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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

Commission File Number: 001-40023

GT BIOPHARMA, INC.
(Exact name of Registrant as specified in its charter)

Delaware	94-1620407
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

8000 Marina Blvd.
Suite 100
Brisbane, CA 94005
(Address of principal executive offices) (Zip code)

(415) 919-4040
(Registrant's telephone number including area code)
Securities registered pursuant to Section 12(b) of the Act: None.
Securities registered pursuant to section 12(g) of the Act:

Title of Securities	Exchanges on which Registered
Common Stock, $.001 Par Value	NASDAQ

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes □ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes □ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		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. □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☒

The aggregate market value of the registrant's common stock, $0.001 par value per share, held by non-affiliates on June 30, 2021 was approximately $372.3 million. As of March 28, 2022, there were 32,122,844 shares of the registrant's common stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

In Part III, portions of the registrant's 2022 Proxy Statement to be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year end.

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PART I

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including any documents which may be incorporated by reference into this Annual Report, contains "Forward-Looking Statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are "Forward-Looking Statements" for purposes of these provisions, including our plans of operation, any projections of revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All Forward-Looking Statements included in this document are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any Forward-Looking Statement. In some cases, Forward-Looking Statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "intends," "believes," "estimates," "potential," or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the Forward-Looking Statements contained herein are reasonable, there can be no assurance that such expectations or any of the Forward-Looking Statements will prove to be correct, and actual results could differ materially from those projected or assumed in the Forward-Looking Statements. Future financial condition and results of operations, as well as any Forward-Looking Statements are subject to inherent risks and uncertainties, including any other factors referred to in our press releases and reports filed with the Securities and Exchange Commission. All subsequent Forward-Looking Statements attributable to the company or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are described under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "GT Biopharma," "GTBP," "we," "us," "our," "the company" and "our company" refer to GT Biopharma, Inc., a Delaware corporation formerly known as DDI Pharmaceuticals, Inc., Diagnostic Data, Inc. and Oxis International, Inc., together with our subsidiaries.

ITEM 1. BUSINESS

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based on our proprietary Tri-specific Killer Engager (TriKE®) fusion protein immune cell engager technology platform. Our TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, resulting in the targeted cell's death. TriKE®s can be designed to target any number of tumor antigens on hematologic malignancies or solid tumors and do not require patient-specific customization.

We are using our TriKE® platform with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, and solid tumors. The platform is scalable, and we are putting processes in place to be able to produce investigational new drug (IND) ready moieties in a timely manner after a specific TriKE® conceptual design. Specific drug candidates can then be advanced into the clinic on our own or through potential collaborations with partnering companies. We believe our TriKE®s may have the ability, if approved for marketing, to be used as both monotherapy and in combination with other standard-of-care therapies.

We are also using our TriKE® platform to develop therapeutics useful for the treatment of infectious disease such as for the treatment of patients infected by the human immunodeficiency virus (HIV). While the use of anti-retroviral drugs has substantially improved the health and increased the longevity of individuals infected with HIV, these drugs are designed to suppress virus replication to help modulate progression to acquired immunodeficiency syndrome (AIDS) and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and re-establish an active HIV infection. For a curative therapy, destruction of these latent HIV infected cells must take place. The HIV-TriKE® contains the antigen binding fragment (Fab) from a broadly neutralizing antibody targeting the HIV-Env protein. The HIV-TriKE® is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells. The HIV-TriKE® induced NK cell proliferation and demonstrated the ability in vitro to reactivate and kill HIV-infected T-cells. These findings indicate a potential role for the HIV-TriKE® in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell's ability to mediate the antibody-directed cellular cytotoxicity (ADCC).

Our initial work has been conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under a program led by Dr. Jeffrey Miller, the Deputy Director. Dr. Miller is a recognized leader in the field of NK cell and IL-15 biology and their therapeutic potential. We have exclusive rights to the TriKE® platform and are generating additional intellectual property for specific moieties.

Immuno-Oncology Platform

Tri-specific Killer Engagers (TriKE®s)

The generation of chimeric antigen receptor, or CAR, expressing T cells from monoclonal antibodies has represented an important step forward in cancer therapy. These therapies involve the genetic engineering of T cells to express either CARs, or T cell receptors, or TCRs, and are designed such that the modified T cells can recognize and destroy cancer cells. While a great deal of interest has recently been placed upon chimeric antigen receptor T, or CAR-T, therapy, it has certain limitations for broad potential applicability because it can require an individual approach that is expensive, time consuming, and may be difficult to apply on a large scale. NK cells represent an important immunotherapeutic target as they are involved in tumor immune-surveillance, can mediate antibody-dependent cell-mediated cytotoxicity (ADCC), contain pre-made granules with perforin and granzyme B and can quickly secrete inflammatory cytokines, and unlike T cells they do not require antigen priming and can kill cells in the absence of major histocompatibility complex (MHC) presentation of antigens. Unlike full-length antibodies, TriKE® constructs are composed of a single-chain fusion protein that binds the CD16 receptor of NK cells directly producing a potent and lasting cytotoxic killing response, interleukin 15 (IL-15) to promote NK cell activation, persistence and proliferation, and a cancer cell targeting moiety. An additional benefit of TriKE® may have been its attractive biodistribution, as a consequence of their smaller size, which we expect to be important in the treatment of solid tumors. In addition to these advantages, TriKE® is designed to be non-immunogenic, have appropriate clearance properties, and can be engineered to target a variety of tumor antigens.

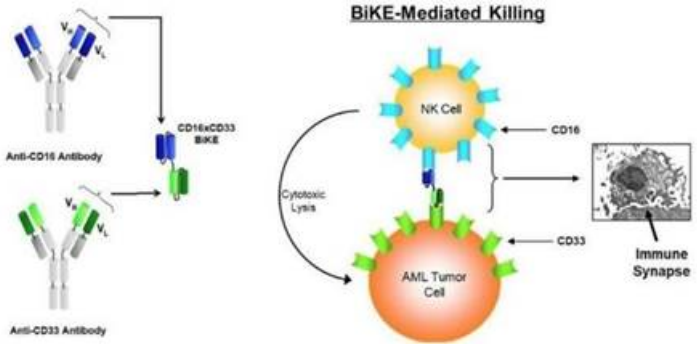
We believe there is a continued unmet medical need for targeted immuno-oncology therapies that can have the potential to be dosed in a patient-friendly outpatient setting, can be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, or be used in conjunction with more traditional cancer therapy. We believe our TriKE® constructs have this potential and therefore we have generated, and intend to continue to generate, a pipeline of product candidates to be advanced into the clinic on our own or through potential collaborations with larger companies.

GTB-3550 TriKE® and Phase 1 Acute Myeloid Leukemia/Myelodysplastic Syndrome (AML/MDS) Phase 1 Clinical Trial

GTB-3550 is the Company's first-generation TriKE® product candidate which is a single-chain, tri-specific recombinant fusion protein construct 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 GTB-3550 Phase 1 clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes and refractory/relapsed acute myeloid leukemia opened for patient enrollment September 2019 and completed enrollment in September 2021. The clinical trial was conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick and Dr. Mark Juckett.

Background and Select Non-Clinical Data

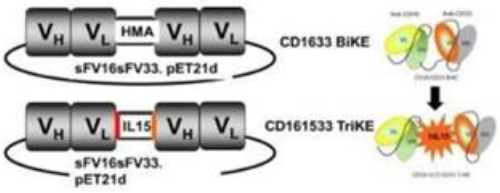
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating receptor on NK cells and CD33 (AML and MDS; see figure below), B7H3 (solid tumors – breast, lung, colon, prostate), PD-L1 (solid tumors), Her2 (Breast, Gastric), or CD19/CD22 (B cell lymphomas) on the tumor cells.



Subsequently, a tri-specific (TriKE®) construct that replaced the linker molecule between the CD16 scFv and the CD33 scFv with a modified IL-15 molecule, containing flanking sequences, was generated, and tested. Data indicates that the CD16 x IL-15 x CD33 potently induce proliferation of healthy donor NK cells, possibly greater than that induced by exogenous IL-15, which is absent in the BiKE platform. Targeted delivery of the IL-15 through the TriKE® also resulted in specific expansion of the NK cells without inducing T cell expansion on post-transplant patient samples.

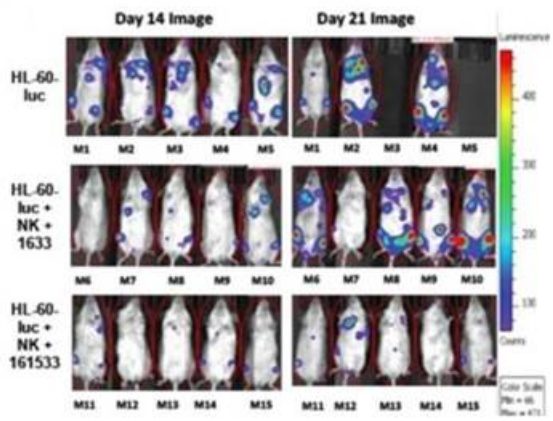
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE® is also capable of potently restoring killing capacity of post-transplant NK cells against CD33-expressing HL-60 targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-15 cytokine into the BiKE platform and also demonstrated the possibility of targeting a variety of cytokines directly to NK cells while reducing off-target effects and the amount of cytokines needed to obtain biologically relevant function.

The figure below is a schematic of a BiKE construct (top) and a TriKE® construct (bottom), which has the modified IL-15 linker between the CD16 scFv and the CD33 scFv components.



The TriKE® constructs were also tested against three separate human tumor cell lines: HL-60 (promyelocitic leukemia), Raji (Burkitt's lymphoma), and HT29 (colorectal adenocarcinoma), in addition to a model for ovarian cancer. All cell lines contained the Luc reporter to allow for in vivo imaging of the tumors. These systems were used to show in vivo efficacy of BiKE (1633) and TriKE® (GTB-3550) against relevant human tumor targets (HL-60-luc) over an extended period of time. The system consisted of initial conditioning of mice using radiation (250-275 cGy), followed by injection of the tumor cells (I.V. for HL-60-luc and Raji-luc, intra-splenic for HT29-luc and IP for ovarian for MA-148-luc), a three-day growth phase, injection of human NK cells, and repeated injection of the drugs of interest, BiKE and TriKE® (three to five times a week). Imaging was carried out at Day 7, 14, and 21, and extended as needed.

The figure below shows the results (tumor burden and mortality) when dosing NK cells alone (top panel), the BiKE version (lacking IL-15) of GTB-3550 (middle panel; called 1633), and the TriKE®, GTB-3550 (bottom panel; then called 161533) in the above human tumor model, HL-60-luc. In the NK-cell-only arm, two out of the five mice were dead by Day 21 with two of the surviving mice having extensive tumor burden as depicted by the colored images. In contrast, all five mice in each of the BiKE and TriKE® arms survived. In addition, the tumor burden in the TriKE®-treated mice was significantly less than in the BiKE-treated mice, demonstrating the improved efficacy from NK cells in the TriKE®-treated mice.



Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. The FDA requested that additional preclinical toxicology, additional information and clarifications on manufacturing, and clinical development plans. The requested additional information and clarifications were completed and incorporated into the IND in eCTD format. We filed the IND amendment in June 2018 and announced on November 1, 2018, that the FDA granted approval of the IND and the Company was authorized to initiate a first-in-human Phase 1 study with GTB-3550 in AML, MDS, and severe mastocytosis. The Phase 1 clinical trial was initiated in September 2019 and closed in September 2021.

Targeting Solid Tumors and Other Potentially Attractive Characteristics

Unlike full-length antibodies, TriKE® is composed of a single-chain fusion protein that binds the CD16 receptor of NK cells directly producing a potentially more potent and lasting response as demonstrated by preclinical studies. An additional benefit due to the smaller size of TriKE® is enhanced biodistribution which we expect to be important in the treatment of solid tumors. In addition to these potential advantages, TriKE® is designed to be non-immunogenic, have appropriate clearance properties and can be engineered quickly to target a variety of tumor antigens. We believe these attributes make them an ideal pharmaceutical platform for potentiated NK cell-based immunotherapies and have the potential to overcome some of the limitations of CAR-T therapy and other antibody therapies.

Examples of our earlier stage solid tumor targeting product candidates are focused on CD33, B7-H3, Her2, PD-L1, CD19, CLEC12A, CD22, and CD133 alone and in combination. We believe these constructs have the potential to target prostate, breast, colon, ovarian, liver, and head and neck cancers. Depending on the availability of drug supply, we hope to initiate human clinical testing for certain of our solid tumor product candidates in 2023.

Efficient Advancement of Potential Future Product Candidates – Production and Scale Up

We are using our TriKE® platform with the intent to bring to market multiple immuno-oncology products that can treat a range of hematologic malignancies and solid tumors. The platforms are scalable, and we are currently working with a third-party product manufacturer investigating the optimal GMP production expression system for TriKE® constructs.

We believe TriKE®s will have the ability, if approved for marketing, to be used as both monotherapy and in combination with standard-of-care therapies.

Immuno-Oncology Product Candidates

GTB-3550

GTB-3550 was our first TriKE® product candidate. It reflected our first-generation TriKE® platform. It is a single-chain, tri-specific scFv 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. We studied this anti-CD16-IL-15-anti-CD33 TriKE® in CD33 positive leukemias, a marker expressed on tumor cells in acute myelogenous leukemia, or AML, myelodysplastic syndrome, or MDS. CD33 is primarily a myeloid differentiation antigen with endocytic properties broadly expressed on AML blasts and, possibly, some leukemic stem cells. CD33 or Siglec-3 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC3, gp67, p67) is a transmembrane receptor expressed on cells of myeloid lineage. It is usually considered myeloid-specific, but it can also be found on some lymphoid cells. The anti-CD33 antibody fragment used for these studies was derived from the M195 humanized anti-CD33 scFV and has been used in multiple human clinical studies. It has been exploited as target for therapeutic antibodies for many years. We believe the recent approval of the antibody-drug conjugate gemtuzumab validates this targeted approach.

GTB-3550 is being replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, targeting CD33 positive relapsed/refractory Acute Myeloid Leukemia (AML) and Myelodysplastic Syndromes (MDS).

About High-Risk Myelodysplastic Syndromes

Myelodysplastic Syndromes is a rare form of bone marrow-related cancer caused by irregular blood cell production within the bone marrow. As a result of this irregular production, MDS patients do not have sufficient normal red blood cells, white blood cells and/or platelets in circulation. High-risk MDS is associated with poor prognosis, diminished quality of life, and a higher chance of transformation to acute myeloid leukemia. The goals of therapy are to reduce disease associated symptoms and the risk of disease progression and death, thereby improving both quality and quantity of life. United States incidence of MDS is estimated to be 10,000 cases per year, although the condition is thought to be under diagnosed. The prevalence has been estimated to be from 60,000 to 170,000 in the United States. Approximately 40% of patients with High-Risk MDS transform to AML, another aggressive cancer with poor outcomes.

About Acute Myeloid Leukemia

Acute myeloid leukemia is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets. The median age at the time of diagnosis is 65–69 years. AML is an aggressive disease and is fatal without anti-leukemic treatment. Among patients treated with chemotherapy, 65% to 80% achieve complete remission. Despite a plethora of novel agents that have been approved by the U.S. Food and Drug Administration since 2017 for treatment of AML, once complete remission (CR) is achieved, approximately 50% of patients age < 60 years of age and up to 90% of patients ≥ 60 years of age will relapse, despite consolidation strategies. Furthermore, while 10–40% of younger AML patients are primarily refractory to AML induction therapy, the number is considerably higher for patients above 60 years (40–60%). The vast majority of fit AML patients will undergo hematopoietic stem cell transplantation (HSCT) after achieving a CR. However, 40% of these patients relapse after HSCT. Thus, refractory or relapsed (r/r) AML is a very common scenario in AML and despite recent advances and new targeted therapies, the management of AML remains a challenge, particularly in older adults ineligible for intensive therapies. According to the National Cancer Institute (NCI), the five-year survival rate is about 35% in people under 60 years old, and 10% in people over 60 years old. Older people whose health is too poor for intensive chemotherapy have a typical survival of five to ten months. AML accounts for approximately 1.8% of cancer deaths in the United States.

About GTB-3550 TriKE® Clinical Trial

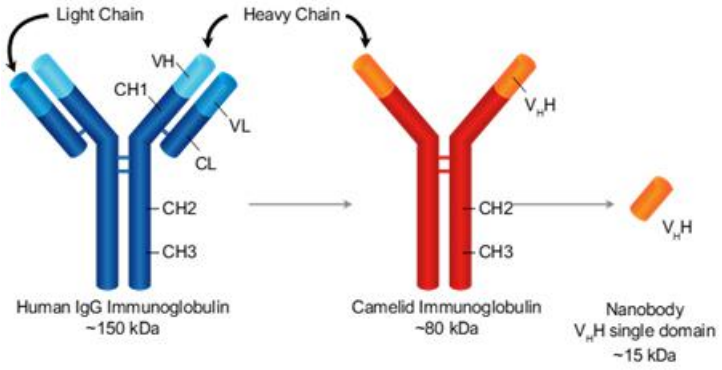
We opened our GTB-3550 Phase 1 clinical trial in September 2019 and enrolled our first patient in January 2020. Patients with CD33+ malignancies (primary induction failure or relapsed AML with failure of one reinduction attempt or high-risk MDS progressed on two lines of therapy) age 18 and older were eligible (ClinicalTrials.gov Identifier NCT03214666). The primary endpoint is to identify the maximum tolerated dose (MTD) of GTB-3550 TriKE®. Correlative objectives include the number, phenotype, activation status and function of NK cells and T cells. From January, 2020 until September, 2021 twelve patients received escalating doses of GTB-3550 in the Phase 1 trial. The results of this trial were presented at several conferences in 2021. To summarize, the therapy was overall well tolerated and safe. There were no serious cases of cytokine release syndrome observed. Four of twelve patients had transient reductions in bone marrow leukemic blast cells. Correlative studies showed activation, proliferation, and persistence of functionally active endogenous NK cells. The results of our first generation GTB-3550 Phase 1 clinical trial support our plans to advance the next generation camelid nanobody into the clinic.

The Next Generation of Camelid Nanobody TriKE®s

Our goal is to be a leader in immuno-oncology therapies targeting a broad range of indications including hematological malignancies and solid tumors. A key element of our strategy includes introducing a next-generation camelid nanobody platform. Camelid antibodies (often referred as nanobodies) are smaller than human immunoglobulin and consist of two heavy chains. These nanobodies have the potential to have greater affinity to target antigens, potentially resulting in greater potency. GT Biopharma is utilizing this camelid antibody structure for all its new TriKE® product candidates.

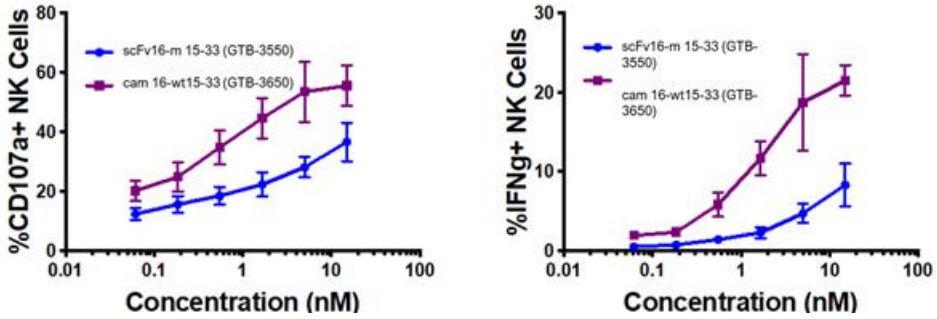
Generation of humanized single-domain antibody targeting CD16 for incorporation into the TriKE® platform

To develop second generation TriKE®s, we designed a new humanized CD16 engager derived from a single-domain antibody. While scFvs consist of a heavy and a light variable chain joined by a linker, single-domain antibodies consist of a single variable heavy chain capable of engaging without the need of a light chain counterpart (see figure below).



These single-domain antibodies are thought to have certain attractive features for antibody engineering, including physical stability, ability to bind deep grooves, and increased production yields, amongst others. Pre-clinical studies demonstrated increased NK cell activation against CD33+ targets including NK cell degranulation (% CD107a+) and IFNg of the single-domain CD16 TriKE® (cam 16-wt15-33; GTB-3650) compared to the original TriKE® (scFv16-m 15-33; GTB-3550) (see figure below). These data were published by Felices M et al (2020) in Cancer Immunol Res.

CD33+ HL60 Targets



GTB-3650

GTB-3650 is a CD33 targeted TriKE® which targets CD33 on the surface of myeloid leukemias. We are advancing GTB-3650 through preclinical studies and anticipate filing an Investigational New Drug (IND) for a Phase 1 clinical trial in the second half of 2022. This study will target patients with relapsed/refractory AML and high grade MDS.

GTB-5550

GTB-5550 is a B7-H3 targeted TriKE® which targets B7-H3 on the surface of advanced solid tumors. We are advancing GTB-5550 through preclinical studies and have initiated a GMP manufacturing campaign in anticipation of filing an IND and initiating a Phase 1 clinical trial in the second half of 2022 and the first half of 2023, respectively. This study will target patients with B7-H3 positive solid tumors.

Oncology Markets

Acute Myeloid Leukemia and Myelodysplastic Syndromes

AML is a heterogeneous hematologic stem cell malignancy in adults with incidence rate of 4.3% per 100,000 populations. The median age at the time of diagnosis is 68 years. AML is an aggressive disease and is fatal without anti-leukemic treatment. AML is the most common form of adult leukemia in the U.S. These patients will require frontline therapy, usually chemotherapy including cytarabine and an anthracycline, a therapy that has not changed in over 40 years. Myelodysplastic syndromes are a heterogeneous group of myeloid neoplasms characterized by dysplastic features of erythroid/myeloid/megakaryocytic lineages, progressive bone marrow failure, a varying percentage of blast cells, and enhanced risk to evolve into acute myeloid leukemia. It is estimated that over 10,000 new cases of MDS are diagnosed each year and there are minimal treatment options; other estimates have put this number higher. In addition, the incidence of MDS is rising for unknown reasons.

B7-H3 Positive Solid Tumors

The B7-H3 protein, which functions as a checkpoint inhibitor, has been identified in many of the most common solid tumor cancers, including but not limited to bladder, breast, cervical, colorectal, endometrial, esophageal, gastric, glioma, kidney, liver, lung, pancreatic, prostate, head and neck cancer, and melanoma. In recent studies, B7-H3 has been identified as a critical promoter of tumor cell proliferation, migration, invasion, epithelial-to-mesenchymal transition, cancer stemness and drug resistance. Because this protein does not seem to be expressed in normal cells, this makes it an attractive target for therapeutic intervention.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We rely on a third-party contract manufacturing operation to produce and/or test our compounds and expect to continue to do so to meet the preclinical and clinical requirements of our potential product candidates as well as for our future commercial needs. We do not have long-term commitments with a third-party product manufacturer. We require in our manufacturing and processing agreements that third-party product manufacturers produce intermediates, active pharmaceutical ingredients, or API, and finished products in accordance with the FDA's current Good Manufacturing Practices (cGMP), and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers to protect our proprietary rights related to our drug candidates.

Patents and Trademarks

Immuno-oncology platform

TriKE® Patents

On August 24, 2021, two patents were issued by the US Patent Office covering our pipeline of clinical and non-clinical product candidates consisting of tri-specific killer engagers, or TriKE®s, designed to target natural killer, or NK, cells and tumor or virus infected cells forming an immune synapse between the NK cell and the tumor cell thereby inducing NK cell activation at that site. The patents broadly include TriKE®s that target the CD16 receptor, which includes the more potent camelid nanobody sequence, an IL-15 activating domain, and any targeting domain.

University of Minnesota License Agreements

2016 Exclusive Patent License Agreement

We are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, ("UofMN") to further develop and commercialize cancer therapies using TriKE® technology developed by researchers at the University to target NK cells to cancer. Under the terms of the 2016 agreement, we received exclusive rights to conduct research and to develop, make, use, sell, and import TriKE® technology worldwide for the treatment of any disease, state or condition in humans. We are responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE® technology, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the University of Minnesota received an upfront payment of $200,000, annual license maintenance fees of $100,000 beginning in 2021, 4% royalty fees (not to exceed 6% under subsequent license agreements or amendments to this agreement), upon sale of a licensed product or a minimum annual royalty payment ranging from $250,000 to $5.0 million. The agreement also includes certain milestone payments totaling $3.1 million, and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales and $5.0 million upon reaching $500 million in cumulative gross sales of licensed products.

2021 Exclusive License Agreement

On March 26, 2021, we entered into an agreement with the UofMN specific to the B7H3 targeted TriKE®. Under the agreement, the UofMN received an upfront license fee of $20,000, and will receive annual license maintenance fees of $5,000 beginning in 2022, 2.5% to 5% royalty fees or minimum annual royalty payments of $250,000 beginning in the first year after the first commercial sale of licensed product, and $2.0 million beginning in the fifth year after the first commercial sale of licensed product. The agreement also includes certain milestone payments totaling $3.1 million and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million in cumulative gross sales of licensed products. There is no double payment intended; if one of the milestone payments has been paid under the 2016 agreement, no further payment is due for the corresponding milestone above.

Employees

At the date of this Annual Report, we had eight full-time employees. Many of our activities are outsourced to consultants who provide services to us on a project basis. As business activities require and capital resources permit, we will hire additional employees to fulfill our company's needs.

Form and Year of Organization

In 1965, the corporate predecessor of GT Biopharma, Diagnostic Data, Inc., was incorporated in the State of California. Diagnostic Data changed its incorporation to the State of Delaware in 1972, and changed its name to DDI Pharmaceuticals, Inc. in 1985. In 1994, DDI Pharmaceuticals merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. On July 17, 2017, we amended our Certificate of Incorporation for the purpose of changing our name from Oxis International, Inc. to GT Biopharma, Inc.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this Annual Report on Form 10-K before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline and you may lose part or all of your investment. In the opinion of management, the risks discussed below represent the material risks known to the company. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, financial condition and operating results and adversely affect the market price of our common stock.

Risks Related to Our Business

Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.

Our business is at an early stage of development. We do not have immune-oncology products in late stage clinical trials. We are still in the early stages of identifying and conducting research on potential therapeutic products. Our potential therapeutic products will require significant research and development and pre-clinical and clinical testing prior to regulatory approval in the United States and other countries. We may not be able to obtain regulatory approvals, enter clinical trials for any of our product candidates, or commercialize any products. Our product candidates may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We have a history of operating losses and we expect to continue to incur losses for the foreseeable future and we may never generate revenue or achieve profitability.

During the year ended December 31, 2021, the Company reported a net loss of $58.0 million and as of December 31, 2021, we had an accumulated deficit of $653.6 million. We have not generated any significant revenue to date and are not profitable, and have incurred losses in each year since our inception. We do not expect to generate any product sales or royalty revenues for the foreseeable future. We expect to incur significant additional operating losses for the foreseeable future as we expand research and development and clinical trial efforts.

Our ability to achieve long-term profitability is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if any of our products under development are successfully developed and produced and thereafter commercialized. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Even if we succeed in commercializing one or more of our product candidates, we expect to continue to incur substantial research and development and other expenditures to develop and market additional product candidates. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain.

We have used a significant amount of cash since inception to finance the continued development and testing of our product candidates, and we expect to need substantial additional capital resources to develop our product candidates going forward and launch and commercialize any product candidates for which we receive regulatory approval.

We may not be successful in generating and/or maintaining operating cash flow, and the timing of our capital expenditures and other expenditures may not result in cash sufficient to sustain our operations through the commercialization of our product candidates. If financing is not sufficient and additional financing is not available or available only on terms that are detrimental to our long-term survival, it could have a material adverse effect on our ability to continue to function. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs in 2022 and beyond;
- scientific and clinical progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

Additional financing through strategic collaborations, public or private equity or debt financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our stockholders, and any debt financings will likely involve covenants restricting our business activities. Further, if we obtain additional funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own.

If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or product development initiatives, any of which could have a material adverse effect on our financial condition or business prospects.

Our research and development costs could exceed our projections requiring us to significantly modify our planned operations.

Our currently projected expenditures for 2022 include approximately $12 million to $14 million for research and development. The actual cost of our programs could differ significantly from our current projections if we change our planned development process. In the event that actual costs of our clinical program, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

The successful development of any product candidate is highly uncertain. It is difficult to reasonably estimate or know the nature, timing and costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any product candidate, due to the numerous risks and uncertainties associated with developing drugs. Any failure to complete any stage of the development of products in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

We have identified material weaknesses in our internal controls over financial reporting and are working to remedy these weaknesses. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We have identified material weaknesses in our internal control over financial reporting as a company, which have resulted in unauthorized transactions involving our assets and common stock. As defined in Regulation 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented, or detected on a timely basis. Specifically, we determined that we had the following material weaknesses in our internal control over financial reporting: (i) inadequate segregation of duties; (ii) risks of executive override; and (iii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both generally accepted accounting principles in the United States of America, or GAAP, and the U.S. Securities and Exchange Commission, or the SEC, guidelines.

As of the date of this Annual Report, we have remediated some of these material weaknesses. The company has taken measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Specifically, the Company has engaged a forensic accountant to review the Company's bank records, transactions with affiliates and/or related parties, expense reimbursement practices and vendor payment practices. That review is ongoing. In addition, the Company's Board of Directors previously designated a Special Committee in August 2021 charged with, among other duties, evaluating the current compliance, compensation, operations and personnel of the Company, and determining actions appropriate to address any deficiencies or inefficiencies identified through such evaluation. Such measures include, but are not limited to the hiring of additional employees in its finance and accounting department; preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks; and identification and documentation of standard operating procedures for key financial activities. The implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

Even if we develop effective internal control over financial reporting, such controls may become inadequate due to changes in conditions, or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of additional material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act, or Section 404, and sufficiently effective requires the investment of substantial time and resources, including by certain members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions to establish effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to timely complete our evaluation, testing and any remediation required to comply with Section 404.

We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, for as long as we are a "smaller reporting company," our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. While we could be a smaller reporting company for an indefinite amount of time, and thus relieved of the above-mentioned attestation requirement, an independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Such undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Our intellectual property may be compromised.

Part of our value going forward depends on the intellectual property rights that we have been and are acquiring. There may have been many persons involved in the development of our intellectual property, and we may not be successful in obtaining the necessary rights from all of them. It is possible that in the future, third parties may challenge our intellectual property rights. We may not be successful in protecting our intellectual property rights. In either event, we may lose the value of our intellectual property, and if so, our business prospects may suffer.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our trade secret or other confidential information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from this information.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may be issued as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any product candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the time during which we would have patent protection for any covered product candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our product candidates.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know-how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secret intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware, with claims that cover the use or manufacture of our product candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes one or more claims of these patents. If our activities or product candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such product candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable.

Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and/or redesign our infringing product candidates or methods, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on commercially reasonable terms, or at all. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our product candidates and our business could materially suffer.

We may desire, or be forced, to seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify product candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those product candidates. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.

While we expect that we will generally seek to gain the right to fully prosecute any patents covering product candidates we may in-license from third-party owners, there may be instances when platform technology patents that cover our product candidates remain controlled by our licensors. If any of our current or future licensing partners that retain the right to prosecute patents covering the product candidates we license from them fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected product candidates may suffer.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming and distract management. If we pursue any litigation, a court may decide that a patent of ours or our licensor's is not valid or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in the applicable jurisdictions.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed.

We are seeking patent protection for some of our technology and product candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and product candidates, our business may be adversely impacted.

In addition, issued patents and pending international applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents unenforceable or by prematurely terminating pending international applications.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.

Our business depends in part on licenses from third parties. These third-party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform could be severely adversely affected.

We will have to hire additional employees to carry on our business operations. If we are unable to hire qualified personnel, we may not be able to implement our business strategy.

We currently have eight fulltime employees. The loss of the services of any of our employees could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business strategy, we will have to hire additional qualified personnel, including in the areas of manufacturing, clinical trials management, regulatory affairs, finance, discovery biology, and business development. We will need to raise sufficient funds to hire and retain the necessary employees.

Moreover, there is intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles, longer histories in the industry and greater ability to provide valuable cash or stock incentives to potential recruits than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we are able to offer as an early-stage company. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

Because of the specialized nature of our business, we are highly dependent on our ability to identify, hire, train and retain highly qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of one or more key executive officers, scientific or operational team members would be significantly detrimental to us. In addition, recruiting and retaining qualified scientific personnel to perform research and development work is critical to our success. Our anticipated growth and expansion into areas and activities requiring additional expertise, such as discovery biology, clinical testing, regulatory compliance, manufacturing and compliance, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities. Accordingly, we may not be able to continue to attract and retain the qualified personnel, which would adversely affect the development of our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, with contractual provisions and other procedures, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employers. Litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with regulations of governmental authorities, such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency, or EMA, to provide accurate information to the FDA or EMA, to comply with manufacturing standards we have established, to comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we currently take and the procedures we may establish in the future as our operations and employee base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by our employees to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our reliance on the activities of our non-employee consultants, research institutions and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.

We rely extensively upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other consultants with expertise in clinical development strategy or other matters. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants and, except as otherwise required by our collaboration and consulting agreements to the extent they exist, can expect only limited amounts of their time to be dedicated to our activities. These research facilities may have commitments to other commercial and non-commercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of time to be dedicated to our research goals.

It may take longer to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the date for the commencement, continuation and completion of our various clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

We expect to rely on medical institutions, academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business.

Clinical drug development for our product candidates is costly, time-consuming and uncertain. Our product candidates are in various stages of development and while we expect that clinical trials for these product candidates will continue for several years, such trials may take significantly longer than expected to complete. In addition, we, the FDA, an institutional review board, or IRB, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, with respect to study participants;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- delays in subject recruitment and enrollment in clinical trials or inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical ability to detect statistically significant treatment effects;
- difficulty in retaining subjects and volunteers in clinical trials;
- difficulty in obtaining the Institutional Review Board's ("IRB") approval for studies to be conducted at each clinical trial site;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations, ("CROs"), clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper formulation and dosing;
- failure by us, our employees, our CROs or their employees or other third-party contractors to comply with contractual and applicable regulatory requirements or to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- changes in applicable laws, regulations and regulatory policies.

If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by U.S. Food and Drug Administration, or the FDA, or similar regulatory authorities outside the United States. In particular, because we are focused on patients with molecularly defined cancers, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trial.

Consistent with our general product development strategy, we intend to design future trials for our product candidates to include some patients with the applicable clinical characteristics, stage of therapy, molecular alterations, biomarkers, and/or cell surface antigens that determine therapeutic options, or are indicators of the disease, with a view to assessing possible early evidence of potential therapeutic effect. If we are unable to locate and include such patients in those trials, then our ability to make those early assessments and to seek participation in FDA expedited review and approval programs, including breakthrough therapy and fast track designation, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised.

We have limited clinical testing and regulatory capabilities, and human clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit our ability to generate revenues from therapeutic products.

We cannot assure you that we will be able to invest or develop resources for clinical trials successfully or as expediently as necessary. In particular, human clinical trials can be very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be affected by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- inability to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA, may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our investigational new drug application, or IND, submissions or the conduct of these trials.

We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated delays. even if we obtain regulatory approval for some of our products, those products may still face regulatory difficulties.

All of our potential products, processing and manufacturing activities, are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

If we violate regulatory requirements at any stage, whether before or after we obtain marketing approval, the FDA may take enforcement action(s) against us, which could include issuing a warning or untitled letter, placing a clinical hold on an ongoing clinical trial, product seizure, enjoining our operations, refusal to consider our applications for pre-market approval, refusal of an investigational new drug application, fines, or even civil or criminal liability, any of which could materially harm our reputation and financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post marketing trials to provide additional evidence of safety and effectiveness. In addition, if we or others identify side effects after any of our adoptive therapies are on the market, or if manufacturing problems occur, regulators may withdraw their approval and reformulations, additional clinical trials, changes in labeling of our products, and additional marketing applications may be required.

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

- the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA and other regulatory authorities;
- data obtained from pre-clinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;
- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate; and/or
- FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales, and could make a search for a collaborative partner more difficult.

Obtaining regulatory approval even after clinical trials that are believed to be successful is an uncertain process.

Even if we complete our planned clinical trials and believe the results were successful, obtaining regulatory approval is a lengthy, expensive and uncertain process, and the FDA or other regulatory agencies may delay, limit or deny approval of any of our applications for pre-market approval for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA may disagree with our interpretation of data from pre-clinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from pre-clinical studies and clinical trials of our product candidates may not be sufficient to support the submission of applications for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;
- the FDA may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA may change their approval policies or adopt new regulations that adversely affect our applications for pre-market approval; and
- the FDA may require simultaneous approval for both adults and for children and adolescents delaying needed approvals, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Before we can submit an application for regulatory approval in the United States, we must conduct a pivotal, registrational trial. We will also need to agree on a protocol with the FDA for a clinical trial before commencing the trial. Registrational clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our early phase trials are successful, the results of the additional trials that we conduct may or may not be successful. Further, our product candidates may not be approved even if they achieve their primary endpoints in registrational clinical trials. The FDA or other foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. Any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory agencies.

In addition, the FDA or other regulatory agencies may also approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements.

We will continue to be subject to extensive FDA regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.

Even if we are successful in obtaining regulatory approval of our product candidates, we will continue to be subject to the requirements of and review by, the FDA and comparable regulatory authorities in the areas of manufacturing processes, post-approval clinical data, adverse event reporting, labeling, advertising and promotional activities, among other things. In addition, any marketing approval we receive may be limited in terms of the approved product indication or require costly post-marketing testing and surveillance. Discovery after approval of previously unknown problems with a product, manufacturer or manufacturing process, or a failure to comply with regulatory requirements, may result in enforcement actions such as:

- warning letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;
- product recalls or seizures or the temporary or permanent withdrawal of a product from the market;
- suspending any ongoing clinical trials;
- temporary or permanent injunctions against our production operations;
- refusal of our applications for pre-market approval or an investigational new drug application; and
- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

The occurrence of any of these actions would likely cause a material adverse effect on our business, financial condition and results of operations.

Many of our business practices are subject to scrutiny and potential investigation by regulatory and government enforcement authorities, as well as to lawsuits brought by private citizens under federal and state laws. We could become subject to investigations, and our failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us. If we fail to comply with U.S. healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.

While payment is not yet available from third-party payors (government or commercial) for our product, our goal is to obtain such coverage as soon as possible after product approval and commercial launch in the U.S. If this occurs, the availability of such payment would mean that many healthcare laws would place limitations and requirements on the manner in which we conduct our business (including our sales and promotional activities and interactions with healthcare professionals and facilities) and could result in liability and exposure to us. In some instances, our interactions with healthcare professionals and facilities that occurred prior to commercialization could have implications at a later date. The laws that may affect our ability to operate include, among others: (i) the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid; (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us under theories of "implied certification" where the government and qui tam relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted "off-label," lacked necessary approval, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and/or disclosures such as the Sunshine Act; and/or (iv) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of healthcare pharmaceutical companies and others in the healthcare space, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, have made it easier for private parties to bring qui tam (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. In addition, the Affordable Care Act amended the federal civil False Claims Act to provide that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false-claims provision. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws. Any future investigations of our business or executives, or enforcement action or prosecution, could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), and lawsuits have been brought challenging aspects of the law at various points. There have been repeated recent attempts by Congress to repeal or replace the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to or any repeal or replacement of the Affordable Care Act, with respect to certain of its provisions or in its entirety. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to use and expand our product platform to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of cancer. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the product's label;
- we may be required to create a medication guide for distribution to patients that outlines the risks of such side effects;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may expend our limited resources to pursue a particular product candidate or indication that does not produce any commercially viable products and may fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our efforts on particular research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and product candidates for specific indications that may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such failure to improperly assess potential product candidates could result in missed opportunities and/or our focus on product candidates with low market potential, which would harm our business and financial condition.

Our products may be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.

Our products may be significantly more expensive to manufacture than we expect or than other therapeutic products currently on the market today. We hope to substantially reduce manufacturing costs through process improvements, development of new methods, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not able to make these, or other improvements, and depending on the pricing of the product, our profit margins may be significantly less than that of other therapeutic products on the market today. In addition, we may not be able to charge a high enough price for any product we develop, even if they are safe and effective, to make a profit. If we are unable to realize significant profits from our potential product candidates, our business would be materially harmed.

We currently lack manufacturing capabilities to produce our therapeutic product candidates at commercial-scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the product.

We expect that we would need to significantly expand our manufacturing capabilities to meet potential demand for our therapeutic product candidates, if approved. Such expansion would require additional regulatory approvals. Even if we increase our manufacturing capabilities, it is possible that we may still lack sufficient capacity to meet demand.

We do not currently have any alternate supply for our products. If the facilities where our products are currently being manufactured or equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity or availability of drug supply, including, but not limited to, if such facilities are deemed not in compliance with current Good Manufacturing Practice, or GMP, requirements, future clinical studies and commercial production for our products would likely be significantly disrupted and delayed. It would be both time-consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with the regulatory requirements.

Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of our products and their long-term commercial prospects could be significantly damaged.

To be successful, our proposed products must be accepted by the healthcare community, which can be very slow to adopt or unreceptive to new technologies and products.

Our proposed products and those developed by our collaborative partners, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and use these products. The products that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our developed products will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our proposed products;
- our ability to create products that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payers.

If the healthcare community does not accept our products for any of these reasons, or for any other reason, our business would be materially harmed.

Our business is based on novel technologies that are inherently expensive and risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of immuno-oncology therapies are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize an immuno-oncology therapeutic product. In general, such products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. Furthermore, the number of people who may use such therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a significant market for such therapies and our ability to capture a share of this market with our product candidates.

Our development efforts with our therapeutic product candidates are susceptible to the same risks of failure inherent in the development and commercialization of therapeutic products based on new technologies. The novel nature of immuno-oncology therapeutics creates significant challenges in the areas of product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience regulating such therapies, and there are few approved treatments using such therapy.

Our competition includes fully integrated biotechnology and pharmaceutical companies that have significant advantages over us.

The market for therapeutic immuno-oncology products is highly competitive. We expect that our most significant competitors will be fully integrated and more established pharmaceutical and biotechnology companies or institutions, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. These companies are developing similar products, and they have significantly greater capital resources and research and development, manufacturing, testing, regulatory compliance, and marketing capabilities. Many of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in certain of our competitors. As a result, these companies may be able to obtain regulatory approval more rapidly than we can and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing drug products that are more effective or less costly to produce or purchase on the market than any product candidate we are currently developing or that we may seek to develop in the future. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval, or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business and ability to achieve profitability from future sales of our approved product candidates, if any.

If competitors develop and market products that are more effective, safer or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited.

Our therapeutic immuno-oncology (IO) development programs face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates. According to Global Data, Thematic Research: Immuno-Oncology (March 2021), as of December 2020, there are 4,822 industry-sponsored clinical trials for immuno-oncology with 422 drugs in development. Phase 2 trials constitute the majority of the IO pipeline, followed by early-stage molecules in Phase 1/2 and Phase 1. For late-stage pipeline products, 484 clinical trials are ongoing in Phase 3, and 51 are in Phase 2/3 development. There are currently 22 marketed immuno-oncology agents. Cancer vaccine products lead the category with 9 products followed by checkpoint modulators with 8 approved drugs. The indications with the most marketed IO agents in the United States are metastatic melanoma and non-small cell lung cancer, with 6 approved products each. The market value of bispecific antibodies, cancer vaccines, checkpoint modulators, cell therapies, and oncolytic viruses globally has increased sharply in the past 10 years with nearly $29 billion in 2019 compared to $370 million in 2010.

As a general matter, we also face competition from many companies that are researching and developing cell therapies. Many of these companies have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and marketing and selling. If we obtain regulatory approval for any of our product candidates, we also will be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources' being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of our technologies and greater availability of capital for investment in these fields.

If we are unable to keep up with rapid technological changes in our field or compete effectively, we will be unable to operate profitably.

We are engaged in activities in the biotechnology field, which is characterized by extensive research efforts and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. Research and discoveries by other biotechnology, pharmaceutical or other companies may render our technologies or potential products or services uneconomical or result in products superior to those we develop. Similarly, any technologies, products or services we develop may not be preferred to any existing or newly developed technologies, products or services.

We may not be able to obtain third-party patient reimbursement or favorable product pricing, which would reduce our ability to operate profitably.

Our ability to successfully commercialize certain of our proposed products in the human therapeutic field may depend to a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations. Reimbursement in the United States or foreign countries may not be available for any products we may develop, and, if available, may be decreased in the future. Also, reimbursement amounts may reduce the demand for, or the price of, our products with a consequent harm to our business. We cannot predict what additional regulation or legislation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive, or if healthcare-related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon our business model.

We may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.

Our business may bring us into conflict with our licensees, licensors or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

We are exposed to the risk of liability claims, for which we may not have adequate insurance.

Since we participate in the pharmaceutical industry, we may be subject to liability claims by employees, customers, end users and third parties. We intend to obtain proper insurance, however, there can be no assurance that any liability insurance we purchase will be adequate to cover claims asserted against us or that we will be able to maintain such insurance in the future. We intend to adopt prudent risk-management programs to reduce these risks and potential liabilities, however, we have not taken any steps to create these programs and have no estimate as to the cost or time required to do so and there can be no assurance that such programs, if and when adopted, will fully protect us. We may not be able to put risk management programs in place, or obtain insurance, if we are unable to retain the necessary expertise and/or are unsuccessful in raising necessary capital in the future. Our failure to obtain appropriate insurance, or to adopt and implement effective risk-management programs, as well as any adverse rulings in any legal matters, proceedings and other matters could have a material adverse effect on our business.

Preclinical and clinical trials are conducted during the development of potential products and other treatments to determine their safety and efficacy for use by humans. Notwithstanding these efforts, when our treatments are introduced into the marketplace, unanticipated side effects may become evident. Manufacturing, marketing, selling and testing our product candidates under development or to be acquired or licensed, entails a risk of product liability claims. We could be subject to product liability claims if our product candidates, processes, or products under development fail to perform as intended. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources, and could damage our reputation and impair the marketability of our product candidates and processes. While we plan to maintain liability insurance for product liability claims, we may not be able to obtain or maintain such insurance at a commercially reasonable cost. If a successful claim were made against us, and we lacked insurance or the amount of insurance were inadequate to cover the costs of defending against or paying such a claim or the damages payable by us, we would experience a material adverse effect on our business, financial condition and results of operations.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our product candidates.

We could be subject to product liability lawsuits if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize our product candidates.

Our inability to retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop. We may wish to obtain additional such insurance covering studies or trials in other countries should we seek to expand those clinical trials or commence new clinical trials in other jurisdictions or increase the number of patients in any clinical trials we may pursue. We also may determine that additional types and amounts of coverage would be desirable at later stages of clinical development of our product candidates or upon commencing commercialization of any product candidate that obtains required approvals. However, we may not be able to obtain any such additional insurance coverage when needed on acceptable terms or at all. If we do not obtain or retain sufficient product liability insurance, we could be responsible for some or all of the financial costs associated with a product liability claim relating to our preclinical and clinical development activities, in the event that any such claim results in a court judgment or settlement in an amount or of a type that is not covered, in whole or in part, by any insurance policies we may have or that is in excess of the limits of our insurance coverage. We may not have, or be able to obtain, sufficient capital to pay any such amounts that may not be covered by our insurance policies.

We rely on third parties to conduct preclinical and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely, and expect to continue to rely, upon third-party CROs to execute our preclinical and clinical trials and to monitor and manage data produced by and relating to those trials. However, we may not be able to establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug product candidates and materially harm our business, operations and prospects.

We will have only limited control over the activities of the clinical research organization (CRO) we will engage to conduct our clinical trials. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on any CRO does not relieve us of our regulatory responsibilities. Based on our present expectations, we, our CROs and our clinical trial sites are required to comply with good clinical practices (GCPs), for all our product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a product candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such product candidate. In addition, our clinical trials are required to be conducted with product produced in compliance with current good manufacturing practice requirements, or cGMPs. Our or our CROs' failure to comply with those regulations may require us to repeat clinical trials, which would also require significant cash expenditures and delay the regulatory approval process.

Agreements governing relationships with CROs generally provide those CROs with certain rights to terminate a clinical trial under specified circumstances. If a CRO that we have engaged terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute CRO, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable trial would experience delays or may not be completed. In addition, our CROs are not our employees, and except for remedies available to us under any agreements we enter with them, we are unable to control whether or not they devote sufficient time and resources to our clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to a failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize, the affected product candidates. As a result, our operations and the commercial prospects for the effected product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We contract with third parties for the supply of product candidates for clinical testing and expect to contract with third parties for the manufacturing of our product candidates for large-scale testing and commercial supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We anticipate continuing our engagement of third parties to provide our clinical supply as we advance our product candidates into and through clinical development, and we depend on third parties to produce and maintain sufficient quantities of material to supply our clinical trials. If these third parties do not produce and maintain adequate supplies of clinical material, our development efforts could be significantly delayed, or could incur substantially higher costs. We expect in the future to use third parties for the manufacture of our product candidates for clinical testing, as well as for commercial manufacture. We plan to enter into long-term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement on satisfactory terms with contract manufacturers to manufacture our product candidates. Additionally, the facilities to manufacture our product candidates must be the subject of a satisfactory inspection before the FDA or other regulatory authorities approve a marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturers for compliance with the FDA's and international regulatory authority requirements for the manufacture of our finished products. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMPs. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved, and may subject us to recalls or enforcement action for products already on the market.

If any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity and other events beyond our control, the occurrence of which could materially harm our business.

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power, and any future blackouts could disrupt our operations. We are vulnerable to a major earthquake, wildfire and other natural disasters, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. We do not carry any business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could cause our business to materially suffer.

Epidemic or pandemic outbreaks such as COVID-19 (coronavirus), natural disasters, whether or not caused by climate change, unusual weather conditions, terrorist acts and political events, could disrupt business and result in halting our clinical trials and otherwise adversely affect our financial performance.

The occurrence of one or more natural disasters, such as tornadoes, hurricanes, fires, floods and earthquakes, unusual weather conditions, epidemic outbreaks, terrorist attacks or disruptive political events in certain regions where our operations are located could adversely affect our business. Epidemic or pandemic outbreaks, such as COVID-19 (coronavirus) could impact our management and our ability to conduct clinical trials. This also may affect the market conditions that would limit our ability to raise additional capital. This could have a sustained material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

There has been a limited public market for our common stock, and we do not know whether one will develop to provide you adequate liquidity. Furthermore, the trading price for our common stock, should an active trading market develop, may be volatile and could be subject to wide fluctuations in per-share price.

Our common stock is listed for trading on the Nasdaq Capital Market under the trading symbol “GTBP”; historically, however, there has been a limited public market for our common stock. We cannot assure you that an active trading market for our common stock will develop or be sustained. The liquidity of any market for the shares of our common stock will depend on a number of factors, including:

- the number of stockholders;
- our operating performance and financial condition;
- the market for similar securities;
- the extent of coverage of us by securities or industry analysts; and
- the interest of securities dealers in making a market in the shares of our common stock.

Even if an active trading market develops, the market price for our common stock may be highly volatile and could be subject to wide fluctuations. In addition, the price of shares of our common stock could decline significantly if our future operating results fail to meet or exceed the expectations of market analysts and investors and actual or anticipated variations in our quarterly operating results could negatively affect our share price.

Other factors may also contribute to volatility of the price of our common stock and could subject our common stock to wide fluctuations. These include, but are not limited to:

- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;

- significant sales of our common stock or other securities in the open market;
- variations in interest rates;
- changes in the market valuations of other comparable companies; and
- changes in accounting principles.

Our outstanding warrants may affect the market price of our common stock.

As of December 31, 2021, we had approximately 32.4 million shares of common stock issuable or issued and outstanding and warrants outstanding for the purchase of up to 221,000 additional shares of common stock at an exercise price of $3.40 per share, and warrants outstanding for the purchase of up to 2,116,000 additional shares of common stock at an exercise price of $5.50 per share, all of which are exercisable as of the date of this Annual Report (subject to certain beneficial ownership limitations). The amount of common stock reserved for issuance may have an adverse impact on our ability to raise capital and may affect the price and liquidity of our common stock in the public market. In addition, the issuance of these shares of common stock will have a dilutive effect on current stockholders' ownership.

Because our common stock may be deemed a "penny" stock, an investment in our common stock should be considered high-risk and subject to marketability restrictions.

Historically, the trading price of our common stock has been $5.00 per share or lower, and deemed a penny stock, as defined in Rule 3a51-1 under the Exchange Act, and subject to the penny stock rules of the Exchange Act specified in rules 15g-1 through 15g-10. Those rules require broker–dealers, before effecting transactions in any penny stock, to:

- deliver to the customer, and obtain a written receipt for, a disclosure document;
- disclose certain price information about the stock;
- disclose the amount of compensation received by the broker–dealer or any associated person of the broker–dealer;
- send monthly statements to customers with market and price information about the penny stock; and
- in some circumstances, approve the purchaser's account under certain standards and deliver written statements to the customer with information specified in the rules.

Consequently, the penny stock rules may restrict the ability or willingness of broker–dealers to sell the common stock and may affect the ability of holders to sell their common stock in the secondary market and the price at which such holders can sell any such securities. These additional procedures could also limit our ability to raise additional capital in the future.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may also limit a stockholder's ability to buy and sell our common stock, which could depress the price of our common stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require a broker-dealer to have reasonable grounds for believing that the investment is suitable for that customer before recommending an investment to a customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. Thus, the FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares of common stock, have an adverse effect on the market for our shares of common stock, and thereby depress our price per share of common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have research coverage by three securities analysts, and we may never obtain research coverage by additional analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock may be negatively affected. In the event that we receive additional securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions may limit the ability of another party to acquire us, which could cause our stock price to decline.

Delaware law and our charter, bylaws, and other governing documents contain provisions that could discourage, delay or prevent a third party from acquiring us, even if doing so may be beneficial to our stockholders, which could cause our stock price to decline. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock.

We do not currently or for the foreseeable future intend to pay dividends on our common stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, any return on your investment in our common stock will be limited to the appreciation in the price of our common stock, if any.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

At the date of the issuance of this Annual Report, we sublease offices comprising of 4,500 rentable square feet at 8000 Marina Blvd, Suite 100, Brisbane, CA 94005 under a sublease that expires on June 30, 2024. We previously leased offices at 9350 Wilshire Blvd, Suite 203, Beverly Hills, CA 90212.

ITEM 3. LEGAL PROCEEDINGS

On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion, an individual ("Lion"), and by Daniel Vallera, an individual ("Vallera"). Lion and Vallera are referred to jointly as the "Plaintiffs". The complaint was filed against GT Biopharma, Inc. and its subsidiary Oxis Biotech, Inc. (either of them or jointly, the "Company"). The Plaintiffs alleged breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. Lion alleged breach of a consulting agreement between Lion and the Company entered into on or about September 1, 2015. Vallera alleged breach of a consulting agreement between Vallera and the Company entered into in or around October, 2018. The Complaint sought actual damages of $1.7 million, for the fair market value of the number of shares of common stock of GT Biopharma, Inc. that at the time of judgment represent 15,000,000 shares of such common stock as of September 1, 2015, and that GT Biopharma, Inc. issue Lion the number of shares of common stock of GT Biopharma, Inc. that at the time of judgment represent 15,000,000 such shares as of September 1, 2015. The Company filed an answer to the complaint denying many allegations and asserting affirmative defenses. A settlement of the case was reached on February 7, 2022 in the amount of $425,000. This amount was fully accrued at both December 31, 2021 and December 31, 2020. The settlement amount was subsequently paid on March 4, 2022.

On March 3, 2021 a complaint was filed by Sheffield Properties in the superior Court of California. County of Ventura. The litigation arose from a commercial lease entered into by GT Biopharma for office space in Westlake Village. In July, 2021 we entered into settlement agreement with Sheffield Properties in the amount of $100,000 that was paid in full on August 6, 2021.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the Nasdaq Capital market under the trading symbol "GTBP." Until May 2009, our common stock was traded on the OTC Bulletin Board ("OTCBB") under the symbol "OXIS." From May 20, 2009 until March 11, 2010, our common stock was traded on Pink OTC Markets Inc. trading platform under the symbol "OXIS." From January 2015 to August 2017, our common stock was quoted on the OTCQB under the "OXIS" trading symbol. From August 2017 to February 11, 2021, our common stock was quoted on the OTCQB under the "GTBP" trading symbol.

Our common stock is also quoted on several European based exchanges including Berlin (GTBP.BE), Frankfurt (GTBP.DE), the Euronext (GTBP.NX) and Paris, (GTBP.PA). The foregoing trading prices exclude trading on these foreign stock markets.

Stockholders

As of March 28, 2022 there were 50 stockholders of record, which total does not include stockholders who hold their shares in "street name." The transfer agent for our common stock is ComputerShare, whose address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129.

Dividends

We have not paid any dividends on our common stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the Board of Directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

Equity Compensation Plan Information

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Recent Issuances of Unregistered Securities

The Company made the following issuances of its unregistered securities pursuant exemptions contained in Section 4(a)(2) or 3(a)(9) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder:

- The Company issued 1,737,861 shares of common stock to consultants as compensatory bonuses after completion of the successful listing on the Nasdaq Capital Market on February 11, 2021;
- The Company issued 1,060,853 shares of common stock in accordance with various consulting agreements.
- The Company issued 708,144 shares of common stock in accordance with a research and development agreement.
- The Company issued 1,125,752 shares of common stock upon exercise of warrants for cash.
- The Company issued 50,000 shares of common stock in accordance with the terms of the employment agreement of an employee.

Repurchase of Shares

We did not repurchase any shares during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE®) technology platform. Our TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKE® is composed of recombinant fusion proteins and interleukin 15 (IL-15), can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

As shown in the accompanying consolidated financial statements, the Company has incurred an accumulated deficit of $653.6 million through December 31, 2021. On a consolidated basis, the Company had cash and cash equivalents of $9.0 million and short-term investments of $23.0 million at December 31, 2021. We anticipate we will have to raise additional capital to fund our selling, general and administrative, and research and development expenses until we have a marketable product. There are no assurances that we will be able to raise the funds necessary to maintain our operations or to implement our business plan. The consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event we cannot continue our operations.

COVID-19

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, customers, economies, and financial markets globally. It has also disrupted the normal operations of many businesses. This outbreak could decrease spending, adversely affect demand for the Company's products, and harm the Company's business and results of operations.

During the year ended December 31, 2021, the Company believes the COVID-19 pandemic did impact its operating results. However, the Company has not observed any impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic. At this time, it is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations, financial condition, or liquidity.

The Company has been following the recommendations of health authorities to minimize exposure risk for its team members, including the temporary closure of its corporate office and having team members work remotely. Most vendors have transitioned to electronic submission of invoices and payments.

Corporate Developments

On February 16, 2021, as a result of the completion of the public offering and the successful listing of our shares of common stock on the Nasdaq Capital Market, 2,353,548 shares of Series J-1 Preferred Stock mandatorily converted at a conversion rate of $3.40 per share into 692,220 shares of our common stock. (See Note 8 of our Financial Statements)

As part of employment agreements with Anthony Cataldo, our former Chief Executive Officer (former CEO) and Michael Handelman, our former Chief Financial Officer (former CFO), these officers received a fully vested stock grant of shares of common stock equal to aggregate of 10% and 1.5% of the fully diluted shares of our common stock (calculated with the inclusion of the current stock holdings of Mr. Cataldo, and Mr. Handelman, upon conversion of options, warrants and convertible notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). In addition, we also granted similar equity compensation to members of our Board of Directors wherein these directors received stock grants equal to 1% and 1.25% of the fully diluted shares of our common stock. Pursuant to these agreements, the common stock issued vested over a period of two years. On February 16, 2021, we completed a qualified equity offering and listing. As a result, we granted these two employees 3,197,662 shares and an additional 1,181,745 shares to directors for a total of 4,379,407 shares of common stock.

On April 23, 2021, our Compensation Committee approved amendments to the compensation terms of Anthony Cataldo, our former CEO and Michael Handelman, our former CFO to increase their base salary and bonus compensation.

On April 23, 2021, Dr. Gregory Berk resigned as a director and accepted employment as our Chief Medical Officer. In connection with his appointment as Chief Medical Officer, the Compensation Committee approved a four-year employment agreement for Dr. Berk.

On August 23, 2021, Dr. Gregory Berk was promoted to the position of President of Research & Development and Chief Medical Officer. Dr. Berk assumed additional responsibilities including discovery, non-clinical development, clinical development, and manufacturing.

On November 5, 2021 the Company terminated the employment of Anthony Cataldo as Chief Executive Officer and Michael Handelman as Chief Financial Officer. On November 8, 2021, the Board appointed Dr. Greg Berk as Interim Chief Executive Officer.

On November 8, 2021, the Board also appointed Michael Breen as Executive Chairman of the Board.

On November 8, 2021, the Board appointed Dr. Gavin Choy as Acting Chief Financial Officer.

On December 15, 2021, Anthony Cataldo resigned as a member of the Company's Board of Directors.

On February 14, 2022, the Company appointed Manu Ohri as the Chief Financial Officer and Dr. Gavin Choy ceased serving as the Acting Chief Financial Officer.

Effective March 2, 2022, the Company appointed Michael Breen as Interim Chief Executive Officer. Dr. Berk ceased serving as the Company's Interim Chief Executive Officer, but continues to serve as its President of Research & Development and Chief Medical Officer.

Issuance of Common Stock in public offering

On February 16, 2021, the Company completed a public offering of 4,945,000 shares of common stock for net proceeds of $24.7 million, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, the Company also granted the investors, warrants to purchase 5,192,250 shares of common stock. The warrants are fully vested, exercisable at $5.50 per share and have a term of five years .(see Note 8 of our Consolidated Financial Statements).

As a result of the completion of the public offering and the listing of its shares of common stock on the Nasdaq Capital Market, convertible notes payable and accrued interest with an aggregate amount of $38.8 million were mandatorily converted at its stated conversion rate of $3.40 per share into 11,413,322 shares of the Company's common stock (see Note 5 of our Consolidated Financial Statements).

Issuance of Common Stock for services - consultants

As part of consulting agreements with certain consultants, the Company agreed to grant these consultants common stock equal to 1% and 3% of the fully diluted shares of common stock of the Company upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, we completed a qualified equity offering and listing. As a result, we granted these consultants 2,850,090 shares of common stock with a fair value of $10,701,394, of which 1,934,817 shares of common stock fully vested immediately while the remaining 915,273 shares of common stock vest over two years. During the year ended December 31, 2021, pursuant to the vesting terms of the consulting agreements, we recorded the corresponding stock compensation expense of $8,981,869. We also issued 1,060,853 shares of common stock with a fair value of $6,836,400 to other consultants for services rendered that will vest over a period of 24 months. In addition, on December 31, 2021, the Company cancelled 278,058 shares of common stock granted to a consultant in February 2021.

At December 31, 2021, there were 550,479 unvested shares of common stock with a grant date fair value of $2,203,126, which will be recognized as stock compensation in future periods based upon the remaining vesting term of the applicable grants.

Issuance of Common Stock for research and development agreement

During the year ended December 31, 2021, the Company issued 189,753 shares of common stock for a research and development agreement valued at $1.3 million. The common shares were valued at the market price at the date of grant.

Issuance of Common Stock upon exercise of warrants

During the year ended December 31, 2021, the Company issued 3,076,017 shares of common stock upon the exercise of warrants resulting in cash proceeds of $16.4 million.

Significant Agreements

TriKE® Agreement

In June 2017, we entered into a co-development partnership agreement with Altor BioScience Corporation in which we will collaborate exclusively in the clinical development of a novel 161533 (GTB-3550) TriKE® fusion protein for cancer therapies using our TriKE® technology. The GTB-3550 Phase 1 clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes and refractory/relapsed acute myeloid leukemia opened for patient enrollment September 2019 and completed enrollment in September 2021. The results of our first generation GTB-3550 Phase 1 clinical trial support our plans to advance the next generation camelid nanobody into the clinic, and as such, no further clinical development will ensue with GTB-3550.

University of Minnesota Scientific Research Agreement

We are a party to a scientific research agreement with the Regents of the University of Minnesota, effective June 16, 2021. This scientific research agreement aims to work with the Company with three major goals in mind: (1) support the Company's TriKE® product development and GMP manufacturing efforts; (2) TriKE® pharmacokinetics optimization in humans; and, (3) investigation of the patient's native NK cell population based on insights obtained from the analysis of the human data generated during our GTB-3550 clinical trial. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE® constructs in support of our product development and GMP manufacturing efforts; (2) TriKE® platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and, (3) gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE® therapy. Most studies will use TriKE® DNA/amino acid sequences created by us under current UMN/GTB licensing terms. The term of this agreement shall expire on June 30, 2023.

The University of Minnesota shall use reasonable efforts to complete the project for a fixed sum of $2.1 million. We paid an initial payment of $541,527 on December 2, 2021, which is to be followed by seven quarterly equal payments of $191,527, the first of which was paid on December 29, 2021. The second quarterly payment was recorded in accounts payable at December 31, 2021. A final payment of $192,470 will be paid within thirty (30) days of receipt of the final report.

Subcontract Manufacturing Agreement

On October 5, 2020, GT Biopharma entered into a Master Services Agreement with a third-party product manufacturer to perform biologic development and manufacturing services on behalf of the Company. At December 31, 2021, the Company's commitments in relation to this agreement totaled approximately $13.0 million, of which $7.5 million was incurred at that date and an additional $5.5 million is in process.

Clinical Trial Agreement

In September 2019, we executed clinical trial agreement with the Regents of the University of Minnesota, to commence enrollment in its first-in-human GTB-3550 TriKE® (CD16/IL-15/CD33) Phase 1, open-label, dose escalation clinical trial for the treatment of CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis. The clinical trial was conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick and Dr. Mark Juckett. The primary objective of the trial was to determine safety and tolerability as well as the maximum tolerated dose of GTB-3550 TriKE®. The hypothesis was that GTB-3550 TriKE® would induce natural killer cell function by targeting malignant cells as well as CD33+ myeloid derived suppressor cells (MDSC) which contribute to tumor induced immunosuppression. Because CD16 is a potent activating receptor on NK cells, this single agent GTB-3550 investigational agent may induce a targeted anti-CD33+ tumor response. The phase 1 trial was completed and closed to accrual in September 2021.

License Agreements

See discussion of Patents and Licenses above under Item 1: Business

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

Research and Development Expenses

During the years ended December 31, 2021 and 2020, we incurred $9.6 million and $485,000 of research and development expenses, respectively. Research and development expenses increased due to $1.3 million in stock compensation to consultants, and the initiation of the Phase 1 clinical trial of our most advanced TriKE® product candidate, GTB-3550 along with progression on other promising product candidates. We anticipate our direct clinical and preclinical expenses to increase significantly in 2022, totaling approximately $12 million to $14 million, as we have completed the Phase 1 clinical trial of our most advanced TriKE® product candidate GTB-3550, and have plans to advance the next generation camelid nanobody into the clinic.

Selling, general and administrative expenses

During the year ended December 31, 2021 and 2020, we incurred $47.9 million and $6.3 million of selling, general and administrative expenses, respectively. The increase in selling, general and administrative expenses is primarily attributable to stock compensation expenses of $32.6 million during the year ended December 31, 2021 as compared to none in the prior year. The remaining increase is due to expenses in support of our planned growth and new public company compliance initiatives in fiscal year 2021. We have incurred additional expenses that consist primarily of personnel costs from our executive, legal, finance, and information technology organizations and related expenditures, as well as third party professional fees and insurance.

Interest Expense

Interest expense was $0.7 million and $3.0 million for the years ended December 31, 2021 and 2020 respectively. The decrease is primarily due to the conversion of all outstanding interest on convertible notes on February 16, 2021. No promissory notes were outstanding as of December 31, 2021.

Change in fair value of derivative liability

Change in fair value of derivative liability resulted in a gain of $0.21 million for the year ended December 31, 2021 compared to a loss of $0.23 million for the year ended December 31, 2020.

Loss on legal settlements

No loss from legal settlements was recorded for the year ended December 31, 2021 while a $5.4 million loss from legal settlements was recorded for the year ended December 31, 2020. Loss from legal settlements resulted due to the Company settling legal claims during the year ended December 31, 2020.

Loss on forbearance agreement

Loss on forbearance settlement were $0 and $12.6 million for the years ended December 31, 2021 and 2020 respectively. Loss on extinguishment resulting from the change in fair value of debt and equity instruments modified due to the forbearance settlement the Company entered into during the year ended December 31, 2020.

Amortization of debt discount

Amortization of debt discount was $0 and $0.32 million for the years ended December 31, 2021 and 2020 respectively. The decrease is due to the adoption of ASU 2020-06 on January 1, 2021 which extinguished the debt discount recorded in 2020 of $4.7 million.

Liquidity and Capital Resources

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. During the year ended December 31, 2021, the Company raised $24.7 million through issuance of common stock, raised $16.4 million through the exercise of warrants and raised $1.2 million from a series of issuances of convertible notes, as compared to $12.5 million raised in the year ended December 31, 2020 through a series of issuances of convertible notes. We anticipate that cash utilized for selling, general and administrative expenses will range between $2 and $4 million in the coming quarters, while research and development expenses will vary depending on clinical activities. The Company reported $32.0 million of cash and short-term investments at December 31, 2021 and anticipates that will be sufficient to fund operations for the following 12 months, and anticipates raising additional funds during the fiscal year 2022.

The consolidated financial statements of the Company have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue in existence.

The Company has incurred substantial losses as of December 31, 2021. The Company anticipates incurring additional losses until such time, it can generate significant sales or revenue from out-licensing of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities; and payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies.

Critical Accounting Policies

We consider the following accounting policies to be critical given they involve estimates and judgments made by management and are important for our investors' understanding of our operating results and financial condition.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oxis Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. Intercompany transactions and balances have been eliminated in consolidation.

Accounting Estimates

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accruals for potential liabilities, valuation of notes payable, assumptions used in deriving the fair value of derivative liabilities, share-based compensation and beneficial conversion feature of notes payable, and valuation of deferred tax assets. Actual results could differ from those estimates.

Stock-Based Compensation

The Company accounts for share-based awards to employees and nonemployees and consultants in accordance with the provisions of Accounting Standards Codification ("ASC") 718, *Compensation-Stock Compensation*. Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting period.

The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

Inflation

We believe that inflation has not had a material adverse impact on our business or operating results during the periods presented.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2021.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This company qualifies as a smaller reporting company, as defined in 17 C.F.R. §229.10(f) (1) and is not required to provide information by this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Please see the consolidated financial statements beginning on page F-1 located in Part IV of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer, principal financial officer and principal accounting officer evaluated the effectiveness of our "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the United States Securities Exchange Act of 1934, as amended), as of December 31, 2021. Based on that evaluation, we have concluded that our disclosure controls and procedures were not effective as of December 31, 2021 as a result of material weaknesses in internal control over financial reporting, and for the period covered by this Annual Report on Form 10-K. The material weaknesses in the Company's internal control over financial reporting and the Company's remediation efforts are described below.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company's principal executive and principal accounting officers and effected by a company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2021, management of the company conducted an assessment of the effectiveness of the company's internal control over financial reporting. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework. In the course of the assessment, material weaknesses were identified in the company's internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Management determined that fundamental elements of an effective control environment were missing or inadequate as of December 31, 2021. The most significant issues identified were:

1) lack of segregation of duties due to small staff and significant reliance on outside consultants;
2) risks of executive override due to lack of established policies, and limited employee staff; and
3) insufficient written policies and procedures for accounting and financial reporting for the requirements and application of GAAP and SEC Guidelines.

Management also determined that inadequate and/or ineffective internal controls over financial reporting resulted in unauthorized transactions involving the Company's assets and common stock. Following the termination of Anthony Cataldo, the Company's former Chief Executive Officer, and Michael Handelman, the Company's former Chief Financial Officer, management determined that in July 2021, Mr. Cataldo obtained a short-term advance from the Company in the amount of approximately $2.6 million. Mr. Cataldo's advance was not memorialized pursuant to customary documentation and was not approved by the Company's Board of Directors. Mr. Cataldo repaid the full amount of the advance through installment payments in October, November and December 2021. Management has also determined that the Company may have issued up to 187,500 shares of its common stock to various parties without documentation supporting the consideration received by the Company in exchange for the issuance of such shares, or the approval of the Company's Board of Directors.

Based on the material weaknesses identified above, management has concluded that internal control over financial reporting was not effective as of December 31, 2021. The Company has begun to take measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Specifically, the Company has engaged a forensic accountant to review the Company's bank records, transactions with affiliates and/or related parties, expense reimbursement practices and vendor payment practices. That review is ongoing. In addition, the Company's Board of Directors previously designated a Special Committee in August 2021 charged with, among other duties, evaluating the current compliance, compensation, operations and personnel of the Company, and determining actions appropriate to address any deficiencies or inefficiencies identified through such evaluation. Such measures have included and/or will include, but not be limited to, hiring of additional employees in the Company's finance and accounting department; preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks; and identification and documentation of standard operating procedures for key financial activities, with additional oversight by the Company's Board of Directors.

Attestation Report on Internal Control over Financial Reporting.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm, due to the deferral allowed under the Jobs Act for small reporting companies.

Changes in Internal Control over Financial Reporting

Other than with respect to the remediation efforts discussed above, there was no change in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Although we have altered some work routines due to the COVID-19 pandemic, the changes in our work environment, including remote work arrangements, have not materially impacted our internal controls over financial reporting and have not adversely affected the Company's ability to maintain operations.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

In accordance with General Instruction G(3) to Form 10-K, the Company intends to file with the SEC the information required by this item not later than 120 days after the end of the fiscal year covered by this Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The Company's consolidated financial statements and related notes thereto are listed and included in this Annual Report beginning on page F-1. The following documents are furnished as exhibits to this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	04/01/2002	3.A	
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011	10-K	03/31/2011	3.2	
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017	8-K/A	03/15/2018	3.1	
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021	8-K	02/11/2021	3.1	
3.5	Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003	10-QSB	08/13/2003	3	
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	8-K	04/04/2019	3.1	
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	10-K	04/16/2021	4.2	
10.1	Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc.	10-Q	08/11/2017	10.3	
10.2	License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc.	10-Q	08/11/2017	10.4	
10.3	Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc.	10-Q	5/15/2020	10.7	
10.4	Note Conversion Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/2017	10.5	
10.5	Amendment Agreement related to Note Conversion Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/2017	10.8	
10.6	Warrant Exercise Agreement, dated August 29, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/2017	10.6	
10.7	Amendment Agreement related to Warrant Exercise Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/2017	10.9	
10.8	Preferred Stock Exchange Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/2017	10.7	
10.9	Amendment Agreement related to Preferred Stock Exchange Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/2017	10.10	
10.10	Securities Purchase Agreement, dated January 9, 2017, among OXIS International, Inc. and the purchasers named therein	8-K	01/13/2017	10.1	
10.11	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.2	

10.12	Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.3
10.13	Securities Purchase Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	01/23/2018	10.1
10.14	Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	01/23/2018	10.2
10.15	Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.3
10.16	Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.4
10.17	Securities Purchase Agreement, dated August 2, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/03/2018	10.1
10.18	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018)	8-K	08/03/2018	4.1
10.19	Stock Pledge Agreement, dated August 2, 2018, by the Pledgors named therein for the benefit of Grushko & Mittman, P.C.	10-Q	08/14/2018	10.10
10.20	Security Purchase Agreement, dated September 7, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/07/2018	10.1
10.21	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018)	8-K	09/07/2018	4.1
10.22	Security Purchase Agreement, dated September 24, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/28/2018	10.1
10.23	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018)	8-K	09/28/2018	4.1
10.24	Securities Purchase Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/2019	10.1
10.25	Registration Rights Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/2019	10.3
10.26	Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019)	8-K	02/06/2019	4.1
10.27	Security Agreement, dated February 4, 2019, among GT Biopharma, Inc. and Alpha Capital Anstalt, as collateral agent	8-K	02/06/2019	10.2
10.28	Securities Purchase Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/2019	10.1
10.29	Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/2019	10.2
10.30	Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019)	8-K	05/24/2019	4.1
10.31	Securities Purchase Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/20/2019	10.1
10.32	Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/20/2019	10.2
10.33	Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019)	8-K	08/20/2019	4.1
10.34	Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.1
10.35	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.2
10.36	Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020)	10-Q	05/15/2020	10.3
10.37	Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.4
10.38	Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.5
10.39	Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020)	10-Q	05/15/2020	10.6
10.40	Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.1

10.41	Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.3
10.42	Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020)	8-K	07/09/2020	4.1
10.43	Form of Standstill and Forbearance Agreement, dated June 23, 2020, between the Company and certain holders of convertible notes and debentures	8-K	06/23/2020	10.1
10.44	Settlement Agreement, dated June 19, 2020, among GT Biopharma, Inc., Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, Anthony Cataldo and Paul Kessler.	8-K	06/19/2020	10.1
10.45	Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/2020	10.1
10.46	Form of Pre-Funded Warrant to Purchase Common Stock, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/2020	10.1
10.47	Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo	8-K	2/21/2018	10.3
10.48	Employment agreement with Anthony Cataldo++	10-Q	8/14/2020	10.11
10.49	Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020)	8-K	9/22/2020	4.1
10.50	Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein	8-K	9/22/2020	10.1
10.51	Master Services Agreement, dated October 5, 2020, between GT Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	10/6/2020	10.1
10.52	Form of First Amendment and Extension of Standstill and Forbearance Agreement	8-K	11/4/2020	10.1
10.53	Form of Secured Convertible Note	8-K	11/9/2020	4.1
10.54	Securities Purchase Agreement	8-K	11/9/2020	10.1
10.55	Settlement Agreement, dated as of November 9, 2020, by and among Adam Kasower, East Ventures, Inc., A British Virgin Islands company, SV Booth Investments III, LLC, a Delaware limited liability company and Theorem Group, LLC, a California LLC and GT Biopharma Inc., a Delaware corporation.	10-Q	11/13/2020	10.19
10.56	Form of Settlement Note, dated November 9, 2020.	10-Q	11/13/2020	10.20
10.57	Board Service Agreement with Bruce Wendel, dated November 11, 2020++	10-Q	11/13/2020	10.22
10.58	Board Service Agreement with Greg Berk, dated November 11, 2020++	10-Q	11/13/2020	10.23
10.59	Consultant Agreement with Michael Handelman, dated November 13, 2020++	10-Q	11/13/2020	10.24
10.60	Form of Amendment to Convertible Note & Standstill Agreement	8-K	12/23/2020	10.1
10.61	Settlement Agreement, dated as of December 22, 2020, by and among Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B, Anthony Cataldo, Paul Kessler and GT Biopharma Inc., a Delaware corporation.	8-K	12/28/2020	10.1
10.62	Settlement Note, dated December 22, 2020, by GT Biopharma Inc. payable to Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	8-K	12/28/2020	10.2
10.63	Form of Second Amendment and Extension of Standstill and Forbearance Agreement.	8-K	02/1/2020	10.1
10.64	Form of Amendment to Convertible Note, dated January 31, 2021	8-K	02/1/2020	10.2
10.65	Board Service Agreement with Rajesh Shrotriya, dated January 12, 2021.++	S-1/A	02/08/2021	10.69
10.66	Board Service Agreement with Michael Breen, dated January 12, 2021. ++	S-1/A	02/08/2021	10.70

10.67	Amendment to Settlement Note with Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	S-1/A	02/08/2021	10.71	
10.68	Form of Securities Purchase Agreement - December 2020 / January 2021 Notes	S-1/A	02/08/2021	10.72	
10.69	Form of December 2020 / January 2021 Note	S-1/A	02/08/2021	10.73	
10.70	Amended and Restated Employment Agreement with Anthony Cataldo, dated April 23, 2021.++	10-Q	5/17/2021	10.1	
10.71	Amended and Restated Employment Agreement with Michael Handelman, dated April 23, 2021.++	10-Q	5/17/2021	10.2	
10.72	Amended and Restated Employment Agreement with Dr. Gregory Berk, dated April 23, 2021.++	10-Q	5/17/2021	10.3	
10.73	Exclusive License Agreement with Regents of the University of Minnesota, dated March 26, 2021.				X
10.74	Research Agreement with Regents of the University of Minnesota, dated June 16, 2021.				X
10.75	Sublease Agreement dated November, 2021, between Aimmune Therapeutics, Inc. (Sublandlord) and GT Biopharma, Inc. (Subtenant)				X
10.76	Employment Agreement with Michael Breen, entered into as of December 31, 2021 with an effective date of November 8, 2021. ++				X
14.1	Code of Ethics	10-K	03/31/2015	14.1	
21.1	Subsidiaries of GT Biopharma, Inc.	10-K	03/31/2015	21.1	
23.1	Consent of Weinberg & Company, P.A.				X
24.1	Power of Attorney (included on signature page)				X
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *				X
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *				X
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

++ Indicates management contract or compensatory plan.
* This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GT Biopharma, Inc.

Dated: March 28, 2022

By: */s/ Manu Ohri*
Manu Ohri, Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael Breen and Manu Ohri, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Michael Breen Michael Breen	Executive Chairman of the Board and Interim Chief Executive Officer (Principal Executive Officer)	March 28, 2022
/s/ Manu Ohri Manu Ohri	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2022
/s/ Bruce Wendel Bruce Wendel	Vice Chairman of the Board	March 28, 2022
/s/ Rajesh Shrotriya Rajesh Shrotriya, M.D.	Director	March 28, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors of
GT Biopharma, Inc.
Brisbane, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GT Biopharma, Inc. (the "Company") as of December 31, 2021 and 2020 and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter Description

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

As discussed in Note 8 to the consolidated financial statements, the Company issues equity awards to certain officers, employees and consultants as compensation (the "Equity Awards"). The fair values of these Equity Awards were determined as of the grant date using a Black-Scholes option-pricing model (the "Black-Scholes Model"). The selection of the valuation methodology and assumptions utilized in the Black-Scholes Model are based, in part, upon assumptions for which management is required to use judgment, particularly the risk-free interest rate, volatility, and dividend yield.

We identified the valuation of the Equity Awards as a critical audit matter because of the significant judgments made by management to determine the grant date fair values. This required a high degree of auditor judgment and an increased expenditure of effort when performing audit procedures to evaluate the reasonableness of management's valuation methodology and related assumptions, including the risk-free interest rate, volatility, and dividend yield.

Our audit procedures related to the determination of the fair values of the Equity Awards, including the valuation methodology and related assumptions such as the risk-free interest rate, volatility, and dividend yield, consisted of the following, among others:

- We obtained an understanding of management's process over the valuation of the Equity Awards, including those over the determination of the valuation methodology and related assumptions, including the risk-free interest rate, volatility, and dividend yield.

- We obtained and read the Equity Award agreements and management's valuation analyses, including supporting schedules and related narrative information.

- We evaluated management's valuation methodology, including the selection of the model to determine the fair values of the Equity Awards.

- We evaluated the reasonableness of management's valuation assumptions and the underlying source information of significant valuation assumptions, including the risk-free interest rate, volatility, and dividend yield.

- We assessed whether management's calculations of the fair values were applied in accordance with the selected methodology, including testing the mathematical accuracy of the valuation analyses.

- We developed independent estimates for the fair values of the Equity Awards based on assumptions utilized by the Company in its calculations.

We have served as the Company's auditor since December 2020.

Weinberg & Company, P.A.
Los Angeles, California
March 28, 2022

PCAOB ID: 572

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,968	$ 5,297
Short-term investments	23,011	-
Prepaid expenses and other current assets	190	364
Total current assets	$ 32,169	$ 5,661
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 8,189	$ 2,243
Accrued expenses	1,901	1,296
Accrued interest	-	4,838
Convertible notes payable (net of discount of $4,519 at December 31, 2020)	-	26,303
Line of credit	31	31
Derivative liability	138	383
Total current liabilities	10,259	35,094
Stockholders' equity (deficit)		
Convertible Preferred stock, par value $0.01, 15,000,000 shares authorized		
Series C - 96,230 shares issued and outstanding at December 31, 2021 and 2020, respectively	1	1
Series J - 0 and 2,353,548 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	2
Common stock, par value $0.001, 750,000,000 shares authorized, 32,061,989 shares and 5,218,122 shares issued and outstanding as of December 31, 2021 and 2020, respectively	32	5
Common stock issuable 327,298 shares at December 31, 2021	1,113	
Additional paid in capital	674,348	566,356
Accumulated deficit	(653,584)	(595,797)
Total stockholders' equity (deficit)	21,910	(29,433)
Total liabilities and stockholders' equity (deficit)	$ 32,169	$ 5,661

The accompanying notes are an integral part of these consolidated financial statements.

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except per share data)

	For the Year Ended December 31,	
	2021	**2020**
Revenues	$ -	$ -
Operating Expenses:		
Research and development	9,591	485
Selling, general and administrative (including $17,234 of stock compensation to officers, directors and employees during the year ended December 31, 2021)	47,924	6,279
Loss from Operations	57,515	6,764
Other (Income) Expense		
Interest income	(38)	-
Interest expense	718	3,003
Change in fair value of derivative liability	(211)	230
Unrealized loss on marketable securities	29	-
Loss on forbearance agreement	-	12,598
Loss on legal settlements	-	5,384
Amortization of debt discount	-	317
Total Other (Income) Expense	498	21,532
Net Loss	$ (58,013)	$ (28,296)
Net loss per share - basic and diluted	$ (2.06)	$ (6.45)
Weighted average common shares outstanding - basic and diluted	28,155,624	4,385,222

The accompanying notes are an integral part of these consolidated financial statements.

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2019	2,450	$ 3	4,105	$ 4	-	$ -	$ 548,184	$ (567,501)	$ (19,310)
Fair value of amended convertible notes and warrants	-	-	-	-	-	-	8,643	-	8,643
Issuance of common and warrants for settlement of litigation	-	-	262	-	-	-	2,246	-	2,246
Beneficial conversion feature on convertible notes payable	-	-	-	-	-	-	5,274	-	5,274
Common shares issued upon conversion of notes payable	-	-	512	1	-	-	1,740	-	1,741
Common shares issued upon exercise of warrants	-	-	240	-	-	-	-	-	-
Issuance of common stock for compensation	-	-	99	-	-	-	269	-	269
Net loss	-	-	-	-	-	-	-	(28,296)	(28,296)
Balance, December 31, 2020	2,450	3	5,218	5	-	-	566,356	(595,797)	(29,433)
Extinguishment of debt discount upon adoption of ASU 2020-06	-	-	-	-	-	-	(4,745)	226	(4,519)
Conversion of Preferred Series J-1 to common stock	(2,354)	(2)	692	1	-	-	1	-	-
Common shares issued upon mandatory conversion of notes payable and accrued interest	-	-	11,086	11	327	1,113	37,675	-	38,799
Common shares issued upon exercise of warrants	-	-	3,074	3	-	-	16,430	-	16,433
Issuance of common stock in public offering, net of cost	-	-	4,945	5	-	-	24,674	-	24,679
Issuance of common stock for research and development agreement	-	-	190	-	-	-	1,355	-	1,355
Issuance of common stock for services	-	-	3,082	3	-	-	15,337	-	15,340
Equity compensation to officers, board of directors and employees	-	-	3,775	4	-	-	17,230	-	17,234
Extinguishment of derivative liability	-	-	-	-	-	-	35	-	35
Net loss	-	-	-	-	-	-	-	(58,013)	(58,013)
Balance, December 31, 2021	**96**	**$ 1**	**32,062**	**$ 32**	**327**	**$ 1,113**	**$ 674,348**	**$ (653,584)**	**$ 21,910**

The accompanying notes are an integral part of these consolidated financial statements.

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Year Ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (58,013)	$ (28,296)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - consultants and research and development	16,695	-
Stock based compensation - officers, directors and employees	17,234	269
Convertible notes payable issued for consulting services	720	-
Amortization of debt discount	-	317
Convertible notes payable issued and fair value of amended convertible notes payable and warrants as part of forbearance agreements	-	12,598
Convertible notes payable issued and fair value of common shares and warrants issued as part of legal settlements	-	5,003
Loss on abandonment of lease	-	60
Change in fair value of derivative liability	(211)	230
Unrealized loss on marketable securities	29	-
Issuance of warrants accounted as derivative liability	-	153
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses	174	242
Increase (decrease) in accounts payable and accrued expenses	7,077	(838)
Increase in accrued interest	689	3,000
Net Cash Used in Operating Activities	(15,606)	(7,262)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(23,040)	-
Net Cash Used in Investing Activities	(23,040)	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants	16,433	-
Proceeds from issuance of common stock	24,679	-
Proceeds from issuance of convertible notes payable	1,205	12,531
Net Cash Provided by Financing Activities	42,317	12,531
Net Increase in Cash	3,671	5,269
Cash at Beginning of Period	5,297	28
Cash at End of Period	$ 8,968	$ 5,297
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	$ -	$ -
Income taxes paid	$ -	$ -
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Extinguishment of unamortized debt discount and adjustment to accumulated deficit upon adoption of ASU 2020-06	$ 4,745	$ -
Beneficial conversion feature of notes payable issued for cash	$ -	$ 4,745
Common stock issued upon conversion of notes payable and accrued interest	$ 38,799	$ 1,741
Accounts payable reclassified to convertible notes	$ 525	$ -
Extinguishment of derivative liability	$ 35	$ -
Conversion of Series J Preferred Stock to Common Stock	$ 2	$ -
Convertible notes payable issued for consulting services	$ -	$ 360
Reclassification of lease liability to accrued expenses	$ -	$ 58

The accompanying notes are an integral part of these consolidated financial statements.

Note 1 – Organization and Operations

In 1965, the corporate predecessor of GT Biopharma Inc. (the Company), Diagnostic Data, Inc., was incorporated in the State of California. Diagnostic Data changed its incorporation to the State of Delaware in 1972 and changed its name to DDI Pharmaceuticals, Inc. in 1985. In 1994, DDI Pharmaceuticals merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. In July 2017, the Company changed its name to GT Biopharma, Inc.

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE®), and Tetra-specific Killer Engager (Dual Targeting TriKE®Dual Targeting TriKE®) platforms. The Company's TriKE® and Dual Targeting TriKE® platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells (NK cells).

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oxis Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Liquidity

The accompanying consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Such assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. For the year ended December 31, 2021, the Company recorded a net loss of $58.0 million of which $33.9 million resulted from non-cash stock compensation, and used cash in operations of $15.6 million. As of December 31, 2021, the Company had a cash and short-term investments balance of $32.0 million, and working capital and stockholders' equity of $22.9 million. Management anticipates that the $32.0 million of cash and cash equivalents, and short-term investments are adequate to satisfy the liquidity needs of the Company for at least one year from the date the Company's 2021 consolidated financial statements are issued.

During the year ended December 31, 2021 the Company raised $24.7 million through issuance of common stock, raised $16.4 million through the exercise of warrants and raised $1.2 million from a series of issuances of convertible notes (see Note 8).

Historically, the Company has financed our operations through public and private sales of common stock, issuance of preferred and common stock, issuance of convertible debt instruments, and strategic collaborations.

Reclassification of Prior Year Presentation

Certain prior year amounts due to the resolution of non-controlling interest in net loss have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

COVID-19

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, customers, economies, and financial markets globally. It has also disrupted the normal operations of many businesses. This outbreak could decrease spending, adversely affect demand for the Company's products, and harm the Company's business and results of operations.

During the year ended December 31, 2021, the Company believes the COVID-19 pandemic did impact its operating results. However, the Company has not observed any impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic. At this time, it is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations, financial condition or liquidity.

The Company has been following the recommendations of health authorities to minimize exposure risk for its team members, including a temporary closure of its corporate office and having team members work remotely. Most vendors have transitioned to electronic submission of invoices and payments.

Accounting Estimates

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accruals for potential liabilities, valuation of notes payable, assumptions used in deriving the fair value of derivative liabilities, share-based compensation and beneficial conversion feature of notes payable, and valuation of deferred tax assets. Actual results could differ from those estimates.

Stock-Based Compensation

The Company accounts for share-based awards to employees and nonemployees and consultants in accordance with the provisions of Accounting Standards Codification ("ASC") 718, *Compensation-Stock Compensation.* Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting period.

The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using a its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

Fair Value of Financial Instruments

Financial Accounting Standards Board ("FASB") ASC 820-10 requires entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet for which it is practicable to estimate fair value. ASC 820-10 defines the fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties.

The three levels of the fair value hierarchy are as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access.

Level 2 Valuations based on quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3 Valuations based on inputs that are unobservable, supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amount of the Company's derivative liability of $0.1 million as of December 31, 2021 was based on Level 2 measurements.

The carrying amounts of the Company's other financial assets and liabilities, such as cash, prepaid expense, accounts payable and accrued expenses, and notes payable, approximate their fair values because of the short maturity of these instruments.

Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. The fair value of the embedded derivatives is determined using a Binomial valuation method at inception and on subsequent valuation dates.

Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

Research and Development Costs

Costs incurred for research and development are expensed as incurred. The salaries, benefits, and overhead costs of personnel conducting research and development of the Company's products comprise research and development expenses. Purchased materials that do not have an alternative future use are also expensed.

Leases

The Company leases our corporate office space under a lease agreement with monthly payments over a period of 12 months. Pursuant to ASC 842, *Leases*, lease assets are presented as operating lease right-of-use assets and the related liabilities are presented as lease liabilities in our consolidated balance sheets. At December 31, 2021 and 2020, we have no leases with an initial term greater than 12 months. However, on November 19, 2021 we entered into a sublease with Aimmune Therapeutics, Inc. for 4,500 square feet of office space located in Brisbane, CA having a commencement date of January 1, 2022 and maturing on June 30, 2024. As the lease had not yet commenced as of December 31, 2021, no related rent expense was recorded in 2021 and no right-of-use asset with a related liability was recorded at December 31, 2021.

Net Loss Per Share

Basic earnings (loss) per share is computed using the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed using the weighted-average number of common shares and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of convertible notes, stock issuable to the exercise of stock options and warrants have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

The following shares were excluded in the computation of the net loss per share because their effect is anti-dilutive:

	December 31,	
	2021	**2020**
A. Warrants to purchase common stock	2,337,274	221,041
B. Convertible notes payable	-	9,065,262
C. Convertible Series J Preferred stock	-	692,220
D. Convertible Series C Preferred stock	-	7
E. Options to purchase common stock	302,500	-
	2,639,774	9,978,530

Concentration

Cash is deposited in one financial institution. The balances held at this financial institution at times may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits of up to $250,000.

The Company has a significant concentration of expenses incurred and accounts payable from a single vendor. Please see Note 4 for further information.

Segments

The Company determined its reporting units in accordance with ASC 280, "*Segment Reporting*" ("ASC 280"). Management evaluates a reporting unit by first identifying its' operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

Management has determined that the Company has one consolidated operating segment. The Company's reporting segment reflects the manner in which its chief operating decision maker reviews results and allocates resources. The Company's reporting segment meets the definition of an operating segment and does not include the aggregation of multiple operating segments.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Credit Losses - Measurement of Credit Losses on Financial Instruments* ("ASC 326"). ASU 2016-13 requires entities to use a forward-looking approach based on current expected credit losses ("CECL") to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. ASU 2016-13 is effective for the Company beginning July 1, 2023, and early adoption is permitted. The Company does not believe the potential impact of the new guidance and related codification improvements will be material to its financial position, results of operations and cash flows.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. Under ASU 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital. Consequently, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. Adoption of the standard requires using either a modified retrospective or a full retrospective approach. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. Adoption of the new standard resulted in a decrease to additional paid-in capital of $4.5 million (see Note 5).

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU 2021-04 provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. An issuer measures the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. ASU 2021-04 introduces a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's consolidated financial statements or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (the "SEC") did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Note 3 - Fair Value of Financial Instruments

The estimated fair values of financial instruments outstanding were (in thousands):

	December 31, 2021			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents	$ 8,968	$ —	$ —	$ 8,968
Short-term investments	23,040	—	(29)	23,011
	$ 32,008	$ —	$ (29)	$ 31,979

	December 31, 2020			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents	$ 5,297	$ —	$ —	$ 5,297
Short-term investments	—	—	—	—
	$ 5,297	$ —	$ —	$ 5,297

The following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and investments, in thousands):

	December 31, 2021			
	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 5,484	$ 5,484	$ —	$ —
Corporate notes and commercial paper	23,011	—	23,011	—
	$ 28,495	$ 5,484	$ 23,011	$ —

Note 4 – Accounts Payable

Accounts payable consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Accounts payable to a third-party manufacturer	$ 6,335	$ -
Other accounts payable	1,854	2,243
Total accounts payable	$ 8,189	$ 2,243

The Company relies on a third-party contract manufacturing operation to produce and/or test our compounds used in our potential product candidates. As of December 31, 2021 the Company was indebted $6.3 million of accounts payable to this vendor.

Note 5 – Convertible Notes Payable

Convertible notes payable consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
A. Notes payable issued for cash	$ -	$ 24,085
B. Notes payable issued for settlement agreements	-	2,528
C. Notes payable issued for forbearance agreements	-	3,849
D. Notes payable issued for consulting services	-	360
	-	30,822
Less unamortized debt discount	-	(4,519)
Convertible notes, net of discount	$ -	$ 26,303

A. Notes Payable Issued for Cash

As part of the Company's financing activities, the Company issued convertible notes payable in exchange for cash. These notes payable were unsecured, bearing interest at a rate of 10% per annum, matured from nine months up to one year from the date of issuance, and were convertible to common stock at an average conversion rate of $3.40 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, the outstanding balance of these notes amounted to $24.1 million.

In January 2021, the Company issued similar notes payable in exchange for cash of $1.2 million. On February 16, 2021, in accordance with the note agreements upon completion of the equity offering discussed in Note 8, these notes were mandatorily converted at a conversion rate of $3.40 per share into 7,438,235 shares of the Company's common stock.

B. Notes Payable Issued for Settlement Agreements

In fiscal 2019 and 2020, the Company issued its convertible notes payable to resolve claims and disputes pertaining to certain debt and equity instruments issued by the Company in prior years. The notes were unsecured, bearing interest at a rate of 10%, matured from nine months up to one year from the date of issuance, and were convertible to common stock at a conversion rate of $3.40 per share, as adjusted, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, outstanding balance of these notes payable for settlement agreements amounted to $2.5 million.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 8, these notes were mandatorily converted at a conversion rate of $3.40 per share into 743,529 shares of the Company's common stock.

C. Notes Payable Issued for Forbearance Agreements

On June 23, 2020, the Company entered into Standstill and Forbearance Agreements (collectively, the "Forbearance Agreements") with the holders of $13.2 million aggregate principal amount of the Convertible Notes (the "Default Notes"), which were in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with any default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that the Company completes a future financing in the amount of $15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2021 (the "Termination Date"). As of December 31, 2020, outstanding balance of the notes payable amounted to $3.8 million.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 8, these notes were mandatorily converted at a conversion rate of $3.40 per share into 1,132,059 shares of the Company's common stock.

D. Notes Payable issued for Consulting Agreements

In prior years, the Company issued its convertible notes payable in exchange for consulting services. These notes payable were unsecured, bearing interest at a rate of 10% per annum, matured from nine months up to one year from the date of issuance, and were convertible to common stock at an average conversion rate of $3.40 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, outstanding balance of these notes payable amounted to $0.4 million.

In January 2021, the Company issued similar notes payable of $0.7 million in exchange for consulting services. In addition, the Company also issued a note payable of $0.5 million in exchange for the cancellation of an unpaid consulting fee that was recorded as part of accrued expenses as of December 31, 2020.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 8, these notes in the aggregate amount of $1.6 million were mandatorily converted at a conversion rate of $3.40 per share into 472,059 shares of the Company's common stock.

As of December 31, 2020, the Company accrued interest of $4.8 million related to these convertible notes payable. During the period ended December 31, 2021, the Company accrued interest of $0.7 million. As a result of the mandatory conversion of the Company's notes payable, on February 16, 2021, total accrued interest amounting to $5.5 million was converted to 1,627,440 shares of common stock.

As a result, total notes payable of $33.3 million and accrued interest of $5.5 million for a total of $38.8 million were mandatorily converted to 11,413,322 shares of common stock of which 327,298 shares were unissued as of December 31, 2021 (see Note 8).

Adoption of ASU 2020-06

In fiscal 2020, the Company recorded a note/debt discount of $4.7 million to account for the beneficial conversion feature that existed on the date of issuance for the above convertible notes payable. The debt discount is being amortized to interest expense over the term of the corresponding convertible notes payable. At December 31, 2020, the Company had recorded an unamortized note/debt discount of $4.5 million.

On January 1, 2021 the Company chose to adopt Accounting Standards Update ("ASU") 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. Under ASU 2020-06, the embedded conversion features are no longer required to be separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital.

As a result of the adoption of ASU 2020-06, the Company extinguished the previously recorded debt discount of $4.7 million by charging the opening additional paid in capital at January 1, 2021. In addition, the Company also adjusted accumulated deficit to account for the derecognition of the $0.2 million interest expense due to the amortization of the debt discount that was recorded in fiscal 2020. As a result of these adjustments, the unamortized debt discount of $4.5 million was extinguished during the year ended December 31, 2021.

Note 6 – Line of Credit

On November 8, 2010, the Company entered into a financing arrangement with Gemini Pharmaceuticals, Inc., a product development and manufacturing partner of the Company, pursuant to which Gemini Pharmaceuticals made a $0.3 million strategic equity investment in the Company and agreed to make a $0.8 million purchase order line of credit facility available to the Company. The principal balance outstanding under the line of credit, which bears interest at the rate of prime plus 2% per annum, amounted to $31,000 as of December 31, 2021 and 2020, respectively.

Note 7 – Derivative Liability

Under authoritative guidance used by the FASB on determining whether an instrument (or embedded feature) is indexed to an entity's own stock, instruments that do not have fixed settlement provisions are deemed to be derivative instruments. The Company has issued certain warrants that included a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder.

As a result, the warrants are classified as liabilities and are bifurcated from the debt host and accounted for as a derivative liability in accordance with ASC 815 and will be re-measured at the end of every reporting period with the change in value reported in the statement of operations.

The derivative liabilities were valued using a Binomial pricing model with the following average assumptions:

	December 31, 2021	December 31, 2020
Risk-free interest rate	1.26%	0.36%
Expected volatility	129%	135%
Expected life (in years)	3.6 years	4.60 years
Expected dividend yield	-	-
Fair Value		
Warrants	$ 138,000	$ 383,000

The risk-free interest rate was based on rates established by the Federal Reserve Bank. The Company uses the historical volatility of its common stock to estimate the future volatility for its common stock. The expected life of the derivative securities was determined by the remaining contractual life of the derivative instrument. For derivative instruments that already matured, the Company used the estimated life. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future.

During 2021, 2,826 warrants were exercised which resulted in an extinguishment of derivative liability charge of $0.03 million. The Company recognized a net gain of $0.21 million and a loss of $0.23 million for the years ended December 31, 2021 and 2020, respectively, to account for the change in fair value of the derivative liability.

Note 8 – Stockholders' Equity (Deficit)

At December 31, 2021, the Company had an authorized capital of 750,000,000 shares of common stock, par value $0.001, and 15,000,000 shares of preferred stock par value $0.01.

On February 10, 2021, the Company effectuated a 1:17 reverse stock split of the Company's issued and outstanding shares of common stock and all fractional shares were rounded up. All share and per share amounts in the accompanying consolidated financial statements have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

Common Stock

Common Stock Issuable

As a result of the mandatory conversion of the notes payable and accrued interest in the aggregate of $38.8 million on February 16, 2021, the Company was obligated to issue a total of 11,413,322 shares of common stock to the respective noteholders.

As of December 31, 2021, the Company had issued 11,085,703 shares of common stock or approximately 97.1% or $37.7 million of the converted notes payable and accrued interest to the respective noteholders. With regards to the remaining 327,298 unissued shares of common stock or $1.1 million of the converted notes payable and accrued interest, the Company is in the process of obtaining the necessary supporting documentation from the respective noteholders which will then be provided to the Company's stock transfer agent as a requirement for the issuance of the common stock certificate (Note 5).

For financial reporting purposes, the Company reported $1.1 million as common stock issuable in the accompanying statements of stockholders' equity to account for the estimated balance of the converted notes payable and accrued interest that the Company has not yet issued the corresponding common stock.

Issuance of Common Stock in public offering

On February 16, 2021, the Company completed a public offering of 4,945,000 shares of common stock for net proceeds of $24.7 million, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, the Company also granted these investors, warrants to purchase 5,192,250 shares of common stock. The warrants are fully vested, exercisable at $5.50 per share and will expire in five years.

As a result of the completion of the public offering and the successful listing of its shares of common stock on the Nasdaq Capital Market, convertible notes with an aggregate principal amount of $33.3 million and accrued interest of $5.5 million mandatorily converted at its stated conversion rate of $3.40 per share into 11,413,322 shares of the Company's common stock (see Note 5).

Issuance of Common Stock for services - consultants

As part of consulting agreements with certain consultants, the Company agreed to grant these consultants common stock equal to 1% and 3% of the fully diluted shares of common stock of the Company upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Market. As a result of this offering, the Company agreed to issue to these consultants 2,850,090 shares of common stock with a grant date fair value of $10.7 million, of which 1,934,817 shares of common stock vested immediately while the remaining 915,273, shares of common stock vests over two years. Pursuant to current accounting guidelines, as the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and then such award is being recorded as compensation expense based upon the vesting term of the grant.

During the period ended December 31, 2021, pursuant to the vesting terms of the agreements, the Company recorded stock compensation expense of $9.0 million related to these consultants. In addition, the Company also issued 1,060,853 shares of common stock with a grant date fair value of $6.8 million to other consultants for service rendered that will vest over a period of 24 months. In addition, on December 31, 2021, the Company cancelled 278,058 shares granted to a consultant in February 2021. As a result, the Company recognized an aggregate of $15.3 million in stock compensation expense based upon the vesting of common stock granted to consultants.

At December 31, 2021, there are 550,479 unvested shares of common stock with a grant date fair value of $2.2 million which will be recognized as stock compensation in future periods.

Issuance of Common Stock for research and development agreement

During the year ended December 31, 2021, the Company issued 189,753 shares of common stock for a research and development agreement valued at $1.4 million. The common shares were valued on the market price at the date of grant.

Issuance of Common Stock upon exercise of warrants

During the year ended December 31, 2021, the Company issued 3,076,017 shares of common stock upon the exercise of warrants resulting in cash proceeds of $16.4 million.

During the year ended December 31, 2020, the Company issued 239,706 shares of common stock upon cashless exercise of warrants.

Issuance of Common Stock upon conversion of notes payable

During the year ended December 31, 2020, the Company issued 511,879 shares of common stock upon conversion of $1.7 million in principal and interest on convertible notes payable.

Issuance of Common Stock for legal settlements

During the year ended December 31, 2020, the Company issued 262,353 shares of common stock pursuant to Settlement Agreements with a fair value of $2.2 million. The common shares were valued on the market price at the date of grant.

As a result of all common stock issuances, the Company had 32,061,989 shares and 5,218,122 shares of common stock issued and outstanding at December 31, 2021 and December 31, 2020, respectively.

Preferred Stock

A. Series J Preferred Stock

At December 31, 2021 and December 31, 2020, respectively, there were 0 and 2,353,548 shares of series J preferred stock issued and outstanding.

Shares of the Series J-1 Preferred Stock were convertible at any time, at the option of the holders, into shares of the Company's common stock at an effective conversion price of $3.40 per share, subject to adjustment for, among other things, stock dividends, stock splits, combinations, reclassifications of our capital stock and mergers or consolidations, and subject to a beneficial ownership limitation which prohibits conversion if such conversion would result in the holder (together with its affiliates) being the beneficial owner of in excess of 9.99% of the Company's common stock. Shares of the Series J-1 Preferred Stock had the same voting rights as shares of the Company's common stock, with the holders of the Series J-1 Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation described above, together with the holders of the Company's common stock on all matters presented to the Company's stockholders. The Series J-1 Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but would participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company's common stock. In the event of the Company's dissolution, liquidation or winding up, the holders of the Series J-1 Preferred Stock would be on parity with the holders of the Company's common stock and would participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

As a result of the completion of the public offering and the successful listing of the Company's shares of common stock on the Nasdaq Capital Market, in February 2021, all outstanding Series J shares were mandatorily converted to 692,220 shares of common stock pursuant to the terms of the conversion agreement.

B. Series C Preferred Stock

At both December 31, 2021 and December 31, 2020, there were 96,230 shares of series C preferred stock, par value $0.01 per share (the "Series C Preferred Stock") issued and outstanding.

As a result of stock splits in previous years, 96,230 shares of Series C Preferred Stock are not convertible. Shares of Series C Preferred Stock have no voting rights. Similarly, as there are no conversion rights, in the event of liquidation, the holders of the Series C Preferred Stock shall not participate in any distribution of the assets or surplus funds of the Company. The holders of Series C Preferred Stock also are not entitled to any dividends if and when declared by the Company's board of directors (the "Board"). No dividends to holders of the Series C Preferred Stock were issued or unpaid through December 31, 2021 and 2020.

C. Series K Preferred Stock

On February 16, 2021, the Board designated 115,000 shares of Series K preferred stock, par value $.01. (the "Series K Preferred Stock").

Shares of the Series K Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company's common stock at an effective conversion rate of 100 shares of common stock for each share of Series K Preferred Stock. Shares of the Series K Preferred Stock have the same voting rights a shares of the Company's common stock, with the holders of the Series K Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation, together with the holders of the Company's common stock on all matters presented to the Company's stockholders. The Series K Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company's common stock. In the event of the Company's dissolution, liquidation or winding up, the holders of the Series K Preferred Stock will be on parity with the holders of the Company's common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

As of December 31, 2021, there were no Series K Preferred stock issued and outstanding.

Warrants and Options

Common Stock Warrants

Stock warrant transactions for the years ended December 31, 2021 and 2020 were as follows:

	Number of Warrants	Weighted-Average Exercise Price
Warrants outstanding at December 31, 2019	106,650	$ 3.40
Granted	382,353	3.40
Forfeited/canceled	(28,256)	3.40
Exercised	(239,706)	-
Warrants outstanding at December 31, 2020	221,041	3.40
Granted	5,192,250	5.50
Forfeited/canceled	-	-
Exercised	(3,076,017)	5.50
Warrants outstanding at December 31, 2021	2,337,274	$ 5.30
Warrants exercisable at December 31, 2021	2,337,274	$ 5.30

On February 16, 2021, as part of the Company's public offering, the Company issued warrants to investors to purchase up to an aggregate of 5,192,250 shares of common stock. The warrants have an exercise price of $5.50 per share, subject to adjustment in certain circumstances and has a term of five years from the date of issuance.

During the year ended December 31, 2021, the Company issued 3,076,017 shares of common stock upon exercise of warrants which also resulted cash proceeds of $16.4 million.

On July 28, 2020, the Company issued a warrant to purchase up to an aggregate of 58,824 shares of common stock at an exercise price of $3.40 per share, subject to adjustment in certain circumstances with a fair value of $0.2 million.

The warrant expires on July 28, 2025. The warrant was issued as compensation for certain services provided to the Company.

In July 2020, pursuant to the Settlement Agreement, the Company issued pre-funded warrants to purchase up to an aggregate of 323,529 shares of common stock (the "Settlement Warrants") at an exercise price of $3.40 per share, subject to adjustment in certain circumstances and will expire on June 19, 2025.

As of December 31, 2021, all issued and outstanding warrants are fully vested and the intrinsic value of these warrants was $0.

Common Stock Options

Stock option transactions for the year ended December 31, 2021 (there were no transactions in 2020):

	Number of Options	Weighted-Average Exercise Price
Options outstanding at December 31, 2020	-	-
Granted	302,500	3.05
Forfeited/canceled	-	-
Exercised	-	-
Options outstanding at December 31, 2021	302,500	$ 3.05
Options exercisable at December 31, 2021	93,825	$ 3.05

On December 31, 2021, the Company granted two employees a total of 302,500 stock options. The stock options are exercisable at $3.05 per share and will expire in 10 years. A portion of the options vested immediately, with the remaining portion vesting over a two year period from the date of grant. The fair value of the options amounted to $808,000 or an average of $2.67 per share and were calculated using a Black-Scholes option pricing model. Assumptions used in the model were: expected term – 5.5 years; expected volatility – 129.0%; risk free interest rate – 1.26% and dividend yield of 0%. Pursuant to the vesting term of the stock options, the Company recorded stock compensation expense of $250,700 for the year ended December 31, 2021.

There was no intrinsic value of the outstanding options as of December 31, 2021, as the exercise price of these options equals the market price.

Note 9 – Commitments and Contingencies

1. Litigation

The Company is involved in certain legal proceedings that arise from time to time in the ordinary course of our business. Except for income tax contingencies, the Company records accruals for contingencies to the extent that our management concludes that the occurrence is probable and that the related amounts of loss can be reasonably estimated. Legal expenses associated with the contingency are expensed as incurred. There is no current or pending litigation of any significance with the exception of the matters that have arisen under, and are being handled in, the normal course of business.

a. On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion and by Daniel Vallera, as individuals. The complaint was filed against GT Biopharma, Inc. and its subsidiary Oxis Biotech, Inc. The Plaintiffs allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. The Company filed an answer to the complaint denying many allegations and asserting affirmative defenses. The Company reached a settlement of the case and paid on March 4, 2022, $425,000 in full and final settlement of the claims (see Note 14). This amount was fully accrued at December 31, 2021 and 2020, respectively.

b. On March 3, 2021, a complaint was filed by Sheffield Properties in the superior Court of California, County of Ventura. The litigation arose from a commercial lease entered into by GT Biopharma, Inc. for office space in Westlake Village in California. In July, 2021 the Company entered into settlement agreement with Sheffield Properties and the payment in the settlement amount of $0.1 million was made on August 6, 2021.

2. Significant Agreements:

Research and Development Agreements

The Company is a party to a Scientific Research Agreement with the Regents of the University of Minnesota, effective June 16, 2021. This scientific research agreement has three major goals: (1) support the Company's TriKE® product development and GMP manufacturing efforts; (2) TriKE® pharmacokinetics optimization in humans; and, (3) investigation of the patient's native NK cell population based on insights obtained from the analysis of the human data generated during our GTB-3550 clinical trial. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE® constructs in support of our product development and GMP manufacturing efforts; (2) TriKE® platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and, (3) gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE® therapy. Most studies will use TriKE® DNA/amino acid sequences created by us under current UMN/GTB licensing terms. The term of this agreement shall expire on June 30, 2023.

The University of Minnesota shall use reasonable efforts to complete the project for a fixed sum of $2.1 million. An initial payment of $541,527 was paid on December 2, 2021, followed by a payment of $191,527 on December 29, 2021 for the quarterly period ending September 30, 2021. The second quarterly payment for the quarter ending December 31, 2021 was recorded in accounts payable at December 31, 2021. Five quarterly payments of $191,527 remain, and a final payment of $192,470 will be payable within thirty (30) days of receipt of the final report.

On October 5, 2020, GT Biopharma entered into a Master Services Agreement with a third-party product manufacturer to perform biologic development and manufacturing services on behalf of the Company. Associated with this, the Company has subsequently signed five Statements of Work for the research and development of products for use in clinical trials. At December 31, 2021, the Company's commitments in relation to these Statements of Work and any related Change Orders totaled approximately $13.0 million, of which $7.5 million was incurred at that date and an additional $5.5 million is in process during fiscal year 2022.

Patent and License Agreements

2016 Exclusive Patent License Agreement

The Company is party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, ("UofMN"), to further develop and commercialize cancer therapies using TriKE® technology developed by researchers at the UofMN to target NK cells to cancer. Under the terms of the 2016 agreement, the Company receives exclusive rights to conduct research and to develop, make, use, sell, and import TriKE® technology worldwide for the treatment of any disease, state, or condition in humans. The Company is responsible for obtaining all permits, licenses, authorizations, registrations, and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE® technology, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the UofMN received an upfront payment of $0.2 million, and an annual License Maintenance fee of $0.1 million beginning in 2021. The agreement also includes 4% royalty fees, (not to exceed 6% under subsequence license agreements or amendments to this agreement or minimum annual royalty payments ranging from $0.25 million to $5.0 million. The agreement also includes certain performance milestone payments totaling $3.1 million, and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million dollars in cumulative gross sales of Licensed Products.

2021 Patent License Agreement

On March 26, 2021, the Company signed an agreement specific to the B7H3 targeted TriKE®. Under the agreement, the UofMN received an upfront license fee of $20,000 and will receive an annual License Maintenance fee of $5,000 beginning in 2022, 2.5% to 5% royalty fees, or minimum annual royalty payments of $0.25 million beginning in the year after the first commercial sales of Licensed Product, and $2.0 million beginning in the fifth year after the first commercial sale of such Licensed Product. The agreement also includes certain performance milestone payments totaling $3.1 million, and one time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million dollars in cumulative gross sales of Licensed Products. There is no double payment intended; if one of the milestone payments has been paid under the 2016 agreement no further payment is due for the corresponding milestone above.

Office Lease Agreement

On November 19, 2021 the Company entered into a sublease with Aimmune Therapeutics, Inc. for 4,500 square feet of office space located in Brisbane, CA having a commencement date of January 1, 2022 and maturing on June 30, 2024. The following table summarizes the Company's future minimum lease payments related to this lease (in thousands):

Year ending	Amount
2022	$ 113
2023	117
2026 and thereafter	60
Total	$ 290

3. Employee Compensation

The following table summarizes the Company's future financial commitment to certain employees pursuant to their respective employment agreements (in thousands):

Year ending	Amount
2022	$ 1,756
2023	1,293

2024	1,012
2025	377
2026 and thereafter	-
Total	$ 4,438

Note 10 – Income Tax

The Company did not record any income tax provision for the years ended December 31, 2021 and 2020 due to the Company's net losses. The Company files income tax returns in the United States ("Federal") and California, Minnesota and Massachusetts ("State") jurisdictions. The Company is subject to Federal and State income tax examinations by tax authorities for all years since its inception. At December 31, 2021, the Company had Federal and State net operating loss carry forwards available to offset future taxable income of approximately $195 million. These carry forwards will begin to expire in the year ending December 31, 2030, subject to IRS limitations, including change in ownership. The Company periodically evaluates the likelihood of the realization of deferred tax assets, and adjusts the carrying amount of the deferred tax assets by a valuation allowance to the extent the future realization of the deferred tax assets is not judged to be more likely than not. The Company considers many factors when assessing the likelihood of future realization of our deferred tax assets, including recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income or loss, the carry-forward periods available to us for tax reporting purposes, and other relevant factors.

At December 31, 2021 and 2020, based on the weight of available evidence, including cumulative losses in recent years and expectations of future taxable income, the Company determined that it was more likely than not that its deferred tax assets would not be realized. Accordingly, the Company has recorded a valuation allowance for 100% of its cumulative deferred tax assets. The components of our deferred tax assets are as follows.

Deferred taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and operating losses and tax credit carryforwards. The significant components of net deferred income tax assets for the Company are (in thousands):

	December 31,	
	2021	**2020**
Deferred tax assets:		
Federal net operating loss carryforward	$ 58,167	$ 39,340
Stock based compensation and other items	7,622	4,779
Intellectual property	62,055	58,504
Patent amortization	4	4
Deferred tax assets before valuation	127,848	102,627
Valuation allowance	(127,848)	(102,627)
Net deferred income tax assets	$ -	$ -

Generally accepted accounting principles requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. Because of the Company’s history of operating losses, management has provided a valuation allowance equal to its net deferred tax assets.

A reconciliation of the federal statutory income tax rate and the effective income tax rate as a percentage of income before income tax provision is as follows for the year ended:

	December 31,	
	2021	**2020**
Federal statutory income tax rate	21%	21%
State tax, net of federal benefit	9%	7%
Change in valuation allowance on net operating loss carryforwards	(30)%	(28)%
Effective income tax rate	0%	0%

Note 11 – Related Party Transaction

During the year ended December 31, 2020, the Company recorded consulting expense of $1.1 million for services rendered by a consultant who was also an owner of approximately 10% of the Company’s issued and outstanding common stock. In addition, the Company also issued a note payable to this consultant of $0.5 million in exchange for the cancellation of unpaid consulting fees of $0.5 million that was recorded as part of accrued expenses at December 31, 2020. There was no similar consulting expense incurred during the period ended December 31, 2021.

Note 12 – Equity Compensation to Officers, Board of Directors and Employees

As part of employment agreements with its former CEO and its former CFO ("Officers"), the Officers received a fully vested stock grant equal to aggregate of 10% and 1.5% of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of the CEO) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). In addition, the Company also granted similar equity compensation to members of the Company's Board of Directors wherein these directors received stock grant equal to 1% and 1.25% of the fully diluted shares of common stock of the Company. Pursuant to the agreement, approximately 33% of the common stock to be issued vested immediately while the remaining 67% will vest over a period of two years.

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Market (see Note 8). As such, 4,379,407 shares of its common stock were granted to these Officers and directors which had a fair value of $18.6 million. Since the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and such awards were recorded as compensation expense as the milestone or performance condition is met and in accordance with its vesting terms.

The Company recognized stock compensation expense of $17.2 million which is comprised of the issuance of 4,053,024 shares of common stock and the vesting of 93,825 stock options to officers, directors and employees for the year ended December 31, 2021. In addition, on December 31, 2021, the Company cancelled 278,058 shares of common stock granted to a Board member in February 2021. The fair value of the 338,883 unvested shares of common stock was $1.7 million and will be recognized as stock compensation expense in future periods.

Note 13 – Internal Control Considerations

Management has determined that inadequate and/or ineffective internal controls over financial reporting resulted in unauthorized transactions involving the Company's assets and common stock. Following the termination of Anthony Cataldo, the Company's former Chief Executive Officer, and Michael Handelman, the Company's former Chief Financial Officer, management determined that in July 2021, Mr. Cataldo obtained a short-term advance from the Company in the amount of approximately $2.6 million. Mr. Cataldo's advance was not memorialized pursuant to customary documentation and was not approved by the Company's Board of Directors. Mr. Cataldo repaid the full amount of the advance through installment payments in October, November and December 2021. Management has also determined that the Company may have issued up to 187,500 shares of its common stock to various parties without documentation supporting the consideration received by the Company in exchange for the issuance of such shares, or the approval of the Company's Board of Directors.

The Company is considering its course of action and potential recourse it may have against these former officers. The Company has taken measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Specifically, the Company has engaged a forensic accountant to review the Company's bank records, transactions with affiliates and/or related parties, expense reimbursement practices and vendor payment practices. That review is ongoing. In addition, the Company's Board of Directors previously designated a Special Committee in August 2021 charged with, among other duties, evaluating the current compliance, compensation, operations and personnel of the Company, and determining actions appropriate to address any deficiencies or inefficiencies identified through such evaluation.

Note 14 – Subsequent Events

On March 3, 2022, the Company settled a case filed by Jeffrey Lions and Daniel Vallera and paid $0.4 million in full and final settlement (see Note 9).

The Company has entered into a sublease with Aimmune Therapeutics, Inc. for 4,500 square feet of office space located in Brisbane, CA having a commencement date of January 1, 2022 and maturing on June 30, 2024.

On February 11, 2022, 60,855 shares of issuable common stock were converted into an equal number of shares of common stock.

Exhibit 10.73

EXCLUSIVE LICENSE AGREEMENT

Regents of the University of Minnesota

and

GT BioPharma Inc.

TECHNOLOGY COMMERCIALIZATION

200 Oak Street, SE | Suite 280 | Minneapolis, MN 55455

OTC Agreement Number: A-2021-0831 | OTC Case Number: **2020-0316**

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (this "Agreement") is made as of the Effective Date by and between Regents of the University of Minnesota, a constitutional corporation under the laws of the state of Minnesota, having a place of business at 200 Oak Street, SE, Suite 280, Minneapolis, Minnesota 55455 (the "University"), and the Licensee identified below.

The Agreement consists of the **Business Terms**, **General Terms** and any attached and referenced exhibits or schedules.

BUSINESS TERMS

1	**LICENSEE**	GT Biopharma, Inc.
2	**TERRITORY**	Worldwide.
3	**ALLOWED FIELD OF USE**	a. "Allowed **Field of Use**" shall mean the human therapeutic use of the **Sequence** in a Protein Biologic as set forth below in 1(a) – (d) Use in a **TriKE** (covered by UMN licensed IP to GT Biopharma); b. Use in a **TriKE** (not covered by UMN licensed IP to GT Biopharma); c. Use in a **BiTE**; d. Use in a **BiKE**; II. For clarification the following are not within the Allowed Field of Use and are not included in this License and no rights are granted to Licensee; a. Any non-human therapeutic use of the Sequence in a Protein Biologic as set forth in Allowed Field of Uses (a-d) b. Any non-therapeutic use of the Sequence in a Protein Biologic as set forth in Allowed Fields of Uses (a-d). c. Any cell based (e.g., T cells, NK cells, Myeloid cells, etc.) delivery or production of a protein containing the Sequence for any therapeutic or non-therapeutic use. d. Any nucleic acid-based delivery or production of a protein containing the Sequence for any therapeutic or non-therapeutic use except for the manufacture of TriKE, BiTE or BiKE therapeutic products set forth under Allowed Fields of Uses (a-d). e. Any virus-based delivery or production of a protein containing the Sequence for any therapeutic or non-therapeutic use except for the manufacture of TriKE, BiTE or BiKE therapeutic products set forth under Allowed Fields of Uses (a-d).

FORM: OGC-SG401
Exclusive Patent License Agreement
Form Date: 12/18/01
Form Revision Date: 6/17/2019

<table>
<tr><td>4</td><td>TERM</td><td>From the Effective Date until the date on which no Licensed Intellectual Property Right is pending or valid and unexpired anywhere in the Territory.</td></tr>
<tr><td>5</td><td colspan="2">LICENSED INTELLECTUAL PROPERTY</td></tr>
<tr><td>5.1</td><td>LICENSED PATENT APPLICATIONS</td><td>
<table>
<tr><td>Patent Application No.</td><td>University Case No.</td><td>Country</td><td>Application Date</td><td>Title</td></tr>
<tr><td>US63/033,989</td><td>2020-316</td><td>US</td><td>6/3/2020</td><td>B7H3-Targeting Peptides, Constructs Containing Same, and Methods of Use</td></tr>
</table>
</td></tr>
<tr><td>5.2</td><td>TECHNICAL INFORMATION</td><td>(i) Amino Acid and DNA sequence information: Licensee acknowledges it has received the foregoing information and University has no further obligation under this Section 5.2.

(ii) Materials and methods needed to make a TriKE, BiKE and a BiTE therapeutics to the extent (a) such materials or methods are included in the patent application; or, if not included in the patent application, (b) are provided by University under a sponsored research agreement with Licensee to the extent one is entered into during 2021.</td></tr>
<tr><td>6</td><td colspan="2">FEDERAL GOVERNMENT RIGHTS

☐ Yes

☒ No</td></tr>
<tr><td>7</td><td colspan="2">PATENT RELATED EXPENSES

University will manage initial patent related expenses which includes US patent filing and the PCT filings. However, at the national phase entry stage of the patent filing, Licensee or Licensees will be responsible for reimbursing University for all past and future Patent Related Expenses including the international phase of the PCT process. Licensee or Licensee(s) shall reimburse University for Patent Related Expenses for US Patent applications, US patents and the international phase of the PCT process within 30 days from receipt of invoice.

If the University enters into a license agreement for the Licensed Intellectual Property with a third party (“Second Licensee”) for a field of use other than the Allowed Field of Use, then Licensee will be issued a credit against future payment obligations (For ex. Performance Milestone Payments and royalties) for 50% of the previously paid Patent Related Expenses paid by the Licensee. Future Patent Related Expenses will be split 50/50 between Licensee and Second Licensee. If the University enters into a license with additional parties other than the Second Licensee, then the Licensee and University will enter into a good faith negotiations to determine a pro rata division of patent expense reimbursement obligations.</td></tr>
</table>

		All Ongoing Foreign Patent Related Expenses. Additionally, and without limiting Licensee's reimbursement obligations in the previous sentence, Licensee shall pre-pay the following Patent Related Expenses with respect to international filings, subject to equitable adjustment if there are multiple licensees. (a) All out-of-pocket expenses for foreign national or regional applications including the examination fee (b) All out-of-pocket expenses for EP validation (c) Exceptional expenses The foregoing will be applied for each subsequent licensee, if any.
8	**SUBLICENSE RIGHTS**	**Yes**
9	**PERFORMANCE MILESTONES**	**Field of Use 1A or 1B:** The Licensee shall achieve the following milestones: a) Perform First dosing of first patient in a Phase I clinical trial for the Licensed Product within 24 months from the Effective Date; b) Perform the first dosing of a patient in a Phase II clinical trial for the Licensed Product within 48 months from the Effective Date. c) Perform the first dosing of a patient in a Phase III clinical trial within 84 months from the Effective Date; d) Obtain regulatory approval for commercial sale of the Licensed Product in the Territory within 120 months from the Effective Date. **Field of Use 1C or 1D:** a) Perform First dosing of first patient in a Phase I clinical trial for the Licensed Product within 24 months from Licensee's selection of Field 1C or 1D; b) Perform the first dosing of a patient in a Phase II clinical trial for the Licensed Product within 48 months from Licensee's selection of Field 1C or 1D. c) Perform the first dosing of a patient in a Phase III clinical trial within 84 months from Licensee's selection of Field 1C or 1D; d) Obtain regulatory approval for commercial sale of the Licensed Product in the Territory within 120 months from Licensee's selection of Field 1C or 1D.

		By March 1 of each year, Licensee will submit a written annual report to University covering the preceding calendar year. The report will include information sufficient to enable University to satisfy reporting requirements of the U.S. Government and for University to ascertain progress by Licensee toward meeting this Agreement's diligence requirement. Each report will describe, where relevant: Licensee's progress toward commercialization of Licensed Product, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, and significant corporate transactions involving Licensed Product. Licensee will specifically describe how each Licensed Product is related to each Licensed Patent.
10	**PAYMENTS**	
10.1	**UPFRONT PAYMENT**	For the Allowed Field of Uses (a) and (b) Licensee shall pay to University $40,000 as an upfront fee, in the following manner: (i) $20,000 due ten (10) days after the Effective Date following the execution of the license agreement; (ii) a second payment of $20,000 due within ten (10) days after the first anniversary date of the Effective date of the license agreement. Licensee shall not use the Licensed Technology in Fields of Use (c) and (d) without notifying University in writing of its election to do so. Upon notice of such election, Licensee shall pay University an upfront fee of $50,000 within 30 days.
10.2	**LICENSE MAINTENANCE FEE**	Beginning on the first anniversary of the Effective date and on each anniversary thereafter until Licensee sells Licensed Product, Licensee will pay to University a yearly maintenance fee of $5,000. For clarification, the fee applies regardless of the Allowed Field of Use elected.
10.3	**RUNNING ROYALTIES ON NET SALES**	Licensee shall pay to University royalties based on Net Sales, whether the sales are made by Licensee or Sublicensee in accordance with the following: For Allowed Field of Use I(A): 1% Royalty of Net Sales of Licensed Products under this Agreement plus 4% of Net Sales of Licensed Products under the separate Exclusive Patent License Agreement #A20170047 between University and Licensee; provided, that if any claims in the patents covered by #A20170047, which are relevant to the manufacture or use the Licensed Product under this Agreement, fail to issue or are otherwise invalid, the royalty rate for Allowed Field of Use 1(A) is 2.5%. For Allowed Field of Use I(B): 2.5% of Net Sales of Licensed Product. For Allowed Field of Use I(C) and/or 1(D): 2.5% of Net Sales of Licensed Product.

		Royalties are paid on a per country basis where patent protection exists. Royalties terminate on a country-by-country basis when the patent rights expire in that country. Royalty Stacking. If Licensee or a sub licensee is required to make royalty payments to a Third Party under an agreement with such third party in connection with the making, using, selling, offering for sale, or importing of any Licensed Product, then up to fifty percent (50%) of such payments (a "**Third Party Payment**") may be offset against the royalty payments due University under Section 10.3; provided that in no event shall the royalties otherwise due University be less than fifty percent (50%) of the royalties that would be payable to University absent the effects of this Section

10.4	**ANNUAL MINIMUM AMOUNT OF RUNNING ROYALTIES**	Beginning in the calendar year in which Licensee first sells Licensed Product ("First Commercial Sale"), and for each year thereafter during the Term, Licensee shall pay to University by January 30 of the following calendar year a minimum royalty as set forth below: A. For the Licensed Product developed under the Allowed Field of Use I(a) and/or I(b): a. The annual minimum Royalties owed per year by Licensee shall be $250,000 beginning in the year after the First Commercial Sale of such Licensed Product. b. The annual minimum Royalties owed per year by Licensee shall increase to $2,000,000 per year beginning in the 5th Year after the First Commercial Sale of such Licensed Product and for every Year thereafter throughout the remainder of the Term. c. No Double Payment Intended: For clarification, if payment of the Annual Minimum Royalty is made under License Agreement A20170047, no separate additional payment is due under this Section 10.4 (1) for Allowed Field of Use I(a) or I(b). B. For the Licensed Products covered under the Allowed Field of Use I(c) and/or I(d): a. The annual minimum Royalties payable per year by the Licensee shall be $250,000 beginning in the year after the First Commercial Sale of such Licensed Product. b. The annual minimum Royalties payable per year by Licensee shall increase to $2,000,000 per year beginning in the 5th Year after the First Commercial Sale of such Licensed Product and every Year thereafter throughout the remainder of the Term. C. The annual minimum royalty is creditable against royalties owed for such year, but is not otherwise available for carryforward or carryback against royalties for other years or for other payments due under this Agreement.
10.5	**Sublicense Revenues**	Licensee shall pay to University a percentage of all Sublicense Revenues it receives from any Sublicensee within 30 days of receipt of such payments as set forth below:

		Sublicense Revenues: For Allowed Field of Use IA and IB: Licensee shall pay the University 25% of all Sublicense Revenues received by Licensee after the initiation of a Phase I clinical trial but prior to the initiation of a Phase III clinical trial Licensee shall pay the University 15% of all Sublicense Revenues received by Licensee after the initiation of a Phase III clinical trial but prior to the First Commercial Sale. Licensee shall pay the University 5% of all Sublicense Revenues received by Licensee after the First Commercial Sale. **No Double Payment Intended**: For clarification, if payment of Sublicense Revenues is due under Agreement A20170047, no separate additional payment is due under this Section 10.5 for Allowed Field of Use I(a) or I(b). If no payment is due under Agreement A20170047, payment is due under this Section. For Allowed Field of Use IC and 1D: Licensee shall pay the University 25% of all Sublicense Revenues received by Licensee prior to the initiation of a Phase III clinical trial Licensee shall pay the University 15% of all Sublicense Revenues received by Licensee after the initiation of a Phase III clinical trial but prior to the First Commercial Sale. After First Commercial Sale, no Sublicense Revenues is payable to UMN.
10.6	**CHANGE OF CONTROL**	For Allowed Field of Use 1A/1B: please see original/existing license agreement; for Allowed Field of Use 1B or 1C/1D: $50,000
10.7	**TRANSFER FEE**	$25,000

10.8	**MILESTONE PAYMENTS** **(Delete check boxes and corresponding language)**	**FIELD OF USE 1A AND 1B** **Performance Milestone Payments** A. $350,000 upon dosing of a first human subject in a Phase II clinical trial of a Licensed Product; B. $500,000 upon dosing of a first human subject in a Phase III clinical trial of a Licensed Product; C. $500,000 upon filing of an BLA with FDA (or EMEA or an equivalent authority in) in any jurisdiction, for a Licensed Product; D. $1,000,000 following the first commercial sale of a first Licensed Product; E. $500,000 for the first commercial sale of a second Licensed Product. F. $250,000 for the first commercial sale of a Licensed Product for any non-human use. **Sales Milestones** (one time): A. $1,000,000 upon reaching 250 Million dollars in cumulative gross sales of Licensed Products. B. $5,000,000 upon reaching 500 Million dollars in cumulative gross sales of Licensed Products. **No Double Payment Intended**: For clarification, if one of the milestone payments above has been paid under EPLA A#20170047, Section 11.9, no further payment is due for the corresponding milestone above. **FIELD OF USE 1C AND 1D** The following milestone payments will apply if Licensee ceases to develop a Licensed Product in Fields 1A or 1B; and, instead develops a Licensed Product in Allowed Field of Use 1C or 1D: **Performance Milestone Payments** G. $350,000 upon dosing of a first human subject in a Phase II clinical trial of a Licensed Product; H. $500,000 upon dosing of a first human subject in a Phase III clinical trial of a Licensed Product; I. $500,000 upon filing of an BLA with FDA (or EMEA or an equivalent authority in) in any jurisdiction, for a Licensed Product; J. $1,000,000 following the first commercial sale of a first Licensed Product; K. $500,000 for the first commercial sale of a second Licensed Product. L. $250,000 for the first commercial sale of a Licensed Product for any non-human use.

		Sales Milestones (one time): C. $1,000,000 upon reaching 250 Million dollars in cumulative gross sales of Licensed Products. D. $5,000,000 upon reaching 500 Million dollars in cumulative gross sales of Licensed Products.
10.9	**AMENDMENT FEE**	Unless waived by University in writing, Licensee shall pay to University, as an amendment fee, five thousand dollars ($5,000) in connection with each Licensee-requested amendment to this Agreement.
11	**LICENSEE'S ADDRESS FOR NOTICE**	Contact: Chief Financial Officer Address: GT Biopharma, Inc. 9350 Wilshire Blvd. Suite 203 Beverly Hills, CA 90212 Phone Email: mh@gtbiopharma.com
12	**LICENSEE'S CONTACT FOR PATENT PROSECUTION CONSULTATION**	Contact: SAME AS ABOVE Address: Phone Email:
13	**LICENSEE'S CONTACT FOR BILLING AND FINANCE**	Contact: SAME AS ABOVE Address: Phone Email:
14	**DEADLINE FOR EXECUTION BY LICENSEE**	If University executes this Agreement first and Licensee fails to execute and return it to University within 30 days of the date of University's signature below, then the Agreement is null and void.

THE PARTIES HEREBY EXECUTE THIS AGREEMENT	
Regents of the University of Minnesota	**GT Biopharma, Inc.**
By: DocuSigned by: Richard Huebsch 0909A2296188462	**By:** 9BA8B31776C143D Anthony Cataldo DocuSigned By: Anthony Cataldo
Rick Huebsch Its: **Executive Director** Technology Commercialization	**Anthony Cataldo** Its: **Chairman & CEO**
Date: March 26, 2021 | 8:20 AM CDT	**Date:** March 26, 2021 | 7:22 AM PDT
The signatory warrants that they are authorized to execute this agreement on behalf of the Regents of the University of Minnesota.	The signatory warrants that they are authorized to execute this agreement on behalf of Licensee

GENERAL TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

In this Agreement:

"**Affiliate**" means an entity that controls Licensee or the Sublicensee, as the case may be, is controlled by Licensee or Sublicensee, or along with Licensee or Sublicensee, is under the common control of a Third Party. An entity shall be deemed to have control of the controlled entity if it: (a) owns, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities of the controlled entity, or (b) has the right, power or authority, directly or indirectly, to direct or cause the direction of the policy decisions of the controlled entity, whether by ownership of securities, by representation on the controlled entity's governing body, by contract, or otherwise.

"BiTE" shall mean a bispecific T-cell engager composed of a T-cell binding/activating domain (e.g., CD3 binder) operably linked to a target cell targeting domain.

"**BiKE**" shall mean a bispecific NK cell engager composed of an NK cell binding/activating domain (e.g., CD16 or NKG2D or NKp30 binders) operably linked to a target cell targeting domain.

"**Change of Control**" means (a) the acquisition by a person or entity of beneficial ownership of the capital stock of Licensee if after the acquisition the person or entity beneficially owns 51% or more of either (i) the total number of the then outstanding shares of common stock of Licensee or (ii) the total number of the then outstanding shares of voting securities of Licensee; or (b) irrespective of whether Licensee is a surviving entity, the consummation of a merger, consolidation, reorganization involving Licensee or other exchange of shares of Licensee in one or a series of related transactions.

"**Early Termination**" means the termination of this Agreement permitted under Section 10.3 (b) of the General Terms.

"**Effective Date**" means the date of the last signature on this Agreement.

"Enforcement Litigation" means any litigation involving the enforcement of Licensed Intellectual Property.

"**Field of Use**" means the field(s) of use described in Section 3 of the Business Terms.

"**Licensed Patent**" means: (i) a patent described in Section 5.1 of the Business Terms and (ii) a patent held by University that arose out of and claimed priority to a Licensed Patent Application. "Licensed Patent" also means any reissues or reexaminations or post-issuance certificates of a Licensed Patent that contain one or more valid claims directed to a Licensed Intellectual Property Right. Any claim of an unexpired Licensed Patent is presumed to be valid unless it has been held to be invalid by a final judgment of a court of competent jurisdiction or the U.S. Patent and Trademark Office or a corresponding foreign patent office, from which no appeal can be or is taken.

"**Licensed Patent Application**" means a patent application described in Section 5.1 of the Business Terms along with continuations, continuation-in-part (but only to the extent the claims are supported by a patent application pending as of the Effective Date) and divisionals of such a patent application.

"**Licensed Product**" means a product or service or part of a product or service in the Allowed Field of Use: (a) the making, using, importing, selling, or providing of which, absent this license, infringes, induces infringement, or contributes to infringement of a Licensed Patent or is otherwise covered by a claim in a Licensed Patent Application;

or (b) which is made with, uses, was derived from, identified or validated by, incorporates, or was developed in whole or in part using any Licensed Technical Information.

"**Licensed Intellectual Property**" means means (i) Section 5.1 Licensed Patent Applications and (ii) Section 5.2 Technical Information **"Licensed Technical Information"** means Section 5.2 Technical Information. "**Licensee**" means the entity identified in Section 1 of the Business Terms.

"**Manufacturing Profits**" means the amount by which actual payments made by a sublicensee to COMPANY for any Licensed Product or components of any Licensed Product exceeds COMPANY's standard costs for manufacture and shipment of such products plus twenty five -five percent (25%).

"**Net Sales**" means all gross revenues derived by Licensee, its Affiliates, or Sublicensees, their distributors or designees from the sale, transfer or other disposition of Licensed Product to an end user. Net Sales excludes the following items: (a) all trade, quantity, and cash discounts actually allowed; (b) all credits and allowances actually granted due to rejections, returns, billing errors, and retroactive price reductions; (c) applicable duties; and (d) applicable excise, sale and use taxes.

"**Patent-Related Expenses**" means costs and expenses (including out-of-pocket attorneys' fees, patent agent fees and governmental fees) that University incurs in filing, prosecuting and maintaining the Licensed Patents.

"**Performance Milestone**" means an act or event specified described in Section 9 of the Business Terms.

"**Protein Biologic**" shall mean a protein product in the absence of cells, nucleic acid, and virus particles.

"**Royalty Consideration**" means any royalty payment received by Licensee from a Sublicensee based on the Sublicensee's sales of Licensed Products.

"**Sequence**" shall mean: (i) the humanized camelid B7H3 single domain (VHH) binder amino acid sequence set forth in Section 5.1 Licensed Patent Application; and (ii) the humanized camelid B7H3 single domain (VHH) binder amino acid sequence to the extent set forth in Section 5.1 Licensed Patent Applications comprising amino acid substitutions or deletions that do not affect targeting of the Sequence.

"**Sublicense**" when used as a noun, means an agreement between Licensee and a third party that contains a grant to University's Licensed Intellectual Property regardless of the name given to the agreement by the parties; when used as a verb, means Licensee's act of entering into any agreement with a third party that contains a grant to University's Licensed Intellectual Property, regardless of the name given to the agreement by the parties.

"**Sublicensee**" means the third party in a Sublicense.

"Sublicense Revenues" means all consideration (e.g., upfront fees, option fees, milestone payments and other similar license fees), in whatever form, received by Licensee from a Sublicensee in consideration of Licensee granting such Sublicensee a sublicense under the Licensed Technology granted to Licensee under this Agreement, provided however, that sublicensing revenue shall *exclude*: (a) royalty payments or similar payments based on sales of Licensed Products; (b) payments specifically allocated by Sublicensee on a commercially reasonable basis for costs to be incurred, or for reimbursement of costs incurred, by Licensee or its Affiliates in the research and development of Licensed Products (including in connection with equipment purchases, manufacturing costs, personnel expenses); (c) payments made by the sublicensee for patent prosecution, enforcement, maintenance and other intellectual property-related expenses; (d) payments to purchase capital stock of Licensee at fair market value (provided, however, that any premium consideration in excess of fair-market value will not be excluded "Technology Premium Equity payments"); and (e) payments for Licensed Products supplied by Licensee (or its Affiliate) at Licensee's standard cost of goods sold (calculated in accordance with generally accepted accounting principles in the U.S.) plus twenty-five percent (25%) for Licensee's Manufacturing Profits.

Notwithstanding the foregoing, in the event that rights or obligations in addition to the Licensed Technology are licensed or sublicensed by Licensee, Licensee will equitably apportion any consideration received by Licensee in consideration of the sublicense under the Licensed Technology, which shall be included in Sublicense Revenues as applicable, and any consideration received by Licensee in consideration of other rights and obligations, which shall not be included in Sublicense Revenues, and Licensee shall provide reasonable documentation to University in support of such apportionment. If University has a good faith objection to the apportionment, then University will give prompt notice to Licensee and the parties shall meet and attempt to agree on which portion of the total payments received by Licensee pursuant to such sublicense would constitute Sublicense Revenues. However, if the parties cannot agree upon such apportionment, senior management from each party will meet to discuss such apportionment and if senior management is unable to reach agreement, each party will select an independent expert with experience in valuation on intellectual property licenses in biotechnology, and the experts so chosen will agree upon such apportionment which shall be final and binding on the parties.

"Technology Premium Equity Payment" means payments to COMPANY equal to A x (B-C), where "A" is the number of COMPANY shares of stock or other units of equity purchased by the sublicensee, "B" is the unit price paid by the sublicense, and "C is the fair market value of the equity which shall be the closing price of COMPANY Common Stock on the last trading day immediately preceding the date such sublicense is executed.
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"**Territory**" means the geographical area described in Section 2 of the Business Terms.

"**Third Party"** means any party other than Licensee or its affiliates.

"Transfer" means the assignment of this License to a third party other than by a Change of Control.

"**TriKE**" shall mean a trispecific NK cell engager composed of an NK cell binding/activation domain operably linked to an NK cell IL-15 activation domain operably linked to a target cell targeting domain.

"**University Indemnitees**" means University, its respective regents, officers, employees, students, agents, faculty, representatives, volunteers, and, if applicable, other institutions with whom University has entered into an inter-institutional agreement covering the Licensed Patents.

"Year" means a calendar year during the term of this Agreement.

1.2 Rules of Interpretation and Convention

In this Agreement, unless the context requires otherwise:

(a) headings are for convenience only and do not affect interpretation;

(b) the singular includes the plural and conversely;

(c) a reference to any statute, rule, regulation or policy includes any amendment, and any statute, rule, regulation or policy replacing it;

(d) all computations and payments made under this Agreement shall be in United States dollars. To determine the U.S. dollar value of transactions conducted in non-United States currencies on any particular day, the parties shall use the exchange rate for that currency as reported in the Wall Street Journal in the most recently published edition prior to the date of the transaction; and

(e) all notices, reports, and other documents and instruments that a party elects or is required to deliver to the other party must be in English.

2. LICENSE

2.1 Grant of License

(a) Subject to the terms and conditions of this Agreement, University grants to Licensee:

(1) An exclusive license under University's rights in the Licensed Patents, Licensed Patent Applications and Licensed Technical Information (to the extent Licensed Technical Information remains in the Licensed Patents and Licensed Patent Applications) to make, have made, use, sell, offer for sale, import, and have imported a Licensed Product in the Territory as set forth in the Allowed Field of Uses (a-d); and

(2) A non-exclusive license under University's rights in Licensed Technical Information to the extent the Licensed Technical Information is no longer in Licensed Patents or Licensed Patent Applications solely to practice those methods and materials needed for Licensee to make, have made, use, sell, offer for sale, import, and have imported a Licensed Product in the Territory as set forth within the Allowed Field of Uses (a-d).

(b) Except as provided in this section, no other rights or licenses, express or implied, are granted to Licensee.

2.2 Retained Rights

Notwithstanding any provision of this Agreement, University retains on behalf of itself and all other non-profit research institutions, the right to practice the Licensed Intellectual Property for research, teaching, and education.

3. SUBLICENSING

3.1 Sublicense Requirements

Licensee shall have the authority only to enter into a Sublicense that:

(a) is subject to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement;

(b) will stipulate that the Sublicensee will not further sublicense; and

(c) provide for its termination upon termination of this Agreement.

3.2 Copy of Sublicenses and Sublicense Royalty Reports

Licensee shall submit to University within 60 days of effective date of Sublicense a copy of each Sublicense, any subsequent amendments and all copies of Sublicensee's royalty reports.

4. PAYMENT, RECORDS, AND AUDIT

4.1 Licensee's Payment Obligation

Licensee shall pay all amounts under Sections 7 and 10 of the Business Terms by the dates indicated therein. Licensee shall pay such amounts by wire transfer, check (payable to the "Regents of the University of Minnesota" and sent to: Regents of the University of Minnesota, NW 5960, PO Box 1450, Minneapolis, MN 55485-5960; reference agreement number on check), or any other method of payment specified by University.

Licensee Responsible for Non-U. S. Taxes

4.2 Licensee Responsible for Non-U.S. Taxes

a. In the event that a licensee or a sublicensee is required by law to deduct or withhold any amount from the payments payable to the University under this agreement, that deduction or withholding shall be allowed. However, notwithstanding such deduction or withholding, the licensee or a sublicensee shall provide the University with such reasonable assistance as is necessary to enable the University to prove that payment of the tax, levy, impost, duty, charge, fee, or set-off has been made and to assist the University to obtain credit in respect of it.

4.3 Interest

All amounts due under this Agreement will bear compound interest at 6% per annum on the entire unpaid balance computed from the due date until the amount is paid.

4.4 Security for Reimbursement of Patent-Related Expenses

University reserves the right to require Licensee to provide and maintain a reasonable advance deposit with University or some other form of security to ensure payment of Patent-Related Expenses.

4.5 Royalty Payments/Sales Reports

Within sixty (60) days after the last day of the second and fourth calendar quarters beginning in the calendar year in which Licensee first sells a Licensed Product, Licensee shall provide to University a written report (even if there are no sales) and earned royalty payment under Section 10.4 of the Business Terms in a form acceptable to University.

4.6 No Refund

Unless prohibited by applicable law, all amounts paid to University (and, if applicable, all equity issued to University under Section 10.1 of the Business Terms) by Licensee are non-refundable.

4.7 Termination Report

Licensee shall pay to University all amounts due under this Agreement and submit to University a written report to include contact information for Sublicensees within 90 days after the Agreement terminates. Licensee will continue to submit royalty payments and reports after the license terminates, until all Licensed Products made or imported under the Agreement have been sold.

4.8 Accounting

Licensee shall maintain (and shall cause each Sublicensee to maintain) records showing manufacture, importation, sale, use, and provision of a Licensed Product for 5 years from the date of sale of that Licensed Product. Records will include information in sufficient detail to enable University or its representative to determine the royalties owed under this Agreement. Upon request by University, Licensee shall deliver to University or its representative, copies of all documents and materials (including electronic records) reasonably relevant to Licensee's and Sublicensee's performance of this Agreement, including, without limitation, copies of all Sublicenses.

4.9 Audit

Licensee shall allow (and shall cause each Sublicensee to allow) University or its designee to examine Licensee's records to verify payments made by Licensee under this Agreement. In connection with such audit, Licensee shall provide (and shall cause each Sublicensee to provide) commodious space at no cost to conduct the audit.

4.10 Paying for Audit

University will pay for any audit done under Section 4.9 of the General Terms. But if the audit reveals an underreporting of royalties due University of 5% or more for the period being audited, Licensee shall pay the audit costs.

4.11 Royalty if Licensee Challenges the Licensed Patent

If Licensee brings an action seeking to invalidate a Licensed Patent, Licensee will pay royalties to University at the rate of two times the royalty rate specified in Section 10.4 of the Business Terms during the pendency of such action. Moreover, should the outcome of such action determine that any claim of a patent challenged by Licensee is both valid and infringed by a Licensed Product, Licensee will pay royalties at the rate of three times the royalty rate specified in Section 10.4 of the Business Terms.

5. GOVERNMENT RIGHTS AND REGULATIONS

5.1 Bayh-Dole Requirements

This Agreement is subject to Title 35, Sections 200-204 of the United States Code. Among other things, these provisions provide the United States Government with nonexclusive rights in the Licensed Patent. They also impose the obligation that any Licensed Products sold or produced in the United States be "manufactured substantially in the United States." Licensee shall ensure all obligations of these provisions are met.

5.2 Compliance with Laws

Licensee shall ensure that the manufacture, use, sale, or transfer of Licensed Products comply with all applicable laws and regulations.

5.3 Export Control

Licensee agrees to comply with U.S. export laws and regulations pertaining to the export of technical data, services and commodities, including the International Traffic in Arms Regulations (22 C.F.R., parts 120-130), the Export Administration Regulations (15 C.F.R., parts 730-744), the regulations administered by the Treasury Department's Office of Foreign Assets Control (31 C.F.R., parts 501-598) and the Anti-Boycott Regulations (15 C.F.R 760). Licensee shall obtain any necessary U.S. government license or other authorization required pursuant to the U.S. export control laws and regulations for the export or re-export of any commodity, service or technical data covered by this Agreement.

5.4 Cooperation with Governmental Requests

Licensee shall comply upon reasonable notice from University with all governmental requests relevant to the Licensed Intellectual Property directed to either University or Licensee and provide all information and assistance necessary to comply with the governmental requests.

5.5 Patent Marking

Licensee and each Sublicensee shall mark all Licensed Products in a manner consistent with their current patent marking practices for their own products provided appropriate notice is given in accordance with 35 USC 287 or other relevant statutes. Where marking is to be performed but the Licensed Product cannot be marked, the patent notice shall be placed on associated tags, labels, packaging, or accompanying documentation either electronic or paper as appropriate.

6. PATENT PROSECUTION AND MAINTENANCE

6.1 Patent Prosecution and Maintenance

University has the sole right to control the preparation, filing, prosecution, and maintenance of the Licensed Intellectual Property. To facilitate consultation with Licensee, University will:

(a) keep Licensee reasonably informed as to the filing, prosecution, and maintenance of the Licensed Patents;

(b) furnish to Licensee copies of material documents relevant to such filing, prosecution and maintenance; and

(c) allow Licensee a reasonable opportunity to comment on material documents filed with any patent office with respect to the Licensed Patents prior to filing.

6.2 Licensee Assistance and Contact

At University's request, Licensee shall provide all information and assistance to University in the filing and prosecution of all Licensed Patents. In furtherance of the foregoing, Licensee designates the person identified in Section 12 of the Business Terms to respond to University's request for consultation and cooperation on a pending matter within 10 business days or sooner as may be required under the circumstances. If Licensee's contact fails to respond in such time period, University, exercising its own judgment and discretion, may respond to the matter as it deems appropriate.

6.3 Patent Expenses

As set forth in Section 7 of the Business Terms, in the event there are multiple Licensees, each Licensee shall pay an equal portion of all patent related costs. GT Biopharma, as the first Licensee, shall be credited a portion of any payments made on a pro rata basis prior to the University licensing rights to others under Licensed Patent Application. Within 30 days after receiving an invoice from University, Licensee shall reimburse University for Patent-Related Expenses unless otherwise provided in this Agreement.

6.4 Licensee Additional Patent Applications

Licensee may file additional patent applications with claims directed toward use of the Sequence or compositions comprising the Sequence that do not overlap the claims of the Licensed Patent. Licensee shall consider any inventive concepts contributed by University personnel to the claims of such additional patent applications in making inventorship determinations. Licensee agrees to provide a draft of any such additional patent applications prior to filing.

7. COMMERCIALIZATION

7.1 Diligence

Licensee shall use its commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the Licensed Intellectual Property and to manufacture and offer to sell and sell Licensed Products as soon as practicable and to maximize sales thereof.

7.2 Performance Milestones

Licensee shall perform, or shall cause to happen or be performed, as the case may be, all the performance milestones described in Section 9 of the Business Terms.

7.3 Commercialization Reports

By March 1 of each year, Licensee will submit a written annual report to University covering the preceding calendar year if applicable. Each report will describe Licensee's progress toward commercialization of Licensed Product,

including work completed, key scientific discoveries, summary of work-in-progress, market plans for introduction of Licensed Product, and significant corporate transactions involving Licensed Product. Licensee will specifically describe how each Licensed Product is related to each Licensed Patent.

8. INFRINGEMENT

8.1 Notification to University

Licensee shall notify University if it believes a third party is infringing a Licensed Patent and provide University with all credible evidence that is has to support this belief.

8.2 Good Faith Negotiations with University Prior to Commencing Infringement Action

Prior to commencing any action to enforce a Licensed Patent, Licensee shall enter into good faith negotiations with University (and, if requested by University, with other licensees) on the desirability of bringing suit, the parties to the action, the selection of counsel, and such other matters. University may not be named (nor is Licensee authorized to name University) as a party in any such action without its prior written consent; such consent shall not be unreasonably withheld by the University.

8.3 Enforcement Litigation

Settlement of any Enforcement Litigation requires the written consent of the University; such consent shall not be unreasonably withheld by the University. Further, any recovery in any Enforcement Litigation in excess of any unrecovered litigations costs and fees will be shared with University as follows:

(b) any payments for past or future sales will be deemed Net Sales and Licensee shall pay University royalties on such payment at the rate specified in Section 10.4 of the Business Terms; and

(c) all other amounts recovered will be deemed Sublicense Consideration and Licensee shall pay University royalties on such amounts at the rate specified in Section 10.6 of the Business Terms.

8.4 Infringement by Licensee of Third Intellectual Property Rights

If any suit, action or proceeding is brought or commenced against Licensee alleging the infringement of a patent or other intellectual property right owned by a Third Party by reason of the manufacture, use or sale of Licensed Products, Licensee shall give University prompt notice thereof. If the validity of a Licensed Patent is questioned in such suit, action or proceeding, Licensee shall have no right to make any settlement or compromise which affects the scope, validity, enforceability or otherwise a Licensed Patent without University's prior written approval.

9. UNIVERSITY NAME AND MARKS

9.1 No Use of University Name or Marks

No provision of this Agreement grants Licensee or Sublicensee any right or license to use the name, logo, or any marks owned by or associated with University or the names, or identities of any member of the faculty, staff, or student body of University. Licensee shall not use and shall not permit a Sublicensee to use any such logos, marks, names, or identities without University's prior written approval.

10. TERMINATION

10.1 University's Right to Terminate for Breach

Except in the case of a Force Majeure event, University may terminate this Agreement if Licensee:

(a) is delinquent on any report or payment;

(b) misses a milestone under Section 9 of the Business Terms;

(c) is in breach of any material provision of this Agreement; or

(d) provides any materially false report.

10.2 Licensee's Right to Remedy Breach

Termination under Section 10.1 of the General Terms takes effect (without any further action by University) 60 days after written notice by University to Licensee of any default under Section 10.1 of the General Terms, unless within that60 -day period Licensee:

(a) remedies the default and notifies University of the same; and

(b) pays to University an administrative fee of $10,000.

10.3 Licensee's Right to Terminate

Licensee may terminate this Agreement:

(a) if University is in default of any material provision of this Agreement and fails to remedy the default within 60 days of Licensee's written notice; or

(b) for convenience ("Early Termination") by delivering to University a written notice of termination at least 60 days prior to the date of termination.

10.4 Effect of Termination.

Upon Termination:

(a) The grant of rights under Section 2.1 of the General Terms terminates. Licensee may, however, sell or dispose of Licensed Products manufactured prior to termination for one year thereafter, provided that Licensee continue to pay royalties on the sale of Licensed Products; and

(b) Upon request, University may grant a license to Sublicensees on financial terms substantially similar to such terms in sublicense provided Sublicensee has performed when due all of its obligations under the Sublicense.

(c) Sublicenses granted by Licensee covering the Licensed Intellectual Property set forth in Section 5 of the Business Terms of this Agreement shall be assigned to University upon request and at University's discretion; provided that University's obligations under such Sublicense shall be consistent with and not exceed University's obligations to Licensee under this agreement and provided that such Sublicensee agrees in a writing sent to University to assume all obligations of this Agreement for the benefit of University, including the obligations to make all payments and provide all reports due under this Agreement.

10.5 Sections of the Agreement Surviving Termination.

Surviving any termination or expiration are:

(a) Licensee's payment obligations for payments accrued prior to termination; and

(b) the provisions of Sections 4.7, 8, 9, 11,12, 13, 14.1, 14.3, 14.4 14.8, and 14.9 of the General Terms, and any other provision that by its nature is intended to survive.

11. INDEMNIFICATION AND INSURANCE

11.1 Indemnification

Licensee shall indemnify, hold harmless, and defend all University Indemnitees against any claim of any kind arising out of or related to the exercise of any rights granted Licensee under this Agreement or Licensee's breach of any provision of this Agreement.

11.2 Insurance

Licensee warrants that it now maintains and will continue to maintain liability insurance coverage appropriate to the risk involved in marketing and selling Licensed Products subject to this Agreement and that the insurance coverage lists University of Minnesota as an additional insured. Upon University's request, Licensee shall present evidence to University that this coverage is being maintained.

12. DISCLAIMER OF WARRANTIES

12.1 Warranties

University warrants that to the best of its actual knowledge as of the date of execution of this Agreement it has the right to grant the licenses to the Licensed Intellectual Property contained in this Agreement.

12.2 Disclaimer of all Other Warranties

UNIVERSITY PROVIDES LICENSEE THE RIGHTS GRANTED IN THIS AGREEMENT AS IS AND WITH ALL FAULTS, IF ANY. UNIVERSITY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED CONCERNING THE LICENSED INTELLECTUAL PROPERTY.

AMONG OTHER THINGS, UNIVERSITY EXPRESSLY DISCLAIMS ANY WARRANTIES CONCERNING AND MAKES NO REPRESENTATIONS:

(a) that each Licensed Patent Application will be allowed or granted or that a patent will issue from a Licensed Patent Application;

(b) concerning the validity, enforceability, interpretation of claims or scope of any Licensed Patent;

(c) that the exercise of the rights or licenses granted to Licensee or a Sublicensee under this Agreement will not infringe or violate a third party's intellectual property rights; or

(d) that the exploitation of Licensed Patent or Intellectual Property Rights will be successful.

13. LIMITATION ON TYPE AND AMOUNT DAMAGES

13.1 Limitation on Type of Damages

University is not liable for any special, consequential, lost profit, loss of business opportunity, expectation, punitive or other indirect damages in connection with any claim arising out of or related to this Agreement.

13.2 Limitation on Amount of Damages.

In no event shall University's liability to Licensee exceed the payments made to University by Licensee during the 6 months prior to the event that gave rise to the claim.

14. MISCELLANEOUS

14.1 Choice of Law and Jurisdiction

The internal laws of the state of Minnesota, without giving effect to its conflict of laws principles, govern the validity, construction, and enforceability of this Agreement. A suit, claim, or other action to enforce the terms of this Agreement may be brought only in the state courts of Hennepin County, Minnesota. Licensee hereby submits to the jurisdiction of that court and waives any objections it may have to that court asserting jurisdiction over Licensee or its assets and property and to venue in that jurisdiction.

14.2 Amendment and Waiver

The Agreement may be amended from time to time only by a written instrument signed by the parties. No term or provision of this Agreement may be waived, and no breach excused unless such waiver or consent is in writing and signed by the party claimed to have waived or consented. No waiver of a breach is to be deemed a waiver of a different or subsequent breach

14.3 Data Practices Act

The parties acknowledge that University is subject to the terms and provisions of the Minnesota Government Data Practices Act, Minnesota Statutes §13.01 et seq. (the "Act"), and that the Act requires, with certain exceptions, University to permit the public to inspect and copy any information that University collects, creates, receives, maintains, or disseminates, including the existence of and the terms of this Agreement.

14.4 Confidentiality

To the extent permitted by law, including as provided in the Act, University shall hold in confidence and disclose only to University employees, agents and contractors who need to know:

(a) the reports described in Sections 3.2, 4.5, 7.3 of the General Terms;

(b) the documents provided under Section 10.10 of the Business Terms; and

(c) the records inspected in accordance with Sections 4.8 and 4.9 of the General Terms. No provision of this Agreement is to be construed to further prohibit, limit, or condition University's right to use and disclose any information in connection with enforcing this Agreement, in court or elsewhere.

14.5 Assignment

Except as provided in Section 14.6 of the General Terms or with University's prior written consent, Licensee shall not effect a Transfer of its interest under this Agreement. Any Transfer attempted to be made in violation of this section is void. Absent the consent of all the parties, an assignment or delegation will not release the assigning or delegating party from its obligations.

14.6 Change of Control

Licensee may assign this Agreement as part of a Change of Control upon prior and complete performance of the following conditions:

(a) Licensee must give University 30-days prior written notice of the assignment, including the new assignee's contact information;

(b) the new assignee must agree in writing to University to be bound by this Agreement; and

(c) University must have received the full Transfer Fee.

14.7 Consent and Approvals

Except as otherwise expressly provided, in order to be effective, all consents or approvals required under this Agreement must be in writing.

14.8 Entire Agreement

The parties intend this Agreement (including all attachments, exhibits, and amendments hereto) to be the final and binding expression of their contract and agreement and the complete and exclusive statement of the terms thereof. The Agreement cancels, supersedes, and revokes all prior negotiations, representations and agreements among the parties, whether oral or written, relating to the subject matter of this Agreement. No representations or statements of any kind made by either party, which are not expressly stated herein, will be binding on such party.

14.9 Enforceability

If a court of competent jurisdiction adjudges a provision of this Agreement to be unenforceable, invalid, or void, such determination is not to be construed as impairing the enforceability of any of the remaining provisions hereof and such provisions will remain in full force and effect.

14.10 No Third-Party Beneficiaries

No provision of this Agreement, express or implied, is intended to confer upon any person other than the parties to this Agreement any rights, remedies, obligations, or liabilities hereunder. No Sublicense may enforce or seek damages under this Agreement.

14.11 Relationship of Parties

In entering into, and performing their duties under this Agreement, the parties are acting as independent contractors and independent employers. No provision of this Agreement creates or is to be construed as creating a partnership, joint venture, or agency relationship between the parties. No party has the authority to act for or bind the other party in any respect.

14.12 Notices

In order to be effective, all notices, requests, and other communications that a party is required or elects to deliver must be in writing and must be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other party at its address set forth below or to such other address as such party may designate by notice given under this Section:

If to University:

University of Minnesota
Technology Commercialization
200 Oak Street, SE
Suite 280
Minneapolis, MN 55455
Fax: 612.624.6554
E-mail: otcagree@umn.edu

For notices sent under Section 8, with a copy to:	University of Minnesota Office of the General Counsel Attn: Director, Transactional Law Services 360 McNamara Alumni Center 200 Oak Street S.E. Minneapolis, MN 55455-2006 Facsimile No.: 612.626.9624 Email: contracts@mail.ogc.umn.edu
If to Licensee:	As indicated in Section 11 of the Business Terms.

14.13 Security Interest

In no event may Licensee grant, or permit any person to assert or perfect, a security interest in Licensee's rights under this Agreement.

14.14 Execution in Counterparts

This Agreement may be executed in counterparts and by facsimile or electronic transmission.

14.15 Force Majeure

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, changes of laws, competent authorities' order, government imposed business closures resulting from "Shelter-in-Place" orders, or omissions or delays in acting by any governmental authority or the other party.

UNIVERSITY OF MINNESOTA

RESEARCH AGREEMENT

THIS AGREEMENT is entered into effective as of June 16, 2021 (the "Effective Date") by and between Regents of the University of Minnesota (the "University"), a public educational institution and a Minnesota constitutional corporation, and GT Biopharma, Inc. (the "Sponsor"), a Delaware Corporation. This Agreement is entered into by the University through its Office of Sponsored Projects Administration.

Purpose

The research program contemplated by this Agreement is of mutual interest and benefit to University and to Sponsor and will further the instructional and research objectives of the University. The research is to be funded by Sponsor and carried out by the University.

NOW, THEREFORE, the parties agree as follows.

Article 1 – Term

The Term of this Agreement shall commence on the Effective Date and unless earlier terminatedas provided in Article 9 shall expire on June 30, 2023 ("Expiration Date"). The parties may extend the term of this Agreement for additional periods with or without additional funding through duly executed amendments.

Article 2- Research Work

2.1 University shall perform the project as set forth in Appendix 1 (the "Project") in accordance with the terms and conditions of this Agreement. Anything in this Agreement to the contrary notwithstanding, Sponsor and University may at any time amend Project by mutual written agreement. Any budgetary information included in the attachments to this agreement is for informational purposes only; the University retains the right to re-budget funds within the funded amount as needed to further project objectives.

2.2 The Project shall be under the direction of Jeffrey Miller, MD ("Principal Investigator"). In the event that the Principal Investigator becomes unable or unwilling to continue Project, and a mutually acceptable substitute is not available, University and/or Sponsor shall have

FORM: OGC-SC750
MN-IP Domestic Research Agreement
Form Date: 02.28.14
Form Last Revised: 06.29.20

the option to terminate said Project in accordance with Article 9. This Agreement does not limit the freedom of individuals participating in this Project to engage in any other research.

Article 3 - Reports and Conferences

3.1 Written progress reports shall be provided by University to Sponsor upon reasonable request or upon completion of each phase of the Project as detailed in Appendix A as applicable. A final report shall be submitted by University within ninety (90) days of the conclusion or early termination of this Agreement.

3.2 During the term of this Agreement, representatives of University will meet with representatives of Sponsor at times and places mutually agreed upon to discuss the progress and results, as well as ongoing plans or changes.

Article 4 - Costs, Billings, and Other Support

4.1 University shall use reasonable efforts to complete the Project for a fixed sum of Two Million Seventy Four Thousand Six Hundred Eighty Six dollars ($2,074,686) ("Contract Price"). The Contract Price does not include any fees payable under Section 8.5.

4.2 Sponsor agrees to make an initial payment of Five Hundred Forty One Thousand Five Hundred Twenty Seven dollars ($541,527 [comprising of one $191,527 quarterly payment plus $350,000 for equipment]) within thirty (30) days of execution of the Agreement. Sponsor then agrees to make seven quarterly equal payments of One Hundred Ninety One Thousand Five Hundred Twenty Seven dollars ($191,527) following receipt of an invoice from the University. The initial invoice will be sent within thirty (30) days following execution of this Agreement. Sponsor shall make a final payment of One Hundred Ninety Two Thousand Four Hundred Seventy dollars ($192,470) within thirty (30) days of receipt of the final report.

Any fees payable under Section 8.5 will be invoiced separately in accordance with Section 8.5.

4.3 University shall acquire title upon acquisition of any equipment purchased or fabricated with funds provided by Sponsor under this Agreement. Sponsor shall provide the following equipment to University under the following conditions:

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[Either (a) indicate "none" or (b) insert a list of equipment to be provided, indicate loan or gift, and attach a signed copy of equipment loan(s) or deed(s) of gift**:]**

NONE.

4.4 Payments made under this agreement shall be in United States dollars and shall be made payable to "Regents of the University of Minnesota". All payments shall be accompanied by the University invoice number, the Contract number, and name of Principal Investigator. Payments shall be sent to:

Regents of the University of Minnesota
NW 5957
P.O. Box 1450
Minneapolis, MN 55485-5957
Ph: 612.624.4313
Fax: 612.626.0321

Article 5 - Nondisclosure

5.1 For purposes of this Agreement, "Confidential Information" means written or tangible information disclosed by either party to the other, which at the time of disclosure is clearly and conspicuously labeled "Confidential" or "Proprietary". Confidential Information shall also include oral and visual disclosures which are identified as confidential at the time of such disclosures and which are confirmed and summarized within fifteen (15) days of the disclosure by the disclosing party in a writing that sets forth the substance of the Confidential Information disclosed. The parties agree to maintain confidentiality of the Confidential Information during the term of this Agreement, including any renewal periods, and for a period of three (3) years from the effective termination or expiration date of this Agreement. Neither party shall use said Confidential Information for any purpose other than those purposes specified in this Agreement. The parties may disclose Confidential Information to employees requiring access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures each such employee shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Neither party will be held financially liable for any inadvertent disclosure, but each will agree to use its reasonable efforts not to disclose any Confidential Information.

5.2 Nothing contained herein will in any way restrict or impair either party's right to use, disclose, or otherwise deal with any Confidential Information which:

5.2.1 At the time of its receipt, is generally available in the public domain, or thereafter becomes available to the public through no act of the receiving party;

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

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

5.2.4 Is required by law (including the Minnesota Government Data Practices Act), and/or regulation or court order to be disclosed. In the event that Confidential Information is required to be disclosed pursuant to this subsection, the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under law.

5.3 Export Controls:

5.3.1 The parties acknowledge that they must comply with export control laws, including the International Traffic in Arms Regulations (ITAR), 22 C.F.R. pts. 120-130; the Export Administration Regulations (EAR), 15 C.F.R. pts. 730-774; and the Foreign Assets Control Regulations, 31 C.F.R. pts. 501-598.

5.3.2 Notwithstanding any other term herein, the University's research in connection with this Agreement shall constitute "fundamental research" for purposes of export control laws. University-generated technical data and software that arise during or result from "fundamental research" are not subject to the ITAR or EAR.

5.3.3 The Sponsor shall not convey technical data, technology, commodities, or software on the U.S. Munitions List, 22 C.F.R. pt. 121, or the Commerce Control List, 15 C.F.R. pt. 774, to the University without the prior written consent of the University's Export Controls Officer (J. Patrick Briscoe, bris0022@umn.edu, 612-625-3860). The University may decline receipt of listed items at its sole discretion and at no penalty.

Article 6 - Publicity

6.1 Sponsor will not use the name, logos and other marks and trade names of University, nor of any member of University's Project staff, in any publicity, advertising, or news release without the prior written approval of an authorized representative of University. University will not use the name, logos and other marks and trade names of Sponsor, nor any employee of Sponsor, in any publicity without the prior written approval of Sponsor.

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

6.3 In accordance U.S. Securities Exchange Commission and other reporting requirements for publicly listed companies, Sponsor shall be allowed to disclose the following non-confidential information without the approval of the University: (1) the existence of the contract; (2) the identity of the University and, if a subcontract is involved, the identity of the prime contractor; and (3) the purpose and the scope of the proposed research. The Sponsor may also disclose information as needed to comply with U.S. government reporting requirements or other such reporting requirements for entering into material agreements.

Article 7 – Publications

7.1 Sponsor recognizes that under University policy the results of the Project must be publishable and agrees that researchers engaged in the Project shall be permitted to present at symposia, national or regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Project. University shall have the final authority to determine the scope and content of any publication; provided, however, that University shall provide copies of any proposed publication at least forty-five (45) days in advance of the publication or presentation to Sponsor to review and object to such publication or presentation because such draft either contains information deemed to be Confidential Information under the provisions of Article 5 of this Agreement, or reveals information that if published within forty-five (45) days

would have an adverse effect on a patent application in which Sponsor owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. In the event that Sponsor notifies the University in writing that the proposed publication or presentation contains Sponsor's Confidential Information, the University shall remove any Sponsor Confidential Information from the draft prior to such publication or presentation. In the event Sponsor requests in writing a delay in publication to file for patent protection, the University and the Researcher shall refrain from making such publication or presentation for a maximum of ninety (90) days from the receipt of such objection, and Sponsor shall indicate with specificity to what manner and degree University may disclose said information during the ninety (90) day period.

7.2 Publication by either party to this Agreement shall give proper credit to the other party for the cooperative character of the investigation.

7.3 TriKE™ is a trademark of GT Biopharma, Inc. TriKE™ shall appear in all publications by University describing any aspect of the Research, and an acknowledgement of financial support from GT Biopharm, Inc. shall also be included in the acknowledgment section of the publication.

Article 8 – Intellectual Property and License of Inventions

8.1 Use of Research Results.

8.1.1 Copyright to copyrightable materials, including computer software, resulting from Project shall vest in University with a royalty-free non-exclusive, non-sublicensable license to Sponsor for its Non-Commercial use. "Non-Commercial" means not primarily intended for or directed towards commercial advantage or monetary compensation. By way of illustration, but without limitation, using software in a process to make a product would be Non-Commercial; selling the software or embedding the software in a product would be a commercial use.

8.1.2 Except for (a) the above limitation on copyrightable works in 8.1.1, (b) University's right to control publication of its own research results, (c) patented and patent-pending University Subject Inventions, and (d) University Confidential Information, Sponsor will have the free, irrevocable, non-exclusive unlimited right to use all research results for any purpose worldwide.

8.2 Subject Inventions.

8.2.1 "Subject Invention" means any patentable invention (excluding design patents) that is first conceived or reduced to practice by one or more employees of University, alone or with others, in performance of the Project. The inventorship of a Subject Invention will be determined in accordance with Title 35 of the United States Code. "Subject Invention" does not include copyrightable material, including source code or software.

8.2.2 "University Subject Inventions" are those Subject Inventions invented solely by employees of University. "Joint Subject Inventions" are those Subject Inventions invented by employees of University jointly with employees of Sponsor.

8.2.3 No rights to University background intellectual property are granted under the terms of this agreement.

8.3 Patent Applications and Costs

8.3.1 Each party shall promptly disclose to the other party in writing any Subject Invention of which that party becomes aware during the Term or afterwards.

8.3.2 Sponsor, in consultation with University, shall have the right to control the preparation, filing, and prosecution of each patent application that is specific to a Subject Invention. Sponsor shall have three (3) months from receipt of an invention disclosure from University to notify University whether it desires to file a patent application on the Subject Invention ("Subject Invention Review Period"). If Sponsor files, then Sponsor shall diligently pursue filing of the patent application in the name of University with respect to University Subject Inventions and in the name of both University and Sponsor in the case of Joint Subject Inventions. Although Sponsor shall have the ultimate decision authority in preparation, filing, and prosecution of each patent application that is specific to a Subject Invention, Sponsor shall keep University's office for Technology Commercialization informed (with copy to otcpatent@umn.edu) as to all material matters relevant to the patent prosecution process and decision matters, and the Sponsor shall give due consideration to any recommendations made by the University concerning the patent prosecution matters. Sponsor and Sponsor's counsel will not contact University inventors regarding drafting and prosecution without first contacting University's office for Technology Commercialization Without limiting the foregoing, Sponsor or Sponsor's counsel shall provide a copy of the draft application and responses to office actions to University at otcpatent@umn.edu and

an opportunity to review and provide comments on such application. Further, Sponsor shall provide, or direct Sponsor's counsel to provide, University with all serial numbers and filing dates, together with copies of all applications and patents that issue therefrom, including copies of all office actions, responses and all other substantive communications to and from the U.S. Patent and Trademark Office and the patent offices in any other jurisdictions. Sponsor shall be responsible for the full expense of Subject Invention patent application and prosecution.

8.3.3 If Sponsor decides (i) not to prepare, file, or prosecute patent applications specific to a Subject Invention within the Subject Invention Review Period, (ii) not to file an application in a particular jurisdiction, (iii) to discontinue prosecution of a pending application or a particular set of claims of a patent application, which set is specific to a Subject Invention, or (iv) not to pay any required fee to maintain a pending patent application or an issued patent, Sponsor shall promptly (but in no event less than 30 days before an action is required) notify University of its decision. In such case, University shall have the right to file, prosecute, and maintain said patent or patent application, or to file an application directed to that abandoned claim set, at its sole discretion and expense and without further obligation to Sponsor.

8.4 Nothing in this Article 8 shall be interpreted in a manner contrary to the publication provisions of Article 7 herein.

8.5 **Sponsor's Licensing Options**. Sponsor shall have an option during the Option Period (as defined herein) with respect to University Subject Inventions that are covered by claims in Licensed Patent and Licensed Patent Applications under the Exclusive Patent License Agreements, dated: 7.18.2017 (A# 20170047) & 3.26.2021 (A# 2021-0831) ("EPLA's") ("Covered Inventions") to add the Covered Inventions to the EPLA's upon payment of $15,000 and written notice to the University during the option period. The EPLA's will then be amended to reflect the addition of the Covered Inventions. This option period expires 6 months from the date the University notifies of the Covered Invention to Sponsor.

As to any University Subject Inventions that are not covered under the EPLA's ("**Other Inventions**"), Sponsor is granted an option to negotiate a license to such inventions on mutually agreeable terms. The option period expires six months from the date University notifies Sponsor of Other Inventions.

8.6 **Reservation of Rights**University retains an irrevocable, world-wide, royalty-free, non-exclusive right to use the Subject Inventions for teaching, research and educational purposes. The University shall have the right to sublicense its rights under this section to one or more non-profit academic or research institutions.

Article 9 - Termination

9.1 Either party may terminate this Agreement upon thirty (30) days prior written notice to the other. Upon submission/receipt of a notice of termination, University shall take measures to stop spending as soon as possible. A final accounting of expenses will be submitted within sixty (60) days of the termination date documenting all expenses incurred and all non-cancellable expenses which Sponsor is responsible for and showing the amount of funding overpaid or owed. If Sponsor has an unpaid balance remaining, Sponsor shall make the final payment within thirty (30) days after receipt of the final invoice. If Sponsor has overpaid, a check for the balance will be included within thirty (30) days of submission of the final accounting.

9.2 In the event of early termination of this Agreement by Sponsor pursuant to Article 9.1, Sponsor shall pay all costs incurred by University as of the date of termination, together with all non-cancellable obligations, which shall include all non-cancelable contracts, graduate assistantships, fellowships and postdoctoral associate appointments, entered into prior to the notice of termination. After termination, any obligation of Sponsor for fellowships, graduate assistantships or postdoctoral associates shall end no later than the end of University's academic year following termination.

9.3 In the event of early termination of this agreement by University pursuant to Article 9.1 or by either party pursuant to Article 2.2, Sponsor shall pay only the costs incurred up to the date of termination.

9.4 In the event that either party hereto shall commit any material breach of or default in any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within ninety (90) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.

9.5 Subject to Article 8.6, termination of this Agreement by either party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. No termination of this Agreement, however effectuated, shall affect the Sponsor's rights and duties hereof, or release the parties hereto from their rights and obligations under Articles 4, 5, 6, 7, 8, 9, 11, 12, 13, 14 and 17.

Article 10 - Independent Contractor

It is expressly understood that University and Sponsor are independent contractors and not the agent, partner, or employee of the other. In this regard, neither party shall have the authority to enter into any contract or agreement to bind the other and shall not represent to anyone that it has such authority, nor shall their respective employees be entitled to any benefits applicable to employee of the other party.

Article 11 - Insurance and Indemnification

11.1 Each party represents that it has and will continue to have at least the following levels of insurance or self-insurance during the term of this Agreement: (i) as to the University, Workers' Compensation in statutory compliance with Minnesota State Law; and (ii) as to both parties, General Liability Insurance in an amount not less than one million dollars ($1,000,000) per occurrence/two million dollars ($2,000,000) annual aggregate. University represents that the University and Principal Investigator have and will continue to have Professional Liability insurance in an amount not less than one million dollars ($1,000,000) per occurrence/two million dollars ($2,000,000) annual aggregate. Sponsor represents that it has and will continue to have Product Liability insurance or self-insurance in an amount not less than one million dollars ($1,000,000) per occurrence/two million dollars ($2,000,000) annual aggregate. Certificates of all insurance detailed above shall be furnished to the other party upon request.

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

11.3 Sponsor shall indemnify, defend, and hold harmless University against any and all claims, costs, or liabilities, including attorneys' fees and court costs at both trial and appellate levels, for any loss, damage, injury, or loss of life (other than that attributable to willful, wanton or intentional acts or omissions of the University) arising out of use by Sponsor or any third party acting on behalf of or under authorization from Sponsor of information,

reports, discoveries, deliverables, materials, products or other results of University's work under this Agreement. Article 11.3 shall apply with the provision that (a) University promptly notifies Sponsor in writing after University receives notice of any claim, (b) Sponsor is given the opportunity, at its option, to participate and associate with University in control, defense, and trial of any claim and any related settlement negotiations and (c) University fully cooperates with Sponsor in the defense of any such claim.

Article 12 – Disclaimer of Warranties

University makes no warranties, express or implied, as to any matter whatsoever, including without limitation, the condition, originality or accuracy of the research or any invention (s) or product(s), whether tangible or intangible, conceived, discovered, or developed under this agreement; or the ownership, merchantability, or fitness for a particular purpose of the research or any such invention or product.

Article 13 – LIMITATION OF LIABILITY FOR BREACH OF CONTRACT

IN NO EVENT SHALL EITHER PARTY'S LIABILITY FOR BREACH OF CONTRACT INCLUDE DAMAGES FOR WORK STOPPAGE, LOST DATA, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFIT), OF ANY KIND. THE UNIVERSITY'S LIABILITY TO SPONSOR FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION PAID TO THE UNIVERSITY UNDER THIS AGREEMENT. EXCEPT FOR SPONSOR'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11.3, SPONSOR'S LIABILITY TO THE UNIVERSITY FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION DUE UNDER THIS AGREEMENT.

Article 14 - Governing Law and Jurisdiction

The internal laws of the state of Minnesota shall govern this Agreement, without giving effect to its conflict of laws principles. All suits, actions, claims and causes of action relating to the construction, validity, performance and enforcement of this Agreement shall be in the courts of Hennepin County, Minnesota.

Article 15 - Assignment

The parties may not assign any rights or obligations of this Agreement without the prior written consent of the other party. Any assignment attempted to be made in violation of this Agreement shall be void.

Article 16 - Agreement Modification

This Agreement shall be amended only in writing duly executed by all the parties to this Agreement. No waiver by any party of any default or nonperformance shall be deemed a waiver of any subsequent default or nonperformance.

Article 17 - Notices

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

If to Sponsor:
Michael Handelman
Chief Financial Officer
GT Biopharma, Inc.
9350 Wilshire Blvd
Suite 203
Beverly Hills, CA 90212
Email: mh@gtbiopharma.com

If to University:
Sarah Danner
Sponsored Projects Administration
University of Minnesota
450 McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455-2070
Telephone: (612) 626-0270
E-Mail: sndanner@umn.edu

with a copy to Principal Investigator
Jeffrey Miller, MD
420 Delaware Street SE
MMC 480
Minneapolis, MN 55455
Telephone: 612-626-4024
E-Mail: mille011@umn.edu

If to University's Office for Technology Commercialization under Section 8.3:

Office for Technology Commercialization
University of Minnesota
280 McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455-2070
Telephone: (612) 624-0550
Fax : (612) 624-6554
E-Mail: umotc@umn.edu

Article 18 - Force Majeure

No party to this Agreement shall be responsible for any delays or failure to perform any obligation under this Agreement due to acts of God, strikes or other disturbances, including, without limitation, war, insurrection, embargoes, pandemics, governmental restrictions, acts of governments or governmental authorities, and any other cause beyond the control of such party.

Article 19 - Entire Agreement

This Agreement (including all attached or referenced exhibits, schedules, appendices, addenda, or other documents) (collectively, the "Attachments") is intended by the parties as the final and binding expression of their agreement and as the complete and exclusive statement of its terms. This Agreement cancels, supersedes and revokes all prior negotiations, representations and agreements among the parties, whether oral or written, relating to the subject matter of this Agreement, including any non-disclosure or confidentiality agreements. To the extent the Attachments contain any terms and conditions that conflict with the terms and conditions of this Agreement or which materially change or add to the terms and conditions contained in this Agreement, such changes will be ignored and given no effect.

Article 20 – Severability

If any provision of this Contract becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible from this Contract and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Contract, the parties will negotiate in good faith to amend the provisions of this Contract to give effect to the original intent of the parties.

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Article 21 - Counterparts

This Agreement may be signed in counterparts, each of which shall be deemed one and the same original.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of on the date first written above.

REGENTS OF THE UNIVERSITY OF MINNESOTA	***SPONSOR***
BY:	BY: Anthony Cataldo
TITLE: Sr. Grant & Contract Administrator	TITLE: Chairman & Chief Executive Officer
DATE: 7/1/21	DATE: 06/26/2021

I have read the above agreement and agree to perform my obligations as principal investigator(s) under this agreement. I also understand and agree to the disposition of rights in inventions, discoveries, and other results as provided by this agreement and to the provisions concerning confidentiality and publications. I will inform students and other participants working on this research of their rights and obligations under this agreement.

Principal Investigator	Co-Principal Investigator *(If Applicable)*
BY:	BY:
TITLE: Professor of Medicine	TITLE:
DATE: 06/30/2021	DATE:

Appendices:
Appendix 1– Description of the Research Project
Appendix 2 – Project Budget

FORM: OGC-SC750
MN-IP Domestic Research Agreement
Form Date: 02.28.14
Form Last Revised: 06.29.20

Appendix 1 – Description of the Research Project

This scientific research agreement aims to continue our work with GT Biopharma with three major goals in mind: (1) support of GT Biopharma's TriKE product development and GMP manufacturing efforts; (2) TriKE pharmacokinetics optimization in humans; and, (3) investigation of the patient's native NK cell population based on insights obtained from the analysis of the human data generated during GT Biopharma's GTB-3550 clinical trial. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE constructs in support of GT Biopharma product development and GMP manufacturing efforts; (2) TriKE platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and, (3) gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE therapy. Most studies will use TriKE DNA/amino acid sequences created by GT Biopharma under current UMN/GTB licensing terms.

Specific AIM #1:
A. Provide support for GT Biopharma's TriKE product development and GMP manufacturing efforts. Studies will analyze GT Biopharma's TriKE Product Candidates for in vitro and in vivo function including but not limited to:

1. CD107a degranulation assay
2. NK cell proliferation assay
3. Target cancer cell surface marker blocking studies
4. in vivo xenogeneic mouse targeted tumor model studies
5. IncuCyte/xCELLigence killing assays

B. Studies will also be conducted in support of GT Biopharma's filing of Investigational New Drug applications related to the evaluation of TriKE Product Candidates in human clinical trials.

Specific AIM #2:

A. Investigate ways to improve pharmacokinetics (PK) of GT Biopharma's TriKE Product Candidates:

1. Evaluate different routes of administration (SQ and bolus intravenous) in mouse models.
2. Evaluate incorporation of moieties which interact with receptors in kidney.

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Specific AIM #3:

A. Evaluate effect of TriKE on the native NK cell population of patients administered TriKE.
   1. Determine the minimum target cancer cell surface receptor density (e.g. Her2, B7H3, PD-L1, companion diagnostics) needed for efficacy.
   2. Evaluate TriKE trafficking in in vivo (e.g. copper labelling [or other])
   3. Determine toxicity profile including serum cytokine levels generally associated with clinical outcomes (toxicity, CRS, response).
   4. Determine the best dosing frequency to sustain efficacy in pre-clinical models.
   5. Understand the trafficking of NK cells from blood to tissue with dosing strategy.
   6. Determine NK cell receptor occupancy and Kd (CD16 and IL-15) in the presence of TriKE.
   7. Determine functional viability of obese vs non-obese patient NK cells in relation to perforin/granzyme inhibition, and suitability of TriKE for treatment of obese (BMI >38) patients.
   8. Evaluate use of possible combination therapeutic strategies with TriKE.

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Appendix 2 – Project Budget

					Year 1	Year 2	Total
Personnel:	**Role on Project**	**Effort**	**urrent Salary**	**Adjusted Base**			
Jeffrey Miller	Co-Principal Investigator	1%	204,700	209,818	2,098	2,140	4,238
		###	*Fringe*		766	781	1,547
Martin Felices	Co-Investigator	5%	97,500	99,938	4,997	5,097	10,094
		###	*Fringe*		1,824	1,860	3,684
Bartosz Grzywacz	Co-Investigator	5%	94,800	97,170	4,859	4,956	9,814
		###	*Fringe*		1,773	1,809	3,582
Todd Lenvik (Molecular)	Researcher 6	30%	80,614	82,629	24,789	25,285	50,073
		###	*Fringe*		9,048	9,229	18,277
To Be Named (Functionals)	Technician	100%	38,000	38,000	38,000	38,760	76,760
		###	*Fringe*		12,084	12,326	24,410
To Be Named (Functionals)	Technician	100%	38,000	38,000	38,000	38,760	76,760
		###	*Fringe*		12,084	12,326	24,410
To Be Named (Mouse Studies)	Technician	100%	38,000	38,000	38,000	38,760	76,760
		###	*Fringe*		12,084	12,326	24,410
Peter Hinderlie (CyTOF)	Researcher 5	10%	54,596	55,961	5,596	5,708	11,304
		###	*Fringe*		2,043	2,083	4,126
Tilahoun Ashenafi (CODEX-Grzywacz)	Researcher 4	20%	69,992	71,742	14,348	14,635	28,984
		###	*Fringe*		5,237	5,342	10,579
Behiye Kodal (Functionals)	Researcher 4	50%	46,915	48,088	24,044	24,525	48,569
		###	*Fringe*		7,646	7,799	15,445
Deepa Kolasari	Project Manager	5%	133,250	136,581	6,829	6,966	13,795
		###	*Fringe*		2,493	2,542	5,035
Subtotal Salaries					201,560	205,591	407,151
Subtotal Fringe					67,081	68,423	135,504
Personnel Total					268,641	274,014	542,655
Consultants							-
Travel					4,000	4,000	8,000
Equipment (shared equipment purchase/maint plans)					350,000		350,000
Supplies:							
Supplies for Miller					79,500	94,500	174,000
Supplies for Felices					79,500	94,500	174,000
CODEX (Grzywacz)					20,000	20,000	40,000
Animal Models					38,000	136,045	174,045
Supplies Total					217,000	345,045	562,045
Other Direct Costs:							
					-	-	-
							-
Other Direct Total					-	-	-
Total Direct Costs					**839,641**	**623,059**	**1,462,700**
Modified Total Direct Costs					489,641	623,059	1,112,700
Total Indirect Costs (55%)					269,303	342,683	611,986
TOTAL COSTS REQUESTED					**1,108,944**	**965,742**	**2,074,686**

FORM: OGC-SC750
MN-IP Domestic Research Agreement
Form Date: 02.28.14
Form Last Revised: 06.29.20

SUBLEASE AGREEMENT

This Sublease Agreement (this "Sublease") is made and executed as of the 19th day of November, 2021 (the "Effective Date"), by and between AIMMUNE THERAPEUTICS, INC. (formerly known as Allergen Research Corporation, Inc.) ("Sublandlord"), a Delaware corporation, and GT BIOPHARMA, INC. ("Subtenant"), a Delaware corporation.

RECITALS:

A. Sublandlord is the tenant under that certain Office Lease by and between HCP Life Science REIT, Inc., as successor-in-interest to Diamond Marina LLC and Diamond Marina II LLC ("Landlord"), and Sublandlord, as tenant, dated February 23, 2015 (the "Original Lease"), as modified by that certain First Amendment to Lease dated August 26, 2015 (the "First Amendment"), that certain Second Amendment to Lease dated June 27, 2017 (the "Second Amendment"), and that certain Third Amendment to Lease dated December 20, 2019 (the "Third Amendment" and together with the First and Second Amendments, the "Amendments" and, the Amendments collectively with the Original Lease, the "Prime Lease", a redacted copy of which is attached hereto and made a part hereof under Exhibit A), for certain office space, totaling approximately 57,361 rentable square feet (the "Prime Premises"), comprising the first (1st), second (2nd), and third (3rd) floors of that certain building located at 8000 Marina Boulevard, Brisbane, California (the "Building"); and

B. Sublandlord desires to sublet to Subtenant, and Subtenant desires to sublet from Sublandlord, the Sublet Space (as hereinafter defined), subject to the terms of the Prime Lease, as incorporated herein, and in accordance with the terms hereof;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublandlord and Subtenant, intending to be legally bound hereby, agree as follows:

Section 1. Demise. Sublandlord hereby leases to Subtenant, and Subtenant hereby leases from Sublandlord, a portion of the Prime Premises (the "Sublet Space") located on the first (1st) floor of the Building, commonly known as "Suite 100," as more particularly shown as the "Expansion Premises" on Exhibit B attached hereto and made a part hereof, subject to the terms and provisions hereof. The parties hereto agree that the Sublet Space comprises approximately 4,500 rentable square feet, which rentable area shall not be subject to adjustment by either Sublandlord or Subtenant.

Section 2. Term. The term of this Sublease (the "Term") shall commence on the date (the "Commencement Date") that Sublandlord has obtained the consent of Landlord referred to in Section 29 hereof (the "Landlord Consent"), and shall expire on June 30, 2024 (the "Expiration Date"), unless such Term hereof is sooner terminated as provided herein or by law or by termination of the Prime Lease. Subtenant shall have no right to extend or renew the Term.

Section 3. Base Rent. Commencing on the Commencement Date and continuing through the Expiration Date, Subtenant shall pay base rent ("Base Rent") to Sublandlord at the

rates set forth in the table below. Except as herein specifically provided, Subtenant's Base Rent shall be payable to Sublandlord without notice or demand and without any abatement, deduction, offset or setoff whatsoever, in lawful money of the United States of America, and in equal monthly installments in advance on the first day of each calendar month during the Term.

Period:	Monthly Rate per Rentable Square Foot	Annual Base Rent	Monthly Base Rent Payments
Months 1 - 12	$2.10	$113,400.00	$ 9,450.00
Months 13 - 24	$2.16	$116,802.00	$9,733.50
Months 25 – End of Term	$2.23	$120,306.00	$10,025.50

Notwithstanding the foregoing, Subtenant's first monthly installment of Base Rent (i.e., $9,450.00) shall be paid to Sublandlord upon Subtenant's execution of this Sublease and applied to Subtenant's first monthly installment of Base Rent due hereunder. Provided that Subtenant complies with all of its Sublease obligations, Sublandlord hereby agrees to conditionally abate Subtenant's Base Rent (but not Additional Rent) for the first (1st) full month following the Commencement Date. If the Commencement Date falls on a date other than the first day of a calendar month, or if the Expiration Date hereunder (or the sooner termination of the Term, if not due to a default of Subtenant) falls on a date other than the last day of a calendar month, the Base Rent (and Subtenant's "Additional Rent," as hereinafter defined) shall be adjusted on a per diem basis to reflect such partial calendar month(s). If Subtenant defaults under this Sublease at any time (beyond any applicable notice and cure period) and if Sublandlord elects to terminate this Sublease as a result of any such default, then the abated rent plus Default Interest thereon as provided in the Sublease shall become immediately due and payable.

Section 4. Operating Expenses; Additional Rent. In addition to Base Rent due hereunder, Subtenant shall pay to Sublandlord, as "Additional Rent" (as such term is defined in the Prime Lease) "Subtenant's Pro Rata Share" of the amount, if any, by which "Operating Expenses" (as such term is defined in the Prime Lease) for each calendar year during the Term exceed Operating Expenses for the Base Year (referred to in the Prime Lease as "Expense Excess"), which amounts shall be payable in the manner and at the times provided in the Prime Lease. For the purpose of computing any Operating Expense payable by Subtenant, the Base Year shall be 2022. For all purposes of this Sublease, "Subtenant's Pro Rata Share" shall be 2.23%.

Section 5. Security Deposit. Subtenant shall deliver to Sublandlord with delivery of this Sublease, a security deposit in the amount of $9,450.00 (the "Security Deposit") to secure the performance of Subtenant's obligations hereunder. Sublandlord may, but shall not be obligated to, apply all or portions of the Security Deposit on account of any failure of Subtenant to perform or observe Subtenant's obligations, covenants, conditions, and agreements under this

Sublease. In the event that Sublandlord properly applies all or a portion of the Security Deposit to Subtenant's obligations hereunder, Subtenant shall be obligated, within five (5) business days of receipt of notice from Sublandlord, to deposit cash with Sublandlord in an amount sufficient to restore the Security Deposit to the full amount. If no default exists on the part of Subtenant hereunder, the Security Deposit or any balance thereof shall be returned to Subtenant within thirty (30) days after the expiration of this Sublease and vacating of the Sublet Space in accordance with the terms and conditions herein. No interest shall be paid by Sublandlord on the Security Deposit. Sublandlord shall not be required to keep the Security Deposit in a segregated account, and the Security Deposit may be commingled with other funds of Sublandlord.

Section 6. Condition of Sublet Space; Existing FF&E. Subtenant hereby acknowledges (i) examining the Sublet Space prior to the Commencement Date, (ii) that it is fully familiar with the condition of the Sublet Space, (iii) that Sublandlord has made no representations or warranties with respect to either the Sublet Space, the Building, or the condition thereof; and (iv) that it accepts the Sublet Space in its current "as is" condition, without any warranties, representations or obligations (either express or implied) on the part of Sublandlord to perform any fit-up work, maintenance, alterations, improvements, replacements, repairs, work or other services thereto, except as specifically set forth in this Sublease. Notwithstanding the foregoing, Sublandlord, to its actual knowledge, represents to Subtenant that as of the Effective Date all mechanical, electrical, plumbing, fire life safety, and HVAC systems servicing the Sublet Space are in good working order.

Sublandlord shall deliver the Sublet Space to Subtenant together with Sublandlord's furniture, fixtures, and equipment currently existing in the Sublet Space, a list of which is attached hereto and made a part hereof as Exhibit C (the "Existing FF&E"). The Existing FF&E shall be provided for Subtenant's use in the Sublet Space during the Term, at no additional charge, solely for Subtenant's lawful and normal office occupancy purposes. Upon Subtenant's last payment of Rent for the Term, Sublandlord shall convey ownership of the Existing FF&E to Subtenant, via a customary bill of sale, for the purchase price of One and 00/100 Dollars ($1.00). Subtenant hereby acknowledges and agrees that the Existing FF&E is being made available to Subtenant without any representation or warranty by Sublandlord as to its condition, state of repair or suitability for Subtenant's use, or any other matter related thereto, and Sublandlord shall have no liability or obligations of any nature whatsoever to Subtenant with respect to the Existing FF&E (including, without limitation, any obligation to repair, maintain or replace same at any time during the Term). Subtenant agrees to maintain the Existing FF&E in at least the same condition as received throughout the Term (subject to ordinary wear and tear and fire and other casualty and replacement in the ordinary course). Subtenant shall promptly remove the Existing FF&E on or prior to the Expiration Date and shall repair any damage occasioned by such removal, and in default thereof, Sublandlord may cause said removal and repairs at Subtenant's expense plus interest thereon at the Default Rate. Notwithstanding the foregoing, in the event that Subtenant and Landlord have entered into a direct lease that provides for, among other things, Subtenant's right to remain in possession of the Sublet Space after the Expiration Date as a direct tenant of Landlord (the "Direct Lease"), then Subtenant shall have no obligation to remove the Existing FF&E from the Sublet Space on or prior to the Expiration Date, provided: (i) Subtenant shall provide Sublandlord with the following no later than ten (10) business days prior to the Expiration Date: (i) reasonable evidence that Landlord and Subtenant have entered into the Direct Lease, (ii) a written release by Landlord in favor of Sublandlord whereby

Landlord shall release Sublandlord of all repair, removal, restoration, and surrender obligations under the Prime Lease applicable to the Sublet Space, and (iii) a written acknowledgment by Landlord in favor of Sublandlord whereby Landlord acknowledges that Subtenant shall be solely responsible for any restoration and repair obligations in the Prime Lease related to a surrender of the Sublet Space.

Section 7. Use; Care of Sublet Space. Subtenant shall use the Sublet Space (i) for general office and administrative uses consistent with Class A office buildings and for no other purpose, and (ii) subject to and in accordance with all of the applicable provisions of the Prime Lease. Subtenant shall maintain, at its expense, the Sublet Space in good working order and repair, ordinary wear and tear and casualty excepted.

Section 8. Subordination; Incorporation. This Sublease is subject and subordinate to all of the covenants, agreements, terms, provisions, conditions and obligations of the Prime Lease, as the same may be amended and/or extended. All of the covenants, agreements, terms, provisions, conditions, obligations and Rules and Regulations of the Prime Lease are hereby incorporated herein by reference with the same force and effect as if they were fully set forth herein, and Subtenant hereby agrees to be bound thereby except as clearly inconsistent with the terms hereof. In addition and without limiting the generality of the foregoing, the Prime Lease is hereby modified as follows:

(A) for purposes of this Sublease only, the following provisions of the Original Lease are either deleted in their entirety or modified as hereinafter stated:

(i) Sections 4.2, 4.3, 4.4, 7.3, 7.4, 9.1, 14.7, and 15.6 are deleted in their entirety; and

(ii) Exhibits A, C, E, and E-1 are deleted in their entirety.

(B) for purposes of this Sublease only, the following provisions of the Amendments are modified as hereinafter stated:

(i) Section 8 and Exhibits A, B, B-1, and C of the First Amendment are deleted in their entirety;

(ii) Sections 7, 8, 9, 10, 11, 12(H), and 12(I) of the Second Amendment, and Exhibits A, B, B-1, and C thereto, are deleted in their entirety; and

(iii) Section 3.2, Exhibit B, and Schedule 1 of the Third Amendment, including the TI Scope List attached thereto, are deleted in their entirety.

(C) for all purposes of this Sublease, whenever the word “Landlord” appears in the Prime Lease it shall be deemed to read “Sublandlord” (except when the word “Landlord” is used in respect of obtaining Landlord’s consent, permission or approval, in which event the word “Landlord” shall mean both Landlord and Sublandlord); whenever the word “Tenant” appears in the Prime Lease it shall be deemed to read “Subtenant”; whenever the word “Lease” appears in the Prime Lease it shall be deemed to read “Sublease”; and whenever the word “Premises” appears in the Prime Lease it shall be deemed to read “Sublet Space”;

(D) notwithstanding any provision herein to the contrary:

(i) the performance by Landlord of its obligations under the Prime Lease, shall, for all purposes hereunder, be deemed to be the performance of such obligations by Sublandlord under the provisions of the Prime Lease incorporated herein by reference, and Sublandlord's obligations under the provisions so incorporated herein, shall be limited to the extent to which such obligations are performed by Landlord under the Prime Lease, and Subtenant agrees to look solely to the Landlord for performance of the same;

(ii) Sublandlord shall not be bound by any warranties and representations made by the Landlord in the Lease;

(iii) whenever any provision of the Prime Lease which has been incorporated herein by reference, requires the tenant under the Prime Lease to take any non-monetary action within a certain period of time after notice from Landlord, then, Subtenant shall take such action within said certain period of time minus three (3) business days; and

(iv) whenever any provision of the Prime Lease requiring Landlord to give notice to the tenant thereunder has been incorporated herein by reference (thus requiring Sublandlord to give such notice to Subtenant) such notice by Sublandlord to Subtenant shall for all purposes hereunder be deemed timely given if given to Subtenant within three (3) business days after receipt by Sublandlord of timely notice from Landlord.

(E) Subtenant covenants and agrees not to violate any of the terms and provisions of the Prime Lease. Subtenant shall be bound by all of the restrictions and limitations placed upon the Sublandlord, as tenant, under the Prime Lease, as if Subtenant were the tenant thereunder.

(F) In the event of the termination or cancellation of the Prime Lease for any reason, Sublandlord shall have no liability or obligation to Subtenant as a result thereof except if such termination is a result of a default, beyond any applicable notice and cure period, by Sublandlord of its obligations under the Prime Lease or this Sublease.

(G) With respect to the performance of any obligations required by the Landlord under the Prime Lease, Sublandlord herein does not undertake and shall have no obligation to perform any of the same. Sublandlord's sole obligation with respect thereto shall be to request the same, after request by Subtenant, and to send all notices required under the Prime Lease to the Landlord. Sublandlord shall reasonably cooperate with Subtenant and (to the extent requested by Subtenant in writing) shall take or refrain from taking all actions reasonably necessary to further the intent of this provision, provided that Subtenant reimburses Sublandlord for all reasonable costs and expenses (including attorney's fees) incurred by Sublandlord in connection therewith.

(H) The rights herein granted by Sublandlord to Subtenant under subsection (G) above shall not be construed as a waiver or release by Sublandlord of Sublandlord's rights and remedies under this Sublease and/or the Prime Lease, nor to permit any default in the terms, provisions and conditions hereof by Subtenant, it being agreed that the rights herein granted to

Subtenant are merely for the convenience of Subtenant to deal with the Landlord with respect to any obligations of the Landlord to Sublandlord under the Prime Lease.

(I) Subtenant covenants and agrees that Subtenant will not do or cause to be done or suffer or permit any act or thing to be done which would or might cause the Prime Lease or the rights of Sublandlord thereunder to be cancelled, terminated or forfeited or which would or might make Sublandlord liable for any damages, claims or penalties.

(J) Subtenant shall have no rights under the Prime Lease or in and to the Sublet Space except as expressly set forth herein or incorporated herein. Specifically, but without limitation, Subtenant shall have no right to exercise any rights of extension, expansion, termination, waiver, consent or any other rights under the Prime Lease. Nothing contained in this Sublease shall be deemed or construed to give Subtenant the right to amend, modify or terminate the Prime Lease or to agree to amend, modify or terminate the Prime Lease.

(K) Subtenant agrees that it shall not enter into any agreements with the Landlord relating to or affecting in any manner the Sublet Space, the Prime Lease, or any rights or obligations thereunder. Specifically, but without limitation, Subtenant shall not enter into any agreements with the Landlord enlarging the Sublet Space or integrating any other premises therewith.

(L) Subtenant shall indemnify, hold, and defend Sublandlord harmless from and against any and all loss, costs, expense (including, without limitation, reasonable attorney's fees), damage or liability incurred by Sublandlord by reason of Subtenant's failure to comply with the provisions hereof.

Section 9. Utility Costs. Subtenant shall be responsible for the cost of all utility services supplying the Sublet Space during the Term, including but not limited to water, sewer, standby water for sprinkler, gas, telephone and all other utilities and other communication services as provided for in the Prime Lease

Section 10. Surrender; Holding Over.

A. At the expiration or sooner termination of the Term, Subtenant shall timely vacate and surrender the Sublet Space vacant, "broom-clean" and in the same condition as existed on the Commencement Date, reasonable wear and tear excepted, and otherwise in accordance with all surrender and other relevant provisions of the Prime Lease.

B. Subtenant shall have no right to hold over at the Sublet Space beyond the Expiration Date or earlier termination of this Sublease. If Subtenant remains in possession after the expiration or earlier termination of the Term, such occupancy shall be as a tenant at sufferance and Subtenant shall pay, as liquidated damages (and not as rent), (i) an amount equal to one hundred fifty percent (150%) of the Base Rent in effect at the time of the expiration or termination of this Sublease, plus Additional Rent, prorated on a daily basis for each such day of continued occupancy, and (ii) all amounts payable by Sublandlord to Landlord under the Prime Lease as a result of such

holdover, including consequential damages. Subtenant hereby agrees to indemnify Sublandlord against and hold Sublandlord harmless from all costs and damages incurred (including reasonable attorney's fees) as a result of such holdover, including but not limited to, all amounts paid by Sublandlord to Landlord pursuant to the Prime Lease as a result of such continued occupancy by Subtenant. Nothing herein shall be deemed to limit Sublandlord's rights to evict Subtenant, or any other rights or remedies legally available to Sublandlord. No receipt of money by Sublandlord from Subtenant after expiration or termination of this Sublease shall reinstate or extend this Sublease without the express written consent of Sublandlord and Landlord.

Section 11. Internet and Security Services. For the first three (3) months of the Term, Sublandlord shall provide Subtenant with network connectivity within the Sublet Space via all floor one (1) switches and wireless access points. In connection therewith, two (2) Virtual Local Area Networks ("VLANs") will be created strictly for use by Subtenant, one (1) wired and one (1) wireless (collectively, the "GT-BIO Network"). During said period, (a) security policies will be put in place by Sublandlord to ensure that the GT-BIO Network can only communicate within such network and to the internet; (b) the GT-BIO Network will be segregated from the VLANs of Sublandlord as such to not allow any communication(s) between the same; and (c) Sublandlord shall provide reasonably necessary administration and support for the GT-BIO Network; provided, however, that Sublandlord shall not be liable for any interruptions in service to the same. After such three (3) month-period, Subtenant shall be responsible, at its sole cost and expense, for all of its IT systems and infrastructure needs in the Sublet Space, subject to the terms and conditions of the Prime Lease.

Section 12. Late Payment. It is agreed that the Base Rent is due and payable in equal monthly installments in advance, and in accordance with terms set forth in the Prime Lease. The parties further agree that late payment by Subtenant to Sublandlord of Base Rent will cause Sublandlord to incur costs not contemplated by this Sublease, the amount of which is extremely difficult to ascertain. Therefore, in the event that any monthly installment of Base Rent required to be made by the Subtenant under this Sublease or any other payment due under this Sublease shall be overdue any such late payments shall be subject to a five percent (5%) late administrative fee and eighteen percent (18%) interest (the "Default Rate") for the purpose of defraying the expenses incurred in handling delinquent payments. Nothing contained in this Section or elsewhere in this Sublease shall prevent Sublandlord from commencing legal proceedings against Subtenant for the non-payment of Base Rent if same is not paid timely.

Section 13. Signage: Subject to Landlord's prior written approval, Subtenant shall be permitted to install identifying signage in the main lobby of the Building and on the entrance to, and within, the Sublet Space. Notwithstanding any provision to the contrary, all signage shall be at Subtenant's sole cost and expense.

Section 14. Alterations. Subtenant shall not make any fit-ups, alterations, improvements or installations in or to the Sublet Space, without obtaining the prior written consents of Sublandlord and Landlord in each instance, and without otherwise complying with all of the applicable provisions of the Prime Lease.

Section 15. Insurance. Subtenant shall comply with and maintain (with respect to the

Sublet Space, and for the benefit of Sublandlord and Landlord), all insurance coverages, requirements and obligations of Sublandlord under the provisions of the Prime Lease. Subtenant shall provide Sublandlord with an insurance certificate satisfying all coverage requirements under the Prime Lease, and naming Sublandlord and Landlord as additional insureds, on or before the Commencement Date.

Section 16. Assignment; Subletting. Subtenant shall not transfer, assign, mortgage or otherwise pledge or encumber this Sublease or any interest hereunder, nor shall Subtenant sublet all or any part of the Sublet Space, nor allow the Sublet Space or any part thereof to be occupied or used by any party other than Subtenant, without obtaining the prior written consents of Sublandlord and Landlord in each instance, and without otherwise complying with all of the applicable provisions of the Prime Lease. Any subsequent sublettings or assignments shall likewise require the prior written consents of Sublandlord and Landlord in each instance. Sublandlord agrees not to unreasonably withhold its consent to any requested assignment or sublease, provided Landlord's consent is obtained, and provided Subtenant's transferee, in Sublandlord's sole but reasonable judgment, would not cause any exposure to claims, liabilities or damages to Sublandlord, and complies with those conditions set forth in Section 14.1 of the Prime Lease. No such subletting or assignment whatsoever by Subtenant (or those holding under, by or through Subtenant) shall limit or release Subtenant's liability under this Sublease.

Section 17. Brokers. Subtenant hereby warrants and represents that it has dealt with no realtors, brokers or agents in connection with this Sublease and its leasing of the Sublet Space other than CBRE, Inc. ("Broker"). Subtenant hereby agrees to indemnify, defend and hold Sublandlord and Landlord harmless from and against any and all claims, losses, liabilities, damages, costs or expenses (including, without limitation, reasonable attorneys' fees and costs) arising or resulting from any other broker(s) who claim to have represented Subtenant in connection with this Sublease. Sublandlord shall pay any commissions due Broker pursuant to a separate agreement. The provisions of this Section shall survive the expiration or sooner termination of the Term.

Section 18. Notices.

A. All notices hereunder must be in writing and shall be sufficiently given for all purposes hereunder if properly addressed and delivered personally by documented overnight delivery service, by certified or registered mail, return receipt requested, at the addresses set forth below. Any notice given personally or by documented overnight delivery service is effective upon receipt. Any notice given by registered mail is effective upon receipt, to the extent such receipt is confirmed by return receipt. Any notice which is refused, unclaimed or undeliverable because of an act or omission of the party to be notified, if such notice was correctly addressed to the party to be notified, shall be deemed communicated as of the first date that said notice was refused, unclaimed or deemed undeliverable by the postal authorities, or overnight delivery service.

If to Sublandlord:

Aimmune Therapeutics, Inc.
8000 Marina Boulevard
Suite 300

Brisbane, CA 94065
Attn.: Real Estate Department

with a copy to:

Day Pitney LLP
One Stamford Plaza, 7th Floor
263 Tresser Boulevard
Stamford, CT 06901
Attn: Robert G. Rahilly, Esq.

If to Subtenant: [_____]

B. The parties may change their addresses for notices set forth above by notice given in accordance with the provisions of this Section.

Section 19. Parking. Subject to Article 1 and Section 2.3 of the Prime Lease (and all other relevant provisions of such Prime Lease), Subtenant shall have the non-exclusive right, on an unassigned and unreserved basis, to use it proportionate share of parking spaces allocated to Sublandlord under the Prime Lease for the accommodation and parking of automobiles of Sublessee and its respective employees and invitees.

Section 20. Prime Lease Termination. If for any reason whatsoever the term of the Prime Lease is terminated prior to the Expiration Date, this Sublease shall thereupon automatically be terminated, as if the Expiration Date were one day prior to the date of termination under the Prime Lease, and Sublandlord shall not be liable to Subtenant by reason thereof.

Section 21. Entire Agreement. This Sublease, together with: (i) all Exhibits attached hereto and made a part hereof; and (ii) all of the terms and provisions of the Prime Lease incorporated herein, constitute the entire agreement between Sublandlord and Subtenant concerning the matters set forth herein, and any prior or contemporaneous agreement or understanding between such parties with respect to the subject matters herein shall have no force or effect.

Section 22. Changes. This Sublease shall not be modified or amended except by a writing signed by the party against whom enforcement of the modification or amendment is sought.

Section 23. Authority. Each party covenants with the other that it has full power and authority to enter into and perform its obligation under this Sublease and the persons executing this Sublease on their behalf are duly authorized to do so by all requisite action.

Section 24. Governing Law. This Sublease shall be governed by and construed in accordance with the internal laws of the State of California without giving effect to any choice or conflict of law provision or rule (whether of the State of California or any other jurisdiction) that would cause the application of laws of any jurisdictions other than those of the State of California.

Section 25. Recitals. The recitals set forth herein are true and correct and are hereby incorporated into this Sublease as if set forth herein at length.

Section 26. Counterparts. This Sublease may be executed in any number of counterparts, each of which shall be deemed to be an original, and all such counterparts shall constitute one agreement. The parties shall be entitled to sign and transmit an electronic signature of this Sublease (whether by facsimile, DocuSign, PDF or other e-mail transmission), which signature shall be binding on the party whose name is contained therein and shall serve as an original.

Section 27. Captions. The captions of the various sections of this Sublease are solely for the purpose of convenience. Such captions are not a part hereof and shall not be deemed in any manner to modify, explain, enlarge or restrict any of the provisions of this Sublease.

Section 28. Severability. If any provision of this Sublease is determined to be unenforceable, Sublandlord and Subtenant hereby agree that such provision may be reformed so that it is enforceable to the maximum extent permitted by law. In the event that any provision of this Sublease cannot be reformed, such provision shall be deemed to be severed from this Sublease, but every other provision of this Sublease shall remain in full force and effect.

Section 29. Landlord Consent. Notwithstanding anything to the contrary contained herein, this Sublease shall have no effect unless and until Landlord shall have given its written consent (the "Landlord Consent") in accordance with Section 14.1 of the Prime Lease.

Section 30. Binding Effect. The terms and provisions of this Sublease shall bind and inure to the benefit of Sublandlord and Subtenant and their respective permitted successors and assigns.

Section 31. Prevailing Party. If there is any legal action or proceeding between Sublandlord and Subtenant to enforce any provision of this Sublease or to protect or establish any right or remedy of either Sublandlord or Subtenant hereunder, the unsuccessful party to such action or proceeding will pay to the prevailing party all reasonable costs and expenses, including reasonable attorneys' fees, incurred by such prevailing party in such action or proceeding and in any appearance in connection therewith; and if such prevailing party recovers a judgment in any such action, proceeding or appeal, such costs, expenses and attorney's fees will be determined by the court handling the proceeding and will be included in and as a part of such judgment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, this Sublease has been duly executed by the parties hereto as of the day and year first above written.

SUBLANDLORD:

AIMMUNE THERAPEUTICS, INC.,
a Delaware corporation

By: Doug Walker
Name: Doug Walker
Title: SVP, Global Information Technology and Facilities

By: Azfar Qureshi
Name: Azfar Qureshi
Title: Head of Finance

SUBTENANT:

GT BIOPHARMA, INC.,
a Delaware corporation

By: G Berk
Name: Dr. Gregory Berk
Title: CEO

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made and entered into by and among GT Biopharma, Inc. ("Parent") and each of its subsidiaries (together with Parent, the "Company") and Michael Breen ("Executive") as of December 31, 2021 and is effective as of November 8, 2021 (the "Effective Date").

WHEREAS, the Company is desirous of employing Executive, and Executive wishes to be employed by the Company in accordance with the terms and conditions set forth in this Agreement.

NOW, THEREFORE, IN CONSIDERATION OF THE MUTUAL COVENANTS AND PROMISES AND OTHER GOOD AND VALUABLE CONSIDERATION, THE RECEIPT OF WHICH IS HEREBY ACKNOWLEDGED, IT IS MUTUALLY AGREED AS FOLLOWS:

1. **Position and Duties**: Executive shall be employed by Parent and each of its subsidiaries as its Executive Chairman of the Board reporting to Parent's Board of Directors. Executive agrees to devote the necessary business time, energy and skill to his duties at the Company. These duties of Executive under this Agreement shall include all those duties customarily performed by a company's Executive Chairman of the Board as well as providing advice and consultation on general corporate matters and other projects as may be assigned by Parent's Board of Directors on an as needed basis. Executive shall perform his duties from the United Kingdom, unless mutually agreed by Executive and Parent. During the term of Executive's employment Executive shall be permitted to serve on boards of directors of for-profit or not-for-profit entities provided such service does not adversely affect the performance of Executive's duties to the Company under this Agreement, and are not in conflict with the interests of the Company.

2. **Term of Employment:** This Agreement shall remain in effect for a period of one year from the Effective Date and thereafter will automatically renew for successive one year periods unless either party provides ninety days' prior written notice of termination. Upon the termination of Executive's employment prior to the expiration of the term of this Agreement, Executive shall receive the applicable benefits set forth in this Agreement. Upon the termination of Executive's employment for any reason, neither Executive nor the Company shall have any further obligation or liability under this Agreement to the other, except as set forth below.

3. **Compensation**: Executive shall be compensated by the Parent for his services to the Company as follows:

(a) **Base Salary**: Executive shall be paid a base salary of $425,000 per year (the "Base Salary"), payable by Parent monthly in cash in accordance with Parent's normal payroll procedures. Executive's Base Salary shall be reviewed on at least an annual basis and may be adjusted as appropriate, but in no event shall it be reduced to an amount below Executive's Base Salary than in effect. In the event of such an adjustment, that amount shall become Executive's Base Salary.

(b) **Benefits**: Executive shall have the right, on the same basis as other senior executives of the Company, to participate in and to receive benefits under any of the Company's employee benefit plans, medical insurance (which extends to Executive's immediate family), as such plans may be

modified from time to time, and provided that in no event shall Executive receive less than (4) four weeks paid vacation per annum, (6) six paid sick days per annum, and (5) five paid personal days per annum.

(c) **Performance Bonus**: Executive shall have the opportunity to earn a performance bonus of seventy-five percent (75%) of the Base Salary in accordance with the Parent's Performance Bonus Plan if in effect ("Target Bonus"); if the Parent does not have a Performance Bonus Plan in effect at any given time during the term of this Agreement, then Parent's Compensation Committee or Board of Directors shall have discretion as to determining bonus compensation for Executive. Notwithstanding the foregoing, Executive shall receive a guaranteed performance bonus of twenty-five percent (25%) of the Base Salary.

(d) **General Grant**: At such time as the Company may issue compensatory shares in accordance with the rules of the Nasdaq Stock Market, LLC and subject to approval by the Compensation Committee of Parent's Board of Directors, the Company shall issue to Executive, pursuant to a stock award agreement, 278,058 shares of common stock of the Company, which shares shall be fully vested. The stock award agreement shall include provisions prohibiting Executive from transferring such shares for a period of 6 months following grant.

(e) **Expenses**: Parent shall reimburse Executive for reasonable travel, lodging, entertainment and meal expenses incurred in connection with the performance of services within this Agreement. Executive shall be entitled to fly Business Class on any flight longer than four (4) hours, and to fly First Class on any flight longer than ten (10) hours, and receive full reimbursement for such flights from Parent.

(f) **Travel**: Executive shall travel as necessary from time to time to satisfy his performance and responsibilities under this Agreement.

4. **Effect of Termination of Employment**:

(a) **Voluntary Termination**: In the event of Executive's voluntary termination from employment with the Company, other than for Change in Control Period Good Reason or for Non Change in Control Good Reason, Executive shall be entitled to no compensation or benefits from the Company other than those earned under Section 3 through the date of his termination and in the case of each stock option, restricted stock award or other Company stock-based award granted to Executive, the extent to which such awards are vested through the date of his termination. In the event that Executive's employment terminates as a result of his death or disability, Executive shall be entitled to a pro rata share of the performance-based bonus, if any, for which Executive is then-eligible pursuant to Section 3(c) (presuming performance meeting, but not exceeding, target performance goals) in addition to all compensation and benefits earned under Section 3 through the date of termination.

(b) **Termination for Cause**: If Executive's employment is terminated by the Company for Cause, Executive shall be entitled to no compensation or benefits from the Company other than those earned under Section 3 through the date of termination and, in the case of each stock option, restricted stock award or other Company stock-based award granted to Executive, the extent to

which such awards are vested through the date of his termination. In the event that the Company terminates Executive's employment for Cause, the Company shall provide written notice to Executive of that fact prior to, or concurrently with, the termination of employment. Failure to provide written notice that the Company is terminating Executive's employment for Cause shall constitute an irrevocable waiver of any contention that the termination was for Cause.

(c) **Involuntary Termination During Change in Control Period**: If Executive's employment with the Company terminates as a result of a Change in Control Period Involuntary Termination, then, in addition to any other benefits described in this Agreement and subject to Executive's execution of a general release of claims against the Company, Executive shall receive the following:

(i) all compensation and benefits earned under Section 3 through the date of the Company's termination of Executive's employment;

(ii) a lump sum payment equivalent to the greater of (a) the bonus paid or payable to Executive for the year immediately prior to the year in which the Change in Control occurred and (b) the Target Bonus under the Performance Bonus Plan, if any, in effect immediately prior to the year in which the Change in Control occurs;

(iii) a lump sum payment equivalent to the remaining Base Salary (as it was in effect immediately prior to the Change in Control) due Executive from the date of Change in Control Period Involuntary Termination to the end of the term in this Agreement or one-half of Executive's Base Salary then in effect, whichever is the greater; and

(iv) reimbursement for the cost of medical, life, disability insurance coverage at a level equivalent to that provided by the Company for a period expiring upon the earlier of: (a) one year; or (b) the time Executive begins alternative employment wherein said insurance coverage is available and offered to Executive. It shall be the obligation of Executive to inform Parent that new employment has been obtained.

Unless otherwise agreed to by Executive, the amount payable to Executive under subsections (i) through (iii), above, shall be paid to Executive in a lump sum within thirty (30) days following the Company's termination of Executive's employment. The amounts payable under subsection (iv) shall be paid monthly during the reimbursement period.

(d) **Termination Without Cause in the Absence of Change in Control**: In the event that Executive's employment terminates as a result of a Non Change in Control Period Involuntary Termination, then, in addition to any other benefits described in this Agreement and subject to Executive's execution of a general release of claims against the Company, Executive shall receive the following benefits:

(i) all compensation and benefits earned under Section 3 through the date of the Company's termination of Executive's employment;

(ii) a lump sum payment equivalent to the greater of (a) the bonus paid or payable to Executive for the year immediately prior to the year in which the Non Change in Control Period

Involuntary Termination occurred and (b) the Target Bonus under the Performance Bonus Plan, if any, in effect immediately prior to the year in which the Non Change in Control Period Involuntary Termination occurs;

(iii) a lump sum payment equivalent to the remaining Base Salary (as it was in effect immediately prior to the Non Change in Control Period Involuntary Termination) due Executive from the date of the Non Change in Control Period Involuntary Termination to the end of the term of this Agreement or one-half of Executive's Base Salary then in effect, whichever is the greater; and

(iv) reimbursement for the cost of medical, life and disability insurance coverage at a level equivalent to that provided by the Company for a period of the earlier of: (a) one year; or (b) the time Executive begins alternative employment wherein said insurance coverage is available and offered to Executive. It shall be the obligation of Executive to inform Parent that new employment has been obtained.

Unless otherwise agreed to by Executive, the amount payable to the Executive under subsections (i) through (iii) above shall be paid to Executive in a lump sum within thirty (30) days following the Company's termination of Executive's employment. The amounts payable under subsection (iv) shall be paid monthly during the reimbursement period.

(e) **Resignation with Good Reason During Change in Control Period**: If Executive resigns his employment with the Company as a result of a Change in Control Period Good Reason, then, in addition to any other benefits described in this Agreement and subject to Executive's execution of a general release of claims against the Company, Executive shall receive the following:

(i) all compensation and benefits earned under Section 3 through the date of Executive's termination of employment;

(ii) a lump sum payment equivalent to the greater of (a) the bonus paid or payable to Executive for the year immediately prior to the year in which the Change in Control occurred and (b) the Target Bonus under the Performance Bonus Plan, if any, in effect immediately prior to the year in which the Change in Control occurs;

(iii) a lump sum payment equivalent to the remaining Base Salary (as it was in effect immediately prior to the Change in Control) due Executive from the date of Executive's Change in Control Period Good Reason termination to the end of the term of this Agreement or one-half of Executive's Base Salary then in effect, whichever is the greater; and

(iv) reimbursement for the cost of medical, life and disability insurance coverage at a level equivalent to that provided by the Company for a period of the earlier of: (a) one year; or (b) the time Executive begins alternative employment wherein said insurance coverage is available and offered to Executive. It shall be the obligation of Executive to inform the Parent that new employment has been obtained.

Unless otherwise agreed to by Executive, the amount payable to the Executive under subsections (i) through (iii) above shall be paid to Executive in a lump sum within thirty (30) days following

Executive's termination of employment. The amounts payable under subsection (iv) shall be paid monthly during the reimbursement period.

(f) **Resignation with Good Reason in the Absence of Change in Control:** If Executive resigns his employment with the Company as a result of a Non Change in Control Period Good Reason, then, in addition to any other benefits described in this Agreement and subject to Executive's execution of a general release of claims against the Company, Executive shall receive the following:

(i) all compensation and benefits earned under Section 3 through the date of Executive's termination of employment;

(ii) a lump sum payment equivalent to a greater of (a) the bonus paid or payable to Executive for the year immediately prior to the year in which Executive resigns and (b) the Target Bonus under the Performance Bonus Plan, if any, in effect immediately prior to the year in which Executive resigns;

(iii) a lump sum payment equivalent to the remaining Base Salary (as it was in effect immediately prior to Executive's resignation) due Executive from the date of Executive's resignation to the end of the term of this Agreement or one-half of Executive's Base Salary then in effect, whichever is the greater; and

(iv) reimbursement for the cost of medical, life and disability insurance coverage at a level equivalent to that provided by the Companies for a period of the earlier of: (a) one year or (b) the time Executive begins alternative employment wherein said insurance coverage is available and offered to Executive. It shall be the obligation of Executive to inform Parent that new employment has been obtained.

Unless otherwise agreed to by Executive, the amount payable to the Executive under subsections (i) through (iii) above shall be paid to Executive in a lump sum within thirty (30) days following Executive's termination of employment. The amounts payable under subsection (iv) shall be paid monthly during the reimbursement period.

(g) **Resignation from Positions**: In the event that Executive's employment with the Company is terminated for any reason, on the effective date of the termination Executive shall simultaneously resign from each position he holds as an officer and, in the event that Executive's employment with the Company is terminated for any reason other than the expiration of the Term or the non-renewal of this Agreement, Executive shall also simultaneously resign from the Board of Directors of each of Parent, its subsidiaries and any of their affiliated entities, unless otherwise agreed by Parent's Board of Directors (with Executive abstaining from such vote).

5. **Certain Definitions:** For the purpose of this Agreement, the following capitalized terms shall have the meanings set forth below:

(a) "Cause" shall mean any of the following occurring on or after the date of this Agreement:

(i) Executive's theft, dishonesty, breach of fiduciary duty for personal profit, or falsification of any employment or Company record;

(ii) Executive's willful violation of any law, rule, or regulation (other than traffic violations, misdemeanors or similar offenses) or final cease-and-desist over, in each case that involves moral turpitude;

(iii) any material breach by Executive of the Company's Code of Professional Conduct, which breach shall be deemed "material" if it results from an intentional act by Executive and has a material detrimental effect on the Company's reputation or business; or

(iv) any material breach by Executive of this Agreement, which breach, if curable, is not cured within thirty (30) days following written notice of such breach from the Company.

(b) "Change in Control" shall mean the occurrence of any of the following events:

(i) Parent is party to a merger or consolidation which results in the holders of the voting securities of Parent outstanding immediately prior thereto failing to retain immediately after such merger or consolidation direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the securities entitled to vote generally in the election of directors of Parent or the surviving entity outstanding immediately after such merger of consolidation;

(ii) a change in the composition of the Board of Directors of the Parent occurring within a period of twenty-four (24) consecutive months, as a result of which fewer than a majority of the directors are Incumbent Directors;

(iii) effectiveness of an agreement for the sale, lease or disposition by Parent of all or substantially all of Parent's assets; or

(iv) a liquidation or dissolution of Parent.

(c) "Change in Control Period" shall mean the period commencing on the date sixty (60) days prior to the date of consummation of the Change in Control and ending one hundred eighty (180) days following consummation of the Change in Control.

(d) "Change in Control Period Good Reason" shall mean Executive's resignation for any of the following conditions, first occurring during a Change in Control Period and occurring without Executive's written consent:

(i) a decrease in Executive's Base Salary, a decrease in Executive's Target Bonus (as a multiple of Executive's Base Salary) under the Performance Bonus Plan, or a decrease in employee benefits, in each case other than as a part of any across-the-board reduction applying to all senior executives of either Company which does not disproportionately impact Executive when compared to similarly situated executives;

(ii) a material, adverse change in Executive's title, authority and responsibilities, as measured against Executive's title, authority and responsibilities immediately prior to such change;

(iii) a requirement that Executive relocate his principal workplace from the United Kingdom;

(iv) any material breach by the Company of any provision of this Agreement, which breach is not cured within thirty (30) days following written notice of such breach from Executive;

(v) any failure of Parent to obtain the assumption of this Agreement by any of Parent's successors or assigns by purchase, merger, consolidation, sale of assets or otherwise; or

(vi) any purported termination of Executive's employment for "material breach of contract" which is purportedly effected without providing the "cure" period, if applicable, described in Section 5(d)(iv), above.

The effective date of any resignation from employment by Executive for Change in Control Period Good reason shall be the date of notification to Parent of such resignation from employment by Executive.

(e) "Non Change in Control Period Good Reason" shall mean Executive's resignation within six months of any of the following conditions first occurring outside of a Change in Control Period and occurring without Executive's written consent:

(i) a decrease in Executive's total cash compensation opportunity (adding Base Salary and Target Bonus, if any) of greater than ten percent (10%);

(ii) a material, adverse change in Executive's title, authority or responsibilities, as measured against Executive's title, authority or responsibilities immediately prior to such change;

(iii) any material breach by the Company of a provision of this Agreement, which breach is not cured within thirty (30) days following written notice of such breach from Executive;

(iv) a requirement that Executive relocate his principal workplace from the United Kingdom; or

(v) any purported termination of Executive's employment for "material breach of contract" which is purportedly effected without providing the "cure" period, if applicable, described in Section 5(e)(iii), above.

The effective date of any resignation from employment by Executive for Non Change in Control Period Good reason shall be the date of notification to Parent of such resignation from employment by Executive.

(f) "Incumbent Directors" shall mean members of Parent's Board of Directors who either (a) are members of Parent's Board of Directors as of the date hereof, or (b) are elected, or nominated for election, to Parent's Board of Directors with the affirmative vote of at least a majority of the

Incumbent Directors at the time of such election or nomination (but shall not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of members of Parent's Board of Directors).

(g) "Change in Control Period Involuntary Termination" shall mean during a Change in Control Period the termination by the Company of Executive's employment with the Company for any reason, including termination as a result of death or disability of Executive, but excluding termination for Cause. The effective date of any Change in Control Period Involuntary Termination shall be the date of notification to Executive of the termination of employment by the Company.

(h) "Non Change in Control Period Involuntary Termination" shall mean outside a Change in Control Period the termination by the Company of Executive's employment with the Company for any reason, including termination as a result of death or disability of Executive, but excluding termination for Cause. The effective date of any Non Change in Control Period Involuntary Termination shall be the date of notification to Executive of the termination of employment by the Company.

6. **Dispute Resolution**: In the event of any dispute or claim relating to or arising out of this Agreement (including, but not limited to, any claims of breach of contract, wrongful termination or age, sex, race or other discrimination), Executive and the Company agree that all such disputes shall be fully addressed and finally resolved by binding arbitration conducted by the American Arbitration Association in the State of Delaware in accordance with its National Employment Dispute Resolution rules. In connection with any such arbitration, Parent shall bear all costs not otherwise borne by a plaintiff in a court proceeding. The Company agrees that any decisions of arbitrator(s) will be binding and in any state that the Company conducts the operation of its business.

7. **Attorneys' Fees**: The prevailing party shall be entitled to recover from the losing party its attorneys' fees and costs incurred in any action brought to enforce any right arising out of the Agreement.

8. Restrictive Covenants:

(a) **Nondisclosure.** During the term of this Agreement and following termination of Executive's employment with the Company, Executive shall not divulge, communicate, use to the detriment of the Company or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereinafter defined) pertaining to the business of the Company. Any Confidential Information or data now or hereafter acquired by Executive with respect to the business of the Company (which shall include, but not be limited to, confidential information concerning the Company's financial condition, prospects, technology, customers, suppliers, methods of doing business and promotion of the Company's products and services) shall be deemed a valuable, special and unique asset of the Company that is received by Executive in confidence as a fiduciary. For purposes of this Agreement "Confidential Information" means information disclosed to Executive or known by Executive as a consequence of or through his employment by the Company (including information conceived, originated, discover or developed

by Executive) prior to or after the date hereof and not generally known or in the public domain about the Company or its business. Notwithstanding the foregoing, none of the following information shall be treated as Confidential Information: (i) information which is known to the public at the time of disclosure to Executive; (ii) information which becomes known to the public by publication or otherwise after disclosure to Executive through no fault of Executive; (iii) information which was rightfully received by Executive from a third party without violating any non-disclosure obligation owed to or in favor of the Company; or (iv) information unrelated to the Company's business which was developed by or on behalf of Executive independently of any disclosure hereunder as shown by written records. Nothing herein shall be deemed to restrict Executive from disclosing Confidential Information to the extend required by law or by any court.

(b) **Non-Competition**. Executive shall not, while employed by the Company, engage or participate, directly or indirectly (whether as an officer, director, employee, partner, consultant, or otherwise), in any business that manufactures, markets or sells products that directly compete with any product of the Company. Nothing herein shall prohibit Executive from being a passive owner of less than 5% of the stock of any entity directly engaged in a competing business.

(c) **Property Rights; Assignment of Inventions.** With respect to information, inventions and discoveries or any interest in any copyright and/or other property right developed, made or conceived of by Executive, either alone or with others, during his employment by the Company arising out of such employment and pertinent to any field of business or research in which, during such employment, the Company is engaged or (if such is known to or ascertainable by Executive) is considering engaging, Executive hereby agrees:

(i) that all such information, inventions and discoveries or any interest in any copyright and/or other property right, whether or not patented or patentable, shall be and remain the exclusive property of the Company;

(ii) to disclose promptly to an authorized representative of Parent all such information, inventions and discoveries or any copyright and/or other property right and all information in Executive's possession as to possible applications and uses thereof;

(iii) not to file any patent application relating to any such invention or discovery except with the prior written consent of an authorized officer of Parent (other than Executive);

(iv) that Executive hereby waives and releases any and all rights Executive may have in and to such information, inventions and discoveries, and hereby assigns to the Company and/or its nominees all of Executive's right, title and interest in them, and all of Executive's right, title and interest in any patent, patent application, copyright or other property right based thereon. Executive hereby irrevocably designates and appoints Parent and each of its duly authorized officers and agents as his agent and attorney-in-fact to act for his and on his behalf and in his stead to execute and file any document and to do all other lawfully permitted acts to further the prosecution, issuance and enforcement of any such patent, patent application, copyright or other property right with the same force and effect as if executed and delivered by Executive; and

(v) at the request of Parent, and without expense to Executive, to execute such documents and perform such other acts as Parent deems necessary or appropriate, for the Company to obtain patents on such inventions in a jurisdiction or jurisdictions designated by Parent, and to assign the Company or their respective designees such inventions and any and all patent applications and patents relating thereto.

9. **General:**

(a) **Successors and Assigns**: The provisions of this Agreement shall inure to the benefit of and be binding upon the Company, Executives and each and all of their respective heirs, legal representatives, successors and assigns. The duties, responsibilities and obligations of Executive under this Agreement shall be personal and not assignable or delegable by Executive in any manner whatsoever to any person, corporation, partnership, firm, company, joint venture, or other entity. Executive may not assign, transfer, convey, mortgage, pledge or in any other manner encumber the compensation or other benefits to be received by him or any rights which he may have pursuant to the terms and provisions of this Agreement.

(b) **Amendments; Waivers**: No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of Parent (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Notices**: Any notices to be given pursuant to this Agreement by either party may be effected by personal delivery or by overnight delivery with receipt requested. Mailed notices shall be addressed to the parties at the addresses stated below, but each party may change its or his/her address by written notice to the other in accordance with this subsection (c). Mailed notices to Executive shall be addressed as follows:

Michael Breen

Email: michaelbreen1@btinternet.com

Mailed notices to the Company shall be addressed as follows:

GT Biopharma, Inc.
9350 Wilshire Blvd., Suite 203
Beverly Hills, CA 90212

(d) **Entire Agreement**: This Agreement constitutes the entire employment agreement among Executive and the Company regarding the terms and conditions of his employment, with the exception of any stock option, restricted stock or other Company stock-based award agreements among Executive and the Company to the extent not modified by this Agreement. This Agreement supersedes all prior negotiations, representations or agreements among Executive and the Company, whether written or oral, concerning Executive's employment by the Company.

(e) **Withholding Taxes**: All payments made under this Agreement shall be subject to reduction to reflect taxes required to be withheld by law.

(f) **Counterparts**: This Agreement may be executed by Parent and Executive in counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

(g) **Headings**: Each and all of the headings contained in this Agreement are for reference purposes only and shall not in any manner whatsoever affect the construction or interpretation of this Agreement or be deemed a part of this Agreement for any purpose whatsoever.

(h) **Savings Provision**: To the extent that any provision of this Agreement or any paragraph, term, provision, sentence, phrase, clause or word of this Agreement shall be found to be illegal or unenforceable for any reason, such paragraph, term, provision, sentence, phrase, clause or word shall be modified or deleted in such a manner as to make this Agreement, as so modified, legal and enforceable under applicable laws. The remainder of this Agreement shall continue in full force and effort.

(i) **Construction**: The language of this Agreement and of each and every paragraph, term and provision of this Agreement shall, in all cases, for any and all purposes, and in any and all circumstances whatsoever be construed as a whole, according to its fair meaning, not strictly for or against Executive or the Company, and with no regard whatsoever to the identity or status of any person or persons who drafted all or any portion of this Agreement.

(j) **Further Assurances**: From time to time, at the Company's request and without further consideration, Executive shall execute and deliver such additional documents and take all such further action as reasonably requested by the Company to be necessary or desirable to make effective, in the most expeditious manner possible, the terms of this Agreement and to provide adequate assurance of Executive's due performance hereunder.

(k) **Governing Law**: Executive and the Companies agree that this Agreement shall be interpreted in accordance with and governed by the laws of the State of Delaware.

(l) **Board Approval**: Parent and each of its subsidiaries warrants to Executive that the Board of Directors of Parent and each of its subsidiaries has ratified and approved this Agreement, and that Parent will cause the appropriate disclosure filing to be made with the Securities and Exchange Commission in a timely manner.

[Signature Page Follows]

IN WHITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

EXECUTIVE

DocuSigned by:
Michael Breen
96A0D458AA3A4C5...
Michael Breen

GT BIOPHAMA, INC.

DocuSigned by:
Gregory Berk
3084EA50FF71447...
Gregory Berk, M.D.
Interim Chief Executive Officer

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Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Michael Breen, certify that:

a) I have reviewed this report on Form 10-K of GT Biopharma, Inc.;

b) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

c) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

d) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

e) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

By: */s/ Michael Breen*
Name: Michael Breen
Title: Interim Chief Executive Officer, Chairman and Director

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Manu Ohri, certify that:

a) I have reviewed this report on Form 10-K of GT Biopharma, Inc.;

b) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

c) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

d) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

e) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2022

By: */s/ Manu Ohri*
Name: Manu Ohri
Title: Chief Financial Officer, Principal Accounting Officer

Exhibit 32.1

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Michael Breen, Chief Executive Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

(i) the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 28, 2022

By: */s/ Michael Breen*
Name: Michael Breen
Title: Interim Chief Executive Officer, Chairman and Director

Exhibit 32.2

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Manu Ohri, Chief Accounting Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

(i) the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 28, 2022

By: */s/ Manu Ohri*
Name: Manu Ohri
Title: Chief Financial Officer, Principal Accounting Officer