications for certificates of invention, divisionals, continuations, substitutions, continuations-in-part, converted provisionals, continued prosecution applications, adjustments, re-examinations, reissues, additions, renewals, revalidations, extensions (including patent term extensions and supplemental certificates), registrations, pediatric exclusivity periods of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

1.42 “Person in the Plant” means an employee, consultant, advisor, agent, or representative of Client located in the Facility during the Services for reasons other than a Manufacturing Audit or Facility visit.

1.43 “Quality Technical Agreement” means the agreement between the Parties defining the quality responsibilities, including CGMP standards, regarding the performance of the Services.

1.44 “Raw Materials” means all materials (such as media, resins, excipients, components, supplies, and other materials) other than Client Components that are utilized by Cytovance in the production of Client Product.

1.45 “R&D Batch” means a Batch manufactured in a research and development laboratory and without any obligation to adhere to CGMP or meet any Specifications.

1.46 “Recall” means a recall, withdrawal, field alert, or similar action relating to any Client Product, whether mandatory or voluntary, regardless of whether the Client Product violates any applicable Law.

1.47 “Recipient” means a Party that receives a Discloser’s Confidential Information.

1.48 “Regulatory Authority” means any agency or authority responsible for regulation of Client Product in the United States, including the FDA. If Cytovance agrees to manufacture Client Product in accordance with EMA regulations, then “Regulatory Authority” also includes the EMA.

1.49 “Research Cell Bank” or “RCB” shall mean an E. coli cell bank or CHO cell bank expressing TriKE Product produced under research conditions used for the production of the R&D Batch. The RCB should be derived from a single E. coli cell clone or CHO cell clone expressing the TriKE product.

1.50 “Service Documentation and Samples” means the Batch Production Records of Client Product, laboratory notebooks, SOPs, or other records related to the performance of Services, as well as samples of Client Products and key Raw Materials used for the manufacture of Client Product that are required to be retained by Cytovance under the Quality Technical Agreement.

1.51 “Service Standard” means Cytovance’s requirement to perform all Services in accordance with industry standards, applicable Law, this Agreement, and the applicable SOW (which may contain Specifications or other acceptance criteria agreed to by the Parties).

1.52 “Services” means the services Cytovance agrees to perform for Client as described in any applicable SOW.

1.53 “SOPs” means standard operating procedures.

1.54 “SOW” means an agreed-upon scope of work that the Parties enter into from time to time that defines the Services to be performed under that scope of work, as amended by one or more Change Orders. A proposal for services becomes a scope of work when it is signed by both Parties. An SOW may also contain the Specifications or other acceptance criteria agreed to by the Parties.

1.55 “Specifications” means the agreed-upon criteria necessary for Cytovance to release a CGMP Batch to Client as defined in the product specifications document approved by Client. The Specifications may be included in the applicable SOW.

1.56 “Third Party” means any person or Entity other than Cytovance and Client.

1.57 “Third Party Expert” means a 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 Parties, and is a recognized expert in the field of NK cell biology and the development of NK cell engagers

1.58 “Third Party Licensed Materials” means materials, technology, or both, licensed to Cytovance by a Third Party for use in development and manufacturing services provided by Cytovance to its clients.

1.59 “TriKE Product” shall mean the single gene protein expression product derived from the DNA sequence and amino acid sequence provided to Cytovance by Client.

2. General Terms of Service.

2.1 **Independent Contractor.** Cytovance is an independent contractor of Client and has complete and exclusive control over its Facilities, equipment, and employees. The relationship between the Parties is not a partnership, joint venture, agency relationship, or similar relationship, and neither Party is the agent, employee, or legal representative of the other.

2.2 **Excluded Services.** Cytovance is under no obligation to produce products which are classified as antibiotics, cytotoxic, or highly active drugs, or are complexed with radioisotopes, all of which generally require segregated and specialized facilities and equipment. Cytovance will notify Client if it becomes aware of any safety or toxicity issues related to Client Product.

2.3 **SOWs.** Each SOW will detail the Services to be performed by Cytovance, including the Deliverables, any Raw Materials to be procured by Cytovance, any outsourced services, the fees and costs to be paid by Client, and any other details or provisions deemed necessary or appropriate by the Parties (which may include the Specifications or other acceptance criteria agreed to by the Parties). Each SOW must be in writing, dated, and signed by the Parties. The Services specified in SOWs are the only Services Cytovance will perform.

2.4 **Change Orders.** Due to the nature of the Services, changes to the scope and duration of Services under an SOW may be necessary, including to: (a) revise the Deliverables, procedures, assumptions, processes, test methods, or outsourced services; (b) comply with applicable Law or amendments to applicable Law; or (c) revise the Services for any other reason, including as necessitated by a force majeure event as described in Section 0. Either Party may propose a change to any Services under any SOW. The Parties must agree to the changes prior implementing the changes in the Services. Any agreed-upon changes to a SOW will be set forth in a Change Order signed by both Parties. Each Change Order will be considered part of the SOW it amends.

2.5 Regulatory Compliance. Client is responsible for complying with all Law and securing all approvals from all Regulatory Authorities and any other governmental or quasi-governmental entities related to the creation, manufacture, use, sale, licensing, and other disposition of Client Components, Client Equipment, Client Technology, and Client Product, including any approvals necessary to transfer Client Components, Client Equipment, and Client Technology to Cytovance for Cytovance's provision of the Services. Client will promptly notify Cytovance if Client fails to maintain any approval from any Regulatory Authority or other governmental or quasi-governmental entity. Cytovance shall maintain its CGMP manufacturing facility and all related quality documentation, processes and systems in compliance with U.S. FDA and other CGMP quality standards.

2.6 Client Cooperation. Client shall support and cooperate with Cytovance in the execution of the Services and shall not engage in any act or omission that may reasonably be expected to prevent or delay the successful execution of the Services. Support and cooperation includes but is not limited to, prompt review and approval of documents requiring Client's signature, timely delivery of accurate methods and materials, and prompt response to other matters.

2.7 Instructions for Client Product. Prior to the Cytovance's manufacturing of any Client Product, Client shall provide Cytovance with reasonable instructions for the proper storage, handling, shipping, and disposal or destruction of all Client Product to be produced, with sufficient time for Cytovance's review and training of its employees.

2.8 Ownership of Deliverables. As between the Parties, Client shall own all Deliverables, but Cytovance may withhold Deliverables (whether completed or in-process) as expressly permitted in this Agreement without any liability to Client.

2.9 Subcontractors. Subject to advance written notice to Client by Cytovance and Client's approval, Cytovance may subcontract the performance of Services to any of its approved subcontractors. Cytovance will provide its list of approved subcontractors to Client upon Client's request. If Cytovance subcontracts any Services, Cytovance will ensure that the subcontracted Services are performed in compliance with this Agreement and Cytovance will be liable to Client for the subcontractor's performance of subcontracted Services as if Cytovance performed those Services for Client. However, Cytovance will have no liability to Client for the acts or omissions of a subcontractor identified by Client and engaged by Cytovance for the performance of subcontracted Services at Client's request.

2.10 Outsourced Services. Outsourced services, such as outsourced testing or analytical services, are not considered subcontracted Services. Cytovance will have no liability to Client for the performance or accuracy of any outsourced services. Any outsourced services to be performed will be specified in the applicable SOW.

2.11 Exclusivity. Cytovance shall not use any of Client's Confidential Information for the benefit of itself or a Third Party, including using Client's Confidential Information to develop, manufacture, or use products or ideas that are similar to or compete with TriKE Product.

3. Payment, Invoicing, and Taxes.

3.1 Payment. Payment of fees and reimbursement of any expenses with respect to Services under a SOW will be set forth in the SOW. Any changes to a SOW may be subject to a change in fees and costs to be paid by Client. Any change of fees or costs must be agreed to by the Parties in a Change Order.

3.2 Non-Refundable Prepayments. Cytovance dedicates significant time, labor, and resources into the preparation, planning, and initiation of the Services under an SOW, the value of which is difficult to measure and determine. Non-refundable prepayments in an SOW are designed to compensate Cytovance for its time, labor, and resources devoted to preparing, planning, and initiating the Services to be performed under the SOW. For this reason, the Parties agree that if Client terminates a SOW for any reason (excepting termination of the SOW for cause), Cytovance will be entitled to keep the non-refundable prepayments as liquidated damages (which the Parties agree does not serve as a penalty) to compensate Cytovance for its significant time, labor, and resources devoted to preparing, planning, and initiating the Services that were terminated by Client.

3.3 Late Payments. Cytovance may charge interest at a rate of 1.5% per month on any pass-due balance owed by Client. Cytovance's failure to bill for interest due is not a waiver of Cytovance's right to charge interest on any pass-due invoice. If full payment of any invoice is not received within 60 days of the date when due, Cytovance may suspend any Services and withhold any Deliverables (whether completed or in-process) without any liability to Client.

3.4 Cytovance Taxes. Cytovance shall pay all taxes, duties, and levies imposed upon Cytovance's performance of Services except for applicable sales and use taxes that by Law Cytovance must add to the cost of Services. These taxes, if any, will be separately stated on Cytovance's invoice to Client.

3.5 Client Taxes. Client shall pay all national, state, municipal, or other sales, use excise, import, property, value added, or other similar taxes, assessments, or tariffs assessed upon or levied against the sale of Client Product from Cytovance to Client or the sale or distribution of Client Product by Client. Cytovance shall notify Client of any such taxes that any governmental authority is seeking to collect from Cytovance, and Client will assume the defense thereof in Cytovance's name. Cytovance will cooperate in such defense at Client's expense.

4. Materials for the Services.

4.1 Client Components.

(a) Sufficiency; Ownership. As defined in an SOW, Client will provide Cytovance with sufficient quantities of Client Components necessary for the performance of the Services. Client shall adequately insure the Client Components against all risk of loss (at replacement value with an industry standard deductible). As between the Parties, all Client Components are and will remain the property of Client. Cytovance shall use the Client Components solely for the purpose of performing Services.

(b) No Hazardous Properties. The Client Components must not contain hazardous properties nor require specific safe handling instructions. If requested by Cytovance, Client will supply Cytovance with material safety data for Client Components. Cytovance will notify Client if Cytovance becomes aware of any safety or toxicity issues related to Client Components.

(c) **Handling of Client Components.** Prior to sending Client Components to Cytovance, Client shall provide Cytovance with reasonable instructions for the proper storage, handling, and disposal of all Client Components, with sufficient time for Cytovance's review and training of its employees.

(d) **Cell Lines Quantities.** Cytovance shall create and maintain sufficient quantities of RCB, MCB, and working cell banks that are required for the development, manufacturing and testing of Client Product. The quantities of RCB, MCB, and working cell bank necessary for the Services will be agreed upon by the Parties in one or more SOWs or Change Orders. Once a MCB is established, 50% of the MCB shall be stored with Client or a Third Party at Client's expense.

(e) **Remedy for Negligently Destroyed Client Components.** If Cytovance negligently destroys or loses a Client Component necessary for the successful completion of the applicable Services, as Client's sole and exclusive remedy, Cytovance will credit to Client's account the fair market value of the Client Component, minus any insurance proceeds available to Client from an insurance policy covering the Client Component or any insurance proceeds that would have been available to Client if the Client Component was insured as required under Section [4.1\(a\)](#).

(f) **Destruction or Return of Client Components.** Within 90 days after the completion of Services under an SOW or the termination of the SOW, whichever occurs first, Client will direct Cytovance to dispose of, destroy, or return to Client or its designee all unused Client Components applicable to that SOW. Client will pay the costs for disposal, destruction, or return of Client Components to Client or its designee. If Client does not direct Cytovance to dispose of, destroy, or return the Client Components within the 90 day period, Cytovance may, in its sole discretion: (i) charge a monthly storage fee for the Client Components until they are returned to Client or its designee or disposed of or destroyed; (ii) dispose of or destroy the Client Components at Client's expense without any liability to Client for the disposal or destruction of the Client Components; or (iii) both (i) and (ii).

(g) **Replenishment of Client Components.** If any Client Components expire or are unusable for any reason, upon notice from Cytovance, Client (at its expense) shall promptly send additional Client Components to Cytovance.

4.2 Raw Materials.

(a) **In General.** Unless otherwise stated in the applicable SOW, Cytovance will be responsible for procuring from its approved vendors and maintaining inventory of all Raw Materials necessary to perform the Services.

(b) **Handling of Raw Materials.** Cytovance will be responsible for adopting, maintaining, and enforcing safety procedures for Cytovance's internal handling and processing of Raw Materials.

(c) **Raw Materials Chosen by Client.** If Client requires the use of a specific Raw Material from a vendor that is not a Cytovance approved vendor, that specific Raw Material must meet Cytovance's quality requirements and Client shall identify a primary and backup supplier for the Raw Material. If Cytovance, in its sole discretion, determines that any vendor of any specific Raw Material requested by Client requires an audit by Cytovance, Client shall pay a fee for the audit as set forth in the applicable SOW.

(d) **Raw Material Specifications.** Unless otherwise agreed in the SOW, Cytovance will create up to three Raw Materials specifications per SOW at no charge to Client. Client will pay Cytovance a fee for the creation of each additional Raw Material specification as set forth in the applicable SOW.

(e) **No Warranty.** Cytovance makes no warranty regarding any Raw Materials used in the Services or incorporated into Client Product. If a Raw Material includes a manufacturer's warranty, Cytovance will transfer any rights it has under the warranty to Client (if allowed by the warranty). Cytovance will not be liable for the performance of any Raw Materials used in the Services or Client Product. However, if Cytovance's negligence causes a Raw Material to fail during the manufacture of a Batch and that failure results in a failed R&D Batch, failed Engineering Batch, or Defective CGMP Manufacturing, the applicable remedy in Section 6.4, Section 7.4, or Section 7.8(f) will apply. Notwithstanding the foregoing, unless otherwise agreed in an applicable SOW, Cytovance warrants it shall only use Raw Materials that comply with the Raw Material specifications set forth in the applicable SOW.

(f) **Replenishment of Raw Materials.** If any Raw Materials expire or are unusable as a result of Cytovance's negligent handling or storage of the Raw Materials, Cytovance will purchase replacement Raw Materials for use in the Services at Cytovance's expense.

(g) **Disposal of Raw Materials.** If any Raw Materials expire or are rendered unusable or the Services requiring the Raw Materials are completed or terminated for any reason, Cytovance will dispose of or destroy the Raw Materials at Client's expense. However, if any unexpired Raw Materials remain after the completion of the Services requiring those Raw Materials, Client may elect, at its expense, to have Cytovance ship the Raw Materials to Client or its designee.

4.3 Third Party Licensed Materials.

(a) **Optional Materials.** Cytovance has access to certain Third Party Licensed Materials that may be used in the Services for development of Client Product and the manufacture of R&D Batches without a separate license between Client and the Third Party. Cytovance shall notify Client in writing of Cytovance's intention to use Third Party Licensed Materials prior to commencing Services. If desired by Client, Cytovance will assist Client in determining what Third Party Licensed Materials may benefit any Client Product.

(b) **Use of Third Party Licensed Materials.** Cytovance shall only use Third Party Licensed Materials in the Services if expressly approved in writing by Client. Cytovance will comply with all restrictions, limitations, and obligations applicable to Cytovance with respect to the Third Party Licensed Materials. If Client agrees to allow Cytovance to use any Third Party Licensed Materials in the Services, Client shall comply with any restrictions, limitations, and obligations applicable to Client with respect to the Third Party Licensed Materials.

(c) **Additional License.** If Client decides to incorporate any Third Party Licensed Materials into Client Product beyond research and development Services, a separate license will be required between the Third Party and Client. Cytovance will connect Client with the Third Party so that Client and the Third Party can negotiate a license for the Third Party Licensed Materials used in the Client Product prior to Cytovance commencing Services. If Client obtains a separate license from the Third Party, Client will comply with all restrictions, limitations, and obligations applicable to the license.

(d) **No Warranty.** Cytovance makes no warranty regarding any Third Party Licensed Materials used in the Services or incorporated into Client Product. Cytovance will not be liable for the performance any Third Party Licensed Material used in the Services or Client Product. However, if Cytovance's negligence causes a Third Party Licensed Material to fail during the manufacture of a Batch and that failure results in a failed R&D Batch, failed Engineering Batch, or Defective CGMP Manufacturing, the applicable remedy in Section 6.4, Section 7.4, or Section 7.8(f) will apply.

(e) **Replenishment of Third Party Licensed Materials.** If any Third Party Licensed Materials expire or are unusable for any reason, upon notice from Cytovance, Client shall promptly pay Cytovance for the procurement of additional Third Party Licensed Materials. However, if Cytovance negligently damages or destroys a Third Party Licensed Material and the Services cannot continue without that Third Party Licensed Material, as Client's sole and exclusive remedy, Cytovance will purchase a replacement Third Party Licensed Material for use in the Services.

(f) **Disposal of Third Party Licensed Materials.** If any Third Party Licensed Materials expire or are rendered unusable or the Services requiring the Third Party Licensed Materials are completed or terminated for any reason, Cytovance will dispose of or destroy the Third Party Licensed Materials at Client's expense.

5. **Equipment for the Services.**

5.1 Cytovance Equipment. Except for Client Equipment, Cytovance will provide all equipment necessary for the Services. If the Services require any specialized equipment and Client elects not to send Client Equipment to Cytovance, the Parties may agree for Cytovance to procure the necessary equipment at Client's expense. Any procurement of additional equipment at Client's expense will be set forth in the applicable SOW. The Parties will agree in the applicable SOW whether the additional equipment is considered Cytovance equipment or Client Equipment.

5.2 Client Equipment. If the Services include any Client Equipment, title to the Client Equipment will remain with Client. Client shall pay for insuring (at replacement value with an industry standard deductible), shipping, installing, validating, revalidating, calibrating, recalibrating, repairing (including preventative maintenance), upgrading (including software and hardware updates), and replacing any Client Equipment. Spare parts provided by Client for Client Equipment will remain the property of Client and will be used by Cytovance only for the Client Equipment. Cytovance will notify Client if it believes any Client Equipment has been damaged, lost, or stolen.

5.3 Remedy for Negligently Damaged Equipment. If Cytovance negligently causes damage to Client Equipment, as Client's sole and exclusive remedy, Cytovance's will credit to Client's account the value of the repairs to the Client Equipment or the fair market value of the Client Equipment, whichever is less, minus any insurance proceeds available to Client from an insurance policy covering the Client Equipment or any insurance proceeds that would have been available to Client if the Client Equipment was insured as required under Section [5.2](#).

5.4 Performance of Client Equipment. Cytovance will have no liability for the performance any Client Equipment during the Services. However, if Cytovance's negligence causes Client Equipment to fail during the manufacture of a Batch and that failure results in a failed R&D Batch, failed Engineering Batch, or Defective CGMP Manufacturing, the applicable remedy in Section [6.4](#), Section [7.4](#), or Section 7.8(f) will apply.

5.5 Storage of Client Equipment. If Client Equipment is not in use during the Services for more than 60 days, Client shall pay a storage fee to Cytovance for the Client Equipment until Cytovance resumes using the Client Equipment for the Services or returns the Client Equipment to Client or its designee.

5.6 Shipment of Client Equipment. If Client Equipment is returned to Client or sent to its designee for any reason, Client shall pay the cost of packaging and shipping (including shipping insurance) the Client Equipment.

6. Research and Development Services.

6.1 Standard of Services. Cytovance will perform research and development Services in accordance with the Service Standard. Because of the experimental nature of research and development Services, Cytovance does not warrant any outcomes or results with respect to any Deliverables resulting from research and development Services, including R&D Batches. However, if Cytovance specifically agrees in writing to follow a specific Manufacturing Process when manufacturing an R&D Batch, Cytovance will manufacture that R&D Batch in accordance with the Manufacturing Process.

6.2 Dispute Regarding Research and Development Services. If the Parties dispute whether Cytovance complied with the Service Standard when completing research and development Services, including Cytovance's adherence to the Manufacturing Process when manufacturing an R&D Batch, the Parties will attempt to resolve the dispute within 30 days. If the dispute is not resolved, the Parties will submit the R&D Batch or other Deliverable, as applicable, and all relevant records and information to a Third Party Expert, mutually agreed upon by the Parties. Neither Party may unreasonably withhold its consent to the appointment of the Third Party Expert.

6.3 Third Party Expert Determination of Dispute.

(a) **Factors for Consideration.** When determining whether Cytovance met the Service Standard when conducting research and development Services, including Cytovance's adherence to the Manufacturing Process when manufacturing an R&D Batch, the Third Party Expert shall consider the information supplied by the Parties, Cytovance's acts and omissions, Client's acts and omissions, and any deficiencies in the Client Technology, Client Components, Client Equipment, and Raw Materials.

(b) **Third Party Expert Decision.** If the Third Party Expert determines that the research and development Services did not meet the Service Standard, or, if applicable, that Cytovance did not manufacture the R&D Batch in accordance with the Manufacturing Process, then Cytovance will pay the fees and expenses of the Third Party Expert and the remedy in Section 6.4 will apply. If the Third Party Expert determines that a failed R&D Batch did not result from Cytovance's failure to adhere to the Manufacturing Process, Client will pay the fees and expenses of the Third Party Expert and Client will have no remedy against Cytovance for the research and development Services or R&D Batch, as applicable. The determination by the Third Party Expert will be final and binding on the Parties absent fraud or manifest error.

6.4 Remedy for Failed Research and Development Services.

(a) **Eligibility for Remedy.** Client will only be entitled to a remedy for failed research and development Services if Client has paid for the failed research and development Services and: (i) Cytovance failed to follow the Service Standard when conducting research and development Services; or (ii) if the dispute concerns an R&D Batch, Cytovance failed to follow the applicable Manufacturing Process when manufacturing an R&D Batch.

(b) **Sole and Exclusive Remedy.** Client's sole and exclusive remedy for failed research and development Services is: (i) a repeat of the failed research and development Services or the manufacture of a replacement R&D Batch, as applicable, at Cytovance's expense; or (ii) a credit to Client's account equal to the fees charged for the failed research and development Services or R&D Batch, as applicable.

(c) **Use of Failed Client Product.** If Client uses Client Product from failed research and development Services for any purpose (excluding testing or analysis to determine whether the R&D Batch failed), Client will not be entitled to a remedy for the failed research and development Services (including any R&D Batches).

7. CGMP Manufacturing Services.

7.1 Engineering Batches.

(a) **Engineering Batches Required.** If the Services include the manufacture of one or more CGMP Batches, Cytovance requires the manufacture of an Engineering Batch prior to the manufacture of the first CGMP Batch at each scale of Client Product (unless the Parties agree in the SOW that no Engineering Batch is necessary). The purpose of the Engineering Batch is to familiarize Cytovance with the intended CGMP Manufacturing Process, observe the Client Technology, Client Components, Client Equipment, and Raw Materials, and reveal whether the intended Master Batch Records, CGMP Manufacturing Process, or Specifications require modifications or changes.

(i) **Refusal of Engineering Batch.** Unless agreed by the Parties in the SOW that no Engineering Batch is necessary, if Client directs Cytovance to forgo a required Engineering Batch required under Section 7.1(a) and the CGMP Batch results in a Non-Conforming CGMP Batch for any reason (excepting Cytovance's gross negligence or willful misconduct), Client will have no remedy against Cytovance for the Non-Conforming CGMP Batch, including the costs of Raw Materials and Client Components utilized in the Non-Conforming CGMP Batch.

(ii) **Intentionally Blank.**

(b) **Client Approval of Manufacturing Process.** Four (4) weeks prior to Cytovance's commencement of the manufacture of any Engineering Batch (or other time period agreed upon by the Parties), all applicable records for the agreed-upon Manufacturing Process (e.g., draft Master Batch Records for the intended CGMP Batch) must be approved by Client so that Cytovance will have adequate time to instruct its employees on the Manufacturing Process as well as complete a dry-run walk through of the Manufacturing Process. Cytovance shall allow Client four (4) weeks (or other time period agreed upon by the Parties) to review Master Batch Records and other documents required for the Manufacturing Process prior to commencement of the manufacture of any Engineering Batch.

(c) **Standard for Engineering Batches.** Cytovance will adhere to the Service Standard and follow the Manufacturing Process when manufacturing each Engineering Batch. However, no Engineering Batch is required to comply with CGMP or meet any Specifications.

7.2 Dispute Regarding Engineering Batches. If the Parties dispute whether Cytovance complied with the Service Standard when completing Service Standard or Manufacturing Process when manufacturing an Engineering Batch, the Parties will attempt to resolve the dispute within 30 days. If the dispute is not resolved, the Parties will submit the Engineering Batch or other Deliverable, as applicable, and all relevant records and information to Third Party Expert, mutually agreed upon by the Parties. Neither Party may unreasonably withhold its consent to the appointment of the Third Party Expert.

7.3 Third Party Determination of Dispute.

(a) **Factors for Consideration.** When determining whether Cytovance met the Service Standard or followed the Manufacturing Process when manufacturing an Engineering Batch, the Third Party Expert shall consider the information supplied by the Parties, Cytovance's acts and omissions, Client's acts and omissions, and any deficiencies in the Client Technology, Client Components, Client Equipment, and Raw Materials.

(b) **Third Party Expert Decision.** If the Third Party Expert determines that Cytovance failed to meet the Service Standard or did not manufacture the Engineering Batch in accordance with the Manufacturing Process, then Cytovance will pay the fees and expenses of the Third Party Expert and the remedy in Section 7.4 will apply. If the Third Party Expert determines that a failed Engineering Batch did not result from Cytovance's failure to adhere to the Manufacturing Process, Client will pay the fees and expenses of the Third Party Expert and Client will have no remedy against Cytovance for the failed Engineering Batch. The determination by the Third Party Expert will be final and binding on the Parties absent fraud or manifest error.

7.4 Remedy for Failed Engineering Batches.

(a) Client will only be entitled to a remedy for a failed Engineering Batch if Client has paid for the failed Engineering Batch and: (A) Cytovance fails to follow the Service Standard when manufacturing the Engineering Batch; or (B) Cytovance fails to follow the applicable Manufacturing Process when manufacturing the Engineering Batch.

(b) At Client's sole discretion, Client's sole and exclusive remedy for a failed Engineering Batch is either: (A) the manufacture of a replacement Engineering Batch at Cytovance's sole expense inclusive of the cost for all replacement Raw Materials and Client Components; or (B) a credit to Client's account equal to the fees charged for the failed Engineering Batch inclusive of the cost for all Raw Materials used in the failed Engineering Batch.

(c) If Client uses Client Product resulting from a failed Engineering Batch for any purpose (exclusive of testing or analysis to determine if the Engineering Batch was manufactured in accordance with the Manufacturing Process), Client will not be entitled to a remedy for the failed Engineering Batch and Client shall pay all fees for the manufacture of the failed Engineering Batch.

7.5 CGMP Batch Manufacturing.

(a) **Standard for CGMP Manufacturing.** Unless otherwise agreed in the SOW (which may also contain the Specifications or other acceptance criteria agreed to by the Parties), Cytovance warrants that each CGMP Batch will be manufactured in accordance with the Service Standard, the SOW, the CGMP Manufacturing Process, and be free of Defective CGMP Manufacturing.

(b) **Specifications.** Specifications must be agreed to in writing. Any changes to Specifications must be agreed upon by the Parties. If Client requests a material change to the Specifications, Cytovance and Client shall discuss and determine if an additional Engineering Batch is required to be manufactured in accordance with Section 7.1.

(c) **Client Approval of CGMP Manufacturing Process.** Six (6) weeks prior to Cytovance's commencement of the manufacture of any CGMP Batch (or other timeline agreed upon by the Parties), all applicable Master Batch Records and other documents required for the CGMP Manufacturing Process must be approved by Client so that Cytovance will have adequate time to instruct its employees on the CGMP Manufacturing Process as well as complete a dry-run walk through of the CGMP Manufacturing Process. Cytovance shall allow Client six (6) weeks (or other timeline agreed upon by the Parties) to review Master Batch Records and other documents required for the CGMP Manufacturing Process prior to commencement of the manufacture of any CGMP Batch.

7.6 Testing of Completed CGMP Batches.

(a) **Testing by Cytovance.** Upon completion of the manufacture of each CGMP Batch, Cytovance will sample and test the CGMP Batch in accordance with the applicable Master Batch Records and any applicable Specifications to assess if the CGMP Batch is a Conforming CGMP Batch.

(b) **Testing by Client.** Upon completion of the manufacture of each CGMP Batch, Cytovance will send to Client a sample of the CGMP Batch for testing and analysis to assess if the CGMP Batch is a Conforming CGMP Batch.

(c) **Conforming CGMP Batch.** If Cytovance and Client determine the completed CGMP Batch is a Conforming CGMP Batch, the appropriate CGMP Batch Documentation will be prepared. As long as any invoice sent to Client for any Services is not 60 or more days past due, Cytovance will deliver the CGMP Batch Documentation to Client for review.

(d) **Non-Conforming CGMP Batch.** If Cytovance and Client determine a completed CGMP Batch is a Non-Conforming CGMP Batch, Cytovance will deliver the Master Batch Records, Batch Production Records, Specifications, and testing results to Client. Cytovance and the Client will also conduct an investigation in accordance with the Quality Technical Agreement to determine the cause of the Non-Conforming CGMP Batch.

7.7 Client Review of CGMP Batch Documentation

(a) **60-Day Review Period.** Upon receipt of the CGMP Batch Documentation for a Conforming CGMP Batch, Client must notify Cytovance in writing of its acceptance or rejection of the Conforming CGMP Batch within sixty (60) days. If Client receives the Conforming CGMP Batch in accordance with Section 7.6(c) above, it may conduct its own testing (or testing done at its behalf by a Third Party) on a Conforming CGMP Batch within this 60 day period to determine whether to accept or reject the Conforming CGMP Batch. During this review period, the Parties will respond within seven days to any reasonable inquiry or request for a correction or change by the other Party with respect to the CGMP Batch Documentation.

(b) **Client Acceptance of Conforming CGMP Batch.** Client shall promptly notify Cytovance if it accepts the Conforming CGMP Batch as Conforming CGMP Product. If accepted by Client, the Conforming CGMP Batch will be considered Conforming CGMP Product as of the date Cytovance determined the CGMP Batch was a Conforming CGMP Batch in accordance with Section 7.6(c). If Client does not notify Cytovance within the 60-day time period that the Conforming CGMP Batch is a Non-Conforming CGMP Batch, on the day following the 60-day time period the Conforming CGMP Batch will be deemed Conforming CGMP Product as of the date that Cytovance determined the CGMP Batch was a Conforming CGMP Batch under Section 7.6(c) and Client will have waived its right to revoke acceptance.

(c) **Client Rejection of Conforming CGMP Batch.** If Client rejects a Conforming CGMP Batch as a Non-Conforming CGMP Batch during the 60-day review period, Client shall promptly notify Cytovance of its rejection in writing, including a detailed explanation of the non-conformity. The Parties will attempt in good faith to resolve any disagreement to determine whether the rejected CGMP Batch is a Conforming CGMP Batch or a Non-Conforming CGMP Batch. Client and Cytovance will follow their respective SOPs during this process.

(d) **Cytovance Investigation of Rejected Conforming CGMP Batch.** If Cytovance agrees that the rejected CGMP Batch is a Non-Conforming CGMP Batch, Cytovance and Client will conduct an investigation in accordance with the Quality Technical Agreement to determine whether the Non-Conforming CGMP Batch resulted from Defective CGMP Manufacturing. If the investigation reveals that the Non-Conforming CGMP Batch did not result from Defective CGMP Manufacturing, Client shall either accept the results of the investigative report or dispute the results in good faith pursuant to Section 7.8. If the investigation reveals that the Non-Conforming CGMP Batch resulted from Defective CGMP Manufacturing, the remedy in Section 7.8(f) will apply.

7.8 Dispute Regarding CGMP Batch.

(a) **Third Party Arbitrator Dispute Resolution.** If the Parties dispute whether a CGMP Batch is a Conforming CGMP Batch or a Non-Conforming CGMP Batch, or the Parties dispute whether a Non-Conforming CGMP Batch resulted from Defective CGMP Manufacturing, the Parties shall engage an independent Third Party Expert to resolve the dispute. If the dispute concerns the CGMP Batch's conformance to the Specifications or Cytovance's adherence to the CGMP Manufacturing Process, the Parties will submit the Master Batch Records, Batch Production Records, Specifications, SOW, and other information relevant to the dispute (including a representative sample of the CGMP Batch, if necessary) to an independent testing laboratory mutually agreed to by the Parties. If the dispute concerns Cytovance's adherence to CGMP, the Parties will submit the Master Batch Records, Batch Production Records, Specifications, SOW, and other information relevant to the dispute to a CGMP consultant mutually agreed to by the Parties.

(b) **Factors for Consideration.** The determination by the Third Party Expert will be final and binding on the Parties absent fraud or manifest error. In making its determination, the Third Party Expert shall consider the information supplied by the Parties, Cytovance's acts and omissions, Client's acts and omissions, and any deficiencies in the Client Technology, Client Components, Client 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 SOW when conducting their analysis.

(c) Third Party Expert Determination.

(i) If the Third Party Expert determines that the CGMP Batch was a Conforming CGMP Batch: (A) the CGMP Batch will be deemed Conforming CGMP Product as of the date that Cytovance and Client determined the CGMP Batch was a Conforming CGMP Batch in accordance with Section [7.6\(c\)](#); and (B) Client shall pay the fees and expenses of the Third Party Expert.

(ii) If the Third Party Expert makes any other determination, including, but not limited to, that the results are inconclusive or that the CGMP Batch was a Non-Conforming CGMP Batch but not as a result of Defective CGMP Manufacturing, Client shall pay the fees and expenses of the laboratory or consultant and will have no remedy against Cytovance for the Non-Conforming CGMP Batch.

(e) Latent Defects. Client will have six (6) months from the date a Conforming CGMP Batch is deemed Conforming CGMP Product to reject the Conforming CGMP Product because of a Latent Defect. However, if Conforming CGMP Product expires prior to the six-month period in the foregoing sentence, then Client will have until the Conforming CGMP Product expires to reject the Conforming CGMP Product because of a Latent Defect. Notice of rejection of Conforming CGMP Product because of a Latent Defect must be in writing and sent to Cytovance within two weeks of the discovery of the Latent Defect. The notice must detail how the Latent Defect resulted from Defective CGMP Manufacturing. The Parties will attempt in good faith to resolve a Latent Defect issue within 30 days of Cytovance's receipt of the Latent Defect notice. If Cytovance admits that the Latent Defect resulted from Defective CGMP Manufacturing, the remedy in Section 7.8(f) will apply. If Cytovance disputes that a Latent Defect resulted from Defective CGMP Manufacturing, the Parties will resolve the dispute in accordance with to Section 7.8.

(f) Replacement CGMP Batch or Credit.

(i) Client's sole and exclusive remedy for a Non-Conforming CGMP Batch resulting from Defective CGMP Manufacturing is, at Client's sole discretion, either:

(1) A replacement CGMP Batch manufactured at Cytovance's expense, including the costs of replacement Raw Materials or

(2) A credit to Client's account equal to the fees charged for the Non-Conforming CGMP Batch, including any fees charged for the Raw Materials used in the manufacture of the Non-Conforming CGMP Batch.

(ii) However, if only a portion of a CGMP Batch is considered non-conforming as a result of Defective CGMP Manufacturing, at Client's sole discretion, Client's sole and exclusive remedy for the partially non-conforming CGMP Batch is either:

(1) A replacement CGMP Batch manufactured at Client's expense minus the fees charged for the manufacture of the partially Non-Conforming CGMP Batch multiplied by the percentage of the partially Non-Conforming CGMP Batch that was non-conforming as a result of Defective CGMP Manufacturing; or

(2) A credit to Client's account equal to the fees charged for the partially non-conforming CGMP Batch (inclusive of the fees charged for the Raw Materials used in the partially non-conforming CGMP Batch) multiplied by the percentage of the partially non-conforming CGMP Batch that was non-conforming as a result of Defective Manufacturing.

(g) **Client's Use of Non-Conforming CGMP Batch.** Client is only allowed to use a Non-Conforming CGMP Batch for testing and analysis to help determine why the CGMP Batch failed.

7.9 Fees for Canceling or Rescheduling a CGMP Batch. Unless a different cancellation provision is expressly stated in an SOW, the Parties agree that if Client cancels or reschedules a CGMP Batch (excepting Client's termination of the applicable SOW for cause), or a Batch is canceled or rescheduled as a result of Sections 8.1, 8.2, or 8.3, Client will pay to Cytovance as liquidated damages (which the Parties agree does not serve as a penalty) an amount equal to a percentage of the fees set forth in the applicable SOW for the canceled or rescheduled CGMP Batch in accordance with the following schedule:

<u>Days Prior Notice to Cytovance</u>	<u>Cancellation Fee for Canceled or Rescheduled CGMP Batch</u>
> 90	0%
60 to 90	50%
< 60	100%

7.10 Termination of CGMP Batches during CGMP Manufacturing. If Client terminates the manufacture of a CGMP Batch after Cytovance commences the CGMP Manufacturing Process for any reason (except termination of the applicable SOW for cause), Cytovance may withhold from Client the Deliverables (whether completed or uncompleted) from such CGMP Batch until Client pays all fees due for the CGMP Batch, which will be prorated according to the Services completed up to the time of termination of the terminated CGMP Batch.

8. Suspension of Services.

8.1 Failure to Pay Invoices. Unless different payment terms are set forth in the applicable SOW, upon notice to Client, Cytovance may immediately suspend any Services at any time, including the withholding of any Deliverables (whether completed or in-process), if Client has failed to pay an invoice within 60 days as required by Section 3.3. Cytovance will have no liability for the suspended Services or withheld Deliverables. Client shall pay any fees under Section 7.9 that result from the rescheduling or cancellation of any Batch affected by the suspension of Services, and any fees for the procurement of additional Raw Materials to replace Raw Materials that expired because of the suspended Services. Cytovance will resume the Services upon full payment of all invoices 60 or more days past due.

8.2 Failure to Maintain Approvals for Client Product. If Cytovance learns, or reasonably suspects in good faith, that Client does not maintain the appropriate approvals from any Regulatory Authorities for any Client Product as required by Section 2.5, Cytovance may, upon notice to Client, immediately suspend any Services, including the withholding of any Deliverables (whether completed or in-process), related to the Client Product at issue. Cytovance will have no liability for the suspended Services or withheld Deliverables. Client shall pay any fees under Section 7.9 that result from the rescheduling or cancellation of any Batch because of the suspension of Services, and any fees for the procurement of additional Raw Materials to replace Raw Materials that expired because of the suspended Services. Cytovance will resume the Services when Client demonstrates to Cytovance's reasonable satisfaction that Client has received and maintains the appropriate approvals from all necessary Regulatory Authorities for the manufacture of that Client Product. Any Services related to other Client Product not affected by this Section will continue in accordance with this Agreement and the applicable SOW.

8.3 Failure to Maintain Intellectual Property Rights. If Cytovance learns, or reasonably suspects in good faith, that Client does not maintain the appropriate intellectual property rights for Cytovance's use of Client Technology, Client Components, Client Equipment, or Client Product as required by Section 15.3(c) or Section 15.3(d), Cytovance may, upon notice to Client, immediately suspend Services and withhold any Deliverables (whether completed or in-process) affected by Client's failure to maintain the appropriate intellectual property rights. Cytovance will have no liability for the suspended Services or withheld Deliverables. Client shall pay any fees under Section 7.9 that result from the rescheduling or cancellation of any Batch because of the suspension of Services, and any fees for the procurement of additional Raw Materials to replace Raw Materials that expired because of the suspended Services. Cytovance will resume the Services when Client demonstrates to Cytovance's reasonable satisfaction that Client has received and maintains the appropriate intellectual property rights required by Sections 15.3(c) or 15.3(d). Any Services not affected by this Section will continue in accordance with this Agreement and the applicable SOW.

8.4 Force Majeure. Cytovance may suspend any Services because of a force majeure event described in Section 0.

9. Document and Sample Retention.

9.1 Cytovance Storage. Cytovance shall keep and maintain Service Documentation and Samples for a period of two (2) years after the completion of the relevant Services. Cytovance shall provide Client with electronic copies of all Service Documentation. Client shall pay all fees associated with such storage and maintenance of the Service Documentation and Samples up front and in full each year as set forth in the relevant SOW.

9.2 Return or Destruction Samples

(e) Conclusion of Storage Period. At the conclusion of the two-year retention period, Cytovance shall contact Client in writing to inquire whether Client desires Cytovance to destroy the Samples or transfer the Samples to Client or its designee. Within twenty (20) business days of receiving the notice from Cytovance, Client shall notify Cytovance in writing of its decision. If Cytovance does not receive an answer from Client within twenty (20) business days of delivery of the notice to Client, Cytovance may destroy the Service Documentation and Samples without any liability to Client.

(f) **Return of Documents and Samples.** If Client elects to have Cytovance transfer the Samples to Client or its designee, Client shall pay all fees and expenses related to the transfer of the Samples, including all shipping charges, shipping insurance, and Cytovance's labor in gathering and preparing the Samples for shipment, prior to the transfer of the Samples. Client shall pay Cytovance for transfer of the Samples net 30 from date of Cytovance Invoice.

10. Shipping.

10.1 In General. All items (including, but not limited to, Client Components, Client Equipment, Client Product, and Raw Materials) shipped from Cytovance to Client or Client's designee are delivered Ex Works (Incoterms 2010) Cytovance Facility. Client is responsible for all costs and risk of loss during shipment. Client shall procure (or have Cytovance procure), at Client's cost, insurance covering damage or loss of any items during shipping.

10.2 Cytovance Responsibilities.

(a) **Adherence to Client Instruction.** Cytovance shall package the items for shipment at Client's expense and in accordance with Client's written and reasonable instructions, or, if no instructions are applicable, then in accordance with Cytovance's SOPs.

(b) **Remedy.**

(i) **Items other than Client Product.** If Cytovance fails to package for shipment any items in accordance with Client's written and reasonable instructions or Cytovance's SOPs, as applicable, and that failure results in the damage or destruction of the item shipped, at Client's sole discretion, Client's sole and exclusive remedy is either: (i) Cytovance will credit to Client's account the value of the repairs (if the item is repairable), or (ii) pay the fair market value of the item (if the item is destroyed), minus any insurance proceeds available to Client from an insurance policy covering the item damaged or destroyed, or any insurance proceeds that would have been available to Client if the item should have been insured under this Agreement.

(ii) **Client Product.** If the item destroyed or damaged is Client Product, at Client's sole discretion, as Client's sole and exclusive remedy, Cytovance will either: (i) remanufacture Client Product at Cytovance sole expense; or (ii) credit to Client's account the fees charged by Cytovance for the portion of the Client Product that was damaged or destroyed as a result of Cytovance's failure to follow Client's written and reasonable instructions or Cytovance's SOPs, as applicable.

10.3 Imports. Client will be the importer of record for any items (including, but not limited to, Client Components, Client Equipment, and Raw Materials) shipped to Cytovance from a foreign country by or on behalf of Client or its designee. Client shall comply with all applicable United States import Laws and all applicable export Laws of the country of exportation. Client shall obtain and pay for any licenses, clearances, and other governmental authorization(s) necessary for the import of any items to Cytovance. Client shall select and pay the freight forwarder, who will solely be Client's agent. Client and its freight forwarder are solely responsible for preparing and filing any documentation required for the import.

10.4 Exports. Client will be the exporter of record for any items (including, but not limited to, Client Components, Client Equipment, Client Product, and Raw Materials) shipped out of the United States to Client or its designee. Client shall comply with all applicable United States export Laws and all applicable import Laws of the country of deportation. Client shall obtain and pay for any licenses, clearances, and other governmental authorization(s) necessary for the export of the items. Client shall select and pay the freight forwarder, who will solely be Client's agent. Client and its freight forwarder are solely responsible for preparing and filing the shipper's export declaration and any other documentation required for the export. In connection with the export of Client Product to Client or its designee, Cytovance will deliver to Client all certificates of analysis, certificates of conformity, and other documentation with respect to the Client Product that is required by applicable Law.

11. Client Product Recalls. If Client performs or is subject to a Recall, Client is responsible for coordinating the Recall. Client shall promptly notify Cytovance if any Client Product is the subject of a Recall and provide Cytovance with a copy of all relevant documents relating to the Recall. Client is responsible for all of the costs and expenses of such Recall, including any expenses incurred by Cytovance as a result of the Recall. Cytovance may notify any Regulatory Authority or other governmental or quasi-governmental authority of the necessity of a Recall of Client Product as required by applicable Law.

12. Audits and Facility Visits.

12.1 Manufacturing Audits.

(a) Duration and Frequency. Client, at its own expense, once per calendar year, upon at least 30 days' prior written notice to Cytovance (or 24 hours' prior written notice to Cytovance in the event of an incident involving the Facility or Services that immediately justifies Client's inspection or attention), may perform a Manufacturing Audit. The Manufacturing Audit must occur during normal business hours at mutually agreeable times, for not more than two business days, and include not more than two Client employees or representatives. All Client employees or representatives conducting the audit must be qualified to conduct a Manufacturing Audit.

(b) Enlarged Audits. If the Parties agree to more than one Manufacturing Audit in a calendar year, or to a Manufacturing Audit that occurs outside normal business hours, lasts for more than two business days, or involves more than two Client employees or representatives, Client shall pay a reasonable fee to Cytovance to compensate Cytovance for accommodating the enlarged Manufacturing Audit. The fee will be specified in an SOW or Change Order.

(c) For Cause Audits. Upon reasonable advance notice to Cytovance, Client may conduct a "for cause" audit if Cytovance exhibits a material deficiency with CGMP requirements relating to Client Product. The notice must set forth the specific deficiency exhibited by Cytovance and the justification for the "for cause" audit. The scope of a "for cause" audit is limited to the material or deficiency contained in the notice to Cytovance and must only directly relate to the Client Product at issue. The timing, duration, and Client employees or representatives allowed to participate in the "for cause" audit must reflect the limited scope of the audit.

(d) **Confidentiality.** All audited information, data, and documents examined during a Manufacturing Audit or “for cause” audit will be treated as Confidential Information of Cytovance (except the information, data, or documents that are Client Confidential Information), and Client may not remove or copy any Cytovance Confidential Information data without Cytovance’s prior written consent.

12.2 Facility Visits.

(a) **Virtual Audit.** Prior to or in connection with the commencement of the Services, Client may conduct a virtual audit of Cytovance’s Facilities. Cytovance will not charge Client for accommodating the virtual audit.

(b) **Duration and Frequency.** Client, at its own expense, up to two times per calendar year, upon at least ten (10) days’ prior written notice to Cytovance, may visit Cytovance’s Facilities to casually observe the Services. The visit must occur during normal business hours at mutually agreeable times, up to four hours during one business day, and include not more than two Client employees or representatives. Access to the Facility is limited to the public areas of the Facility and the areas of the Facility in which Client Product is in process. However, access to the actual manufacturing suite where Client Process is being manufactured is prohibited.

(c) **Enlarged Facility Visits.** If the Parties agree to more than two Facility visits in a calendar year, or to a Facility visit that occurs outside normal business hours, lasts for more than four hours or occurs over more than one business day, or involves more than two Client employees or representatives, Client shall pay a reasonable fee to Cytovance to compensate Cytovance for accommodating the enlarged Facility visit. The fee will be specified in an SOW or Change Order.

12.3 Person in the Plant. If necessitated by the Services and agreed upon by the Parties, Client may have one or more Persons in the Plant. Each Person in the Plant will not be an employee, agent, or independent contractor of Cytovance for any purpose. Cytovance’s fees for supporting the Person(s) in the Plant will be set forth in the SOW.

12.4 Liability of Client. All Client employees and representatives conducting the initial virtual audit, a Manufacturing Audit, or “for cause” audit, visitors to the Facility on Client’s behalf, and Person(s) in the Plant must: (a) adhere to all Cytovance safety procedures and Facility access rules and restrictions while located at the Facility; (b) not interfere with Cytovance’s operations or employees; and (c) refrain from inquiring about and investigating other clients of Cytovance or services provided by Cytovance to other clients. Cytovance may remove any individual from the Facility at any time for failing to adhere to the rules in this Section or any other reasonable rules or procedures implemented by Cytovance. Client will be liable to Cytovance for all damages caused by the acts or omissions of its employees and representatives conducting a Manufacturing Audit or “for cause” audit, visitors to the Facility on Client’s behalf, and Person(s) in the Plant.

12.5 Regulatory Authority's Audit of Cytovance. Any notice from Cytovance to Client regarding a Regulatory Authority's audit or inspection of Cytovance or the Facility will be handled in accordance with the Quality Technical Agreement.

13. Intellectual Property.

13.1 Inventorship. Inventorship of any Invention will be determined according to the patent laws of the United States of America.

13.2 Client Inventions. As between the Parties, Client will own all right, title and interest in and to any Client Inventions. Cytovance hereby irrevocably sells, assigns, and transfers to Client all of Cytovance's right, title, and interest in and to all Client Inventions. Cytovance shall cooperate with Client as may be necessary for the perfection, enforcement, or defense of any intellectual property rights in or to any Client Inventions.

13.3 Licenses to Cytovance. Client grants to Cytovance a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense to a subcontractor in accordance with Section [2.9](#)) to make, have made, use, and have used Client Technology, Client Inventions, Client Components, Client Equipment, and Client Product solely to the extent necessary to perform Services in accordance with this Agreement and the relevant SOW.

13.4 Cytovance Inventions. As between the Parties, Cytovance will own all right, title, and interest in and to any Cytovance Inventions that were discovered, first conceived, made, developed, or reduced to practice in performance of the Services. Except in the case of Cytovance Inventions which include or is based on Client Technology, Client hereby irrevocably sells, assigns, and transfers to Cytovance all of Client's right, title, and interest in and to all Cytovance Inventions. Client shall cooperate with Cytovance as may be necessary for the perfection, enforcement, or defense of any intellectual property rights in or to any Cytovance Inventions.

13.5 Licenses to Client. Cytovance grants to Client a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense) to use, have used, make, and have made Cytovance Inventions incorporated into Client Product solely for the purposes of making, having made, using, offering to sell, selling, having sold, importing, and exporting Client Product. However, the non-exclusive license from Cytovance to Client for the use of Cytovance's Keystone Expression System® or Cytovance's CHO expression system is not included in this Agreement, and will be set forth in a separate license agreement between Cytovance and Client.

13.6 No Implied Licenses. This Agreement does not confer upon a Party any right, title, or interest to or under any Patent, Know-How, or other intellectual property right owned or controlled by the other Party, except for those rights expressly granted in this Section [13](#). All rights, title, and interests not expressly conveyed herein are reserved by the respective Parties.

13.7 Technology Transfer Assistance. Client, at its option, may elect to engage a Third Party to perform the Services or services substantially similar to the Services during or after the termination or expiration of this Agreement. Cytovance will provide assistance to Client in transferring to the Third Party any and all of Client's rights in Client Inventions, Client Product, Client's licensed rights to Cytovance Inventions, and any other technology, processes, methodologies, and information necessary for the making, scale-up, processing, manufacture, filling, or bulk packaging of Client Product. However, Client shall compensate Cytovance for its time complying with this Section at an agreed-upon rate and reimburse Cytovance for its out-of-pocket expenses. Additionally, Client will be liable to Cytovance for any breach by the Third Party of any licenses from Cytovance to Client with regards to the Client Product under Section 13.5.

14. Confidentiality.

14.1 Disclosure of Confidential Information. The Parties may disclose its Confidential Information to the other in connection with this Agreement. Each Discloser warrants that it owns or is otherwise authorized to disclose its Confidential Information to the Recipient and that disclosure of its Confidential Information will not violate any obligations it has to any other Third Party. If a Discloser's Confidential Information contains any confidential or proprietary information belonging to another Third Party, the Discloser warrants that it is authorized to disclose that Third Party's information to the Recipient.

14.2 Previous Disclosures of Confidential Information. All information considered Confidential Information under the *Mutual Confidential Disclosure Agreement*, effective September 12, 2019 between the Parties is considered Confidential Information under this Agreement. This Agreement will control the handling of any Confidential Information of either Party, regardless of whether the Confidential Information was received under the agreement referred to in the foregoing sentence or under this Agreement.

14.3 Recipient Obligations. The Recipient may use the Discloser's Confidential Information solely for the Services and in furtherance of this Agreement. The Recipient shall not disclose to any Third Party any Confidential Information of the Discloser. The Recipient shall use at least the same degree of care to preserve the confidentiality of the Discloser's Confidential Information as the Recipient uses to protect its own Confidential Information, but in no event less than a reasonable standard of care. The Recipient shall promptly notify the Discloser upon the Recipient's discovery of any unauthorized use or disclosure of the Discloser's Confidential Information.

14.4 Excluded Information. Any idea, documents, data, or information, in any form or medium, is not considered "Confidential Information" of the Discloser if the Recipient can demonstrate with competent evidence that such data or information: (a) is or becomes generally known or available through no breach of this Agreement by the Recipient; (b) is already known by the Recipient at the time of receiving the information from the Discloser; (c) is furnished to the Recipient by a Third Party on a non-confidential basis and the Third Party is not known or suspected by the Recipient to be bound by confidentiality obligations to the Discloser; or (d) is independently developed by the Recipient without any use of the Discloser's Confidential Information. An exception to Confidential Information will not apply to a combination of items of Confidential Information if one or more individual items of the combination, but not all, fall within the exception.

14.5 Permitted Disclosures.

(a) **Authorized Agents.** The Recipient may disclose the Discloser's Confidential Information to its Authorized Agents in connection with the performance of Services or exercising Recipient's rights under this Agreement who have signed confidentiality agreements containing, or are otherwise bound by, confidentiality obligations at least as restrictive as those in this Agreement.

(b) **Compelled Disclosure.** The Recipient may disclose the Discloser's Confidential Information in response to a valid order, rule, or regulation of a court or governmental body with competent jurisdiction. However, the Recipient shall first give notice to the Discloser (if legally permissible and practicable) so that the Discloser may intervene and seek a protective order or other remedy.

(c) **Investors and Acquirers.** The Recipient may disclose the Discloser's Confidential Information to actual or prospective Third Party investors, lenders, or acquirers of the Recipient to the extent relevant and for the purpose of evaluating any actual or potential investment, lending relationship, or acquisition of the Recipient if each such Third Party is bound by obligations of confidentiality and non-use substantially consistent with those contained in this Agreement and the Recipient informs the Third Party of the restrictions and obligations under this Agreement prior to such disclosure.

(d) **Client Product Disclosures.** Client may disclose Cytovance's Confidential Information: (i) to potential investors, acquirers, or licensees of Client Product, (ii) to Regulatory Authorities in Investigational New Drug Applications; or (iii) to obtain governmental licenses or marketing approval, including a Biologics License Application, regarding Client Product. However, Client must limit disclosure of Cytovance's Confidential Information to what is reasonably necessary to satisfy the applicable requirements of such regulatory agency and seek to avoid or minimize any disclosure to the public of such Confidential Information.

14.6 Ownership; No License. As between the Parties, the Discloser's Confidential Information is the property of the Discloser. Except as described in Section [13](#), this Agreement does not grant the Recipient any property rights, by license or otherwise, to any of the Discloser's Confidential Information, nor to any intellectual property right based on the Discloser's Confidential Information.

14.7 Return or Destruction of Confidential Information. Upon termination or expiration of this Agreement, if requested in writing by the Discloser, the Recipient shall promptly return to the Discloser or destroy (and certify the destruction of) the Discloser's Confidential Information in the Recipient's possession. However, the Recipient may retain one copy of the Discloser's Confidential Information for legal or regulatory compliance reasons and will not be required to access or delete electronic backup, active archive, or archived copies of the Discloser's Confidential Information that were generated in accordance with the Recipient's bona fide backup or archiving practices. Any copies of the Discloser's Confidential Information retained by the Recipient will remain subject to the confidentiality and non-use provisions of this Agreement (and exceptions thereto).

14.8 Term of Confidentiality. A Recipient's obligations under this Agreement (and exceptions thereto) with respect to confidentiality and non-use of the Discloser's Confidential Information will remain binding upon the Recipient for a period of five years after the date of this Agreement's expiration or termination.

15. Representations and Warranties.

15.1 General Covenants, Representations and Warranties. Each Party represents and warrants to the other Party that:

(a) It has the full right and authority to enter into this Agreement and to perform this Agreement in accordance with its terms.

(b) Neither the execution of this Agreement nor the performance of or compliance with this Agreement will: (i) conflict with or result in a breach of any provision of the Party's certificate of incorporation, bylaws, or similar governing documents; or (ii) conflict with any obligations to, or any agreements with, any Third Party.

(c) It has obtained and will at all times during the term of this Agreement maintain and comply with all licenses, permits, and authorizations necessary to perform its obligations under this Agreement as required by applicable Law.

(d) It is in good standing under the laws of each state or other jurisdiction in which it is incorporated or engages in business activities.

15.2 Cytovance Representations and Warranties. Cytovance represents and warrants to Client that:

(a) Cytovance will perform the Services in accordance with the Service Standard and Client Product will be manufactured in accordance with the applicable Manufacturing Process and, if a CGMP Batch, be manufactured free of Defective CGMP Manufacturing.

(b) Cytovance is not under investigation by the FDA for debarment, nor is Cytovance presently or in the last five years been debarred, pursuant to 21 U.S.C. §335a or any other similar applicable Law, and Cytovance will not knowingly use the services of any person or Entity debarred or suspended under 21 U.S.C. § 335a in any capacity related to the Services.

(c) Cytovance will not knowingly hire or retain as an officer or employee any individual who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Food, Drug, and Cosmetic Act.

(d) At all times during the Services Cytovance will maintain adequate comprehensive public liability and property damage insurance, or equivalent programs of self-insurance, with single limits of at least \$2,000,000 per occurrence and \$5,000,000 in the aggregate. Cytovance agrees to issue to Client a Certificate of Insurance evidencing such coverage within 30 days of Client's written request. Any deductible and self-insurance retention is the sole responsibility of Cytovance.

15.3 Client Representations and Warranties. Client represents and warrants to Cytovance that:

- (a) Client shall: (i) provide complete and accurate scientific data necessary to Cytovance's performance of Services; (ii) provide Cytovance with all information necessary to effect the reliable transfer of Client Technology to Cytovance for performance of the Services; (iii) provide Cytovance with sufficient Client Components necessary for the performance of Services; (iv) if applicable, review and approve in-process and finished Client Product test results; and (v) be responsible for the preparation of all Client Product-related submissions to Regulatory Authorities and other governmental and quasi-governmental entities.
- (b) Client will maintain all appropriate regulatory approvals required by Section 2.5. Client will promptly notify Cytovance if it fails to maintain any of these approvals.
- (c) Client will retain all rights, title, and interest in and to Client Components, Client Equipment, Client Technology, and Client Product necessary for Cytovance's performance of Services, including all rights necessary for Cytovance to manufacture Client Product in accordance with this Agreement. Client will promptly notify Cytovance if it fails to maintain any of these rights.
- (d) Cytovance's use of Client Components, Client Equipment, Client Technology, and Client Product will not violate or infringe on the Patents, Know-How, trademarks, service marks, copyrights, any other intellectual property right, or confidential information of any Third Party. Client will promptly notify Cytovance if it learns or suspects that any of these Third Party will be violated by Cytovance's use of Client Components, Client Equipment, Client Technology, and Client Product.
- (e) Client will hold, use, market, sell, and dispose of any Deliverables provided by Cytovance to Client in accordance with all applicable Law.
- (f) Client will procure and maintain, from the Effective Date through the date that is two years after the expiration date or last date of use (whichever is later) of all Client Product produced under this Agreement, commercial general liability, clinical trial product liability, and contractual liability insurance coverage (the "Client Insurance"). Each type of coverage of the Client Insurance must cover amounts not less than \$3,000,000 per occurrence and must be with an insurance carrier reasonably acceptable to Cytovance. Client shall name Cytovance as an additional insured on the Client Insurance and Client shall promptly deliver a certificate of Client Insurance and endorsement of additional insured to Cytovance evidencing such coverage. If Client fails to furnish such certificates or endorsements, or if at any time during the term of this Agreement Cytovance learns of the cancellation or lapse of the Client Insurance and Client fails to rectify the same within 10 days after notice from Cytovance, Cytovance, at its option, may terminate this Agreement. Any deductible and self-insurance retention is the sole responsibility of Client.

15.4 Warranty Disclaimer. EXCEPT FOR THE WARRANTIES EXPRESSLY STATED IN THIS SECTION 15 AND SECTION 14.1, NEITHER PARTY PROVIDES TO THE OTHER PARTY ANY WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIALS AND SERVICES PROVIDED UNDER THIS AGREEMENT, AND EACH PARTY WAIVES ALL SUCH WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

16. Limitations of Liability.

16.1 Remedies for Failed Services. THE REMEDIES IN SECTION [4.1\(e\)](#), SECTION [4.2\(f\)](#), SECTION [4.3\(e\)](#), SECTION [5.3](#), SECTION [6.4](#), SECTION [7.4](#), SECTION 7.8(f), AND SECTION [10.2\(b\)](#), AS APPLICABLE, CONSTITUTE THE SOLE AND EXCLUSIVE REMEDY OF CLIENT AND THE SOLE AND EXCLUSIVE LIABILITY OF CYTOVANCE FOR FAILED SERVICES OR NON-CONFORMING DELIVERABLES CAUSED BY ANY REASON WHATSOEVER. UNDER NO CIRCUMSTANCES WILL CYTOVANCE BE LIABLE FOR INDIRECT, COLLATERAL, SPECIAL, CONSEQUENTIAL, PUNITIVE, OR OTHER DAMAGES, LOSSES, OR EXPENSES IN CONNECTION WITH THE PRODUCTION OR DELIVERY OF DELIVERABLES UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, LOSS OF USE, LOST PROFITS, THE COST OF COVER, OR THE COST OF A RECALL, REGARDLESS OF WHETHER SUCH CLAIMS FOR DAMAGES ARE FOUNDED IN TORT, CONTRACT, STATUTE, OR OTHER SOURCES OF LAW.

16.2 Limit of Liability.

(a) **Waived Damages.** WITHOUT LIMITING A PARTY'S DUTY TO DEFEND AND INDEMNIFY THE OTHER PARTY AGAINST A THIRD PARTY CLAIM AS DESCRIBED IN SECTION [17](#), NEITHER PARTY WILL BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL, EXEMPLARY, OR SPECIAL DAMAGES, WHETHER OR NOT FORESEEABLE, ARISING IN CONNECTION WITH THE DEFAULT OR BREACH OF ANY OBLIGATION OF THE OTHER PARTY UNDER THIS AGREEMENT, ANY SOW, THE QUALITY TECHNICAL AGREEMENT, OR ANY OTHER DOCUMENTS RELATED THERETO.

(b) **Maximum Liability.** NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL CYTOVANCE'S TOTAL LIABILITY TO CLIENT EXCEED SIX MILLION DOLLARS.

17. Indemnification.

17.1 By Client.

(a) **Duty to Defend.** Except to the extent a claim for indemnification results from the fraud or criminal conduct of Cytovance, Client shall defend each and all Cytovance Indemnitees against any Third Party lawsuit, action, claim, demand, assessment, proceeding, or subpoena (collectively, a “Claim”) arising directly or indirectly from or related to one or more of the following: (i) Client’s breach, violation, non-compliance, or non-performance of any of the terms of this Agreement; (ii) Client’s gross negligence or willful misconduct; (iii) the acts and omissions of any person who visits the Facility on behalf of Client, including auditors, Facility visitors, and Persons in the Plant; (iv) the destruction of Client Components in accordance with Section [4.1\(e\)](#); (v) any suspension of Services or withholding of Deliverables (whether completed or in-process) in accordance with Section [3.3](#) or Sections [8.1–8.3](#); (vi) the destruction of Service Documentation and Samples in accordance with Section [9.2](#); (vii) Client’s violation of the terms of any Third Party Licensed Materials used in the production of Client Product or incorporated into Client Product; (viii) the marketing, distribution, or use of any Deliverables (including, but not limited to, Client Product, Conforming CGMP Product, and Client Product from Non-Conforming CGMP Batches); (ix) any allegation that the composition of matter or use of Client Technology infringes the Patents, Know-How, trademarks, service marks, copyrights, any other intellectual property rights, or confidential information rights of a Third Party; and (x) any allegation that the composition of matter or use of Deliverables infringes the Patents, Know-How, trademarks, service marks, copyrights, any other intellectual property rights, or confidential information rights of a Third Party.

(b) **Duty to Indemnify.** In addition to Client’s duty to defend, with regards to any Claim in Section [17.1\(a\)](#), except to the extent a claim for indemnification results from the fraud or criminal conduct of Cytovance, Client shall indemnify any Cytovance Indemnitee against any loss, cost, damage, or expense, including attorney fees and litigation expenses (collectively, “Loss”), awarded to any Third Party or agreed to in a settlement by Cytovance with that Third Party in accordance with Section [17.4](#).

(c) **Breach of Duty to Defend or Indemnity.** If Client breaches its duty to defend and indemnify a Cytovance Indemnitee in accordance with Sections [17.1\(a\)](#) and Section [17.1\(b\)](#), Client shall reimburse that Cytovance Indemnitee for its attorney fees and any Loss incurred as a result of the Third Party Claim and the reasonable attorney fees and litigation expenses incurred by that Cytovance Indemnitee in recouping the Loss from Client.

17.2 By Cytovance.

(a) **Duty to Defend.** Except to the extent a claim for indemnification results from the fraud or criminal conduct of Client, Cytovance shall defend each and all Client Indemnitees against any Third Party Claim arising directly or indirectly from or related to one or more of the following: (i) Cytovance’s breach, violation, non-compliance, or non-performance of any of the terms of this Agreement; (ii) Cytovance’s gross negligence or willful misconduct; (iii) Cytovance’s breach of its obligations with respect to any Third Party Licensed Materials used by Cytovance in the Services; and (iv) any claim that Cytovance Technology infringes the Patents, Know-How, trademarks, service marks, copyrights, any other intellectual property rights, or confidential information rights of a Third Party.

(b) **Duty to Indemnify.** In addition to Cytovance’s duty to defend, with regards to any Claim in Section [17.2\(a\)](#), except to the extent a claim for indemnification results from the fraud or criminal conduct of Client, Cytovance shall indemnify Client against any Loss awarded to any Third Party or agreed to in a settlement by Client with that Third Party in accordance with Section [17.4](#).

(c) **Breach of Duty to Defend or Indemnity.** If Cytovance breaches its duty to defend and indemnify a Client Indemnitee in accordance with Sections [17.2\(a\)](#) and Section [17.2\(b\)](#), Cytovance shall reimburse that Client Indemnitee for its attorney fees and any Loss incurred and the reasonable attorney fees and litigation expenses incurred by that Client Indemnitee in recouping the Loss from Cytovance.

17.3 Indemnification Procedure.

(a) **Notice of Claim.** A Cytovance Indemnitee or Client Indemnitee entitled to defense and indemnification under Section 17.1 or Section 17.2 (the “Indemnified Party”) shall inform the indemnifying Party (the “Indemnifying Party”) of the Third Party Claim giving rise to the duty to defend and indemnify within seven days after receiving notice of such Claim. Delayed or late notice will not absolve an Indemnifying Party of its indemnification obligations to the Indemnified Party, but the Indemnifying Party will not be responsible for any Loss resulting solely from a delayed or late notice.

(b) **Acceptance of Claim.** Within seven (7) days of receipt of the notice of Claim, the Indemnifying Party shall give the Indemnified Party notice of whether it accepts or in good-faith disputes its duty to defend and indemnify. If the Indemnifying Party accepts its duty to defend and indemnify, the Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party, at its own expense and with counsel of its choice, will have the right to participate in the defense of any Claim that has been assumed by the Indemnifying Party.

(c) **Dispute of Duty to Indemnify.** An Indemnifying Party’s good-faith dispute of its duty to defend and indemnify does not absolve the Indemnifying Party of its actual duty to defend and indemnify the Indemnified Party. Moreover, the Indemnified Party is free pursue any remedy available at law, equity, and as described in Section 17.1(c) or Section 17.2(c), as applicable, to require the Indemnifying Party to fulfill its duty to defend and indemnify.

17.4 **Settlement with a Third Party.** No Indemnifying Party will be obligated to indemnify an Indemnified Party in connection with any settlement of a Claim made by the Indemnified Party without the Indemnifying Party’s written consent. However, the Indemnifying Party shall not unreasonably withhold, condition, or delay its consent. If an Indemnifying Party receives notice of the Indemnified Party’s intent to settle a Claim and does not respond within seven days, the Indemnifying Party will be presumed to have consented to the settlement.

18. Terms of this Agreement, the Quality Technical Agreement, and SOWs.

18.1 Term of this Agreement.

(a) **Initial Term.** The term of this Agreement commences on the Effective Date and ends on the fifth anniversary of the Effective Date or the date this Agreement is terminated pursuant to Section 19, whichever occurs first, subject to the provisions of Section 18.4.

(b) **Limited Extension.** In the event Section 18.4 applies, this Agreement will continue solely with respect to any in-process SOW until that SOW(s) is completed or is terminated, and no other SOWs may be entered into by the Parties under this Agreement.

(c) **Extension of Term.** Regardless of whether Section 18.4 applies, prior to the expiration of the initial term of this Agreement, the Parties may agree in writing to extend the term of this Agreement, with or without modification or amendment.

18.2 Term of Quality Technical Agreement.

(a) **Initial Term.** The term of the Quality Technical Agreement will expire upon the termination of this Agreement, subject to the provisions of Section 18.4 if not otherwise renewed as part of any extension of this Agreement as set forth in Section 18.1(c).

(b) **Limited Extension.** In the event Section 18.4 applies, the Quality Technical Agreement will continue solely with respect to the in-process SOW until that SOW(s) is completed or is terminated.

18.3 Term of SOW. The term of any SOW will expire on the earlier of: (i) the completion of Services under such SOW; or (ii) the date such SOW is terminated pursuant to Section 19. The termination of any SOW will not cause the termination of this Agreement, the Quality Technical Agreement, or any other SOW.

18.4 Termination of Agreement and Uncompleted SOWs. If this Agreement is terminated or expires and a SOW is then in process but has not yet completed, the SOW will continue in accordance with its terms and the terms of this Agreement and the Quality Technical Agreement (if applicable to any in-process SOW) until completion of the SOW or the termination of the SOW pursuant to Section 19.

19. Justifications for Termination.

19.1 Termination for Convenience.

(a) **Termination of Agreement.** Client may terminate this Agreement for convenience by providing one hundred eighty (180) days' prior written notice to Cytovance. Upon receipt of such notice of termination for convenience, Cytovance will scale down the affected portion of any in-process SOW and avoid (or minimize, where non-cancelable) any further related expenses. All fees and reimbursements, if any, for termination of this Agreement will be paid as set forth in Section 20.

(b) **Termination of SOW.** Unless otherwise stated in the SOW, Client may terminate any SOW for convenience by providing 90 days' prior written notice to Cytovance. Upon receipt of such notice of termination for convenience, Cytovance will scale down the affected portion of the SOW and avoid (or minimize, where non-cancelable) any further related expenses. All fees and reimbursements, if any, for termination of an SOW under this Section will be paid as set forth in Section 20.

19.2 Termination for Bankruptcy. Upon 30 days written notice to the other Party, either Party may terminate this Agreement if the other Party files for bankruptcy, reorganization, liquidation, or receivership proceedings (or is forced into such proceedings by another party), or the other Party assigns a substantial portion of its assets for the benefit of creditors.

19.3 Termination for Force Majeure. Upon written notice to the other Party, either Party may terminate this Agreement if a force majeure event results in a delay of either Party's performance under this Agreement for a period that exceeds 90 days as described in Section 0.

19.4 Termination for Cause.

(a) **Notice of Breach.** If either Party believes that the other is in material breach of this Agreement or an SOW, the Party may deliver notice of the breach to the breaching Party. The Party receiving the notice will have seven days from receipt of such notice to dispute the breach in good faith or commence a cure of the breach. If the Party receiving the notice commences a cure, it will have 60 days from receipt of the notice of breach to complete the cure, except when the breach is a non-payment of an invoice, in which case the breach must be cured within 15 days from the date of notice.

(b) **Failure to Remedy Breach.** If the Party receiving the notice of breach fails to cure or dispute the breach within the applicable periods set forth Section [19.4\(a\)](#), the Party delivering the notice of breach may terminate this Agreement or the applicable SOW, effective upon delivery of notice of termination to the other Party.

(c) **Dispute Regarding Breach.** If the Party receiving the notice of breach in good faith disputes that it is in breach or disputes that it failed to cure or remedy the breach, the matter will be addressed under Section [22](#). In such event, the notifying Party may not terminate this Agreement for cause until the date that it has been determined in accordance with Section [22](#) that the allegedly breaching Party is in material breach of this Agreement.

20. Effect of Termination.

20.1 Prior Obligations. Termination or expiration of this Agreement or any SOW will not relieve either Party of any obligations (including payment obligations) which accrued prior to the date of termination or expiration.

20.2 Payments to Cytovance. If Client terminates this Agreement or any SOW or Change Order for any reason, Client shall reimburse Cytovance for all: (i) Raw Materials, Third Party Licensed Materials, outsourced services, other supplies or services ordered by, and any other obligations incurred by, Cytovance pursuant to the terminated SOW(s) or Change Order(s) prior to termination; (ii) work-in-process commenced by Cytovance pursuant to any terminated SOW(s) or Change Order(s); and (iii) completed Client Product at applicable fees as of the date of termination. Any remaining Client Components will be handled pursuant to Section [4.1\(f\)](#). Any remaining Raw Materials will be handled pursuant to Section [4.2\(g\)](#). Storage fees for Client Equipment will accrue under Section [5.5](#) until the Client Equipment is returned to Client or its designee in accordance with Section [5.6](#).

21. Correspondence and Notices.

21.1 Ordinary Course Notices. Correspondence, reports, documentation, and any other written communications between the Parties in the ordinary course of performing this Agreement must be delivered by hand, or sent by mail, fax, or email or to the employee or agent of the other Party who is designated by the other Party to receive such written communication.

21.2 Other Notices. Any notices regarding this Agreement, other than ordinary course communications, must be delivered to the other Party at the address specified below or at such other address as the other Party specifies in writing. The notice must be in writing and will be deemed given: (a) upon personal delivery to the appropriate address; (b) if sent by certified mail to a recipient in the same country, three business days after the date of mailing (if mailed internationally, then seven business days after the date of mailing), or the date that the recipient signs for the delivery, whichever occurs first; or (c) if sent by reputable overnight courier, the next business day that the courier regularly makes deliveries.

All correspondence to Client must be addressed as follows:

GT Biopharma, Inc.
9350 Wilshire Blvd., Suite 203
Beverly Hills, CA 90212
Attention: Anthony Cataldo, CEO and Steve Weldon, CFO

All correspondence to Cytovance must be addressed as follows:

Cytovance Biologics, Inc.
800 Research Parkway, Suite 200
Oklahoma City, Oklahoma 73104
Attention: Matt Delaney, VP of Business Development
Email: mdelaney@cytovance.com
info@cytovance.com

with a copy to:

John B. Davis & Associates, PLLC
101 Park Avenue, Suite 250
Oklahoma City, Oklahoma 73102
Attention: John B. Davis
Email: john@jbdavislaw.com
info@jbdavislaw.com

22. Dispute Resolution.

22.1 Disputes Regarding Client Product. Any dispute regarding Cytovance's performance of research and development Services, including the manufacture of an R&D Batch, the manufacture of an Engineering Batch, or the manufacture of a CGMP Batch (including Latent Defects) will be handled in accordance with Section 6.2, Section 7.2, and Section 7.8, as applicable.

22.2 Good Faith Negotiations. Prior to initiating any court, administrative, or other action to enforce or terminate this Agreement, the claimant shall give notice to the other Party detailing the nature of the dispute and all relevant facts. Upon the other Party's receipt of the notice, the Parties shall in good faith attempt to resolve such dispute. No court, administrative, or other action may be initiated until the Parties have exhausted good faith settlement attempts by direct negotiation, which will take no more than 30 days unless otherwise agreed by the Parties.

22.3 Injunctive Relief. If the either Party breaches this Agreement, the aggrieved Party may suffer an irreparable injury that no remedy at law would adequately compensate the aggrieved Party for such injury. Accordingly, the aggrieved Party will have the right to enforce this Agreement by injunction or other equitable relief, without bond and without prejudice to any other rights and remedies that the aggrieved Party may have for the other Party's breach of this Agreement.

22.4 Choice of Law and Venue. This Agreement is governed by and will be construed in accordance with the laws of the State of Delaware without regard to its conflicts of laws principles and, if applicable, the federal laws of the United States. Any lawsuit regarding this Agreement must take place in the state courts of Delaware located in New Castle County, Delaware, and each Party consents to the jurisdiction of these courts. However, if federal jurisdiction exclusively applies to any issue regarding this Agreement, each Party consents to the jurisdiction of the federal courts located in New Castle County for resolution of that issue and the remaining issues (if any) may be heard by that federal court or the Delaware state courts in New Castle County in accordance with applicable subject matter jurisdiction rules.

22.5 Attorney Fees. The successful Party in any litigation or other dispute resolution proceeding to enforce the terms and conditions of this Agreement will be entitled to recover from the other Party reasonable attorney fees and related costs incurred in connection with such litigation or dispute resolution proceeding, to be determined by the presiding court or other dispute resolution official.

23. Publicity. Without the prior written consent of the other Party, neither Party will make any public announcement, issue any press release, nor use the name of the other Party or its employees in any advertising or sales promotional material.

24. Non-solicitation of Employees. From the Effective Date until 12 months after the expiration or termination of this Agreement, neither Party may, nor cause a Third Party to, directly solicit or recruit any employee, consultant, or contractor of the other Party to terminate his, her, or its relationship with the other Party in order to accept or enter into any employment or independent contractor or other business relationship with any Third Party. However, either Party may engage, hire, or enter into business with any employee, consultant, or contractor of the other Party who contacted the Party without direct solicitation or recruitment by the Party or a Third Party at the direction of the Party. Additionally, this Section does not prohibit either Party, whether by itself or through a Third Party, from advertising any open positions of employment to the general public.

25. Force Majeure.

25.1 Force Majeure Event. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, earthquakes, hurricanes, acts of nature, embargoes, war, acts of war (whether declared or not), acts of terrorism, insurrections, riots, civil unrest, labor strikes, lockouts or other labor disturbances, epidemics, pandemics or other public health disasters, acts of God, government imposed business closures resulting from "Shelter-in-Place" orders, or omissions or delays in acting by any governmental authority.

25.2 Effect of Force Majeure Event. Any time specified or estimated for completion of performance inhibited by a force majeure event will be automatically extended for a period of 90 days from the end of such event to allow the affected Party(ies) to recover from the disability caused by the event. When a force majeure event occurs, the Parties will discuss in good faith the force majeure event's impact on the Services. If the force majeure event results in a delay of performance that exceeds 90 days, either Party may, but is not obligated to, terminate this Agreement.

25.3 Services Invalidated by Force Majeure Event. If any part of the Services is invalid as a result of a force majeure event and this Agreement is not terminated as a result of the force majeure event, Cytovance will, upon written request from Client, but at Client's sole cost and expense, repeat that part of the Services affected by the disability.

26. English Language. This Agreement, the Quality Technical Agreement, each SOW and Change Order, including their respective amendments, modifications, waivers, and other related documents, any notices required by this Agreement, and all litigation or dispute resolution proceedings relating to this Agreement must be in the English language. The English language will control any documents or proceedings also translated into another language.

27. Amendment and Modification. This Agreement may be amended or modified only by a written instrument duly executed by an authorized representative of each Party.

28. Waiver. A Party's waiver of any right or remedy under this Agreement must be in writing and signed by an authorized representative of the waiving Party. A Party's failure to enforce any right or remedy under this Agreement is not a waiver of any rights or remedies unless a written waiver is obtained from that Party.

29. Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party. Notwithstanding the foregoing sentence, either Party may, without the consent of the other Party, assign this Agreement to its Affiliate or to its successor in interest in connection with a sale, merger, acquisition, or similar transaction involving substantially all of its stock or assets. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section is null and void and of no legal effect.

30. **Binding Effect.** The terms and conditions of this Agreement are binding upon, and will inure to the benefit of, the Parties and their respective successors and assigns.
31. **Conflicts.** In the event of a conflict between the terms and conditions of this Agreement and any SOW, the terms and conditions of this Agreement will control. In the event of a conflict between any of the provisions of the Quality Technical Agreement and this Agreement with respect to quality responsibilities, including compliance with CGMP, the provisions of the Quality Technical Agreement will control. In the event of any other conflict between the provisions of the Quality Technical Agreement and this Agreement or any SOW (e.g., commercial terms, pricing, and dispute resolution), the provisions of this Agreement or the SOW, respectively, will prevail.
32. **Severability.** The provisions of this Agreement are severable and if any provision of this Agreement is determined to be invalid, illegal, or unenforceable for any reason, such provision will be adjusted rather than voided, to the extent possible, in order to achieve the intent of the Parties to this Agreement, and if adjustment is not possible, the provision will be severed from this Agreement. The remaining provisions of this Agreement will not be affected by the adjustment or severing of the invalid, illegal, or unenforceable term.
33. **No Third-Party Beneficiaries.** No third-party beneficiary rights are intended by this Agreement.
34. **Captions.** Captions are for reference only and may not affect the meaning or interpretation of this Agreement.
35. **Survival.**
36. **No Strict Construction.** This Agreement has been prepared jointly and will not be strictly construed against either Party
37. **Entire Agreement.** This Agreement, together with the Quality Agreement and each SOW, constitutes the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof.
38. **Counterparts.** This Agreement and each SOW may be executed electronically and in counterparts in any format, including facsimile versions or electronically delivered versions, each of which will be deemed to be an original and will fully bind each Party who has executed it, but all such counterparts together will constitute one and the same agreement.

[Remainder of page intentionally blank; signature page follows]

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

GT Biopharma, Inc.

Cytovance Biologics, Inc.

By: //ss _____

By: //ss _____

Name: Anthony Cataldo

Name: Mathew Delaney

Title: Chairman & CEO

Title: VP Marketing & Business Development

GT BIOPHARMA ANNOUNCES EXPANDED TRIKE PARTNERSHIP WITH CYTOVANCE BIOLOGICS
Sign \$6,000,000.00 Agreement

BEVERLY HILLS, CALIFORNIA, October 6, 2020 / Accesswire / -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) a company focused on developing innovative therapeutic treatments based on its proprietary NK cell engager (TriKE™) platform announced today that it had entered into a partnership agreement with Cytovance® Biologics, a USA-based contract development and manufacturing organization (CDMO) and a subsidiary of the Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (“Hepalink”).

Under the terms of the partnership agreement, Cytovance will be the exclusive GMP manufacture for three of the Company’s TriKE™ therapeutic product candidates. Cytovance will manufacture TriKE™ in accordance with GMP using Cytovance’s proprietary Keystone® bacterial or mammalian expression systems. Subject to the completion of certain milestones by Cytovance, GT Biopharma has the option to pay Cytovance up to \$6 million for its manufacturing services in either cash or in shares of the Company’s common stock valued at the time Cytovance achieves each of several milestones over the next 12 months.

Matt Delaney, MBA, M.I.B., Vice President Business Development & Marketing of Cytovance said “we are pleased to have been selected as GT Biopharma’s exclusive GMP manufacturer for its first three TriKE™ product candidates.” Mr. Delaney also stated “we believe our proprietary Keystone® bacterial or mammalian expression systems will deliver high production yields of TriKE™ further enhancing economies of scale.”

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented “we are pleased to have the opportunity to expand our partnership with Cytovance.” Mr. Cataldo further stated “the flexibility and breadth of our TriKE™ therapeutic platform allows us to quickly adapt to new disease targets, and rapidly advance TriKE™ product opportunities into the clinic.”

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology and infectious disease therapeutic products based our proprietary Tri-specific Killer Engager (TriKE™) platform. Our TriKE™ platform is designed to harness and enhance the cancer cell and virus infected cell killing using the patient's immune system NK cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using proprietary TriKE™ technology developed by researchers at the university to target NK cells.

About GTB-3550 TriKE™ FDA Clinical Trial

GTB-3550 is the Company's first TriKE™ product candidate being initially developed for the treatment of acute myeloid leukemia (AML). GTB-3550 is a tri-specific recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. The NK cell stimulating cytokine human IL-15 portion of the molecule provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We are presently evaluating GTB-3550 in a Phase I/II clinical trial (ClinicalTrials.gov [NCT03214666](https://clinicaltrials.gov/ct2/show/study/NCT03214666)) for the treatment of CD33 positive leukemias such as AML, myelodysplastic syndrome and other CD33+ hematopoietic malignancies.

About Cytovance® Biologics

Cytovance® Biologics is a leading biopharmaceutical Contract Development and Manufacturing Organization (CDMO) that excels in the rapid and cost-effective development and manufacture of large molecule active pharmaceutical ingredients (APIs) from both mammalian cell culture and microbial fermentation such as monoclonal antibodies, fragment antibodies, bispecific antibodies, enzymes, fusion proteins, vaccines, and other biological products including plasmid DNA and cell-based therapeutics. In addition to our clinical and commercial CGMP API manufacturing services, Cytovance offers well-integrated development services supporting the entire product lifecycle including cell line development, cell banking, microbial strain development, process and analytical development, and process characterization. A centralized, responsive program management team coordinates all critical chemistry, manufacturing and controls (CMC) activities for each client program including technology transfer, development, production, raw materials management, QC testing, ICH stability studies, and regulatory support. Our 140,000 sq. ft. state-of-the-art facilities in Oklahoma City are designed to meet the U.S., EU, and other global regulatory standards.

About Cytovance® Biologics Keystone Expression System™

The *Keystone Expression System*™ is an *E. coli*-based protein production platform that combines industry leading DNA synthesis technologies for gene and vector design (ATUM, Newark, CA) with Cytovance's standard microbial platforms for cell substrate development, fermentation, pilot, and CGMP manufacture with standard analytics and a phase-appropriate CMC approach.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the Company's expectations regarding the development of GTB-3550 TriKE™ including its intended therapeutic effect, and plans to conduct future clinical trials in humans. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "outlook", "believes", "target", "hopes", "intends", "estimates", "expects", "projects", "plans", "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not a guarantee of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended December 31, 2019 in the section titled "Risk Factors" in Part I, Item 1A and in our subsequent filings with the Securities and Exchange Commission, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our contemplated clinical trials for any of our drug product candidates, or to meet the FDA's requirements with respect to safety and efficacy, (iii) our ability to identify patients to enroll in our clinical trials in a timely fashion, (iv) our ability to achieve approval of a marketable product, (v) design, implementation and conduct of clinical trials, (vi) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vii) the market for, and marketability of, any product that is approved, (viii) the existence or development of treatments that are viewed by medical professionals or patients as superior to our products, (ix) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, and social conditions, and (x) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

For more information, please visit www.gtbiopharma.com.

Anthony Cataldo
800-304-9888
