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, 2020

Commission File Number: 000-08092

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

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

9350 Wilshire Blvd.
Suite 203
Beverly Hills, CA 90212
(Address of principal executive offices) (Zip code)

(800) 304-9888
(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	None

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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 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	☐ (Do not check if a smaller reporting company)	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, 2020 was approximately $8.9 million. As of April 12, 2021, there were 28,393,960 shares of the registrant's common stock, $0.001 par value, issued or issuable and outstanding.

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PART I

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Report, including any documents which may be incorporated by reference into this 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 report.

Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "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 off our proprietary Tri-specific Killer Engager (TriKE™) fusion protein immune cell engager technology platform. Our TriKE platform generate 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 can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas 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, sarcoma and solid tumors. The platform is scalable, and we are putting processes in place to be able to produce IND-ready moieties in a timely manner after a specific TriKE conceptual design. After conducting market and competitive research, specific moieties can then be advanced into the clinic on our own or through potential collaborations with larger companies. We are also evaluating, in conjunction with our Scientific Advisory Board, additional moieties designed to target different tumor antigens. We believe our TriKE may have the ability, if approved for marketing, to be used as a monotherapy, augment the current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

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 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 prop

Immuno-Oncology Platform

Tri-specific Killer Engagers (TriKEs)

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 and 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. We believe there is a continued 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 GTB-3550 TriKE™ Phase I/II Clinical Trial

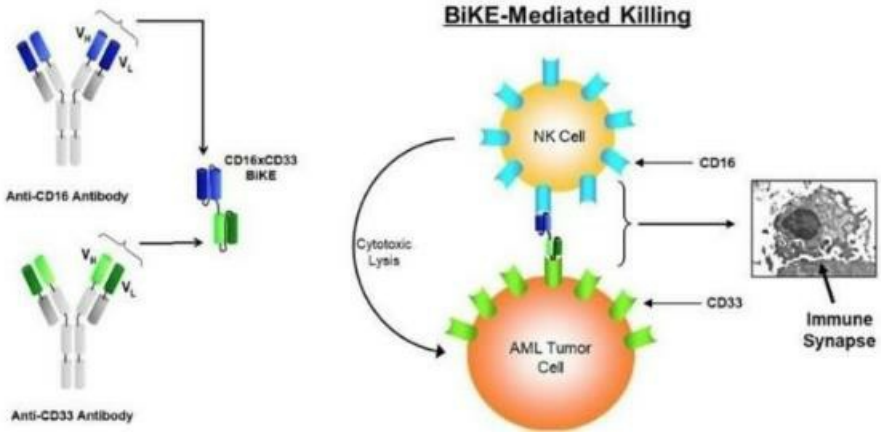
GTB-3550 is the Company's first TriKE™ product candidate which is a single-chain, tri-specific recombinant fusion protein construct composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. The GTB-3550 Phase I/II clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis opened for patient enrollment September 2019. The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick. Additional clinical trial sites planned as we progress to the Phase II expansion part of the clinical trial.

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.

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 TriKE may have been 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 quickly to target a variety of tumor antigens.

Background and Select Non-Clinical Data

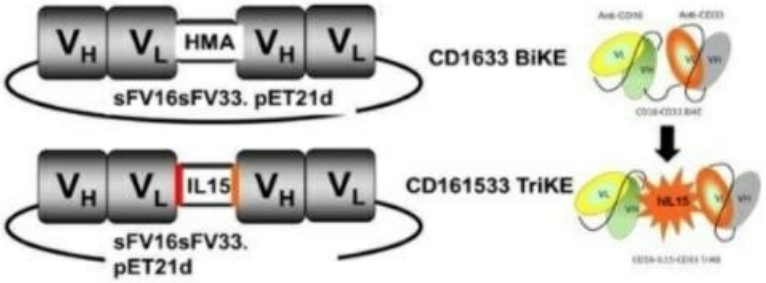
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating receptor on NK cells and CD33 (AML and MDS; see figure below), CD19/CD22 (B cell lymphomas), or EpCAM (epithelial tumors (breast, colon, and lung)) 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 indicate that the CD16 x IL-15 x CD33 and CD16 x IL-15 x EpCAM TriKEs 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.

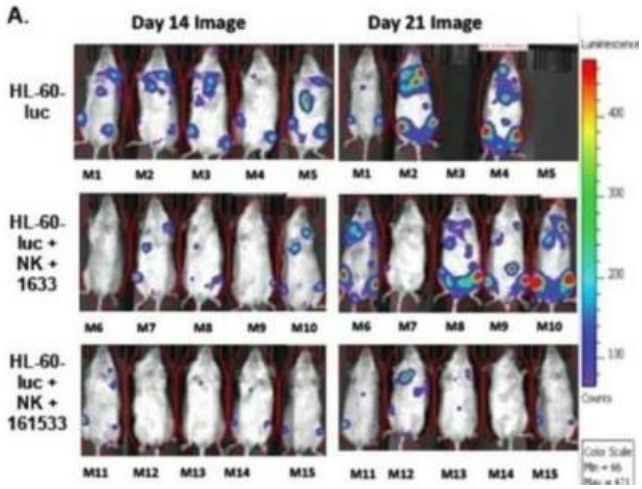
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE is also capable of potently restoring killing capacity of post- transplant NK cells against CD33-expressing HL-60 Targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-5 cytokine into 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.

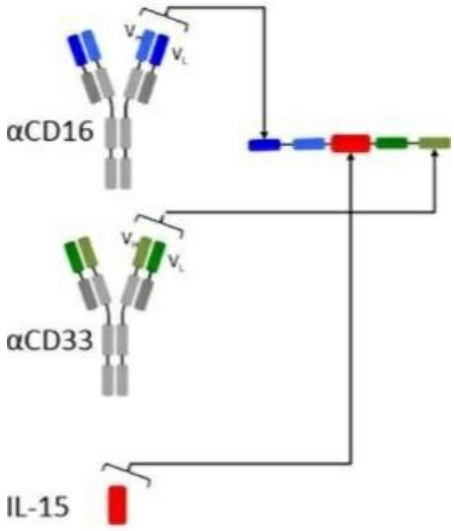
Figure A below shows the results (tumor burden and mortality) when dosing NK cells alone (top panel), the BiKE version (lacking IL-15) of GTB-3550 (middle panel; called 1633), and the TriKE, GTB-3550 (bottom panel; then called 161533) in the above human tumor model, HL-60-luc. In the NK-cell-only arm, 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.



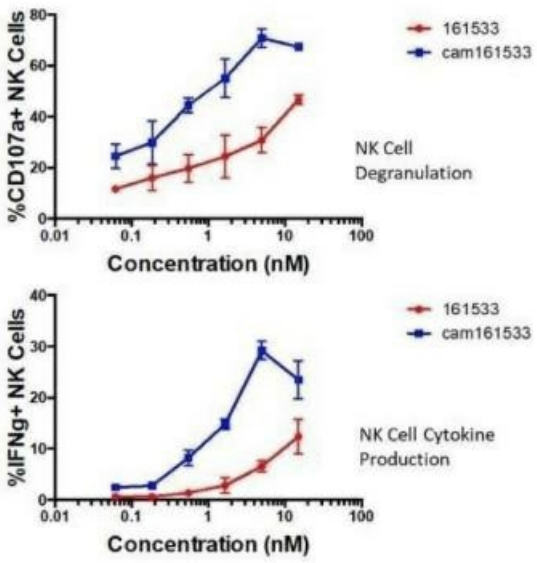
Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. FDA requested that additional preclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested some additional information and clarifications on the manufacturing (CMC) and clinical packages. The requested additional information and clarifications were completed and incorporated by us into the IND in eCTD format. We filed the IND amendment in June 2018 and announced on November 1, 2018 that we had received notification from the FDA that the IND was open and the Company was authorized to initiate a first-in-human Phase 1 study with GTB-3550 in AML, MDS and severe mastocytosis. We began the Phase 1 clinical trial in September 2019.

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

To develop second generation TriKEs, 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 activity (NK Cell Degranulation) and functionality (NC Cell Cytokine Production) of the single-domain CD16 TriKE (GTB-C3550) compared to the original TriKE (GTB-3550) (see figure below). These data were presented at the 2017 American Society of Hematology Conference.



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 EpCAM, Her2, Mesothelin (mesothelioma and lung adenocarcinoma), and CD133 alone and in combination. We believe certain of 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 2021.

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, sarcomas and solid tumors. The platforms are scalable, and we are currently working with several third parties investigating the optimal GMP production expression system for TriKE constructs.

We believe TriKE will have the ability, if approved for marketing, to be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, or be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

Immuno-Oncology Product Candidates

We are initially targeting certain hematologic malignancies as we believe our product candidates may have certain advantages over existing and other in-development products. Our TriKE product candidates, GTB-3550 and GTB-C3550, are single-chain, tri-specific scFv recombinant fusion proteins composed of the variable regions of the heavy and light chains (or heavy chain only) of anti-CD16 antibodies, wild-type or a modified form of IL-15 and the variable regions of the heavy and light chains of an antibody designed to precisely target a specific tumor antigen. We utilize the NK stimulating cytokine human IL-15 as a crosslinker between the two scFvs which is designed to provide a self-sustaining signal leading to the proliferation and activation of NK cells thus enhancing their ability to kill cancer cells mediated by antibody-dependent cell-mediated cytotoxicity (ADCC).

GTB-3550

GTB-3550 is our first TriKE product candidate. 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 intend to study 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, and other hematopoietic malignancies. 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 that will be 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.

About High-Risk Myelodysplastic Syndromes

MDS 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. 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. 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 roughly 1.8% of cancer deaths in the United States.

About GTB-3550 TriKE™ Clinical Trial

We opened our GTB-3550 Phase I/II 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 are 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.

Our Strategy

Our goal is to be a leader in immuno-oncology therapies targeting a broad range of indications including hematological malignancies, sarcoma and solid tumors. Key elements of our strategy are to:

Rapidly advanced our Tri-specific Killer Engagers (TriKEs), GTB-3550 and GTB-C3550

Our TriKE product candidates have the potential to be groundbreaking therapies targeting a broad range of hematologic malignancies, sarcomas and solid tumors. We are preparing to study GTB-3550, an anti-CD16-IL-15-anti-CD33 TriKE in CD33 positive leukemias, a marker expressed on tumor cells in AML, MDS and other myeloid malignancies. We began a Phase 1 clinical trial in September 2019 and enrolled our first patient in January 2020 for patients with relapsed/refractory AML. The Phase 1 trial will be a dose finding study. We expect this will be closely followed by Phase 2 trials to determine the most efficacious dosing and cycles with the aim to maximize efficacy while minimizing on-target, off-disease adverse events.

GTB-C3550 is a next-generation, follow-on, to our lead TriKE, GTB-3550. GTB-3550 studies will help inform the development of GTB-C3550. We believe this will de-risk the GTB-C3550 program as the data being generated will help to make informed decisions on which, or both, will be brought into later phase studies and in which patient populations.

Utilize our TriKE platform technologies to develop a robust pipeline of targeted immuno-oncology products targeting a wide range of hematologic malignancies, sarcomas and solid tumors for development on our own and through potential collaborations with larger pharmaceutical companies

We are using our TriKE platform with the intent to bring to market multiple, targeted, off-the-shelf therapies that can treat a range of hematologic malignancies, sarcomas and solid tumors. The platforms are scalable and we are currently working with several third parties investigating the optimal expression system of the TriKE constructs which we expect to be part of a process in which we are able to produce IND-ready moieties in approximately 90-120 days after the construct conceptual design. After conducting market and competitive research, specific moieties can then be rapidly advanced into the clinic on our own or through potential collaborations with larger pharmaceutical companies.

We believe our TriKE will have the ability, if approved for marketing, to be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, or be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

Oncology Markets

B-cell Lymphomas/Leukemias

B-cell lymphoma is a type of cancer that forms in B cells (a type of immune system cell). B-cell lymphomas may be either indolent (slow- growing) or aggressive (fast-growing). Non- Hodgkin lymphoma has an incidence rate of 19.4 per 100,000 per year and B-cell lymphomas make up most (about 85%) of NHL in the United States. There are many different types of B-cell non- Hodgkin lymphomas. These include Burkitt lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), diffuse large B-cell lymphoma, follicular lymphoma, and mantle cell lymphoma.

Acute Lymphoblastic Leukemia

Acute lymphoblastic leukemia, or ALL, is an acute form of leukemia, or cancer of the white blood cells, characterized by the overproduction and accumulation of immature white blood cells, known as lymphoblasts. In persons with ALL, lymphoblasts are overproduced in the bone marrow and continuously multiply, causing damage and death by inhibiting the production of normal cells (such as red and white blood cells and platelets) in the bone marrow and by spreading (infiltrating) to other organs.

"Acute" is defined by the World Health Organization standards, in which greater than 20% of the cells in the bone marrow are blasts. Chronic lymphocytic leukemia is defined as having less than 20% blasts in the bone marrow. Acute lymphoblastic leukemia is seen in both children and adults; the highest incidence is seen between ages 2 to 3 years (>90 cases per 1 million per year). ALL is the most common cancer diagnosed in children and represents approximately 25% of cancer diagnoses among children younger than 15 years. Among children with ALL, approximately 98% attain remission, and approximately 85% of patients aged 1 to 18 years with newly diagnosed ALL treated on current regimens are expected to be long-term event-free survivors, with over 90% surviving at 5 years.

Myeloid Leukemias

Acute Myeloid Leukemia

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 (MDS) 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.

Sarcomas

A sarcoma is a type of cancer that develops from certain tissues, like bone or muscle. Bone and soft tissue sarcomas are the main types of sarcoma. Soft tissue sarcomas can develop from soft tissues like fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. They can be found in any part of the body. Most of them develop in the arms or legs. They can also be found in the trunk, head and neck area, internal organs, and the area in back of the abdominal cavity (known as the retroperitoneum). Sarcomas are not common tumors, and most cancers are the type of tumors called carcinomas.

The most common types of sarcoma in adults are undifferentiated pleomorphic sarcoma (previously called malignant fibrous histiocytoma), liposarcoma, and leiomyosarcoma. Certain types occur more often in certain areas of the body than others. For example, leiomyosarcomas are the most common abdominal sarcoma, while liposarcomas and undifferentiated pleomorphic sarcoma are most common in legs. But pathologists (doctors who specialize in diagnosing cancers by how they look under the microscope), may not always agree on the exact type of sarcoma. Sarcomas of uncertain type are very common. (American Cancer Society, Cancer Facts & Figures 2019)

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 small number of third-party manufacturers to produce 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 all of our commercial needs. We do not have long-term agreements with any of these third parties. We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce active pharmaceutical ingredients, or API, and finished products in accordance with the FDA's current Good Manufacturing Practices, or cGMP, and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

Patents and Trademarks

Immuno-oncology platform

University of Minnesota License Agreement

We (through our wholly owned subsidiary Oxis Biotech, Inc.) are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, 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 agreement, we receive 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 shall be 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 in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the University of Minnesota will receive an upfront license fee, royalty fees ranging from 4% to 6%, minimum annual royalty payments of $250,000 beginning in 2022, $2,000,000 in 2025, and $5,000,000 in 2027 and certain milestone payments totaling $3,100,000.

Employees

As of December 31, 2020, we had three 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 prospectus 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, 2020, the Company reported a net loss of $28.3 million and as of December 31, 2020, we had an accumulated deficit of $596 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 at least four years. 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 in order 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 next 12 months. 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 2021 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. Additional financing may not be available on acceptable terms, or at all. 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.

Research and Development Investment

Our currently projected expenditures for 2021 include approximately $12 million to $15 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 have not yet remedied 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. 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 report, we have not remediated these material weaknesses. The company intends to take measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Such measures will include, but not be limited to hiring of additional employees in its finance and accounting department, although the timing of such hires is largely dependent on our securing additional financing to cover such costs; 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 in order 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 issue 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 period of 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. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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 executive officers and employees to operate our business. If we are unable to hire qualified personnel, we may not be able to implement our business strategy.

We currently have only two fulltime employees. The loss of the services of any of our employees could delay our product development programs and our research and development efforts. We do not maintain key person life insurance on any of our officers, employees or consultants. 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, and business development. We will need to raise sufficient funds to hire the necessary employees and have commenced our search for additional key 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, or scientific officers, 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 clinical testing, regulatory compliance, manufacturing and marketing, 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 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 in the course of 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 IRB approval for studies to be conducted at each clinical trial site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- 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, or 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 any 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, Phase 3 trial. We will also need to agree on a protocol with the FDA for a clinical trial before commencing the trial. Phase 3 clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our Phase 2 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 Phase 3 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 quitam (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 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 a recent analysis by InVentiv Health there are over 800 companies developing approximately 1500 cancer immunotherapies via 4000 development projects across 535 targets. According to the Pharmaceutical Manufacturers Research Association Medicines in Development for Cancer 2018 Report, there were 135 drugs in development for the treatment of lymphoma, including non-Hodgkin lymphoma, which accounts for nearly five percent of all new cancer diagnoses.

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 ultimately 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, agricultural, 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 in the event that 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 CRO we will engage to conduct our clinical trials including the University of Minnesota for our phase 1/2 clinical trial for GTB-3550. 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, or GCPs, for all of 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. In order 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.

We have not held regular annual meetings in the past, and if we are required by the Delaware Court of Chancery to hold an annual meeting pursuant to Section 211(c) of the Delaware General Corporation Law, or the DGCL, it could result in the unanticipated expenditure of funds, time and other Company resources.

Section 2.2 of our bylaws provides that an annual meeting shall be held each year on a date and at a time designated by our board of directors, and Section 211(b) of the DGCL provides for an annual meeting of stockholders to be held for the election of directors. Section 211(c) of the DGCL provides that if there is a failure to hold the annual meeting for a period of 13 months after the latest to occur of the organization of the corporation, its last annual meeting or last action by written consent to elect directors in lieu of an annual meeting, the Delaware Court of Chancery may order a meeting to be held upon the application of any stockholder or director. Section 211(c) also provides that the failure to hold an annual meeting shall not affect otherwise valid corporate acts or result in a forfeiture or dissolution of the corporation.

We have not held regular annual meetings in the past because a substantial majority of our stock is owned by a small number of stockholders, making it easy to obtain written consent in lieu of a meeting when necessary. In light of our historical liquidity constraints, handling matters by written consent has allowed our Company to save on the financial and administrative resources required to prepare for and hold such annual meetings. To our knowledge, no stockholder or director has requested our Company's management to hold such an annual meeting and no stockholder or director has applied to the Delaware Court of Chancery seeking an order directing our company to hold a meeting. However, if one or more stockholders or directors were to apply to the Delaware Court of Chancery seeking such an order, and if the Delaware Court of Chancery were to order an annual meeting before we are prepared to hold one, the preparation for the annual meeting and the meeting itself could result in the unanticipated expenditure of funds, time, and other Company resources.

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 now 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 April 12, 2021, we had approximately 28.4 million shares of common stock outstanding and issued or issuable and had outstanding warrants for the purchase of up to approximately 78,400 additional shares of common stock at an exercise price of $3.40 per share, warrants for the purchase of up to approximately 4,268,280 additional shares of common stock at an exercise price of $5.50 per share and warrants for the purchase of up to approximately 247,250 additional shares of common stock at an exercise price of $6.875 per share, all of which are exercisable as of the date of this prospectus (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 low-priced "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 ofcommon stock, and thereby depress our price per share ofcommon 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 only one securities analyst, 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

We currently maintain offices at 9350 Wilshire Blvd, Suite 203, Beverly Hills, CA 90212. We previously maintained offices at 310 N. Westlake Blvd., Suite 206, Westlake Village, CA 91362.

ITEM 3. LEGAL PROCEEDINGS

On December 24, 2018, Empery Asset Master, Empery Tax Efficient, LP, and Empery Tax Efficient II, LP (collectively, "Plaintiffs) filed in the N.Y. Supreme Court, Index No. 656408/2018, alleging causes of action against the Company for Breach of Contract, Liquidated Damages, Damages, and Indemnification. The claims arose out of a securities purchase agreement entered into between Plaintiffs and the Company pursuant to which the Company issued convertible notes and warrants to Plaintiffs in or around January 2018. Plaintiffs allege, inter alia, that the Company failed to pay Plaintiffs' outstanding principal on or before the July 23, 2018 maturity date of said notes, failed to convert a portion of said notes in response to Plaintiffs' conversion notice, and failed to timely adjust the exercise price of said warrants. At issue are notes issued to Plaintiffs in the aggregate principal amount of approximately $2.2 million and warrants representing the right of Plaintiffs to acquire an aggregate of 480,352 shares of common stock in the Company. On or about June 19, 2020, the parties settled the litigation including the execution of a settlement agreement and mutual release. The litigation was dismissed with prejudice on or about June 24, 2020.

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 allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. Lion alleges breach of a consulting agreement between Lion and the Company entered into on or about September 1, 2015. Vallera alleges breach of a consulting agreement between Vallera and the Company entered into in or around October, 2018. The complaint seeks actual damages of $1,670,000, for the fair market value of the number of shares of GT Biopharma, Inc. that at the time of judgment represent 15,000,000 shares of such stock as of September 1, 2015, and that GT Biopharma, Inc. issue Lion the number of common shares 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. Discovery has commenced, and trial is scheduled for May 22, 2022.

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 is quoted on the OTCQB under the "OXIS" trading symbol. From August 2017 to February 11, 2021, our common stock has been 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).

Stockholders

As of March 22, 2021 there were 51 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

The information included under the heading "Equity Compensation Plan Information" in Item 12 of Part III of this report, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters." is hereby incorporated by reference into this Item 5 of this report.

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:

- In November 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issues convertible notes in an aggregate principal amount of $350,000, which notes are convertible into the Company's common stock at an initial conversion price of $0.20 per share.
- In December 2020 and January 2021, the Company entered into securities purchase agreements with certain purchasers pursuant to which the Company issues convertible notes in an aggregate principal amount of $8,985,000, which notes are convertible into the Company's common stock at an initial conversion price of $0.20 per share.

In addition, the Company made the following issuances of its unregistered common stock pursuant exemptions from the registration requirements of the Securities Act:

- 11,386,435 shares of common stock in connection with (i) the conversion of the Company's convertible notes or debentures and (ii) payments of interest in lieu of cash with respect to the Company's convertible notes or debentures;
- 83,825 shares of common stock in connection with the exercise of certain settlement warrants on or after February 16, 2021;
- 692,220 shares of common stock in connection with the conversion of all outstanding shares of Series J-1 Preferred Stock on February 23 and March 17, 2021;
- 5,491,638 shares of common stock to certain of the Company's directors, executive officers and consultants as compensatory bonuses after completion of the successful listing on the Nasdaq Capital Markets on February 11, 2021;
- 576,720 shares of common stock upon exercise of warrants for cash subsequent to December 31, 2020
- Subsequent to December 31, 2020, the Company issued 4,945,000 of shares of its common stock in exchange for cash

Repurchase of Shares

We did not repurchase any shares during the fourth quarter of the fiscal year covered by this report.

ITEM 6. SELECTED FINANCIAL DATA

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 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 $595,628,000 through December 31, 2020. On a consolidated basis, the Company had cash and cash equivalents of $5,297,000 at December 31, 2020. Because our lack of funds, we will have to raise additional capital in order to fund our selling, general and administrative, and research and development expenses. 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 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, 2020, 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

TriKE Agreements

In March 2017, we entered a new one-year Sponsored Research Agreement with the University of Minnesota. The purpose of this agreement is to determine toxicities and in vivo behavior in our TriKE technology, which we license from the University of Minnesota.

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 TriKE fusion protein for cancer therapies using our TriKE technology.

License Agreements

In July 2016, we executed an exclusive worldwide license agreement with the Regents of the University of Minnesota, 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 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 shall own 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 will receive an upfront license fee, royalty fees, and certain milestone payments.

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™ Phase I/II clinical trial for the treatment of certain types of leukemia. The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick. The open-label, dose-escalation Phase I portion of the trial will evaluate GTB-3550 TriKE™ in patients with CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis, and will determine safety and tolerability as well as the pharmacologically active dose and maximum tolerated dose of GTB-3550 TriKE™.

Collaboration Agreement

On March 10, 2020 we entered into a collaboration agreement with Cytovance® Biologics, a USA-based contract development and manufacturing organization (CDMO) and a subsidiary of the Shenzhen Hepalink Pharmaceutical Group Co., Ltd. ("Hepalink"), to provide development services for a TriKE™ therapeutic for the treatment of coronavirus infection. Under the terms of the collaboration agreement, the companies will focus on preparing sufficient quantities of our coronavirus TriKE drug product for preclinical evaluation using Cytovance's *E. coli*-based *Keystone Expression System*™ and subsequently, will scale-up production using Cytovance's GMP microbial manufacturing platform for evaluation of TriKE in humans to treat coronavirus infection.

Financing

	December 31, 2020	December 31, 2019
A. Notes payable issued for cash	$ 24,085,000	$ 12,998,000
B. Notes payable issued for settlement agreements	2,528,000	300,000
C. Notes payable issued for forbearance agreements	3,849,000	-
D. Notes payable issued for consulting services	360,000	-
	$ 30,822,000	$ 13,298,000

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 are unsecured, bear interest at a rate of 10% per annum, mature in six months up to one year from the date of issuance, and are convertible to common stock at an average conversion rate of $19.65 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, 2018, outstanding balance of these notes payable amounted to $10,673,000.

During the year ended December 31, 2019, the Company issued similar notes payable in the aggregate of $3,827,000 in exchange for cash. These notes payable are unsecured, bear interest at a rate of 10% per annum mature in six months up to one year from the date of issuance, and are convertible to common stock at an average conversion rate of $5.74 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions.

In addition, during 2019, notes payable of $1,502,000 were converted to 205,000 shares of common stock.

As of December 31, 2019, outstanding balance of these notes payable issued for cash amounted to $12,998,000.

During the year ended December 31, 2020, the Company issued similar notes payable in the aggregate of $12,531,000 in exchange for cash. These notes payable are unsecured, bear interest at a rate of 10% per annum, mature in six months up to one year from the date of issuance, and are convertible to common stock at a 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. In addition, during 2020, notes payable of $1,444,000 plus accrued interest were converted to 478,510 shares of common stock.

As of December 31, 2020, outstanding balance of these notes payable issued for cash amounted to $24,085,000. In addition, total notes payable matured and past due as of December 31, 2020 amounted to $16,111,000.

B. Notes Payable Issued for Settlement Agreements

During the year ended December 31, 2019, the Company issued notes payable of $300,000 as part of a debt settlement agreement. The notes are unsecured, bear interest at a rate of 10%, mature in six months up to one year from the date of issuance, and are convertible to common stock at a conversion rate of $10.20 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, 2019, outstanding balance of notes payable issued for settlement agreements amounted to $300,000.

During the year ended December 31, 2020, the Company entered into settlement agreements with certain unrelated parties to resolve claims and disputes pertaining to certain debt and equity instruments issued by the Company to these parties in prior years.

As part of the agreement, the Company agreed to the following considerations:

a. Issuance of convertible notes payable in the aggregate of $2,228,000. The notes are unsecured, bear interest at a rate of 10%, mature in six months up to one year from the date of issuance, and are convertible to common stock at a 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;
b. Cash payment of $380,000;
c. Issuance of 262,353 shares of common stock with a fair value of $1,225,000; and
d. Issuance of warrants to purchase 323,529 shares of common stock. The warrants are fully vested, exercisable at $3.40 per share and will expire in five years with an estimated fair value of $1,021,000 using a BlackScholes option price model.

As of December 31, 2020, outstanding balance of these notes payable for settlement agreements amounted to $2,528,000. In addition, total notes payable matured and past due as of December 31, 2020 amounted to $518,000.

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”).

The obligations of the holders to forbear from exercising their rights and remedies under the Default Notes pursuant to the Forbearance Agreements will terminate on the earliest of (i) the Termination Date, (ii) the date of any bankruptcy filing by the Company or its subsidiaries, (iii) the date on which the Company defaults on any of the terms and conditions of the Forbearance Agreements or (iv) the date the Forbearance Agreements are otherwise terminated or expire.

In exchange for the forbearance agreement, the Company agreed to the following considerations:

a. Amendment of the $13.2 million Default Notes (together with default amounts and accrued and unpaid interest) to include a provision that will convert these notes payable into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of the Company's preferred stock, which are convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

b. Amendment of warrants granted to certain noteholders in prior year to include the following terms: (i) the exercise price of all warrants to purchase common stock held by holders of the Default Notes will be reduced to equal the conversion price of the Default Notes and (ii) the number of shares of common stock underlying such warrants shall be increased so that the total exercise price of all such warrants after the decrease in the exercise price equals the total exercise price of all such warrants prior to the decrease in the exercise price. Further, the expiration date of all such warrants shall be extended for three years following the closing date of any New Financing.

c. Issuance of notes payable in the aggregate of $3,955,000. The notes are unsecured, bear interest at a rate of 10% per annum, mature in six months up to one year from the date of issuance, and are convertible to common stock at a 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 the notes payable amounted to $3,849,000. Total notes payable matured and past due as of December 31, 2020 amounted to $135,000.

D. Notes Payable issued for Consulting Agreements

During the year ended December 31, 2020, the Company issued notes payable of $360,000 in exchange for consulting services. The notes are unsecured, bears interest at a rate of 10%, matures in one year from the date of issuance and convertible to common stock at a 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 $360,000. In addition, total notes payable matured and past due as of December 31, 2020 amounted to $20,000.

Subsequent to December 31, 2020, convertible notes and accured in interest aggregating $38,714,000 were converted into 11,386,435 shares of common stock at conversion prices.

Subsequent to December 31, 2020, the Company issued 4,945,000 shares of its common stock to investors for net cash proceeds of $24,882,000 pursuant to our February 2021 Offering Circular.

Subsequent to December 31, 2020, the Company issued 660,545 shares of common stock upon exercise of warrants for cash proceeds of $3,200,000.

Subsequent to December 31, 2020, the Company issued convertible notes payable in the aggregate of $1,205,000 in exchange for each. The Company also issued notes payable of $545,000 to a related party. The Company is currently in the process of determining the appropriate accounting for these notes payable totaling $2,275,000.

Subsequent to December 31, 2020, the Company issued convertible notes payable for cash proceeds of $1,205,000. The Company is currently in the process of determining the appropriate accounting for these notes payable.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

Research and Development Expenses

During the year ended December 31, 2020 and 2019, we incurred $485 thousand and $1.7 million of research and development expenses, respectively. Research and development costs decreased due primarily to the reduction of employee, consultant and preclinical expenses. We anticipate our direct clinical and preclinical costs to increase significantly in 2021, totaling approximately $12 to $15 million, as we have initiated the Phase 1 clinical trial of our most advanced TriKe product candidate, GTB-3550 and anticipate entering Phase II in late second quarter of 2021.

Selling, general and administrative expenses

During the year ended December 31, 2020 and 2019, we incurred $6.3 million and $9.8 million of selling, general and administrative expenses, respectively. The decrease in selling, general and administrative expenses is primarily attributable the reduction of payroll and stock compensation expenses.

Loss on impairment

For the year ended December 31, 2019, the Company entered into an Asset Purchase Agreement (the "Agreement"), pursuant to which the Company sold its rights, titles and interests, including associated patents, to the pharmaceutical product designated by the Company as GTB-004 (the "Product"). Under the Agreement, the Product was purchased by DAS Therapeutics, Inc. who the Company believes was well positioned to take over the clinical development of the Product including obtaining timely approval by the FDA.

The Company received $200,000 at closing. The Company will also participate in the future commercial value of the Product by receiving $6,000,000 upon the achievement of certain sales objectives. In addition, the Company will receive a royalty equal to 1.5% of U.S. sales until such time as the last of the patents associated with the Product expires. The Company reflected a loss in the year ended December 31, 2019 totaling $20,463,000.

As a result of the loss reported on the sale of the Product, as well as the response received on inquiries related to the other two projects, the Company determined that the remaining value related to these remaining projects should be fully impaired. During the year ended December 31, 2019, the Company reported an impairment charge for these projects totaling $4,599,000.

There was no similar transaction for the year ended December 31, 2020.

Loss on disposal of assets

During the year ended December 31, 2020 and 2019, we incurred $0 and $20.5 million of loss on impairment, respectively. For the year ended December 31, 2019, the Company recorded an intangible asset impairment charge of $20.5 million related to the portfolio of CNS IPR&D assets, which represents the excess carrying value compared to the fair value. The impairment charge was the result of the sale of certain assets and prioritization for immuno-oncology development candidates. Company experienced changes in key senior management, led by the appointment of a CEO with extensive experience in oncology drug development. These changes resulted in the prioritization for immuno-oncology development candidates relative to the CNS development candidates acquired from Georgetown Translational Pharmaceuticals. In conjunction with these strategic changes, limited internal resources have delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio.

There was no similar transaction for the year ended December 31, 2020.

Interest Expense

Interest expenses were $3.0 million and $2.1 million for the years ended December 31, 2020 and 2019 respectively. The increase is primarily due tothe increase in convertible notes payable as well as accrual of default interest from 10% to 8% of past dueconvertible notes payables.

Loss on legal settlements

Loss on legal settlements were $5.4 million and $0 million for the years ended December 31, 2020 and 2019 respectively. The increase is primarily due to legal settlements the Company entered into during the year ended December 31, 2020 as compared to none in the year ended December 31, 2019.

Loss on forbearance agreement

Loss on forbearance settlement were $12.6 million and $0 million for the years ended December 31, 2020 and 2019 respectively. The increase is primarily due to loss on extinguishment as a result of the change in fair value of debt and equity instruments modified as a result of the forbearance settlement the Company entered into in during the year ended December 31, 2020 as compared to none in the year ended December 31, 2019.

Amortization of debt discount

Amortization of debt discount were $0.3 million and $0 million for the years ended December 31, 2020 and 2019 respectively. The increase is primarily due to the increase in debt discount recorded on new convertible notes payable the Company entered into in during the year ended December 31, 2020 as compared to none in the year ended December 31, 2019.

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, 2020, the Company raised $12.5 million through a series of issuances of Convertible Notes as compared to $3.5 million during the year ended December 31, 2019. We anticipate that cash utilized for selling, general and administrative expenses will range between $1 and $2 million in the coming quarters, while research and development expenses will vary depending on clinical activities. Subsequent to December 31, 2020, the Company raised additional funding of $27.2 million through an equity financing in February 2021.

The 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 and has cash 5.3 million as of December 30, 2020. The Company anticipates incurring additional losses until such time, if ever, that 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. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies. Management has also implemented cost saving efforts, including reduction in executive salaries and reduced travel. Management believes that these ongoing and planned financing endeavors, if successful, will provide adequate financial resources to continue as a going concern for at least the next nine months from the date the financial statements are issued; however, there can be no assurance in this regard. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

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.

Reverse Stock Split

On February 10, 2021, the Company completed 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 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.

Accounting Estimates

The preparation of 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 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.

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, 2020.

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 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 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, 2020. Based on that evaluation we have concluded that because a material weakness in the Company's internal control over financial reporting existed as of December 31, 2020, that our disclosure controls and procedures were not effective as of the end of the period covered by this Annual Report on Form 10-K. The material weakness 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 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 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 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, 2020, 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 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, 2020. The most significant issues identified were:

1) lack of segregation of duties due to very small staff and significant reliance on outside consultants,
2) risks of executive override also 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.

Based on the material weaknesses identified above, management has concluded that internal control over financial reporting was not effective as of December 31, 2020. As the company's operations increase, the company intends to take measures to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Such measures will include, but not be limited to 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.

Changes in Internal Control over Financial Reporting

Other than as described above, no changes in our internal control over financial reporting were made during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On February 23, 2021, 5,491,638 shares of common stock were issued to certain of the Company's directors, executive officers and consultants as compensatory bonuses pursuant to the exemption contained in Section 4(a)(2) of the Securities Act after completion of the successful listing on the Nasdaq Capital Markets on February 11, 2021.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and position held by each of our executive officers and directors as of March 31, 2021. Directors are elected for a period of one year and thereafter serve until the next annual meeting at which their successors are duly elected by the stockholders.

Name	Age	Position
Anthony J. Cataldo	68	Chief Executive Officer and Chairman of the Board
Michael Handelman	62	Chief Financial Officer
Bruce Wendel	67	Vice Chairman of the Board
Greg Berk	62	Director
Michael Breen	58	Director
Rajesh Shrotriya	76	Director

Anthony J. Cataldo was appointed Chief Executive Officer and Chairman on March 15, 2019. Previously he served as Vice Chairman of the Board since January 2019. Mr. Cataldo has extensive experience with the Company, having served on the Board of Directors from July 2014 until November 2018, also serving as Chief Executive Officer from November 2014 to September 2017 and Executive Chairman of the Board from September 2017 to February 2018 during that time. Prior to joining the Company, from February 2011 until June 2013, Mr. Cataldo served as Chairman and CEO/Founder of Genesis Biopharma, Inc. (now known as Iovance Biotherapeutics, Inc.). Mr. Cataldo is credited with developing the Stage Four Cancer treatment for melanoma known as Lion/Genesis using assets acquired from the National Cancer Institute (NIH). Mr. Cataldo also served as non-executive co-chairman of the board of directors of MultiCell Technologies, Inc., a supplier of functional, non-tumorigenic immortalized human hepatocytes from February 2005 until July 2006.

Michael Handelman was appointed Chief Financial Officer on November 13, 2020. Mr. Handelman is Chairman of the Board of Directors and Secretary of GoooGreen, Inc. He previously served as Chief Financial Officer of Clickstream Corporation since October 2015. He served as Chief Financial Officer of Lion Biotechnologies, Inc. from February 2011 until June 2015, and was a member of the Lion Bio Board of Directors from February 2013 until May 2013. Mr. Handelman served as the Chief Financial Officer and as a financial management consultant of Oxis International, Inc., a public company engaged in the research, development and commercialization of nutraceutical products, from August 2009 until October 2011. From November 2004 to July 2009, Mr. Handelman served as Chief Financial Officer and Chief Operating Officer of TechnoConcepts, Inc., formerly a public company engaged in designing, developing, manufacturing and marketing wireless communications semiconductors, or microchips. Prior thereto, Mr. Handelman served from October 2002 to October 2004 as Chief Financial Officer of Interglobal Waste Management, Inc., a manufacturing company, and from July 1996 to July 1999 as Vice President and Chief Financial Officer of Janex International, Inc., a children's toy manufacturer. Mr. Handelman was also the Chief Financial Officer from 1993 to 1996 of the Los Angeles Kings, a National Hockey League franchise. On October 24, 2019 Mr. Handelman filed a petition in bankruptcy, which was subsequently dismissed on December 16, 2019. Mr. Handelman is a certified public accountant and holds a degree in accounting from the City University of New York.

Bruce Wendel was appointed as a director on November 12, 2020. From April 2018 to May 2019, Mr. Wendel served as the Chief Business Development Officer for Prometic Biotherapeutics, Inc., a pharmaceutical development company. Mr. Wendel also served as Chief Strategic Officer of Hepalink USA, the U.S. subsidiary of Shenzhen Hepalink Pharmaceutical Company from February 2012 to July 2017, and Chief Executive Officer of Scientific Protein Laboratories, LLC from December 2014 to June 2015. He also served as a director of ProMetic Life Sciences Inc. and Vice Chairman and Chief Executive Officer at Abraxis BioScience, LLC, where he oversaw the development and commercialization of Abraxane® and led the negotiations that culminated in the acquisition of the company by Celgene Corporation in 2010. He began his 14 years at Bristol-Myers Squibb as in-house counsel before shifting to global business and corporate development where he served in roles of increasing responsibility. Subsequently, he was VP of Business Development at IVAX Corporation, and at American Pharmaceutical Partners, Inc. Mr. Wendel earned a juris doctorate degree from Georgetown University Law School, and a B.S. from Cornell University.

Dr. Greg Berk was appointed as a director on November 12, 2020. Prior to joining the Company, Dr. Berk has served as a private consultant in the field of drug development and is the Chief Medical Officer of Celularity, a privately owned company. Previously, he served as Chief Medical Officer at Verastem as and President, Chief Medical Officer and Board Member of Sideris Pharmaceuticals. From May 2012 until January 2014, Dr. Berk was Chief Medical Officer of BIND Therapeutics. Prior to this, he was Chief Medical Officer at Intellikine, a privately held biotechnology company focused on the discovery and development of novel PI3 Kinase and mTOR inhibitors. Intellikine was acquired by Takeda/Millennium in January 2012. He also served as Senior Vice President of Global Clinical Development at Abraxis BioScience, where he was responsible for the company's overall clinical strategy, including efforts to expand the indications for their lead clinical program (Abraxane®). Dr. Berk obtained his medical degree from Case Western Reserve University, and completed his internship, residency and fellowship in internal medicine, hematology and medical oncology, at the Weill Medical College of Cornell University and New York Presbyterian Hospital, where he also served as a faculty member from 1989-2004. During this time Dr. Berk served as an investigator on several industry-sponsored and cooperative group oncology clinical trials, including the pivotal trials for Gleevec® and Avastin®.

Michael Breen was appointed as a director on January 13, 2021.Prior to joining the Company, Mr. Breen served as a senior partner in the global law firm of Clyde & Co., specializing in all aspects of corporate law, including mergers and acquisitions and fund management regulatory issues, which included advising clients in the biotechnology and health sciences sectors. Prior to joining Clyde & Co., Mr. Breen served as a senior partner and managing partner in the London law firm of Edward Lewis. Prior to his time at Edward Lewis, he was also a partner at Robert Gore & Company. Between 2002 and 2005, Mr. Breen was managing director of the Sports and Entertainment Division of Insinger de Beaufort Bank, a Dutch private banking, asset management and trust group. From 2001 to 2007 Mr. Breen also served as a non-executive director and co-owner of Damon Hill Holdings Limited, a multi franchise motor dealer group. Mr. Breen also serves as a director of a Los Angeles based hedge fund, Bristol International Fund, Limited and a Cayman Islands fund, Bristol Investment Fund, Limited. He also serves as a director of Wizard Brands Inc., an OTCQB Bulletin Board company. Mr. Breen is also a non-executive director and co-owner of Colorsport Images Limited, a sports photographic agency and library. He is the Chair of Trustees of Sturts Community Trust, a charity which brings together a diverse range of social initiatives centered around a sustainable 90 acre organic biodynamic farm offering land based work opportunities and individualized support and dwellings for adults with a learning disability. Mr. Breen is a U.K. qualified solicitor/attorney who holds an Honours LL.B. degree in law from the University College of Wales, Aberystwyth and qualified as a solicitor of the Supreme Court of Judicature of England and Wales in 1988. Mr. Breen is a former member of the International Bar Association, British Association for Sport and the Law, Law Society of England and Wales, and Holborn Law Society.

Dr. Rajesh Shrotriya was appointed as a director on January 13, 2021. Prior to joining the Company, until 2017, Dr. Shrotriya served as Chairman of the Board and Chief Executive Officer of Spectrum Pharmaceuticals, Inc. from August 2002 and a director since June 2001. From September 2000 to April 2014, Dr. Shrotriya also served as President of Spectrum Pharmaceuticals, Inc. and from September 2000 to August 2002, Dr. Shrotriya also served as Chief Operating Officer of Spectrum. Prior to joining Spectrum, Dr. Shrotriya held the position of Executive Vice President and Chief Scientific Officer from November 1996 until August 2000, and as Senior Vice President and Special Assistant to the President from November 1996 until May 1997, for SuperGen, Inc., a publicly-held pharmaceutical company focused on drugs for life-threatening diseases, particularly cancer. From August 1994 to October 1996, Dr. Shrotriya held the positions of Vice President, Medical Affairs and Vice President, Chief Medical Officer of MGI Pharma, Inc., an oncology-focused biopharmaceutical company. Dr. Shrotriya spent 18 years at Bristol-Myers Squibb Company, an NYSE-listed pharmaceutical company, in a variety of positions, most recently as Executive Director, Worldwide CNS Clinical Research. Previously, Dr. Shrotriya held various positions at Hoechst Pharmaceuticals, most recently as Medical Advisor. Dr. Shrotriya was an attending physician and held a courtesy appointment at St. Joseph Hospital in Stamford, Connecticut. In addition, he received a certificate for Advanced Biomedical Research Management from Harvard University. Dr. Shrotriya received an M.D. from Grant Medical College, Bombay, India, in 1974; a D.T.C.D. (Post Graduate Diploma in Chest Diseases) from Delhi University, V.P. Chest Institute, Delhi, India, in 1971; an M.B.B.S. (Bachelor of Medicine and Bachelor of Surgery — equivalent to an M.D. in the U.S.) from the Armed Forces Medical College, Poona, India, in 1967; and a B.S. in Chemistry from Agra University, Aligarh, India, in 1962. Currently, Dr. Shrotriya is a member of the Board of Directors of CASI Pharmaceuticals, Inc., a NASDAQ-listed biopharmaceutical company, and on the Board of Trustees at the UNLV Foundation.

Board Committees, Compensation Committee Interlocks and Insider Participation.

The Audit Committee consists of Mr. Breen, as Chair and as audit committee financial expert, Dr. Shrotriya and Mr. Wendel. The Compensation Committee consists of Dr. Berk as Chair, Mr. Wendel and Mr. Breen. The Nominating and Governance Committee consists of Mr. Wendel, as Chair, Dr. Shrotriya and Mr. Breen.

Director Independence.

Mr. Wendel, Dr. Berk, Mr. Breen and Dr. Shrotriya each qualify as an "independent director" as defined by Item 407 of Regulation S-K.

We have elected to use the definition for "director independence" under the Nasdaq Stock Market's listing standards, which defines an "independent director" as "a person other than an officer or employee of us or its subsidiaries or any other individual having a relationship, which in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director." The definition further provides that, among others, employment of a director by us (or any parent or subsidiary of ours) at any time during the past three years is considered a bar to independence regardless of the determination of our Board.

Code of Ethics

A copy of the company's code of ethics is attached to this annual report as exhibit 14.1

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons who own more than 10% of a registered class of the company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("SEC"). Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the company with copies of all Section 16(a) forms they file. All of our executive officers and directors filed the required reports; however, each of Mr. Handelman, Mr. Wendel, Dr. Berk, Mr. Breen and Dr. Shrotriya filed their Form 3 and Form 4 late.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth certain information concerning the annual and long-term compensation for services rendered to us in all capacities for the fiscal years ended December 31, 2020 and 2019 of all persons who served as our principal executive officers and as our principal financial officer during the fiscal year ended December 31, 2019. No other executive officers received total annual compensation during the fiscal year ended December 31, 2020 in excess of $100,000. The principal executive officer and the other named officers are collectively referred to as the "Named Executive Officers."

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($) (2)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($) (3)	Total ($)
Anthony J. Cataldo (5)	20	$ 362,000	$ -	$ -	$ -	$ -	$ -	$ -	$ 362,000
Chief Executive Officer	19	$ 225,000	$ -	$ 1,281,000	$ -	$ -	$ -	$ 75,000	$ 1,581,000
Michael Handelman (7)	20	$ 74,833	$ -	$ -	$ -	$ -	$ -	$ -	$ 74,833
Chief Financial Officer	19	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Steven Weldon (6)	20	$ 219,662	$ -	$ -	$ -	$ -	$ -	$ -	$ 219,662
Former Chief Financial Officer	19	$ 230,000	$ -	$ 823,500	$ -	$ -	$ -	$ -	$ 1,053,500
Raymond Urbanski, M.D., Ph.D. (4)	20	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Former Chief Executive Officer	19	$ 318,000	$ -	$ -	$ -	$ -	$ -		$ 318,000

(1) The amounts in this column represent the aggregate grant date fair value of the restricted stock awards and restricted stock units, determined in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. GT Biopharma determines the grant date fair value of the awards by multiplying the number of units granted by the closing market price of one share of GT Biopharma common stock on the award grant date. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting or the sale of the common stock awards.

(2) This column represents option awards computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures related to service-based vesting conditions. For additional information on the valuation assumptions with respect to the option grants, refer to Note 1 of our financial statements in this Annual Report. These amounts do not correspond to the actual value that will be recognized by the named executives from these awards.

(3) The amount in this column represents compensation earned under Consultant Agreements with the Company.

(4) Dr. Urbanski was appointed Chief Medical Officer on September 1, 2017, President of May 9, 2018, and Chief Executive Officer on July 3, 2018. He resigned as Chief Executive Officer on March 15, 2019.

(5) Mr. Weldon was appointed Chief Financial Officer on March 20, 2019 and resigned as Chief Financial Officer and member of the Board of Directors November 10, 2020. He was previously the Chief Financial Officer from November 3, 2014 until October 11, 2018.

(6) Mr. Cataldo was appointed Chief Executive Officer on March 15, 2019. Mr. Cataldo previously served as our Chief Executive Officer from March 2009 to August 2011 and again in November 2014 to September 1, 2017. He was Executive Chairman from September 1, 2017 to February 14, 2018, and has been providing services to the Company under a Consultant Agreement since February 14, 2018.

(7) Mr. Handelman was appointed Chief Financial Officer on November 11, 2020

Employment Agreements

Effective August 11, 2020, the Company and Mr. Cataldo entered into the Cataldo Agreement with respect to Mr. Cataldo's continued employment as Chief Executive Officer of the Company. The Initial Term of the Cataldo Agreement is three years with the option of automatic one-year renewals thereafter. Mr. Cataldo will be paid a cash salary of $30,000 per month, together with customary benefits, expense reimbursement and the possibility of performance bonuses. Mr. Cataldo will receive a stock grant equal to ten percent of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of Mr. Cataldo) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Cataldo Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). Mr. Cataldo will be entitled to certain additional severance payments and other benefits in connection with a Change in Control Period Involuntary Termination or a Non Change in Control Period Involuntary Termination (each as defined in the Cataldo Agreement) or his resignation as a result of a Change in Control Period Good Reason or Non Change in Control Period Good Reason (each as defined in the Cataldo Agreement). Following the Effective Date, Mr. Cataldo will also continue to serve as the chairman of the board of the Company.

Effective August 11, 2020, the Company and Mr. Weldon entered into the Weldon Agreement with respect to Mr. Weldon's continued employment as the Chief Financial Officer of the Company. The Initial Term of the Weldon Agreement was three years with the option of automatic one-year renewals thereafter. Mr. Weldon was paid a cash salary of $25,000 per month, together with customary benefits, expense reimbursement and the possibility of performance bonuses. Mr. Cataldo received a stock grant equal to seven percent of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of Mr. Weldon) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Weldon Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). Mr. Weldon was entitled to certain additional severance payments and other benefits in connection with a Change in Control Period Involuntary Termination or a Non Change in Control Period Involuntary Termination (each as defined in the Weldon Agreement) or his registration as a result of a Change in Control Period Good Reason or Non Change in Control Period Good Reason (each as defined in the Weldon Agreement). Mr. Weldon resigned as Chief Financial Officer and as a director of the Company on November 11, 2020. Mr. Weldon had no disagreement relating to the Company's financial reports or corporate filings.

In July 2016, we executed an exclusive worldwide license agreement with the Regents of the University of Minnesota, 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 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 shall own 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 will receive an upfront license fee, royalty fees, and certain milestone payments.

On October 19, 2018, the Company entered into an Executive Employment Agreement with Dr. Urbanski, reflecting his current position as Chief Executive Officer of the Company. Under the terms of this agreement, Dr. Urbanski's annual salary is essentially unchanged from his previous positions. Dr. Urbanski is also entitled to participate in the Company's bonus plans. Under the Executive Employment Agreement, the Company has agreed that upon shareholder approval of a Stock Option Plan, it will recommend to the Board that the Company grant Dr. Urbanski a Non-Qualified stock option to purchase 2,971,102 shares of the Company's common stock having an exercise equal to the fair market value of the shares on the date of the Agreement. The stock option grant would vest according to the following schedule: (i) 1,250,000 fully vested shares upon signing of the agreement, (ii) 1,250,000 shares on January 1, 2019, and (iii) 471,102 shares on January 1, 2020. On March 15, 2019, Dr, Urbanski resigned his position as Chief Executive Officer, President and Chairman of the Board.

Stock Option Grants

The following table sets forth information as of December 31, 2020, concerning unexercised options, unvested stock and equity incentive plan awards for the executive officers named in the Summary Compensation Table.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($) Option Expiration Date
Michael Handelman	-	-	-	$ -
Anthony Cataldo	-	-	-	$ -

Director Compensation

Mr. Wendel and Dr. Berk will each receive an annual stipend of $20,000.00 for director compensation, with Mr. Wendel receiving an additional $5,000.00 annually for chairing the Nominating Committee and $5,000.00 annually as a member of the Audit Committee, and Dr. Berk receiving an additional $5,000.00 annually for chairing the Compensation Committee and $5,000.00 annually as a member of the Nominating Committee. The Company will also grant stock awards of shares of common stock of the Company equal to 1.25%, in the case of Mr. Wendel, and 1.00%, in the case of Dr. Berk, of the number of fully diluted shares of common stock of the Company, calculated on the fully diluted equity of the Company upon the Company's national exchange financing date.

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of April 12, 2021, (a) by each person known by us to own beneficially 5% or more of any class of our common stock, (b) by each of our named executive officers, (c) by each of our directors and (d) by all our current executive officers and directors as a group. As of April 12, 2021, there were 28, 572,770 shares of our common stock issued or issuable. Shares of common stock subject to warrants that are currently exercisable or exercisable within 60 days of April 12, 2021 are deemed to be outstanding for purposes of computing the percentage ownership of that person but are not treated as outstanding for computing the percentage ownership of any other person. Unless indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Except as otherwise indicated, the address of each stockholder is c/o GT Biopharma, Inc. at 9350 Wilshire Blvd., Suite 203, Beverly Hills, CA 90212. We have prepared the following table and the related notes based on information filed with the SEC, supplied to us by the relevant stockholder or estimated based on our internal records, which may not include shares held by a stockholder in "street name."

	Shares Beneficially Owned	
Name and Address of Beneficial Owner	**Number**	**Percentage**
Certain Beneficial Owners		
Bristol Capital, LLC (1)	972,418	3.5%
Bristol Investment Fund Ltd. (1)	1,192,292	4.3%
Michael Bigger (2,3)	2,303,281	8.0%
Red Mango Enterprises Limited (3,4)	1,737,365	6.2%
Directors and Executive Officers		
Anthony J. Cataldo	3,162,928	11.3%
Michael Handelman	417,086	1.5%
Bruce Wendel	350,840	1.3%
Greg Berk	278,058	1.0%
Michael Breen	278,058	1.0%
Rajesh Shrotriya	278,058	1.0%
Directors and Executive Officers as a Group – 6 persons	4,765,027	21.0%

(1) The address of record is 662 N. Sepulveda Blvd., Ste 300, Los Angeles, CA 90049. Paul Kessler, as manager of Bristol Capital Advisors, LLC, the investment advisor to Bristol Investment Fund, Ltd. ("BIF") and Bristol Capital, LLC ("BC"), has voting and investment control over the securities held by BIF and BC. Mr. Kessler disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(2) The address of record is 11434 Glowing Sunset Lane, Las Vegas, NV 89135. Based on the beneficial owner's Schedule 13G filed February 17, 2021, shares beneficially owned consist of 729,029 shares of common stock owned by Bigger Capital Fund, LP, 425,000 shares of common stock issuable upon exercise of warrants owned by Bigger Capital Fund, LP, 724,252 shares of common stock owned by District 2 Capital Fund LP, and 425,000 shares of common stock issuable upon exercise of warrants owned by District 2 Capital Fund LP. The warrants are subject to a 4.99% beneficial ownership limit. The percentage set forth above assumes the exercise of all such warrants does not give effect to the beneficial ownership limit. Mr. Bigger disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(3) The address of record is Pictet & Cie (Europe) S.A. Hong Kong Branch, 9/F Chater House 8 Connaught Road Central, Hong Kong. We have been advised that Chi Kan Tang exercises voting and investment power over the securities held by Red Mango Enterprises Limited.

Equity Compensation Plan Information

The following is a summary of our equity compensation plans at December 31, 2019:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights (b)	Number of Securities Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders (1)	40	$ 877.50	-
Equity compensation plans not approved by security holders	-	$ -	-
Total	40	$ 877.50	-

(1) As of December 31, 2019, we had options issued and outstanding to purchase 40 shares of common stock under our 2014 Stock Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Director Independence

Mr. Wendel, Dr. Berk, Mr. Breen and Dr. Shrotriya each qualify as an "independent director" as defined by Item 407 of Regulation S-K.

We have elected to use the definition for "director independence" under the Nasdaq Stock Market's listing standards, which defines an "independent director" as "a person other than an officer or employee of us or its subsidiaries or any other individual having a relationship, which in the opinion of our Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director." The definition further provides that, among others, employment of a director by us (or any parent or subsidiary of ours) at any time during the past three years is considered a bar to independence regardless of the determination of our Board of Directors.

Related Party Transactions

During the year ended December 31, 2020, the Company recorded consulting expense of $1,160,000 for services rendered by a consultant who was also an owner of approximately 10% of the Company's issued and outstanding common stock.

During the year ended December 31, 2019, the Company recorded consulting expense of $1,140,000 to a consultant who was also an owner of approximately 10 % of the Company's issued and outstanding common stock.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Seligson & Giannattasio, LLP was our independent registered public accounting firm for the fiscal years ending December 31, 2019. The following table shows the fees that were paid or accrued by us for audit and other services provided by Seligson & Giannattasio, LLP for the 2020 and 2019 fiscal years.

	2020	2019
Audit Fees (1)	$ 75,000	$ 70,500
Audit-Related Fees (2)	$ -	$ -
Tax Fees (3)	$ -	$ 4,000
All Other Fees	$ -	$ -
Total	$ 75,000	$ 74,500

(1) Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Form 10-Q quarterly reports and services that are normally provided in connection with statutory or regulatory filings for the 2020 and 2019 fiscal years.

(2) Audit-related fees represent fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported above under “Audit Fees.”

(3) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.

All audit related services, tax services and other services rendered by Seligson & Giannattasio, LLP were pre-approved by our Board of Directors or Audit Committee. The Audit Committee has adopted a pre-approval policy that provides for the pre-approval of all services performed for us by Seligson & Giannattasio, LLP. The policy authorizes the Audit Committee to delegate to one or more of its members pre-approval authority with respect to permitted services. Pursuant to this policy, the Board delegated such authority to the Chairman of the Audit Committee. All pre-approval decisions must be reported to the Audit Committee at its next meeting. The Audit Committee has concluded that the provision of the non-audit services listed above is compatible with maintaining the independence Seligson & Giannattasio, LLP.

On December 28, 2020, Seligson & Giannattasio, LLP resigned as our independent registered public accounting firm. On December 31, 2020, the Board appointed Weinberg & Company, P.A. to serve as our independent registered public accounting firm for the fiscal year ending December 31, 2020.

No fees were paid or accrued by us for audit or other services provided by Weinberg & Company, P.A. for the 2020 fiscal year, other than payment of a retainer towards the $75,000 for the upcoming audit of the financial statements for the year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The Company's 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

		Incorporated by Reference			
Exhibit Number	**Exhibit Description**	**Form**	**Date**	**Number**	**Filed Herewith**
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	04/01/02	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	08/13/03	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				X
10.1	Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc.	10-Q	08/11/17	10.3	
10.2	License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc.	10-Q	08/11/17	10.4	
10.3	Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc.	10-Q	5/15/20	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	11/14/17	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	11/14/17	10.8	
10.6	Warrant Exercise Agreement, dated August 29, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/17	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	11/14/17	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	11/14/17	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	11/14/17	10.10	
10.10	Securities Purchase Agreement, dated January 9, 2017, among OXIS International, Inc. and the purchasers named therein	8-K	01/13/17	10.1	
10.11	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/17	10.2	
10.12	Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/17	10.3	
10.13	Securities Purchase Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	1/23/18	10.1	
10.14	Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	1/23/18	10.2	
10.15	Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	1/23/18	10.3	

10.16	Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	1/23/18	10.4
10.17	Securities Purchase Agreement, dated August 2, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/03/18	10.1
10.18	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018)	8-K	08/03/18	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	08/14/18	10.10
10.20	Security Purchase Agreement, dated September 7, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/07/18	10.1
10.21	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018)	8-K	09/07/18	4.1
10.22	Security Purchase Agreement, dated September 24, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/28/18	10.1
10.23	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018)	8-K	09/28/18	4.1
10.24	Securities Purchase Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/19	10.1
10.25	Registration Rights Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/19	10.3
10.26	Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019)	8-K	02/06/19	4.1
10.27	Security Agreement, dated February 4, 2019, among GT Biopharma, Inc. and Alpha Capital Anstalt, as collateral agent	8-K	02/06/19	10.2
10.28	Securities Purchase Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.1
10.29	Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.2
10.30	Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019)	8-K	05/24/19	4.1
10.31	Securities Purchase Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.1
10.32	Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.2
10.33	Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019)	8-K	05/15/20	4.1
10.34	Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/20	10.1
10.35	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/20	10.2
10.36	Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020)	10-Q	05/15/20	10.3
10.37	Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/20	10.1
10.38	Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/20	10.2
10.39	Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020)	10-Q	05/15/20	10.3
10.40	Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/20	10.1
10.41	Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/20	10.3
10.42	Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020)	8-K	07/09/20	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	06/23/20	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	06/19/20	10.1
10.45	Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/20	10.2
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	06/19/20	10.3
10.47	Executive Employment Agreement, dated October 19, 2018, among GT Biopharma, Inc. and Raymond W. Urbanski	10-Q	11/14/18	10.17
10.48	Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo	8-K	2/21/18	10.3

10.49	Employment agreement with Anthony Cataldo	10-Q	8/14/20	10.11	
10.50	Employment agreement with Steven Weldon	10-Q	8/14/20	10.12	
10.51	Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020)	8-K	9/22/20	4.1	
10.52	Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein	8-K	9/22/20	10.1	
10.53	Master Services Agreement, dated October 5, 2020, between Gt Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	10/6/20	10.1	
10.54	Form of First Amendment and Extension of Standstill and Forbearance Agreement	8-K	11/4/20	10.1	
10.55	Form of Secured Convertible Note	8-K	11/9/20	4.1	
10.56	Securities Purchase Agreement	8-K	11/9/20	10.1	
10.57	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	11/13/20	10.19	
10.58	Form of Settlement Note, dated November 9, 2020.	10-Q	11/13/20	10.20	
10.59	Steve Weldon Letter of Resignation, dated November 11, 2020	10-Q	11/13/20	10.21	
10.60	Board Service Agreement with Bruce Wendel, dated November 11, 2020	10-Q	11/13/20	10.22	
10.61	Board Service Agreement with Greg Berk, dated November 11, 2020	10-Q	11/13/20	10.23	
10.62	Consultant Agreement with Michael Handelman, dated November 13, 2020	10-Q	11/13/20	10.24	
10.63	Form of Amendment to Convertible Note & Standstill Agreement	8-K	12/23/20	10.1	
10.64	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	12/28/20	10.1	
10.65	Settlement Note, dated December 22, 2020, by GT Biopharma Inc. payable to Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	8-K	12/28/20	10.2	
10.66	Form of Second Amendment and Extension of Standstill and Forbearance Agreement.	8-K	2/1/20	10.1	
10.67	Form of Amendment to Convertible Note, dated January 31, 2021	8-K	2/1/20	10.2	
10.68	Board Service Agreement with Rajesh Shrotriya, dated January 12, 2021.	S-1/A	02/08/2021	10.69	
10.69	Board Service Agreement with Michael Breen, dated January 12, 2021.	S-1/A	02/08/2021	10.70	
10.70	Amendment to Settlement Note with Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	S-1/A	02/08/2021	10.71	
10.71	Form of Securities Purchase Agreement - December 2020 / January 2021 Notes	S-1/A	02/08/2021	10.72	
10.72	Form of December 2020 / January 2021 Note	S-1/A	02/08/2021	10.73	
14.1	Code of Ethics	10-K	03/31/16	14.1	
21.1	Subsidiaries of GT Biopharma, Inc.	10-K	03/31/16	21.1	
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	Interactive Data File				X

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: April 16, 2021

By: /s/ Anthony Cataldo
Anthony Cataldo

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/ Anthony J. Cataldo Anthony J. Cataldo	Chief Executive Officer and Chairman of the Board	April 16, 2021
/s/ Michael Handelman Michael Handelman	Chief Financial Officer(Principal Accounting Officer)	April 16, 2021
/s/ Bruce Wendel Bruce Wendel	Vice Chairman of the Board	April 16, 2021
/s/ Greg Berk Greg Berk	Director	April 16, 2021
/s/ Michael Breen Michael Breen	Director	April 16, 2021
/s/ Rajesh Shrotriva Rajesh Shrotriva	Director	April 16, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors of
GT Biopharma, Inc.
Beverly Hills, CA

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of GT Biopharma, Inc. (the "Company") as of December 31, 2020 and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year 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, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during the year ended December 31, 2020, the Company incurred a net loss and utilized cash in operations, and at December 31, 2020, had a stockholders' deficit. Also, at December 31, 2020, the Company is in default on notes payable and convertible notes payable in the aggregate amount of $16.8 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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.

Accounting for Issuance of Convertible Debt

During the year ended December 31, 2020, the Company issued $19.1 million of principal in convertible debt as described in Note 4 to the consolidated financial statements. The accounting for the transaction required management to assess as to whether any embedded features required bifurcation and separate valuation. Additionally, the transaction required management to perform an analysis on the embedded conversion features to discern whether such conversion features were beneficial conversion features requiring separate classification within equity in the consolidated financial statements. During the year ended December 31, 2020, the Company recognized a total of approximately $5.3 million related to the determined beneficial conversion features.

Auditing management's determination of the accounting for these transactions was challenging due to the complexity and significant judgement involved in assessing the embedded features of the convertible notes for separate accounting, and assessing the determination of whether the conversion feature should be accounted for as a beneficial conversion feature within equity in the consolidated financial statements.

To test the Company's determination of the accounting for the convertible debt, our audit procedures included, among others, inspection of the related debt agreements and testing management's application of the relevant accounting guidance. We tested the value of the recognized beneficial conversion features by assessing the reasonableness of the assumptions used in the valuation and recalculated such amounts. In addition, we tested the completeness and accuracy of the underlying data supporting the significant assumptions and estimates.

Accounting for Extinguishment of Past Due Convertible Debt

In June 2020, the Company entered into the Forbearance Agreements with the holders of $13.2 million of convertible debt that was past due as described in Note 4 to the consolidated financial statements. Under the terms of the Forbearance Agreements, the holders were issued an additional $4 million worth of convertible notes and the conversion feature of the instruments was modified so that the instrument was convertible at the lower of $3.40 or 75% of the stock price in the next qualified offering. The accounting for the transaction was complex, as it required management to assess these modifications and discern whether such modifications were significant enough to require extinguishment accounting, which management concluded was required. Extinguishment accounting required the fair value measurement of the post modification convertible notes and recognition of the difference between such fair value and the carrying value of the premodification convertible notes as a loss on extinguishment of debt. The Company recognized a loss on extinguishment of debt of approximately $12.6 million related to this modification. The Company also utilized a valuation specialist in the determination and valuation of the fair value of this new debt instrument.

We identified the evaluation of the accounting treatment for these transactions and the corresponding valuation of the new debt instruments as a critical audit matter, because of the significance of the account balance and the significant judgements used in determining the appropriate accounting model to recognize these transactions and in the determination of the fair value of the new debt instruments. Complex auditor judgment and specialized skills and knowledge were involved in evaluating the Company's interpretation of applicable accounting rules and the valuation of the new debt instrument.

The primary procedures we performed to address this critical audit matter included the following. We inspected relevant documentation related to the forbearance agreement to evaluate the Company's determination of the appropriate accounting model, including assessing and evaluating management's application of relevant accounting standards to the transaction. We evaluated and assessed the reasonableness of the valuation models used by the third-party specialist to value the convertible debt instruments. We tested the reasonableness of the significant assumptions used in the valuation model, including testing the accuracy and completeness of the data used to determine such assumptions. We developed an independent expectation using market data sources, models and key assumptions determined to be relevant and reliable and compared such independent expectation to the Company's estimate. In addition, we ascertained the competence and objectivity of the third-party valuation specialist engaged by the Company to calculate the fair values, as well as independently assessing the professional competence, experience and objectivity of the Company's third-party valuation specialist.

Professionals with specialized skill and knowledge were utilized by the Firm to assist in the evaluation of the Company estimate of fair value and the development of our own independent expectation.

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

Weinberg & Company, P.A.
Los Angeles, California
April 16, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of GT Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of GT Biopharma, Inc. and subsidiaries (the "Company") as of December 31, 2019, and the related consolidated statements of operations, stockholders' equity and cash flows for the year the 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 consolidated financial position of the Company and subsidiaries as of December 31, 2019 and the consolidated results of its operations and its consolidated cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis of Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audit 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 consolidated 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred significant recurring losses. The realization of a major portion of its assets is dependent upon its ability to meet its future financing needs and the success of its future operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

/s/ Seligson & Giannattasio, LLP
Seligson & Giannattasio, LLP

We served as the Company's auditor from 2008 through December 28, 2020.

White Plains, New York
March 30, 2020

GT BIOPHARMA, INC AND SUBSIDIARIES
Consolidated Balance Sheets
(In Thousands, Except Par Value and Share Data)

	December 31, 2020	December 31, 2019
ASSETS:		
Current assets		
Cash and cash equivalents	$ 5,297	$ 28
Prepaid expenses	364	246
Total Current Assets	5,661	274
Deposits	-	12
Operating lease right-to-use asset	-	110
TOTAL ASSETS	$ 5,661	$ 396
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 2,243	$ 1,940
Accrued expenses	1,296	2,379
Accrued interest	4,838	2,029
Convertible notes payable, of which $16.8 were past due at December 31, 2020 (net of discount of $4,519 and $91)	26,303	13,207
Operating lease liability	-	120
Line of Credit	31	31
Derivative liability	383	-
Total current liabilities	35,094	19,706
Stockholders' Deficit:		
Convertible Preferred stock, par value $0.01, 15,000,000 shares authorized:		
Series C - 96,230 shares issued and outstanding at December 31, 2020 and 2019, respectively	1	1
Series J - 2,353,548 shares issued and outstanding at December 31, 2020 and 2019, respectively	2	2
Common stock, par value $0.0001, 2,000,000,000 shares authorized, 5,218,122 and 4,104,982 shares issued and outstanding as of December 31, 2020 and 2019, respectively	52	41
Additional paid in capital	566,309	548,147
Accumulated deficit	(595,628)	(567,332)
Noncontrolling interest	(169)	(169)
Total stockholders' deficit	(29,433)	(19,310)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 5,661	$ 396

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

GT BIOPHARMA, INC AND SUBSIDIARIES
Consolidated Statements of Operations
(In Thousands, Except Share Data)

	For the Year Ended December 31,	
	2020	**2019**
Revenues	$ -	$ -
Operating Expenses:		
Research and development	485	1,667
Selling, general and administrative	6,279	9,790
Loss on impairment		4,599
Loss from Operations	6,764	16,056
Other (Income) Expense		
Loss on disposal of assets	-	20,463
Interest expense	3,003	2,128
Loss on legal settlements	5,384	-
Loss on forbearance agreement	12,598	-
Change in fair value of derivative liability	230	-
Amortization of debt discount	317	-
Total Other Expense, net	21,532	22,591
Net Loss	$ (28,296)	$ (38,647)
Net loss per share		
Basic and diluted	$ (6.45)	$ (0.01)
Weighted average common shares outstanding		
Basic and diluted	4,385,222	3,383,941

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		Additional Paid in	Accumulated	Non Controlling	
	Shares	Amount	Shares	Amount	Capital	Deficit	Interest	Total
Balance, December 31, 2018	1,260	$ 2	2,979	$ 22	$ 540,200	$ (528,685)	$ (169)	$ 11,370
Issuance of preferred shares	1,190	1			1,139			1,140
Common share issued upon conversion of notes			205	3	1,357			1,360
Beneficial conversion feature on convertible notes					158			158
Issuance of common stock for compensation			921	16	5,293			5,309
Net loss						(38,647)		(38,647)
Balance, December 31, 2019	2,450	3	4,105	41	548,147	(567,332)	(169)	(19,310)
Fair value of amended convertible notes and warrants					8,643			8,643
Issuance of common shares and warrants for settlement of litigation			262	10	2,236			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**	**$ 52**	**$ 566,309**	**$ (595,628)**	**$ (169)**	**$ (29,433)**

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (28,296)	$ (38,647)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	4
Amortization of debt discount	317	505
Stock based compensation	269	5,308
Loss on impairment of long-lived assets	-	4,599
Loss on disposal of assets	-	20,494
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	230	
Issuance of warrants accounted as derivative liability	153	
Effect of changes in:		
Prepaid expenses	242	(216)
Accounts payable and accrued expenses	(838)	3,154
Accounts payable - related parties	-	-
Accrued interest	3,000	1,140
Net Cash Used in Operating Activities	(7,262)	(3,659)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Disposal of fixed assets	-	200
Net Cash Used in Investing Activities	-	200
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of notes payable	12,531	3,527
Payment of notes payable	-	(100)
Net Cash Provided by Financing Activities	12,531	3,427
Net Increase (Decrease) in Cash	5,269	(32)
Cash at Beginning of Period	28	60
Cash at End of Period	$ 5,297	$ 28
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	$ -	$ -
Income taxes paid	$ -	$ -
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Beneficial conversion feature of notes payable issued for cash	$ 4,745	$ -
Common stock issued upon conversion of notes payable and accrued interest	$ 1,741	$ 1,381
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™), Tetra-specific Killer Engager (Dual Targeting TriKEDual 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, or NK cells.

Note 2 –Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying consolidated financial statements, for the year ended December 31, 2020, the Company incurred a net loss of $28.3 million and used cash in operating activities of $7.3 million, and at December 31, 2020, the Company had a stockholders' deficit of $29.4 million. Also, at December 31, 2020, the Company is in default on notes payable and convertible notes payable in the aggregate amount of $16.8 million. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that these financial statements are issued. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

At December 31, 2020, the Company had cash on hand in the amount of $5.3 million.Subsequent to December 31, 2020, the Company received cash of $24.9 million from the sale of 4,945,000 shares of its common stock pursuant to a public offering and $4.4 million from issuance of convertible notes payable and exercise of warrants for a total cash proceeds of $29.3 million. 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. 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, payments from potential strategic research and development, and licensing and/or marketing arrangements with pharmaceutical companies. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected. Management estimates that the current funds on hand will be sufficient to continue operations through the next six months**.** The Company's ability to continue as a going concern is dependent upon its ability to continue to implement its business plan.

Note 3 – 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. Intercompany transactions and balances have been eliminated in consolidation.

Reverse Stock Split

On February 10, 2021, the Company completed 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 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.

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, 2020, 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.

Accounting Estimates

The preparation of 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 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

FASB Accounting Standards Codification ("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 $383,000 as of December 31, 2020 was based on Level 2 measurements.

The carrying amounts of the Company's other financial assets and liabilities, such as cash, accounts receivables, inventory, prepaid expense, accounts payable and accrued payables 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 are 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.

Advertising Costs

The Company has marketing relationship agreements with various online companies such as portal networks, contextual sites, search engines and affiliate partners. Advertising costs are generally charged to the Company monthly per vendor agreements, which typically are based on visitors and/or registrations delivered to the site or at a set fee. Agreements do not provide for guaranteed renewal and may be terminated by the Company without cause. Such advertising costs are charged to expense as incurred. There were no advertising expenses incurred during the years ended December 31, 2020 and 2019, respectively.

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 software products comprise research and development expenses. Purchased materials that do not have an alternative future use are also expensed.

Leases

We lease our corporate office space under a lease agreement with monthly payments over a period of 60 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 (see Note 7).

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.

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

	December 31, 2020	December 31, 2019
A. Options to purchase common stock	-	3
B. Warrants to purchase common stock	221,041	106,650
C. Convertible notes payable	9,065,262	3,911,176
D. Convertible Series J Preferred stock	692,220	692,220
E. Convertible Series C Preferred stock	7	7
	9,978,530	4,710,056

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.

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.

Restatement

The Company identified an accounting error related to the recognition of loss on extinguishment of debt reported in prior quarterly periods. As a result, the Company is restating its unaudited condensed consolidated balance sheets and the statements of operations as of June 30, 2020 and September 30, 2020 (see Note 13)

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 ASU No. 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.* ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective January 1, 2024, for the Company. Early adoption is permitted, but no earlier than January 1, 2021, including interim periods within that year. Management is currently evaluating the effect of the adoption of ASU 2020-06 on the consolidated financial statements, but currently does not believe ASU 2020-06 will have a significant impact on the Company's accounting for its convertible debt instruments as they are not considered indexed to the Company's own stock. The effect will largely depend on the composition and terms of the financial instruments at the time of adoption.

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 4 – Convertible Notes Payable

Convertible notes payable consisted of the following:

	December 31, 2020	December 31, 2019
A. Notes payable issued for cash	$ 24,085,000	$ 12,998,000
B. Notes payable issued for settlement agreements	2,528,000	300,000
C. Notes payable issued for forbearance agreements	3,849,000	-
D. Notes payable issued for consulting services	360,000	-
	30,822,000	13,298,000
Less unamortized debt discount	(4,519,000)	(91,000)
Convertible notes, net of discount	$ 26,303,000	$ 13,207,000

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 are unsecured, bears interest at a rate of 10% per annum matures in six months up to one year from the date of issuance and convertible to common stock at an average conversion rate of $19.65 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, 2018, outstanding balance of these notes payable amounted to $10,673,000.

During the year ended December 31, 2019, the Company issued similar notes payable in the aggregate of $3,827,000 in exchange for cash. These notes payable are unsecured, bears interest at a rate of 10% per annum matures in six months up to one year from the date of issuance and convertible to common stock at an average conversion rate of $5.74 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. The Company also determined that certain of these notes payable contained a beneficial conversions feature (BCF) cost of $158,000 since these notes' were issued when the trading price of the Company's stock was greater than the average conversion price of $5.74 per share. The BCF was accounted as a debt discount and is being amortized over the corresponding term of the notes payable to interest expense. In addition, during 2019, notes payable of $1,502,000 were converted to 205,000 shares of common stock and the Company amortized the debt discount of $505,000.

As of December 31, 2019, outstanding balance of these notes payable issued for cash amounted to $12,998,000 and unamortized debt discount of $91,000.

During the year ended December 31, 2020, the Company issued similar notes payable in the aggregate of $12,531,000 in exchange for cash. These notes payable are unsecured, bears interest at a rate of 10% per annum matures in six months up to one year from the date of issuance and convertible to common stock at a 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. The Company also determined that certain of these notes payable contained a beneficial conversions feature (BCF) cost of $4,745,000 since certain of these notes' were issued when the trading price of the Company's stock was greater than the average conversion price of $3.40 per share. The BCF was accounted as a debt discount and is being amortized over the corresponding term of the notes payable to interest expense. In addition, during 2020, notes payable of $1,444,000 plus accrued interest were converted to 478,510 shares of common stock and the Company amortized the debt discount of $317,000.

In addition, in June 2020, the Company entered in a forbearance agreement with certain noteholders of past due notes payable in the aggregate of $13.2 million (see discussion at "C").

As of December 31, 2020, outstanding balance of these notes payable issued for cash amounted to $24,085,000 and unamortized debt discount of $4,519,000.

B. Notes Payable Issued for Settlement Agreements

During the year ended December 31, 2019, the Company issued notes payable of $300,000 as part of a debt settlement agreement. The notes are unsecured, bears interest at a rate of 10%, matures in six months up to one year from the date of issuance and convertible to common stock at a conversion rate of $10.20 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, 2019, outstanding balance of notes payable issued for settlement agreements amounted to $300,000.

During the year ended December 31, 2020, the Company entered into settlement agreements with certain parties such as Empery Asset Master Ltd., Empery Tax Efficient, LP, Empery Tax Efficient II, LP, Adam Kasower, East Ventures, Inc., SV Booth Investments III, LLC, and Theorem Group, LLC to resolve claims and disputes pertaining to certain debt and equity instruments issued by the Company to these parties in prior years.

As part of the agreement, the Company agreed to the following considerations:

a. Issuance of convertible notes payable in the aggregate of $2,228,000. The notes are unsecured, bears interest at a rate of 10%, matures in six months up to one year from the date of issuance and convertible to common stock at a 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. The Company also determined that certain of these notes payable contained a beneficial conversions feature cost of $530,000 since these notes' were issued when the trading price of the Company's stock was greater than the conversion price of $3.40 per share;
b. Cash payment of $380,000;
c. Issuance of 262,353 shares of common stock with a fair value of $1,225,000; and
d. Issuance of warrants to purchase 323,529 shares of common stock. The warrants are fully vested, exercisable at $3.40 per share and will expire in five years with an estimated fair value of $1,021,000 using a BlackScholes option price model.

Pursuant to current accounting guidelines, the Company recorded a loss of $5,384,000 to account the cash paid and the fair value of debt and equity instruments issued in these settlement agreements.

As of December 31, 2020, outstanding balance of these notes payable for settlement agreements amounted to $2,528,000.

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 are currently in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes have 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").

The obligations of the holders to forbear from exercising their rights and remedies under the Default Notes pursuant to the Forbearance Agreements will terminate on the earliest of (i) the Termination Date, (ii) the date of any bankruptcy filing by the Company or its subsidiaries, (iii) the date on which the Company defaults on any of the terms and conditions of the Forbearance Agreements or (iv) the date the Forbearance Agreements are otherwise terminated or expire.

In exchange for the forbearance agreement, the Company agreed to the following considerations:

a. Amendment of the $13.2 million Default Notes (together with default amounts and accrued and unpaid interest) to include a provision that will convert these notes payable into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes onthe date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of the Company's preferred stock, which are convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

b. Amendment of warrants granted to certain noteholders in prior year to include the following terms: (i) the exercise price of all warrants to purchase common stock held by holders of the Default Notes will be reduced to equal the conversion price of the Default Notes and (ii) the number of shares of common stock underlying such warrants shall be increased so that the total exercise price of all such warrants after the decrease in the exercise price equals the total exercise price of all such warrants prior to the decrease in the exercise price. Further, the expiration date of all such warrants shall be extended for three years following the closing date of any New Financing.

c. Issuance of notes payable in the aggregate of $3,955,000. The notes are unsecured, bears interest at a rate of 10% per annum, matures in six months up to one year from the date of issuance and convertible to common stock at a 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.

In accordance with ASC 450-70, modifications or exchanges are considered extinguishments with gains or losses recognized in current earnings if the terms of the new debt and original instrument are substantially different. The instruments are considered "substantially different" when the present value of the cash flows under the terms of the new debt instrument is at least 10% different from the present value of the remaining cash flows under the terms of the original instrument. Pursuant to ASC 470, the Company accounted the forbearance transaction as an extinguishment of debt which acquires the measurement of the modified debt and additional consideration to be at fair value.

The Company determined the fair value of amended notes payable and warrants at the date of the agreement to be $28,976,000. The fair value of the host component of the notes payable was determined by discounting the future cash flows related to the notes at a market rate of interest. The conversion features of the notes payable were determined using a Monte Carlo valuation which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the conversion features, and future dividends. The fair value of the warrants was determined using a binomial option pricing model. The incremental difference between the old debt deemed extinguished and the fair value of the new debt recognized amounted to $8,643,000 and was accounted loss on forbearance agreement and additional paid in capital. In addition, the Company also accounted the issuance of the new notes payable of $3,955,000 as part of loss on forbearance agreement for a total loss of $12,598,000.

In addition, during 2020, notes payable of $106,000 plus accrued interest were converted to 33,369 shares of common stock.

As of December 31, 2020, outstanding balance of the notes payable amounted to $3,849,000.

D. Notes Payable issued for Consulting Agreements

During the year ended December 31, 2020, the Company issued notes payable of $360,000 in exchange for consulting services. The notes are unsecured, bears interest at a rate of 10%, matures in one year from the date of issuance and convertible to common stock at a 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 $360,000.

As of December 31, 2020, total outstanding convertible notes payable that are matured and past due amounted to $16,824,000.

On February 11, 2021, all outstanding notes payable in the aggregate of $32 million and accrued interest of $5.5 million were converted to 11million shares of common stock (see Note 12)

Note 5 – 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 $250,000 strategic equity investment in the Company and agreed to make a $750,000 purchase order line of credit facility available to the Company. The outstanding principal of all advances under the line of credit will bear interest at the rate of interest of prime plus 2% per annum.

As of December 31, 2020 and 2019, outstanding balance of this credit line amounted to $31,000, respectively and is past due.

Note 6 – Derivative Liability

During the year ended December 31, 2020, the Company issued certain warrants that contained a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder upon occurrence of certain change in control type events.

In accordance with ASC 480, the fair value of these warrants are classified as a liability in the Consolidated Balance Sheet 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, 2020	July 2020 (date of inception)
Stock Price	$ 7.21	$ 3.06
Risk-free interest rate	0.36%	0.26%
Expected volatility	135%	134%
Expected life (in years)	4.6 years	5 years
Expected dividend yield	-	-
Fair Value:		
Warrants	$ 383,000	$ 153,000

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 the year ended December 31, 2020, the Company recognized a loss of $230,000 to account the change in fair value of the derivative liability.

Note 7 – Lease

In September 2018, the Company signed a three year lease agreement for its corporate office in Westlake Village, Ventura County. Monthly lease payment amounted to $5,000 up to $6,000 over the term of the lease.

The Company accounted the lease pursuant to ASC 842, Lease. Pursuant to ASC 842, Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The operating lease ROU asset includes any lease payments made and excludes lease incentives

As a result, the Company recorded right-of-use assets of $174,000 and lease liabilities of $174,000. In accordance with ASC 842, the right-of-use assets are being depreciated over the life of the underlying lease, and monthly lease payments are being recorded as reductions to the lease liability and imputed interest expense.

The components of lease expense and supplemental cash flow information related to leases for the period are as follows:

	Year ended December 31, 2020	Year ended December 31, 2019
Lease Cost		
Operating lease cost (included in general and administration in the Company's statement of operations)	$ -	$ 118,000
Other Information		
Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2020 and 2019	$ -	$ 120,000
Weighted average remaining lease term – operating leases (in years)	-	4.1
Average discount rate – operating leases	-%	10.0%

During fiscal 2020, as a result of the Covid-19 pandemic and various disputes with the landlord, the Company abandoned the leased area. Subsequently, the Company was sued by the landlord for $250,000 (see Note 10). As a result of abandonment of the facility and the existing lawsuit with the landlord, at December 31, 2020, the Company wrote off the unamortized ROU asset of $56,000 and reclassified the $58,000 operating lease liability as part of accrued expenses. As of December 31, 2020, the Company believes it has made adequate provision for any settlement of this matter.

The Company has no other leases at December 31, 2020 that requires to be accounted in accordance with ASC 842.

Note 8 – Stockholders' Deficit

Common Stock

The following were transactions during the year ended December 31, 2020:

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 $1,740,000 in principal and interest on convertiblenotes payable.

Issuance of Common Stock for services

During the year ended December 31, 2019, the Company issued 920,588 shares of common stock with a fair value of $5,309,000 to officers of the Company for services rendered.

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 $2,246,000. 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, 2020, the Company issued 239,706 shares of common stock upon cashless exercise of warrants.

The following were transactions during the year ended December 31, 2019:

Issuance of Common Stock for settlement of debt

During the year ended December 31, 2019, the Company issued a total 204,954 shares of common stock upon conversion of $1,361,000 in principal and interest on senior convertible notes.

Issuance of Common Stock for services

During the year ended December 31, 2019, the Company issued 920,588 shares of common stock with a fair value of $5,309,000 to officers of the Company for services rendered.

Preferred Stock

A. Series J Preferred Stock

On September 1, 2017, the Board designated 2,000,000 shares of Series J preferred stock (the "Series J Preferred Stock"). On the same day, the Board issued 1,513,548 shares of Series J Preferred Stock in exchange for the cancellation of certain indebtedness.

In the first quarter of 2019, it was discovered that a certificate of designation with respect to the Series J Preferred Stock had never been filed with the Office of the Secretary of State for the State of Delaware. Despite the fact the Company had issued shares of Series J Preferred Stock, the issuance of those shares was not valid and was of no legal effect.

To remedy the situation, on April 4, 2019, the Company filed a certificate of designation with the Office of the Secretary State for the State of Delaware designating a series of preferred stock as the Series J-1 preferred stock, par value $0.01 per share (the "Series J-1 Preferred Stock"). On April 19, 2019, the Company issued 840,000 shares of Series J-1 Preferred Stock. The issuance was in lieu of the Series J Preferred Stock that should have been issued on September 1, 2017, and in settlement for not receiving preferred stock until 20 months after the debt for which the stock was issued was cancelled. The Company reflected the fair value of this Series J Preferred stock of $1,140,000 as part of general and administrative costs in fiscal 2019.

Shares of the Series J-1 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 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 or 692,220 shares of common stock. Shares of the Series J-1 Preferred Stock have the same voting rights a 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 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 J-1 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.

B. Series C Preferred Stock

The 96,230 shares of Series C preferred stock, par value $0.01 per share (the "Series C Preferred Stock"), are convertible into 7 shares of the Company's common stock at the option of the holders at any time. The conversion ratio is based on the average closing bid price of the common stock for the fifteen consecutive trading days ending on the date immediately preceding the date notice of conversion is given, but cannot be less than $3.40 or more than $4.9113 common shares for each share of Series C Preferred Stock. The conversion ratio may be adjusted under certain circumstances such as stock splits or stock dividends. The Company has the right to automatically convert the Series C Preferred Stock into common stock if the Company lists its shares of common stock on the Nasdaq National Market and the average closing bid price of the Company's common stock on the Nasdaq National Market for 15 consecutive trading days exceeds $3,000.00. Each share of Series C Preferred Stock is entitled to the number of votes equal to 0.26 divided by the average closing bid price of the Company's common stock during the fifteen consecutive trading days immediately prior to the date such shares of Series C Preferred Stock were purchased. In the event of liquidation, the holders of the Series C Preferred Stock shall participate on an equal basis with the holders of the common stock (as if the Series C Preferred Stock had converted into common stock) in any distribution of any of the assets or surplus funds of the Company. The holders of Series C Preferred Stock are entitled to noncumulative 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, 2020 and 2019.

Stock Options

Stock option transactions for the years ended December 31, 2020 and 2019:

	Number of Options	Weighted Average Exercise Price
Outstanding, December 31, 2018	66	$ 22,440
Granted	-	-
Exercised	-	-
Expired	(63)	17,340
Outstanding, December 31, 2019	3	$ 22,440
Granted	-	-
Exercised	-	-
Expired	(3)	-
Outstanding, December 31, 2020	-	-
Exercisable, December 31, 2020	-	-

Stock Warrants

Stock warrant transactions for the years ended December 31, 2020 and 2019:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2018:	106,650	$ 3.40
Granted	-	-
Forfeited/canceled	-	-
Exercised	-	-
Outstanding at December 31, 2019:	106,650	$ 3.40
Granted	382,353	3.40
Forfeited/canceled	(28,256)	3.40
Exercised	(239,706)	-
Outstanding at December 31, 2020	221,041	$ 3.40
Exercisable at December 31, 2020	221,041	$ 3.40

As of December 31. 2020, the intrinsic value of these warrants amounted to $842,000.

The following were transactions during the year ended December 31, 2020:

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 $153,000 (see Note 6). 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 (see Note 4).

There was no warrant transactions during the year ended December 31, 2019.

Note 9 – Loss on Impairment and Disposal of Assets

On September 1, 2017, the Company entered into an Agreement and Plan of Merger whereby it acquired 100% of the issued and outstanding capital stock of Georgetown Translational Pharmaceuticals, Inc. (GTP). In exchange for the ownership of GTP, the Company issued a total of 16,927,878 shares of its common stock, having a share price of $15.00 on the date of the transaction, to the three prior owners of GTP which represented 33% of the issued and outstanding capital stock of the Company on a fully diluted basis. $253.8 million of the value of shares issued was allocated to intangible assets consisting of a portfolio of three CNS development candidates, which are classified as IPR&D.

For the year ended December 31, 2018, the Company recorded an intangible asset impairment charge of $228.5 million related to the portfolio of CNS IPR&D assets within Operating Expenses, which represents the excess carrying value compared to fair value. The impairment charge was the result of both internal and external factors. In the 3rd quarter of 2018, the Company experienced changes in key senior management, led by the appointment of a new CEO with extensive experience in oncology drug development. These changes resulted in the prioritization of immuno-oncology development candidates relative to CNS development candidates. In conjunction with these strategic changes, limited internal resources delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio. In light of this shift in market strategy, the Company performed a commercial assessment and a valuation of the CNS IPR&D assets, both to assess fair value and support potential future licensing efforts. The valuation indicated an excess carrying value over the fair value of these assets, resulting in the impairment charge noted above.

The fair value of the CNS IPR&D assets was determined using the discounted cash flow method which utilized significant estimates and assumptions surrounding the amount and timing of the projected net cash flows, which includes the probability of commercialization, the assumption that the assets would be out-licensed to third-parties for continued development for upfront licensing fees and downstream royalty payments based on net sales, and expected impact of competitive, legal and/or regulatory forces on the projections, as well as the selection of a long-term growth rate; the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and the tax rate, which seeks to incorporate the geographic diversity of the projected cash flows.

On September 19, 2019, the Company entered into an Asset Purchase Agreement (the "Agreement"), pursuant to which the Company sold its rights, titles and interests, including associated patents, to the pharmaceutical product designated by the Company as GTB-004 (the "Product"). Under the Agreement, the Product was purchased by DAS Therapeutics, Inc. who the Company believes is well positioned to take over the clinical development of the Product including obtaining timely approval by the FDA.

The Company received $200,000 at closing. The Company will also participate in the future commercial value of the Product by receiving$6,000,000 upon the achievement of certain sales objectives. In addition, the Company will receive a royalty equal to 1.5% of U.S. sales until such time as the last of the patents associated with the Product expires. The Company reflected a loss in the year ended December 31, 2019 totaling $20,463,000.

As a result of the loss reported on the sale of the Product, as well as the response received on inquiries related to the other two projects, the Company determined that the remaining value related to these remaining projects should be fully impaired. During the year ended December 31, 2019, the Company reported an impairment charge for these projects totaling $4,599,000.

Note 10 – Commitments and Contingencies

1. Litigation

We are involved in certain legal proceedings that arise from time to time in the ordinary course of our business. Except for income tax contingencies, we record 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, 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 allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. Lion alleges breach of a consulting agreement between Lion and the Company entered into on or about September 1, 2015. Vallera alleges breach of a consulting agreement between Vallera and the Company entered into in or around October, 2018. The Complaint seeks actual damages of $1,670,000, for the fair market value of the number of shares of GT Biopharma, Inc. that at the time of judgment represent 15,000,000 shares of such stock as of September 1, 2015, and that GT Biopharma, Inc. issue Lion the number of common shares 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. Discovery has commenced and trial is scheduled for May, 2022. The Company believes the case is without merit and will defend it vigorously.

b. On March 3, 2021 a complaint was filed by Sheffield Properties in the superior Court of California. County of Ventura. The litigation arises from a commercial lease entered into by GT Biopharma for office space in Westlake Village. GT Biopharma has been served but has not yet answered the complaint. Sheffield Properties seeks damages in excess of $250,000. We intend to vigorously defend against these claims (see Note 7).

2. Employment Commitments

a. Effective August 11, 2020, the Company and Mr. Cataldo, CEO, entered into the Cataldo Agreement with respect to Mr. Cataldo's continued employment as Chief Executive Officer of the Company. The Initial Term of the Cataldo Agreement is three years with the option of automatic one-year renewals thereafter. Mr. Cataldo will be paid a cash salary of $30,000 per month, together with customary benefits, expense reimbursement and the possibility of performance bonuses. Mr. Cataldo will receive a stock grant equal to ten percent of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of Mr. Cataldo) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Cataldo Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). Mr. Cataldo will be entitled to certain additional severance payments and other benefits in connection with a Change in Control Period Involuntary Termination or a Non Change in Control Period Involuntary Termination (each as defined in the Cataldo Agreement) or his resignation as a result of a Change in Control Period Good Reason or Non Change in Control Period Good Reason (each as defined in the Cataldo Agreement). Following the Effective Date, Mr. Cataldo will also continue to serve as the chairman of the board of the Company.

b. Effective November, 11, 2020, the Company appointed Mr. Handelman as Chief Financial Officer on an interim basis. Effective November 13, 2020, the Company and Mr. Handelman entered into the Handelman Agreement with respect to Mr. Handelman's service as Chief Financial Officer of the Company. The term of the Handelman Agreement is indefinite, subject to ninety days prior written notice of termination. Pursuant to the Handelman Agreement, Mr. Handelman will receive a monthly consulting fee of $15,000, along with the opportunity to earn a discretionary bonus. Mr. Handelman will also serve as the principal accounting officer of the Company. On December 14, 2020 the Company and Mr. Handelman entered into an Agreement with respect to Mr. Handelman's continued employment as Chief Financial Officer of the Company. The Initial Term of the Handelman Agreement is three years with the option of automatic one-year renewals thereafter. Mr. Handelman will be paid a cash salary of $21,000 per month, together with customary benefits, expense reimbursement and the possibility of performance bonuses. The cash salary will increase to $25,000 with the successful up list onto the NASDAQ stock exchange. Mr. Handelman will receive a stock grant equal to one and half percent of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Cataldo Agreement (with such stock to vest and be delivered within 30days after the national markets qualified financing). Mr. Handelman will be entitled to certain additional severance payments and other benefits in connection with a Change in Control Period Involuntary Termination or a Non Change in Control Period Involuntary Termination (each as defined in the Agreement) or his resignation as a result of a Change in Control Period Good Reason or Non Change in Control Period Good Reason (each as defined in the Agreement).

3. Research and Development Agreement:

We are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, 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 agreement, we receive 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 in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. We are presently evaluating GTB-3550, our lead TriKE therapeutic product candidate in a Phase I/II clinical trial. Under the agreement, the University of Minnesota received an upfront license fee which was recorded in prior year, royalty fees ranging from 4% to 6%, minimum annual royalty payments of $0.25 million beginning in 2022, $2.0 million in 2025, and $5.0 million in 2027 and certain milestone payments totaling $3.1 million.

Note 11 – Income Tax

The Company did not record any income tax provision for the years ended December 31, 2020 and 2019 due to the Company's net losses. The Company files income tax returns in the United States ("Federal") and California ("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, 2020, the Company had Federal and State net operating loss carry forwards available to offset future taxable income of approximately $39 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, 2020 and 2019, 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.

	December 31,	
	2020	2019
Deferred tax assets:		
Federal net operating loss carryforward	39,340,000	36,803,000
Stock based compensation and other items	4,779,000	
Intellectual property	58,504,000	58,504,000
Accrued expense	-	1,262,000
Patent amortization	4,000	4,000
Deferred tax assets before valuation	102,627,000	96,573,000
Valuation allowance	(102,627,000)	(96,573,000)
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, 2020	December 31, 2019
Federal statutory income tax rate	21%	21%
State tax, net of federal benefit	7%	7%
Change in valuation allowance on net operating loss carry-forwards	(28%)	(28%)
Effective income tax rate	0%	0%

Note 12 – Related Party Transactions

During the year ended December 31, 2020, the Company recorded consulting expense of $1,133,000 for services rendered, of which, $525,000 was included as part of accrued expenses as of December 31, 2020 for a consultant who is also an owner of approximately 10% of the Company's issued and outstanding common stock.

During the year ended December 31, 2019, the Company recorded consulting expense of $1,140,000 to a consultant who is also an owner of approximately 10 % of the Company's issued and outstanding common stock. There was no outstanding balance due to the consultant as of December 31, 2019.

Note 13- Restatement of Prior Quarters (unaudited)

Management of GT Biopharma, Inc. and its audit committee, identified an accounting error in the recognition of an additional loss on extinguishment of debt of $8,643,000 as a result of the June 2020 forbearance agreements that was not previously recorded (see Note 4). As a result, the previously filed unaudited condensed consolidated balance sheets as of June 30, 2020 and September 30, 2020, and the related condensed consolidated statements of operations and stockholders' deficiency, may no longer be relied upon. The Company has restated its unaudited condensed consolidated balance sheets as of June 30, 2020 and September 30, 2020 and the related condensed consolidated statements of operations and stockholders' deficiency. The restatement did not affect the previously reported assets and liabilities in the corresponding financial statements.

The effects of the discrepancy discovered related to the accounting error on the previously filed Form 10-Q's are summarized as follows:

Condensed Consolidated Statement of Operations for the three months ended June 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Other income (expense)	$ (7,221)	$ (8,643)	$ (15,864)
Net loss	(8,779)	(8,643)	(17,422)
Net loss per common share - basic and diluted	$ (0.12)	$ (0.12)	$ (0.24)

Condensed Consolidated Statement of Operations for the six months ended June 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Other income (expense)	$ (7,859)	$ (8,643)	$ (16,502)
Net loss	(10,487)	(8,643)	(19,130)
Net loss per common share - basic and diluted	$ (0.15)	$ (0.12)	$ (0.27)

Condensed Consolidated Statement of Stockholders' Deficit as of June 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Preferred share	$ 25	$ -	$ 24
Common share	75	-	75
Additional paid-in capital	550,411	8,643	559,054
Noncontrolling interest	(169)	-	(169)
Accumulated deficit	(577,819)	(8,643)	(586,462)
Total Shareholder deficit	$ (27,499)	$ -	$ (27,499)

The effects of the discrepancy discovered related to the accounting error on the previously filed Form 10-Q for the three and nine months ended September 30, 2020 are summarized as follows:

Condensed Consolidated Statement of Operations for the three months ended September 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Other income (expense)	$ (931)	$ (8,643)	$ (9,574)
Net loss	(2,876)	(8,643)	(11,519)
Net loss per common share - basic and diluted	$ (0.04)	$ (1.13)	$ (1.16)

Condensed Consolidated Statement of Operations for the nine months ended September 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Other income (expense)	$ (8,790)	$ (8,643)	$ (17,433)
Net loss	(13,363)	(8,643)	(22,006)
Net loss per common share - basic and diluted	$ (0.18)	$ (0.12)	$ (0.30)

Condensed Consolidated Statement of Stockholders' Deficit as of September 30, 2020 (unaudited)

	Previously Reported	Adjustment	As Restated
Preferred share	25	-	25
Common share	78	-	78
Additional paid-in capital	550,984	8,643	559,627
Noncontrolling interest	(169)	-	(169)
Accumulated deficit	(580,695)	(8,643)	(589,338)
Total Shareholder deficit	(29,777)		(29,777)

Note 14- Subsequent Events

Subsequent to December 31, 2020, convertible notes and accrued in interest aggregating $38,714,000 were converted into 11,386,435 shares of common stock at conversion prices. Of this amount $35,660,000 was principal and accrued interest as of December 31, 2020. The remaining $3,054,000 was principal, and accrued interest subsequent to December 31, 2020

Subsequent to December 31, 2020, the Company issued 4,945,000 shares of its common stock to investors for net cash proceeds of $24,882,000 pursuant to our February 2021 Offering Circular.

Subsequent to December 31, 2020, the Company issued 660,545 shares of common stock upon exercise of warrants for cash proceeds of $3,200,000.

The following unaudited proforma information are based on the Company's historical financial statements as of December 31, 2020 after giving effect to the subsequent conversion notes payable to equity and sale of common shares for cash.

Account	December 31, 2020 – As reported	December 31, 2020 – Proforma (unaudited)
Cash and cash equivalents	$ 5,297	$ 33,379
Total Assets	5,661	33,743
Convertible notes	26,303	-
Accrued interest	4,838	-
Total Current Liabilities	35,094	3,953
Preferred stock	3	3
Common stock	52	67
Additional paid in capital	566,309	625,517
Ammulated deficit	(595,628)	(595,628)
Non controlling interest	(169)	(169)
Total Stockholders' Equity (Deficit)	$ (29,433)	$ 29,790

Subsequent to December 31, 2020, the Company issued 5,491,638 shares of common stock with a fair value of $34,762,000 to officers and directors as incentive for the completion of our February 2021 Offering Circular.

Subsequent to December 31, 2020, the Company issued convertible notes payable in the aggregate of $1,205,000 in exchange for cash. The Company also issued notes payable of $545,000 in exchange for consulting services. In addition, accrued expenses of $525,000 from a related party that was recorded as of December 31, 2020 (Note 12) was cancelled in exchange for a convertible note payable. The Company is currently in the process of determining the appropriate accounting for these notes payable totaling $2,275,000.

Exhibit 4.2

CERTIFICATE OF DESIGNATION OF

PREFERENCES, RIGHTS AND LIMITATIONS OF

SERIES K PREFERRED STOCK OF

GT BIOPHARMA, INC.

GT BIOPHARMA, INC. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware, DOES HEREBY CERTIFY that, pursuant to authority conferred upon the Board of Directors by the Restated Certificate of Incorporation of the Corporation, as amended, and pursuant to the provisions of Section 151 of the General Corporation Law of the State of Delaware, the Board of Directors, by resolutions adopted to be effective on February 22, 2021, duly determined that 115,000 of the authorized shares of Preferred Stock, $0.01 par value per share, of the Corporation shall be designated "Series K Preferred Stock," and duly adopted a resolution providing for the voting powers, designations, preferences and relative, participating, optional or other rights, and the qualifications, limitations and restrictions, of the Series K Preferred Stock, which resolution is as follows:

"RESOLVED, that the Board of Directors, pursuant to the authority vested in it by the provisions of the Restated Certificate of Incorporation of the Corporation, as amended, hereby authorizes the issuance of 115,000 shares of Preferred Stock, $.01 par value, of the Corporation (and fractions thereof in one-one hundredth increments), which shall be designated as "Series K Preferred Stock" (the "Series K Preferred Stock"), with each share of Series K Preferred Stock having a stated value of $1.00 (the "Stated Value") and having the following designations, powers, preferences and relative, participating, optional and other special rights, and the qualifications, limitations and restrictions:

1. Definitions.

As used herein, the following terms shall have the following meanings:

(a) "Board" shall mean the Board of Directors of the Corporation

(b) "Common Stock" shall mean the Corporation's common stock, par value $0.001 per share.

(c) "Issuance Date" shall mean the date on which the first share of Series K PreferredStock is issued.

(d) "Liquidation" shall mean any voluntary or involuntary liquidation, dissolution or winding-up of the Corporation.

(e) "Preferred Stock" shall mean the Corporation's preferred stock, par value $0.01 per share.

(f) "Securities Act" shall mean the Securities Act of 1933, as amended.

2. Rank. The Series K Preferred Stock will rank on parity to any class or series of our capital stock hereafter created specifically ranking by its terms on parity with the Series K Preferred Stock.

3. Dividends. Shares of Series K Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series K Preferred Stock will participate, on an as-if-converted-to-common stock basis (without giving effect to the "Beneficial Ownership Limitation" set forth in Section 6L), in any dividends to the holders of common stock.

4. Voting Rights. Shares of Series K Preferred Stock will have the same voting rights as shares of common stock with each share of Series K Preferred Stock entitled to vote on an as-converted basis (after giving effect to the "Beneficial Ownership Limitation" set forth in Section 6L) at a meeting of the shareholders of the Corporation.

5. Liquidation Preference. In the event of our liquidation, dissolution or winding up, holders of the Series K Preferred Stock will have a liquidation preference equal to $0.01 per share of Series K Preferred Stock and thereafter shall be on parity with the holders of our common stock and will participate, on an as-if-converted-to-common stock basis (without giving effect to the "Beneficial Ownership Limitation" set forth in Section 6L), in any distributions to the holders of common stock.

6. Conversion Rights. The holders of shares of Series K Preferred Stock shall have the following conversion rights:

A. *Conversion Rate.* Each share of the Series K Preferred Stock is convertible into 100 shares of Common Stock (the "Conversion Rate") at any time at the option of the holder.

B. *Upon Extraordinary Common Stock Event.* Upon the happening of an Extraordinary Common Stock Event, shares of Series K Preferred Stock shall be impacted in the same way our shares of common stock were impacted by the Extraordinary Common Stock Event. An "Extraordinary Common Stock Event" shall mean: (i) the issuance of additional shares of Common Stock as a dividend or other distribution on the outstanding shares of Common Stock, (ii) the subdivision of outstanding shares of Common Stock into a greater number of shares of Common Stock, or (iii) the combination of the outstanding shares of Common Stock into a smaller number of shares of Common Stock, in each case other than pursuant to a transaction provided for in Section 6C or 6D.

C. *Capital Reorganization or Reclassification.* If the shares of Common Stock issuable upon conversion of Series K Preferred Stock shall be changed into the same or a different number of shares of any class or classes of stock, whether by reorganization, reclassification or otherwise (other than a subdivision or combination of shares or stock dividend provided for in Section 6B, or a reorganization, merger, consolidation or sale of assets provided for in Section 6D), then and in each such event, the holders of shares of Series K Preferred Stock shall have the right thereafter to convert such shares into the kind and amount of shares of stock and other securities and property receivable upon such reorganization, reclassification or other change by the holders of the number of shares of Common Stock into which such shares of Series K Preferred Stock were convertible immediately prior to such reorganization, reclassification or other change, all subject to further adjustment as provided herein.

D. *Reorganization, Merger or Consolidation.* If at any time or from time to time there shall be a reorganization, reclassification or recapitalization of the capital stock (other than a subdivision, combination, reorganization, reclassification or exchange of shares provided for elsewhere in this Section 6) (a "Reorganization"), then as a part of such Reorganization, provision shall be made so that each holder of Series K Preferred Stock shall thereafter be entitled to receive upon conversion of such shares of Series K Preferred Stock, the number of shares of stock or other securities or property to which a holder of the number of shares of Common Stock into which such holder's shares of Series K Preferred Stock were convertible immediately prior to such Reorganization would have been entitled upon consummation of such Reorganization. In any such case, appropriate adjustment shall be made in the application of the provisions of this Section 6 with respect to the rights of the holders of Series K Preferred Stock after the Reorganization to the end that the provisions of this Section 6 (including adjustment of the Conversion Value then in effect, and the number of shares of Common Stock issuable upon conversion of the Series K Preferred Stock) shall be applicable after that event in as nearly equivalent a manner as may be practicable.

E. *Exercise of Conversion Privilege.* To exercise the conversion right set forth in Section 6A, a holder of shares of Series K Preferred Stock shall surrender the certificates representing the shares being converted to the Corporation at its principal office, and shall give written notice to the Corporation at that office that such holder elects to convert such shares. Such notice shall also state the name or names (with address or addresses) in which the certificates for shares of Common Stock issuable upon such conversion shall be issued. The certificates for shares of Series K Preferred Stock surrendered for conversion shall be accompanied by proper assignment thereof to the Corporation or in blank. The date when such written notice is received by the Corporation, together with the certificates representing the shares of Series K Preferred Stock being converted, shall be deemed the "Conversion Date." As promptly as practicable after the Conversion Date, the Corporation shall issue and deliver certificates to each holder of shares of Series K Preferred Stock so converted, or on its written order, such certificates as it may request, for the number of whole shares of Common Stock issuable upon the conversion of such shares of Series K Preferred Stock in accordance with the provisions of this Section 6, and cash as provided in Section 6J, in respect of any fraction of a share of Common Stock issuable upon such conversion. Such conversion shall be deemed to have been effected immediately prior to the close of business on the Conversion Date, and at such time the rights of the holder as holder of the converted shares of Series K Preferred Stock shall cease and the person or persons in whose name or names any certificates for shares of Common Stock shall be issuable upon such conversion shall be deemed to have become the holder or holders of record of the shares of Common Stock represented thereby.

F. *Cash in Lieu of Fractional Shares.* No fractional shares of Common Stock or scrip representing fractional shares shall be issued upon any conversion of shares of Series K Preferred Stock. Instead of any fractional shares of Common Stock which would otherwise be issuable upon conversion of shares of Series K Preferred Stock, the Corporation shall pay to the holder of shares of Series K Preferred Stock which were converted a cash adjustment in respect of such fractional shares in an amount equal to the same fraction of the Market Price per share of the Common Stock at the close of business on the Conversion Date. The determination as to whether or not any fractional shares are issuable shall be based upon the total number of shares of Series K Preferred Stock so converted at any one time by any holder thereof, and not upon each share of Series K Preferred Stock so converted.

G. *Partial Conversion.* In the event some but not all of the shares of Series K Preferred Stock represented by a certificate surrendered by a holder are converted, the Corporation shall execute and deliver to or on the order of the holder, at the expense of the Corporation, a new certificate representing the number of shares of Series K Preferred Stock which were not converted.

H. *Reservation of Common Stock.* The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of effecting the conversion of shares of Series K Preferred Stock, such number of shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding shares of Series K Preferred Stock, and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of Series K Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purpose.

I. *No Reissuance of Series K Preferred Stock.* Shares of Series K Preferred Stock which are converted into shares of Common Stock as provided herein shall not be reissued.

J. *Issue Tax.* The issuance of certificates for shares of Common Stock upon conversion of any shares of Series K Preferred Stock shall be made without charge to the holders thereof for any issuance tax in respect thereof; provided that the Corporation shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than that of the holder of the shares of Series K Preferred Stock which are being converted.

K. *Closing of Books.* The Corporation will at no time close its transfer books against the transfer of any shares of Series K Preferred Stock or of any shares of Common Stock issued or issuable upon the conversion of any shares of Series K Preferred Stock in any manner which interferes with the timely conversion of such shares of Series K Preferred Stock, except as may otherwise be required to comply with applicable securities laws.

L. *Beneficial Ownership Limitation.* The Corporation shall not effect any conversion of the Series K Preferred Stock, and a Holder shall not have the right to convert any portion of the Preferred Stock, to the extent that, after giving effect to the conversion set forth on the applicable Notice of Conversion, such Holder (together with such Holder's Affiliates, and any Persons acting as a group together with such Holder or any of such Holder's Affiliates (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Series K Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (i) conversion of the remaining, unconverted Stated Value of Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, the Preferred Stock or the Warrants) beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 6L, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. To the extent that the limitation contained in this Section 6L applies, the determination of whether the Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder wall be deemed to represent to the Corporation each time it delivers a Notice of Conversion that such Notice of Conversion has not violated the restrictions set forth in this paragraph and the Corporation shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 6L, in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request (which may be via email) of a Holder, the Corporation shall within two Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Series K Preferred Stock held by the applicable Holder. A Holder, upon notice to the Corporation, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 6L applicable to its Preferred Stock provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of this Series K Preferred Stock held by the Holder and the provisions of this Section 6L shall continue to apply. Any such increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Corporation and shall only apply to such Holder and no other Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6L to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of Preferred Stock.

7. Miscellaneous.

(a) The Corporation covenants that all shares of Common Stock which may be issued upon conversions of shares of Series K Preferred Stock will upon issuance be duly and validly issued, fully paid and nonassessable, free of all liens and charges and not subject to any preemptive rights.

(b) No share or shares of Series K Preferred Stock acquired by the Corporation by reason of redemption, purchase, conversion or otherwise, shall be reissued, and all such shares shall be cancelled, retired and eliminated from the shares which the Corporation shall be authorized to issue."

The number of shares of Series K Preferred Stock authorized is 115,000, none of which have been issued.

IN WITNESS WHEREOF, this Certificate of Designation has been signed by an authorized officer of the Corporation as of the date first written above.

By: /s/ Anthony Cataldo
Name: Anthony Cataldo
Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Anthony Cataldo, 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: April 16, 2021

By: /s/ Anthony Cataldo
Name: Anthony Cataldo
Title: Chief Executive Officer, Chairman and Director

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Michael Handelman, 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: April 16, 2021

By: /s/ Michael Handelman
Michael Handelman
Chief Financial Officer and 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, Anthony Cataldo, 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, 2020 (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: April 16, 2021

By: /s/ Anthony Cataldo
Name: Anthony Cataldo
Title: 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, Michael Handelman, Chief Financial Officer and Principal 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, 2020 (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: April 16, 2021

By: /s/ Michael Handelman
Michael Handelman
Chief Financial Officer and Principal Accounting Officer